PHYSICIAN-FOCUSED PAYMENT MODEL TECHNICAL ADVISORY COMMITTEE

PUBLIC MEETING

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

Thursday, September 6, 2018
8:30 a.m.

COMMITTEE MEMBERS PRESENT:

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

STAFF PRESENT:
Susan Bogasky, Office of the Assistant Secretary for Planning and Evaluation (ASPE)
Audrey McDowell, ASPE
Ann Page, ASPE
Sarah Selenich, Designated Federal Officer (DFO), ASPE
Steve Sheingold, PhD, ASPE
Sally Stearns, PhD, ASPE

AGENDA PAGE

An Innovative Model for Primary Care Office Payment
Submitted by Jean Antonucci, MD

PRT: Harold Miller (lead), Tim Ferris, MD, MPH and Kavita Patel, MD, MSHS
Staff Lead: Audrey McDowell

APM for Improved Quality and Cost in Providing Home Hemodialysis to Geriatric Patients Residing in Skilled Nursing Facilities
Submitted by Dialyze Direct

PRT: Harold Miller (lead), Jeffrey Bailet, MD, and Rhonda Medows, MD
Staff Lead: Sally Stearns

P R O C E E D I N G S

[8:44 a.m.]

*** Opening Remarks by Chair Bailet and CMS Leadership**

CHAIR BAILET: So good morning, and welcome to this meeting of the Physician-Focused Payment Model Technical Advisory Committee, known as PTAC. Welcome to the members of the public who are here and are able to attend in person, and welcome as well to those participating over the phone or over the live stream. Thank you all for your interest in this meeting.

This is the PTAC's fifth public meeting that includes deliberations in voting on proposed Medicare physician-focused payment models submitted by members of the public.

We want to thank the stakeholders who took the time and energy to submit proposals, especially those who are here today. Your hard work and dedication to improving our health care system is appreciated.

Including the four proposals we will deliberate on over the next day and a half, we have received 25 full proposals to date and an additional 15 letters of intent to submit a proposal. This demonstrates the continued

interest of physicians in applying their day-to-day experiences, knowledge, and expertise to payment reform, and we are grateful for their efforts.

We are also excited because today three leaders within the Department of Health and Human Services will be joining us to make public remarks, Alex Azar, the Secretary of Health and Human Services; Seema Verma, the Administrator of the Centers for Medicare and Medicaid Services. And Adam Boehler, Director of the Innovation Center at CMS and Senior Advisor on Value-Based Transformation and Innovation will also speak this morning.

We are eager to hear their remarks. Each of them has also made time to speak with PTAC this summer so that we could better understand how our work as a committee aligns with the direction of the Department.

The Congress established PTAC to provide advice to the Secretary regarding physician payment models. We are grateful for the Secretary joining us today to speak about how we can help him achieve his vision for value-based transformation and innovation. We are grateful for CMS leadership joining us today, who will put that vision into action.

In addition to the Committee's sessions with

senior HHS leadership, the members of PTAC have been hard at work since our last public meeting in March. Our Preliminary Review Teams, or PRTs, review the four proposals we will discuss over the next day and a half and have been actively reviewing other proposals that will be deliberated at future public meetings.

Our next public meeting will be held here in the Great Hall of the Humphrey Building December 10th and 11th. At that meeting, that will mark two years of being open for business to receive models from the public.

We have also been exercising our new authority to provide initial feedback to submitters of proposed models, which was granted to us by the Bipartisan Budget Act of 2018. Initial feedback, when provided, is given by the PRTs and is at the discretion of the PRT reviewing proposal.

We have also been and are continuing to seek public comment on our processes. A request for public comment is posted on the ASPE PTAC website. In addition, the Committee will hear from stakeholders tomorrow after we conclude our proposal deliberations.

One simple reminder to the extent that questions may arise as we consider your proposal, please reach out to

the staff through the ptac@hhs.gov email. Again, that email address is ptac@hhs.gov. We have established this process in the interest of consistency in responding to submitters and members of the public and appreciate everyone's cooperation in using it.

Today, we will deliberate on three proposals, and we will deliberate on one proposal tomorrow. To remind the audience, the order of activities for each proposal is as follows.

First, PTAC members will make disclosures of potential conflicts of interest and announce whether they will not vote on a particular proposal.

Second, discussion of each proposal will begin with presentations from the Preliminary Review Teams.

Following the PRT's presentation and some initial questions from PTAC members, the Committee looks forward to hearing comments from the proposal submitters and the public.

The Committee will then deliberate on the proposal. As deliberations conclude, I will ask the Committee whether they are ready to vote on the proposal. If the Committee is ready to vote, each Committee member will vote electronically on whether the proposal meets each

of the Secretary's 10 criteria.

The last vote will be an overall recommendation to the Secretary of Health and Human Services, and finally, I will ask PTAC members to provide any specific guidance to ASPE staff on key comments they would like included in the report to the Secretary.

A few reminders as we begin discussions of the first proposal. PRT reports are reports from three PTAC members to the full PTAC and do not represent the consensus or positions of the PTAC. PRT reports are not binding. The full PTAC may reach different conclusions from those contained in the PRT report, and finally, the PRT report is not a final report to the Secretary of Health and Human Services. Following this meeting, PTAC will write a new report that reflects the deliberations and discussions of the full PTAC, which will then be sent to the Secretary.

It is our job to provide the best possible recommendations to the Secretary, and I expect that our discussions over the next day and a half will accomplish this goal.

I would like to take this opportunity to thank my PTAC colleagues, all of whom give countless hours to the careful and expert review of the proposals we receive.

Thank you again for your work, and thank you to the public for participating in today's meeting in person via live stream and by phone.

So let's go ahead and get started. The first proposal we will discuss today is the Acute Unscheduled Care Model: Enhancing Appropriate Admissions, which was submitted by the American College of Emergency Physicians.

So we understand that the Secretary is going to join us. So what we'd like to do is I'll start with myself, introduce each of the Committee members, and any disclosures, conflicts of interest that need to be made, and then we'll probably break for the Secretary's arrival.

*** Committee Member Disclosures**

CHAIR BAILET: So I am Dr. Jeffrey Bailet. I am the executive vice president of Health Care Quality and Affordability with Blue Shield of California, and I have no conflicts to disclose.

Bruce.

MR. STEINWALD: I'm Bruce Steinwald. I'm a health economist here in Northwest Washington. I do some work with the Brookings Institution as well, and I have nothing to disclose.

DR. CASALE: Paul Casale, cardiologist and

executive director of New York Quality Care, the ACO for New York-Presbyterian, Columbia, and Weill Cornell.

I have no disclosures.

MR. MILLER: Hi. I'm Harold Miller. I'm the president and CEO of the Center for Healthcare Quality and Payment Reform.

I do have a disclosure. In 2015 and 2016, long time ago, I provided assistance to the American College of Emergency Physicians as they were first thinking about developing payment model concepts, and one of those proposals that we talked about at that point was similar to the proposal that they have submitted for review by the PTAC.

I was not involved in this proposal at all, but I am going to recuse myself from voting and from deliberation on the proposal because of my past involvement.

DR. TERRELL: Good morning. I'm Dr. Grace Terrell. I'm a general internist that is part of the Wake Forest Baptist Health System in North Carolina. I'm also the CEO of Envision Genomics, which is a precision medicine company, and I am on the board of CHESS, which is a population health management company.

I have no conflicts to disclose.

DR. FERRIS: Good morning. I'm Tim Ferris. I'm a primary care physician at Mass General in Boston and the CEO of the Mass General Physicians Organization. I serve on the board of a for-profit commercial company, Health Catalyst, in Utah. I also serve on the board of the National Health Service in England.

I have no conflicts with this proposal.

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

I have no disclosures.

DR. BERENSON: I'm Bob Berenson. I'm an institute fellow with the Urban Institute.

My only disclosure is that as a senior official at CMS a while ago and in more recent years in my current position, I have had professional interactions with ACEP but not about this or any other potential physician-focused payment model.

DR. PATEL: Kavita Patel. I'm an internist in D.C. and a fellow at the Brookings Institution and nothing to disclose.

DR. NICHOLS: Len Nichols. I'm a health economist. I direct the Center for Health Policy Research

and Ethics at George Mason University, and I have no conflicts to disclose.

CHAIR BAILET: Thank you, everyone.

So we're going to go ahead and shuffle some chairs here for just a second while the Secretary comes down.

Thank you.

[Pause.]

CHAIR BAILET: Good morning. Good morning, everyone.

At this time, we're honored to have Secretary Alex Azar here today offering public remarks. The Secretary was sworn in as the twenty-fourth Secretary of Health and Human Services on January 29th of this year. He brings with him valuable experience from both the private sector and public sector, including prior service here at HHS as General Counsel and then as Deputy Secretary.

We appreciate his combination of public and private sector experience, as our work as PTAC resides at the intersection between government, the private community, and other stakeholders. The members of PTAC have had the privilege of speaking with the Secretary in June, a conversation that helped strengthen our partnership and

helped PTAC understand his vision on value-based care and how our work can best move this vision forward.

We are grateful the Secretary has taken time out of his busy schedule to speak here today. Please join me in welcoming Secretary Alex Azar.

[Applause.]

SECRETARY AZAR: Well, good morning, everyone, and it's great to be here with the PTAC, and I want to thank everyone for the opportunity to speak with you today and to address the PTAC.

First, thank you for your work as part of this Committee. It is incredibly hard work, and I'd also like to thank everybody who is outside of the formal institution of the PTAC who contributes to your work as well. I know that there are many people standing behind the actual members of the PTAC.

You are members signed up for a complicated and time-intensive task because you care deeply about building a health care system that serves patients better and about the role that physicians play in that transformation.

It's a significant time commitment. I know. I've seen your work. I've been the rigor of your analysis, and I see the considerable expertise you bring to the

table, and we're incredibly grateful for what you do.

One of the priorities that I have picked out for HHS for us to focus on at the highest level, the most ambitious and furthest reaching is transforming our health care system into one that pays for health and wellness rather than sickness and procedures.

Mantras like that and especially the term "value-based care" are so common in health care circles that we don't often pause to consider what they should really mean.

The outcome we're aiming for is pretty simple, though -- better health care at a lower price. But the question of how we deliver that outcome is much more complicated.

There's been some progress on some of the tools that we need to execute this transformation. We have more alternative payment models, more coordinated care, and more value-based compensation than ever before, and that's thanks to some of the individuals whose paintings and portraits are up in the wall right there, starting with Mike Leavitt, Secretary Sebelius, and of course, the work of Secretary Burwell in driving forward this value-based transformation and the foundations of this bipartisan effort.

But the results that we hope for have not always materialized. As just one example, we saw in the analysis that CMS released at the beginning of August that the burgeoning number of accountable care organizations have not delivered significant savings with all costs and incentives are taken into account.

But, notably, the best results that we've seen have been in ACOs that took on two-sided risk, where providers have real accountability for outcomes.

We've also seen better results from physician-run ACOs as opposed to hospital-run ACOs, interestingly.

Without real accountability, we're just offering bonuses on top of payments that may be too high already. That's why we've now proposed, through Administrator Verma's work, to simplify the ACO system into two tracks, requiring them to take on risk much sooner.

And as our CMMI director, Adam Boehler, put it last week, if this means somewhat fewer ACOs, then so be it. We need strategies and models that provide better care at a lower price, not just new models for the sake of new models and not new systems of payment for old systems that aren't open to real change.

In some cases, as I've said before, that's going

to mean mandatory models from CMMI and other mandatory reforms. Requiring participation can be necessary to determine whether a model really works, but it may also be necessary to meet what we see as an urgent need for reform.

I am impatient. I think our whole system is impatient. We need the change. We need it now. We need it quickly, and so we need your support for it. But we're not going to be overzealous in determining how these reforms happen. We're interested in driving the outcome that we want rather than micromanaging how to get there.

Let me give you an example. I've got a relative who is currently in a rehab hospital, and I was sitting there with him. And one of the nurses came in and started complaining, knowing my job, had started complaining to me about CMS's staffing ratios.

I sort of scratched my head. I just have a natural instinct on these things, and I scratched my head and I said, "What the devil do we have to do with telling facilities their staffing ratios?" It was just sort of a natural, immediate response.

We take the oversight of health care facilities very seriously at CMS and at HHS. It is important. We must insist on quality, but if you talk to any patient

about what they want from health care, it's not process. It's outcomes. The outcome that we want from my relative at that rehab hospital is that whenever he is done with his care, he walks out rather than in a wheelchair. It's a pretty simple measure. You only get paid if you achieve that, and he can walk out; and you ought to get paid less if he can't walk out when we're all done with the course of care. So that's really what value-based care means to me at least.

We need to tell you the what, better care at a lower price, and we're going to reward you for delivering it, but how you deliver it needs to be up to you.

We also want to take a broad view of how providers can take on risk and earn rewards for good outcomes. This means not just episodic bundles where providers can take on risk. That's important, and that does satisfy an important need where we have episodic care.

But we also need longer term, longitudinal models, where real rewards will be paid for keeping patients healthy and hot of high-cost care settings.

To oversee these efforts, earlier this year, the Administrator and I appointed Adam Boehler as our senior advisor for Value-Based Transformation and Innovation in

addition to his hat as the head of CMMI.

You will hear him discuss later today the four P's of driving toward value: making patients into empowered customers, making providers into accountable navigators of the health system, paying for outcomes, and preventing disease before it occurs or progresses.

CMMI will soon be launching new bold models that fall into these areas, and we hope you use them as guideposts for your work on PTAC. Getting better value from our health system and paying for value requires empowering patients to be consumers, but realistically -- and I do think we all recognize this -- patients are going to need physicians to help them navigate the complex health care system as learned intermediaries, and we need to give those physicians the right incentives to guide patients in making choices that will lead to good and positive outcomes. We are very interested in ideas that can help our physicians fill this critical gap.

Without physicians playing a key role, the transformation that we need for American health care will never be possible, and PTAC's perspective, therefore, is absolutely critical as we drive towards value.

A number of the models that have been advanced by

PTAC have significantly influenced models that we have in the works, but working with all of you, we want to go much further. As we work on the transformation that I've described today, Adam, Administrator Verma, and I see PTAC as a crucial avenue for ideas and input.

But PTAC is more than that too. You all are really advisors to me, helping me to discern what needs to be done to make physicians' ideas a reality and inform HHS about how we can help.

All physicians interested in putting forth ideas to deliver better care at a lower price are going to find an attentive ear form Adam, Administrator Verma, and from me and from the entire Trump administration.

I know all of you are interested in those goals, so I look forward to a close partnerships with you in the years to come. Thank you again for having me here today, and I hope you have an exceptionally productive meeting today. Thank you so much.

CHAIR BAILET: Thank you, Mr. Secretary.

[Applause.]

CHAIR BAILET: So I'd like to now introduce Administrator Seema Verma from the Centers of Medicare and Medicaid Services. She was sworn in as the fifteenth

Administrator of CMS on March 14th of 2017. Administrator Verma is an incredibly experienced health care policy professional.

As the architect of the historical Healthy Indiana Plan, she helped create and implement the nation's first consumer-directed Medicaid program.

She's also made it a priority to collaborate with PTAC, speaking and spending time with us about how our work fits into the CMS's ongoing efforts with value-based care.

At this time, please join me in welcoming Administrator Seema Verma. Thank you.

[Applause.]

MS. VERMA: Thank you, Jeff, and thanks for inviting me here today. It's a pleasure to be with you.

As you heard, Secretary Azar has made it very clear that value-based transformation is the top priority for HHS, and CMS is very committed to making this vision a reality.

So when we're looking at the area of value -- and you heard the Secretary, I think, articulate what value is, delivering quality outcomes at the best possible -- the lowest cost. And so at CMS, we're starting not only thinking about models but thinking about how do we remove

barriers to providers delivering value to the health care system. So it's not just about payment models, but there's many things that are standing in the way of innovation and providers delivering high-quality care.

One of the things that he mentioned, which we're very focused on, is regulatory burden. Last year, we started an effort called Patients Over Paperwork. We put out RFIs, and we heard from literally thousands of providers. We went across the nation talking to rural providers. We talked to urban providers, and we went to a variety of different settings. And we heard some of the common issues that providers are facing in terms of regulatory burden.

Some of the things that we heard about were measurement and quality measurement and the burden of having to report all these measures to CMS, and so we created another initiative called Meaningful Measures. And just this year, we've taken out 100 measures across CMS quality reporting, and what we have found is that a lot of the measures that are out there are process-oriented. They're not outcome-oriented. They're taking a lot of time for providers to report, and so we've started. This is just the beginning of that process. We'd like to get to a

point with our quality measures that providers don't have to do anything actively, that we can easily get that information from electronic medical records, that we can get that information from registries or claims data. And so we're going to continue our work on addressing some of the concerns around quality measurements.

We've also taken effort on E&M codes, for example. We put out a proposal, and we're looking for comments on how we can address some of the day-to-day burdens that providers are facing.

Also looking at Stark Law and a variety of different issues, all sort of premised on the idea that regulatory burden is preventing our providers from being innovative and from delivering high-quality care. So that's one piece of it.

And the other piece of it, obviously, is looking at how do we pay for value and creating new models. We're very excited to have Adam's leadership in CMMI, and one of the things I've asked him to do is as we're looking at models to think about how we can include the patient in that as well. It's very important, obviously, that payers are aligned and providers are aligned, but actually activating the patient in that, I think is very important

as well.

So what you'll see from us over the next year is efforts to include the patient. We're trying to empower our patients to seek high-quality and value care, and in order to do that, we need to give them the tools that they need, whether it's issues around interoperability, whether it's having more cost data available to them, and also quality data. So we're looking at trying to create more transparency across the system so we can empower our patients to seek high-quality, value-based care.

One of my main concerns, however, as we're looking at where we are today in terms of providers in the value-based system, we have only about 14 percent of providers in the Medicare program today that are taking on risk.

Now, from my perspective, value doesn't always mean everybody taking full risk, and what we want to create is many opportunities for providers to participate in value-based models, but understanding that not every provider is going to want to take two-sided risk. So we want to create as many opportunities as possible.

But the more risk a provider takes, we want to also create incentives to do that by providing more

waivers, waivers form a lot of those regulatory burdens that stand in their way in creating innovative high-quality care.

So you're going to see, again, more models from us. I'm concerned that we don't have enough models, and that's why I'm particularly very supportive of the work that PTAC has done.

This year, you're going to see us focused on some of the models that PTAC has recommended. We're focusing on some of the highest cost areas in the health care systems. So we're looking at end-stage renal disease, cancer care, chronic disease, individuals with serious medical conditions, and a lot of the work that PTAC has done has informed the development of these models.

So we really appreciate your efforts. I've always said that the best ideas don't come from Washington, and we need to hear from providers on the front lines. As we're developing models, it's really important to understand what's going to work and what's not going to work, and the PTAC's particular experience is very important to us. We recognize that that's a crucial component to us developing models.

So we're excited to continue the work, and just

echoing what the Secretary said, we really appreciate all the work that's been done. We recognize that you are volunteers, and the technical assistance and the insight that you have provided us has been very helpful. And you're going to see a lot of that, a lot of your expertise included in the models ahead.

So thank you for your work.

CHAIR BAILET: Thank you, Administrator Verma.

[Applause.]

MR. BOEHLER: Everybody is leaving me.

[Laughter.]

CHAIR BAILET: That's okay, Adam. How is your chair feeling?

MR. BOEHLER: It's good.

CHAIR BAILET: It's good. Okay, very good.

So I now have the honor of introducing our next speaker, Adam Boehler, senior advisor to the Secretary for Value-Based Transformation and Innovation, CMS deputy administrator and director of the Center for Medicare and Medicaid Innovation.

Mr. Boehler brings with him extensive experience with many innovative ventures across multiple facets of the private health care industry, including health care

technology, laboratory management services, and health care analytics.

He founded and led one of the largest home-based medical groups in the country, Landmark Health. Mr. Boehler became CMS deputy administrator and CMMI director in April of this year.

Speaking with PTAC in June and July to share his vision for the Innovation Center and how he will engage with the PTAC, please join me in welcoming Mr. Adam Boehler.

[Applause.]

MR. BOEHLER: Thank you, Jeff.

Someone told me last night that a mark of power in Washington is how simple your title is, and so from that perspective, I'm powerless.

[Laughter.]

MR. BOEHLER: Thank you for inviting me to my first PTAC meeting. You just heard from the Administrator and the Secretary about our commitment to value-based care, and as director of the CMS Innovation Center and as Secretary Azar's senior advisor for Value-Based Transformation and Innovation, I'm going to spend a little bit of time talking about how we're planning to achieve it

and then how that relates to the critical mission at PTAC and how we're going to work together.

First, as Secretary Azar mentioned, the four components to HHS's value-based strategy, we used P's, four P's to make them easy to remember. The first it patients as empowered consumers. We're interested in using transparent and competitive markets to promote access and choice for our patients. We're interested in making our patients and the American patient first on our agenda in everything that we do.

Second, physicians as accountable patient navigators. We want to create new arrangements for physicians to take accountability for their patients, whether that's in primary care, whether that's in specialties, and we want to empower the physician community. We want to take away burden that doesn't add value and let physicians focus on their patients.

The third P is payment for outcomes. We want to modernize what are outdated payment rules sometime sand pay for results.

And then, finally, prevention of disease before it occurs. Our system today operates in silos. Medical is siloed from housing, from food, from social services.

That's not how you would set up the system if you were designing it today, and we're interested in breaking down those silos to the benefit of Americans.

Physician-focused models and the work done by PTAC is critical to this strategy and driving this strategy. The purpose of the CMMI, the Center for Medicare and Medicaid -- our innovation center, is to create models that lower cost and improve quality. And it's simple.

So when I came, I spent a lot of time initially with my team looking at our existing model portfolio. We wanted to learn what worked and what didn't work. So we went through with a fine-tooth comb, and we said these models are not reducing cost as much as we wanted to or not improving quality. How can we improve them, or should we end them? And we did that.

And then there were some that we noticed had great results, and we doubled down on those, and that influenced our decision-making as we thought about new models.

In new models, we started to identify the elements that have made us successful in the past, and qualitatively, there are three things that kept surfacing: models that were transparent or open about sharing data,

models that were simple -- health care is complex, and the best way to create models that people can depend on and drive care is to simplify it as much as possible -- and finally, accountability. We need to empower our model participants to succeed, but then we also need to hold them accountable for that.

I'm excited about the different internal ideas that have come to me, but most excited about those external by a number of the ideas that PTAC has brought forward to us by other ideas from stakeholders, by people in the audience, that can achieve the greatest impact. And I'll tell you, we're pretty myopic on our focus. It's what is going to improve quality outcomes, lower cost, and drive choice for the American patient.

I'm proud to say that we introduced our first model under my tenure. It's one focused on -- it's called Integrated Care for Kids, and it's focused on the opioid crisis. That's our first model in the opioid space, and so I'm excited to announce that. And there will be multiple others that we'll announce soon.

In my tenure at HHS, I've been here close to five months. I've had the opportunity to interact directly with PTAC, with the members, and appreciated that opportunity,

and I want it to be clear that I very much appreciate the work that PTAC has done in the past and what they'll do in the future. Both the Administrator, the Secretary, and I are committed to working with PTAC.

We're eager to implement the models that are proposed, and we're eager to evaluate them in terms of ability to improve quality outcomes, reduce cost, to drive a transparent, simple, and accountable future.

I also want to be direct because there's been some question as to our commitment that we are working very aggressively on several models that have been pushed forward by the PTAC and recommended by the PTAC. These are several models that are focused in important areas: chronic kidney disease, primary care redesign, serious illness. They're active, and they're directly based on the work of PTAC.

We're using PTAC's thoughtful analysis and comments from the stakeholders, including RPA, AAFP, C-TAC, AAHPM to inform and drive our work in those areas. We're speaking to those stakeholders directly on an ongoing basis too to continue to develop those models in areas that TPAC recommended that we develop those models.

I've been personally impressed with the rigor of

the PTAC work and appreciate their recommendations.

We've also had conversations recently with the Icahn School of Medicine at Mount Sinai and the Marshfield Clinic about services delivered in the home, a personal area of passion for me given my background delivering home-based care.

CMS has benefitted directly from PTAC's recommendations and comments on proposals. I recommend that prospective physician-focused models continue their work with PTAC because PTAC's recommendations will weigh very heavily on this administration.

I'd like to thank PTAC for your ongoing hard work and commitment. You all have day jobs, and yet you spend so much time here because of your interest in advancing health care for our country. And I really appreciate that.

I'm very much looking forward to the input from today and tomorrow's meetings and from future input as well, so thank you for having me.

CHAIR BAILET: Thank you, Adam.

[Applause.]

CHAIR BAILET: We're going to take a five-minute break and then rejoin the meeting. Thank you.

[Recess.]

* **Acute Unscheduled Care Model (AUCM): Enhancing Appropriate Admissions. Submitted by the American College of Emergency Physicians (ACEP)**

CHAIR BAILET: All right. So we want to thank the administration for joining us this morning and thank them for their comments. The PTAC is not going to make any further comments about their presentations this morning, but we are, we will do that tomorrow morning.

Right now, in the interest of time, we're going to go ahead and get started with the first review of the proposal of the Acute Unscheduled Care Model: Enhancing Appropriate Admissions, as submitted by the American College of Emergency Physicians.

Dr. Tim Ferris is the PRT lead. Myself and Len Nichols are on the PRT. So I'd like to turn it over to my esteemed colleague, Dr. Tim Ferris.

* **PRT Report to the Full PTAC**

DR. FERRIS: Jeff, thank you very much.

And I'm going to start off with a few general comments and first thank the submitters -- thank you -- and make a few comments about their submission in general.

So just deciding to submit demonstrates as commitment to finding a solution to a pressing national

problem, and so thank you for making that commitment and decision.

We just heard from the Secretary and the Administrator and the head of CMMI with lots of other titles about value and cost, and then they get up and leave the room and we talk about the details, right? And the details are really, really complicated and really, really hard because it's very easy to say value and cost, but it's actually very hard to measure them.

And so I just want to stress how we appreciate on the PRT how difficult this is. The concepts are straightforward, but the details are complex. They involve difficult tradeoffs, and the submitters have done us all a great service through their careful and thorough explication of their proposal.

I also want to thank you for your patience with our questions and our process. We learned a lot from you and recognize that we know a lot less about the delivery of care in emergency departments than you do, and we recognize we are unlikely to have a completely accurate review and look forward to further dialogue as we continue this process of learning about your ideas.

And, finally, I want to thank the members of the

PRT. As we just heard, we spend many hours on these, and in the process, we get to know each other pretty well. And I apologize to my fellow PRT members for that additional knowledge.

[Laughter.]

DR. FERRIS: So I'm going to spend a bit of time going through the proposal overview, and then I'll speed up when I get through the actual -- because I don't think it's necessary for us to walk through all these slides. These slides are publicly available. Everyone can read them, and so I'm going to try to hit the highlights. And I'm going to ask my PRT colleagues to keep me honest, and where I miss an important point, we'll have time. But I think we want to move this along so that we can get to the discussion part of this.

Mr. Chair, I'm going to suggest again that I don't need to review the composition and role of the PRT. That's all publicly available, and we'll get to the discussion.

CHAIR BAILET: Sure. Okay.

DR. FERRIS: Thank you.

So proposal overview. This is a model, both a care model and a payment model, that is about an episode of

care in the emergency department and the period of time post discharge from the emergency department. The goals are to create an incentive system about the decisions made by the emergency department physicians, and that incentive system is intended to create higher-value care.

How is that done? Well, it's done through a general model that is well known to anyone who looks at models, which is an episode framework, and critical to any episode framework is the definition of the episode. In fact, many episodes -- this is one of the critical details, is finding a starting point for an episode that is easily identifiable, quantifiable, and then figuring out what the downstream -- what is included in that episode.

And I think our submitters have done a terrific job with very specific details on this. Again, you can read it, but there's a number of qualifying diagnoses, which on disks, which are evaluated from discharge documentation, where that episode starts with the visit to the ED.

Also important is to identify the risk-bearing entity, so who is bearing the risk in this proposed payment model. And in this case, there are several different methods in the real world for aggregating emergency

department physicians, and this proposal includes actually, as far as I can tell, all of the different ways that emergency department physicians are aggregated, either as independent physician groups, faculty practice plan settings, or employed physicians.

Accounting for the heterogeneity in the way physicians are organized is actually one of the typical stumbling blocks in these proposals.

Moving to the next slide, in terms of the qualifying ED case -- and this, again, gets into the details here, but it's discharge home, discharge to an observation stay, or an inpatient admission. All of those are the three things that can happen from an emergency department. I suppose there are a couple others that are rare.

And then moving to the next step getting into a little bit more detail about the ED observation as compared to a non-ED observation, so for those who are not in health care, observation stays in the hospital can be classified -- or are managed by different groups, and different hospitals manage observation stays differently. Sometimes ED doctors are in charge of those observation stays. Sometimes ED doctors are not in charge of those hospital

stays. This may seem like a micro distinction, but actually, in this payment model, it comes up, and so that's why I am highlighting it.

The other thing that is very important in any episode model is how do you derive the target price, and it turns out in all episode models, that is a challenging issue that involves a certain number of tradeoffs. I'll get into that in a second.

The second one is how do you interface. How do the quality metrics merge with and inform the performance estimates, or are they directly related to the target price and discount, or are they handled separately? Those are both two thorny issues that our submitters have dealt with explicitly.

First, going to the target price, so the target price is facility-specific, so it's based on historical claims experience, that is one of several ways to handle target price.

One of the main advantages of using that technique is risk adjustment across other organizations because very challenging, especially when you're dealing with such a narrow focus on a particular set of conditions, and so using historical controls actually provides a

relatively safe starting place, but also introduces some potential issues. And we'll get to that.

The other thing, I want to be very clear, at least from the perspective of the PRT, for the public, how do you succeed? And I am going to just state this conceptually, how one might succeed in this. We are talking about the decisions of emergency department doctors around certain conditions where there is as high variance in whether or not a patient is admitted. That means that there is discretion within that condition, and that succeeding in a shared savings model means reducing the number of admissions.

Let me just be really clear about that. I state that because the second issue is quality, and critical to this is understanding that if you are reducing admissions, are you making sure through your quality measures that you are making sure that in this creation of value, you are not inappropriately discharging patients?

The submitters have dealt with this, and fortunately for them -- actually, our system is very good at measuring what happens after a discrete episode, and therefore, it is possible information act to measure mortality and readmissions after discharge. So I wish that

situation happened more often in health care, but it does provide us with a discrete way to both understand -- to create an incentive, to create higher-value care, but also measure whether or not that incentive is having a deleterious effect on health. So that's a critical aspect of their proposal.

I'm not going to go into the details, but we'll probably get into this in discussion more about the target price. I think at this point, the key thing is to just hit the overview.

Another thing that comes up frequently on these payment models that PTAC reviews is -- I'll use the expression "meeting participants where they are," and I think our submitters have done a nice job of providing options for how to participate. Some groups are more ready to take on risk and how quickly they take on that risk, and the submitters have created a very nice set of options that deal with the main issues around risk, the risk sharing, the stop-loss thresholds, and the performance measures.

Then, finally, the performance measures fall into three categories. They are the key categories: patient engagement experience, which is certainly measurable; process and care coordination, a critical piece of this;

and most importantly, outcomes.

And then, finally, in the model overview the proposal does discuss process steps in safe discharge home and the ED physician communication at discharge that's around care coordination, and also Medicare waivers were raised as a mechanism for participants to be -- to get -- actually get around -- "getting around" isn't the right term -- to avoid some of the regulatory hurdles that would stand in the way of best functioning in this model. Maybe that's the right way to say it.

So, with that overview of the model, I'm going to move to the summary of the PRT review. You will see of the 10 criteria, the PRT concluded that it did not meet criterion on 2 and No. 3 and No. 7, and No. 3 is a high priority.

You'll also note that those were not unanimous on the PRT. So we had a lot of discussion. They were majority conclusions, and so, clearly, I look forward to the discussion with the full PRT around some of the thornier issues that we were dealing with.

And I will now move to our summary of those thornier issues. Overall, the model approached ED payment policy in a new way, conceptually aligned with value over

volume, and provides an opportunity for a new group of physicians, physicians who currently don't have an opportunity to participate in an APM.

The PRT was impressed with the data-driven selection of eligible conditions. I didn't talk about that. That's well documented, but I did note in passing they did select conditions that do have a high variability in admission. That was taken by the PRT as evidence that there is some ability to move the threshold for admission, and because there is so much discretion, there is significant academic literature in precisely these conditions that show that safe alternative management strategies are available to physicians in the ED for these conditions.

We also were impressed with how they sized the incentive. This is a Goldilocks problem -- not too big, not too small -- and the careful attention to patient safety.

I'm now going to list our main concerns in a summary way, and we'll get into them in more detail. The exclusion of non-ED physicians caring for observation patients admitted through the ED. I'll focus on this now rather than later on when I go through the details and try

to get right to the nub of this concern.

The nub of this concern is that these are clinically identical patients managed by -- in different hospitals in different groups. It was a concern to the PRT that in one avenue, they would be under an incentive. In another avenue, they wouldn't be under that incentive. I look forward to the conversation, but that struck us as being problematic from a care delivery perspective.

I suppose it could be cast as two different incentive models and therefore two different care models potentially within the same institution. Like my institution actually has three different ways of being admitted to observation. We have an ED-managed observation unit. We have a department of medicine-managed observation unit, and we have observation in the hospital managed by whoever. So these different mechanisms, and we were not certain that having an incentive system placed on one and not the others couldn't be problem, so looking forward to that discussion.

The lack of process quality measures that would permit sharing of best practices, this is one of those left hand/right hand economist things. This is from my economics, you know, that one hand. What you really want

is a one-armed economist because you don't want the left hand and the right hand. Well, this is one of those tradeoff situations where you want to have the number of metrics small to decrease the burden. On the other hand, having process metrics does in fact, help spread best practices, and the PRT had some -- we had a discussion about whether or not there was a little bit too light on the process metrics, understanding that we also didn't want to overburden this.

The use of facility-specific approach to pricing without including a regional or national benchmark, let me pause on this as well. This gets a little arcane, but as we have discussed in this forum before -- and I may not articulate this as well as some of my economist friends, so I'm sure they'll chime in. But if you have -- I'm going to do this by using a scenario approach. If you have a scenario where you have a hospital that tends to have a low threshold for admission of these patients, they could actually perform quite well and do quite well under this model.

A similar hospital across town or in a different city actually has a very high threshold for admission to the hospital, and I will say we see this a lot throughout

the United States. Hospitals that are very full tend to have a very high threshold for admission on one of these discretionary conditions, and hospitals that are relatively empty, I will say, tend to have a much lower threshold for admission.

How this model, this incentive model would play out under those two scenarios, you could see a hospital that is, quote/unquote, "worst performing" from an admission threshold perspective could actually do quite well under this model, where as a hospital which is actually doing already a baseline quite well could do quite poorly under this model. That was a concern to us and look forward to the discussion.

And you could see how regional and national -- the inclusion of regional or national benchmarks for admission thresholds could mitigate that concern.

And then, finally, the challenges with the feedback loop of communication among the participating providers, we did not reach complete clarity in our discussions about the care coordination, the ED to who's catching the ball of the patients and how is that coordinated specifically.

So those were our main issues.

Being the indulgence of the PTAC Committee, I'm going to go now really fast through the specific things.

I see a smile from my Chair. I'm going to take that as license.

So, on scope, scope, it was unanimous, meets criterion. You can all read this. Maybe I will pause for one additional personal commentary here on scope since I have the floor, and that is, we did discuss the fact that there are a limited number of conditions here. And so, actually, the total dollar value, we heard from the Secretary about they want big stuff.

The total dollar value of what's being proposed here is actually pretty small in the scope of health care in the United States. The number of physicians it affects is pretty large in terms of scope, but I will say having implemented these models, there is a beneficial effect, what might be termed a "Hawthorne effect," that occurs within an organization that is implementing a model, which is it is generally true that if physicians are operating under a model for a certain narrow set of what they do -- and there's some literature to suggest this -- that beneficial effect bleeds into everything that they do.

So I just want to put that note in. This was not

something that we discussed on the PRT, so I will take criticism and critique of that observation. But there is significant potential, despite the limited number of conditions here, for this to affect the behavior of the physicians in all their work within the EDs that they're working if this model was implemented.

So, Jeff, you're now cutting me off.

CHAIR BAILET: I'm not cutting you off, Tim. I just want to embellish upon the comment you just made that I think is important.

I agree that the number of conditions to start are small, but the construct of the model is that additional conditions, as this model unfolds, will continue to expand. And I think that will -- if you think about -- if you fast-forward, if it's successful, that does provide a much bigger footprint and aligns with what the Secretary would like to see. So I just thought that that was an important to add.

MR. FERRIS: That's great, and so I did skip over that, but that is an explicit part of the model. And thank you, Jeff, for that addition. So that's scope.

Quality and cost, met criteria, majority conclusion. So because it's majority conclusion, I should

pause and just say you can read the fourth bullet there are the concerns that we raised, and I already mentioned the other issues related to quality. So I think I'll keep going.

The payment method was it does not meet. This was a majority conclusion.

I will say on this one that -- and I've already gone through this issue, so I actually won't pause, but this has to do with the historical benchmark approach and our concerns related to the payment methodology there.

Again, you can read these. This is continued on the payment methodology. I'm not going to go through this. I think I covered the critical points.

Value over volume, met criterion, unanimous.

Flexibility, met criterion, unanimous.

I hope I'm not giving anyone short thrift here.

Ability to evaluate, met criterion, unanimous.

So integration and care coordination, I have already stated what our concerns were around integration and care coordination. We said it did not meet. That was a majority conclusion, so obviously not unanimous, and therefore was a point of discussion.

Patient choice, met criterion, unanimous. I

might pause and just say here, we did talk about this quite a bit because there is a disclosure issue here.

In general, again, speaking just personally, I'm in favor of transparency and patients understanding that if they're in not usual care, which I would say this is not usual care, that they are informed of that.

So the ED is an interesting place for having discussions about doing something differently. There's actually a huge body of literature about how challenging it is to actually have a valid informed consent process in the ED because, by definition, you are there for an urgent problem, and it's the asymmetry there in, for lack of a better word, power in having an informed conversation about sort of is it okay.

So I think we satisfied ourself here that patient choice was met, but I did want to flag that we had a significant discussion about this.

And then, finally -- or not finally -- patient safety. Patient safety, I should also say -- I'm going to repeat something that I said earlier -- here, the critical issue is the potential to harm patients here of this, and I don't want to gloss over it because we need to address it full straight on.

I do think professionally in the ED, it is doing what's right for the patient is the first-order issue for any physician in any ED, and that the financial incentives affect behavior at the margin, which is as it should be. And so we satisfied ourself that both the professional situation, which is the first-order issue, and the financial situation, that the safety issues are in place for this model, but I don't want to gloss over the significance of what it is, what's being proposed.

And then health information technology met criterion.

So I'm going to conclude there and ask maybe Len Nichols, my esteemed colleague, and then I'll turn to our Chair to keep us going.

Thank you.

DR. NICHOLS: So, Tim, you did a great job, except for one point, and that was complaining about the two-armed economist because you see, in fact, every single elucidated point you just did so magnificently had nuance. You take away one hand, my son, you can't do your job. So just be careful when you're picking economists that way to pick the right arm.

[Laughter.]

CHAIR BAILET: That's it, Len?

DR. NICHOLS: You can have an honorary PhD in economics.

CHAIR BAILET: So thank you both. Thank you, Tim, not only for your comments today but also more importantly for leading the PRT. There was a lot of discussion, and I want to applaud the proposal submitters for proposing a model that is I think invaluable for the emergency medicine physician colleagues around the country that they can potential participate in. And I applaud you for your efforts and look forward to the discussion.

So what I'd like to do now is bring the -- what? Yep.

DR. NICHOLS: So I did remember one point I wanted to make, and this will be attempt at substantive.

CHAIR BAILET: Yeah.

DR. NICHOLS: You did a nice job of explaining the nuance around our ultimate majority, but not unanimous, decision on payment methodology. And I just wanted to say I think it is true that our agreement was that the flaw that the majority saw in the payment model had to do with using simply facility-specific historical cost.

That could be fixed relatively easily. So I

would just like to put out there, when you come up and talk about it, you might want to address your thoughts on that issue.

That's it.

CHAIR BAILET: Thank you, Len.

And before we have the proposal submitters come to the table, I'd like to ask the rest of the Committee if they have questions for the PRT, clarifying questions that we might be able to answer.

Bob and then Kavita.

*** Clarifying Questions from PTAC to PRT**

DR. BERENSON: Yeah. Heaven forbid that I should ask a question that sounds a little cynical, but why change now? Right?

[Laughter.]

DR. BERENSON: Here's my concern or question. It seems to me there's a very strong incentive here for the ED group that's taking risk with the episode payment to make their money by simply not having patients get designated as observation or inpatient admissions, that that's where the major savings are going to come, essentially taking the hospitals money. And that, in fact, some people who would be eligible for billing as, let's say, an observation stay

simply wouldn't be billed for an observation stay because they would stay under the control of the ED observation.

So my question goes to, Did you explore at all the potential for conflict between what the ED group is doing and the fact that the hospital still controls with the GUR committee billing Medicare and how that conflict would be resolved, or have I missed something here?

I see real conflict between the hospital and the ED group, and so is it something that you explored at all?

DR. FERRIS: I'll ask my colleagues to chip in here, but we had concerns around that, and so I'm going to ask that you address that question to the submitters.

Maybe I'll just pause on that. Let's get into the discussion, but I think it's a very important question, Bob, not necessarily cynical.

CHAIR BAILET: Kavita.

DR. PATEL: This might be a good question for PRT and the submitters, but if you think about what patients want, they would probably prefer to be cared for in the home. But it sounds like you've already touched on this kind of murky area of what is this handoff or where would care coordination, particularly in scenarios where there might not be -- I mean, I'm often on the receiving end of

calls from the ED covering my colleagues in primary care. I really have no context, and I'm just trying to like put out fires. So that might qualify as coordination, but it's probably not really coordination.

So was there any conversation about process measures or some ideation about how that could be benefitted? And I again think this might be good for the submitters as well.

DR. FERRIS: I also suggested we -- you asked that -- because that was one of our concerns, and I think it's a great question.

I did want to actually go back to Bob with one thing. The problem of the intergroup potential conflict between groups within an organization goes away in an employment model, and we did discuss that and noticed that. So there is a subgroup of hospital organizational frameworks out there in which your concern just simply isn't a concern, I think, but let's --

DR. BERENSON: I mean, I got the point that employment would be different, but it seems to be employed ER docs, for example, would be uninterested in pursuing this model because it's in the hospital's interest to bill for observation stays and up-code for admissions and the --

if they're employed, they don't have a direct interest in countering that, so this would seem to be a model that is mostly applicable to independent ED groups, I guess would be my sense.

Am I wrong there? What would be the appeal to an employed ED group to participate in that?

DR. FERRIS: Simply wanting to be part of the solution.

CHAIR BAILET: That was cynical.

[Laughter.]

CHAIR BAILET: Okay. Bruce.

MR. STEINWALD: My question has to do with observation stays.

Tim, the way you characterized it, you made it sound to me like different hospitals do it differently for reasons that are kind of unrelated to efficiency or good medical care. They just do it differently, and then you mentioned your own organization does it three different ways. Is there really a problem there? It just seems to me that since they're all part of the same organization -- even if they're not employed, they're on the medical staff -- that there ought to be a way of reconciling the fact that some of the observation stays are not under the

control of the ED physicians, but at the same time, they are within the same organization. So it just doesn't -- you made an issue of it. It just doesn't seem like to me, as a non-clinician, that it should be a major issue.

DR. FERRIS: I guess I would say -- and, again, like our prior questions, these are great questions to ask. I think we discussed there is a potential, but not a necessary problem. And you could imagine, for example, if the proposal was to hold the group accountable, no matter what way the patient went, then that would -- in an employed situation, the doctors would have to all sort of talk to each other and coordinate, right? Oh, shocking.

And you could imagine that could also happen when they are the parts of different financial -- financially distinct organizations. So I think that's the point you're trying to make, right? That those discussions and that coordination and fundamentally that accountability, you could still build in accountability. You would just -- if it was different financial risk groups, you would just have to have agreements between those financial risk groups.

So it is not a necessary problem, but it is a potential problem. But it would have to be mitigated through some set of -- and the mitigation strategy would be

different, depending on how the organization is constructed.

CHAIR BAILET: I guess I'd also like to add, Bruce, that there are other mitigating circumstances that influence where patients end up. I mean, it's certainly possible that the patient would qualify to be in an ED observation circumstance, but if that's full, then they'd end up in a different part of the hospital. Taking judgment aside, those are other mitigating circumstances that influence the difference, and we talked about that. And we're going to talk more about that with the submitters, so thank you.

Grace and then Paul.

DR. TERRELL: So I think in a previous public meeting, your teenage kids who were listening in went into hysterics when I talked about existentialism.

DR. FERRIS: Mm-hmm. Yes, that's correct.

DR. TERRELL: So get them ready, okay?

DR. FERRIS: Okay.

[Laughter.]

DR. TERRELL: Because I think we are really talking about Immanuel Kant and --

DR. FERRIS: Yeah.

DR. TERRELL: -- you know, categoricals here, and by that, I mean we really have to get our definitions precise to get at the questions that you all were rising.

I'm talking about the fact that we need to understand what an ED physician is. Is it a hypothetical categorical or an imperative categorical to use Kant's terms?

But what I'm actually talking about is when I was at Duke in medical school in the 1980s, there was no such thing as an emergency department. There was no such things as ED doctors. In fact, they were disdained as this new-fangled concept when really everything should either be medicine or surgery.

Over the time I was in residency training at Wake Forest, it was a specialty that was really significant and important to the whole functioning of the system. In this system, we've gotten a lot of other specialties too that are trying to meet the needs of our system as it is, such as hospitalist, extensivist, which this could be construed as being a new form of extensivist.

So my question to you, but I'm hoping also that our colleagues will kind of address this when you get forward, is as we are going through and trying to create

categories or the way we're actually treating medical care and care models, which is what this is about, a better way of doing it, but yet we've got these specialties in the way that we're paying things now, how much wiggle room is there in that? Right? I mean, that's what you're really talking about with the problem with the observation and the different ones.

Did the PRT get hung up on the definition of what an ED physician was as opposed to the ability of a group of physicians who happen to mostly be employed in the emergency department in this current situation at this current point in time, taking care of patients in a certain way? Is this really something we've got to look at not only for this model, but for all of them as different specialties come in from their point of view? So how much did you all get into the actual issue and aspect of it being about somebody who was calling themselves an ED provider?

DR. FERRIS: It is always safe to invoke Immanuel Kant in a PTAC meeting if you want to make sure that you have stymied the respondent.

[Laughter.]

DR. FERRIS: So, Grace, your comments are right

on. I will only try to reframe them and say so much of the payment system in health care is -- or what we're attempting to do, I think of as mitigating the fact that we have divided ourselves up into all of these -- from a health care perspective, microscopic categories, and we are now creating systems that in some ways reinforce because it's really a mitigation strategy for the fact that we have now groups of doctors who spend all of their time in the ED. And many of the --

DR. TERRELL: For the better.

DR. FERRIS: For the better, but many of the proposals are attempting to create better value by actually paying more -- by actually asking the doctor to pay more attention to the intersection points, which is our payment system, as currently constructed, doesn't provide them with any incentive to do. So I'd say to me, it's an absolutely legitimate description of our situation, but I'm not going to try to do the exercise of thinking about what an alternative universe might look like where we don't pay this way.

The PRT did accept the current payment system as a --

DR. TERRELL: As a categorical imperative.

DR. FERRIS: As a categorical imperative.

CHAIR BAILET: All righty. Paul.

DR. CASALE: Okay. It's difficult to follow that question. I feel a little stymied myself.

But my question is much more granular. So having lived in the world of chest pain centers and center ops, you know, like for half my life, this question is more around patient choice because, as you know, patients are often confused when they're in the ED or in a different unit or in the hospital. They often view it all the same, and then when they get the bill later, they find out that actually their copays were much higher because they were in observation versus inpatient, et cetera, and, you know, there's rules around informing patients and such.

But I just wondered if there was any discussion around, whether it's related to patient choice, if the physicians sort of have this incentive model, if that's somewhat in conflict, and how would you sort of be sure the patient understood that?

DR. FERRIS: I'm going to embellish on that. It's a great question, and I just want to -- because not everyone listening will know -- certainly, the PRT members know that, in fact, how Medicare pays in a fee-for-service

system, there a potential financial penalty to the patient to not be admitted. And it's a great question.

We did. I think we did raise it, but I don't think we discussed it at length. So it's a terrific question. I welcome your question of our submitters.

CHAIR BAILET: Any other comments, questions from the Committee at this point?

[No response.]

CHAIR BAILET: Well, then we'd like to have the proposal submitters come up to the table, and feel free to introduce yourselves. You have 10 minutes for your remarks. Thank you.

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

DR. PILGRIM: Thank you very much.

Just for clarity, we have prepared remarks. Interestingly, they are almost all on point with the discussion we've heard so far, and I'm happy to do that. Thank you for that preview.

We can certainly do the remarks. Are there also questions you'll ask us directly in response?

CHAIR BAILET: Yes, absolutely. Yes, when you're finished.

DR. PILGRIM: Then maybe we'll do as planned, then, our prepared remarks.

I am Dr. Randy Pilgrim. I'm an emergency physician. I'm the co-chair of ACEP's alternative payment model task force along with my colleague, Dr. Bettinger. And we are here also with Dr. Sue Nedza, who was instrumental in both the structure as well as the data verification for the model that you have in front of us. The three of us are 3 of 39,000 emergency physicians that are part of ACEP, and we're here representing many who have helped us along the way, along with your help. We are very appreciative of your insight, your insightfulness around this, and that's much appreciated, with all the work we've put in.

So I'll start with our comments, and we probably will embellish even what our prepared remarks are based on this discussion shortly after we have our 10 minutes here.

This acute unscheduled care model, I think you guys nailed this. I think you understand what this is. That was a great summary of that. Thank you very much.

We have -- after approximately three years of work, when the alternative payment model task force was established, we talked about and looked at approximately a

dozen potential models, and we brought this one forward largely because of the 150 million patient encounters that we're going to see this year in the nation's emergency departments. Almost all of them are acute and unscheduled care, and many of them come to us with undifferentiated conditions that are either further differentiated and defined, and many of those, approximately 80 percent of those, are sent back home. Approximately 20 percent on average are actually hospitalized. Some are observation; some are full admissions.

What's unique about our station in the health care ecosystem is that we sit at the very nexus of inpatient and outpatient care, and I know from the range of physicians that are here, the discussions that you have with your facility's emergency departments, you understand where that is. We are highly influential in the decision to admit the patient, but we are not solely influential in that. And so we developed a model that is designed to capture the uniqueness of that setting in the ecosystem and stand on behalf of transformative care, patient benefit, and betterment for the health care system, which we heard about earlier today.

The APM that we have, importantly, is designed to

provide resources that are not currently available to emergency physicians and accountability along with those resources. The resources are primarily through the waivers, but the accountability is more longitudinal. So, yes, this is a transformative model, which again you have identified.

And here we sit on the fiftieth anniversary this year of the American College of Emergency Physicians. We're celebrating this. Right as we established this specialty, legitimized it, one of the younger specialties, as you mentioned, Grace, and already we have to transform what we're doing, and we think that's exactly what we ought to do. We think we ought to extend our reach into the patients' lives.

Frankly, we do it, anyway. Right now, we do it when they bounce back to us and we see them again. We want to be more meaningfully involved with them in a cost-effective way and in a way that engages them better. We think we can do that.

So just as we're celebrating our anniversary, we're transforming already, and thank you again for your help.

I'm going to turn this over to Dr. Nedza, in

essence, for our prepared comments on some of your questions, concerns, and constraints, and then we have probably some more embellishments based on our discussion.

In summary, we do believe that the model we have is both practical, that it will be adopted, and as you'll hear from some telephonic comments by the Emergency Medicine Practice Management Association, it will meet the requirements and the interest of many different practice models, as Dr. Ferris was mentioning earlier.

We also do think that we can continue to work to make this model better and are eager to do that.

First, though, let's hear from Dr. Nedza about some of the constraints from our prepared remarks.

Thanks.

DR. NEDZA: Thank you, Dr. Pilgrim.

We appreciate the thoughtful review of the PRT and are really pleased to find substantial agreement around the model, but as the PTAC has discussed in detail this morning, there are certain areas that need clarification and discussion. We've seen four major concerns through our conversations with the PRT as well as the written documents that we have reviewed today.

These include observation stays, which is why we

out it number one; the target price methodology, even though money doesn't always come second; barriers to care coordination and the measurements of quality within the model.

The first we'll talk about is to address the alignment of ED observation services with other ED discharges. At the core, the model is focused on providing infrastructure through waivers, financial incentives through reconciliation payments, and data through administrative or registry data; to enable emergency department physicians to assume additional risk for safely discharging patients to the home environment.

It was with this in mind that we aligned the ED discharge home and the ED observation stays together. We realized that this has created unnecessary complexity in the model and especially as we were trying to explain it to the PRT and might induce physicians to shift utilization from ED observation to non-ED observation status to avoid risk and, thus, develop inappropriate incentives. Therefore, we agree with the PRT that this distinction should be eliminated, and that all observation stays should be treated the same.

The ED observation stays are a very small

proportion where they're actually billed this way. So we've discussed this, and we're very comfortable with the change.

One other question that Grace brought up that I'd like to address is that we're using Part B claims here to identify the conditions. So it's the final diagnosis, principal diagnosis of the emergency department physician on that particular claim, quite often done by an outside entity, not the hospital, and it's going to be done as a participant at the TIN level. So, therefore, between the place of service and the emergency department, the TIN, we're using those to identify these claims, not necessarily how we designate ourselves, because we have lots of internists and others that work in our practices.

The second concern cited was your target price methodology questions. The decision to include all qualifying ED visits and services within 30 days of the visit, regardless of disposition, holds the participant responsible for ensuring coordination of care across all settings. This includes those patients admitted to inpatient observation or discharge home.

So these episodes are triggered, regardless of the discharge disposition, and all of those cases are

included.

While the participants would be accountable for spending associated with all of these visits, the ability to use the waivers could apply only to those episodes where the patient was discharged to the home environment, and one of our concerns continue to be overlap with other CMS innovation projects. And if we would have put our reach into the observation visits or into the inpatient setting based on patient's discharge diagnosis or some of the other incentives around care coordination, there was the potential for overlap. So we chose to only allow those waivers to be used, again, in the discharge home setting.

We did decide to do this at the facility level. We recognized the clinical episode spending and discharge dispositions vary across types of hospitals; ED capacity, as Dr. Ferris mentioned; the disease burden in the population, as our colleagues in Population Health recognize; and the availability of specialty providers and community resources. That drives a great deal of our admission decisions.

This made peer identification critical in any setting using a blended target rate. So in order for us to define who a target or a peer hospital be for a blended

rate at a regional level, similar to that what is done in BPCI Advanced, we didn't have the methodology to do that, and this model was created before that methodology existed. So we chose to go with the facility level.

For that reason, we did not include the regional benchmarks, and we decided that such benchmarks might be a barrier to participation because most of us don't understand who our peers are and who might be included in those benchmarks. But ACEP is open to exploring a gradual move to more comprehensive target methodology once we have the ability to do that. So blended rate, regional rate, national is certainly in the cards as we go forward.

Finally, what I'd like to address is the transfer of care from the ED to the inpatient setting. There's a lot of rules in the hospital conditions -- the participation, Joint Commission. We've seen IHI initiatives, a lot of different things, and we buy -- because we don't have admitting privileges -- have to coordinate with whoever is going to assume care.

I apologize for not including that in the model, but we believe there were enough things in place currently on the inpatient side to be valuable.

That said, the development of the safe discharge

assessment and shared decision-making that explicitly is included in the QPS, we felt that that information would be transmitted most likely through an enterprise EHR to the inpatient setting or in discussions, so that we would indeed be enhancing the ability of our colleagues who are either going to be taking over observation services or the inpatient setting to manage those patients differently and to better understand the patients' requirements.

There was a question about the 30-day length in the episode as well. This is a bit of a stretch for us, but our data showed us that up to 20 percent of patients were never seen by another Part B provider within 30 days. That shocked us, some of the other work that was done.

So we are comfortable with the 30 days, which is quite a stretch for emergency physicians.

So I will end my comments here with just a quick mention of the quality measures. We did align our measures with CMS's meaningful measures activity and other reports that HHS has funded, and we look forward to the data coming out of this model to allow us to build more robust process measures in the future.

Dr. Pilgrim.

DR. PILGRIM: As we conclude our remarks here and

then take questions, we have more to say about the target pricing for this discussion. We think we can say more about the process of care coordination and how to do that, as was mentioned earlier, potentially about the conflict, which I think is largely erased by our agreement with you, actually. It was a good incisive comment that observation is observation; the clinical conditions are identical. I think that's a good and a very acceptable change for us.

Briefly, though, in conclusion, we do think, based on our vetting of this within the college and without, outside the college, that this broadly applicable. We do think it's transformative. So there would be a change dynamic that we will encounter, no doubt about that.

But we also think that this is flexible enough to encourage broad participation. Some of our endorsements, I think have mentioned that previously as well.

We also think there's going to be a significant impact. I thought it was a great discussion that the two of you had earlier about the initial conditions, which are presentation-based, and a wide variety of diagnoses result from those.

And you are exactly right, Dr. Ferris. Once you begin changing those practices in a practice, there's a

generalized effect that does occur, but we'll make that more explicit as we advance the model and mature it over time.

Finally, in the transformational efforts here, we do think that this does hit on the first conditions in the first presentations that are very significant. Abdominal pain, chest pain, syncope, those are the bread and butter of our lives in the emergency department, large numbers of patients from that.

We also think, though, in closing that this model will help close an important gap that we see. Emergency medicine is frequently either very indirectly or not at all involved in alternative payment models that exist, and we think that's a missed opportunity. So rather than try to compete with them, we try to propose something that would close that gap, and please know that if in fact this is recommended, we will work with you on any constraints or issues in the detail. You have our commitment to do that.

We also want to promote adoption and support integration into the greater APM portfolio.

Thank you.

CHAIR BAILET: Thank you.

Now we'll open it up to the Committee.

DR. NICHOLS: Well, Mr. Chairman, I was just going to move that we let them elaborate, as they suggested they were prepared to, before we ask the questions.

CHAIR BAILET: Yeah, yeah. Sure. Please.

DR. PILGRIM: So I'll kind of facilitate our comments.

Dr. Bettinger, do you want to comment on the issue of target pricing, facility-based or not?

DR. BETTINGER: Thanks, Randy.

Yeah. We gave this a lot of consideration from the beginning, and we researched what peer-reviewed material was out there. And we were pretty much unsatisfied that there was a validated methodology for peer-reviewed comparison on the topic that we're talking about, to the point that if this was going to be a voluntary APM, which of course it is, we did not think that a peer-reviewed or -- excuse me -- a geographic methodology would be acceptable to most emergency physician groups.

And that's why we started with the target price methodology based upon the facility-specific target. We knew that that would attract the most number of emergency physician groups, especially those that had a high admission or a high target price calculation. Those

physicians would be, if given the resources, more than willing, we think, to join the APM.

At the same time, conversely, those low-admitting, low target price facilities, they would still have the resources to allow them to improve even further. So we thought it was a win-win in that regard.

That same win-win philosophy also applied to CMS because right from the beginning, we understood from all the literature that was coming out that this was going to have to pass muster with CMS. If we came up with a geographic facility -- excuse me -- a geographic benchmark, those hospitals that were as far as a win-win in a high-admission, high target price, that would be a win for CMS. They would be able to see savings almost immediately in those facilities, and at the same time, those low-admitting hospitals would still be able to improve.

Conversely for CMS, the lose-lose proposition is that in those facilities, since this is voluntary, if the benchmark was set too high, those high-admitting facilities were not going to participate. CMS would see no savings there.

And, conversely, in those high -- excuse me -- those low-admitting facilities, they would be eligible for

reconciliation payments possibly without changing their processes at all.

We knew CMS was going to be an important customer here, and that was one of the reasons that we stayed with a facility-specific target price.

DR. PILGRIM: So, in summary, just to append to that before the next issue, if there's other questions about that, we were worried -- and I think, Dr. Ferris, as you mentioned -- we were worried about sort of artificial winds here, and we thought that the facility-specific pricing absent another method would probably diminish that.

I personally have worked in facilities that admit 35 percent of all of the patients, and I've worked in facilities that admit 12 percent of all the patients. And artificially applying a benchmark, even risk-adjusted, I don't think is consistent with the goals.

That said, we're wide open. So that if unintended consequences do not happen with other methods, we're open to that. As Jeff said, the adoption was of concern to us.

Before moving to the next item, Mr. Chairman, should we pause for questions?

CHAIR BAILET: Yeah. Len and Grace.

DR. NICHOLS: So I appreciate your bracketed comments there and the continued -- I get why you did it, okay? It makes perfect sense, day one, but I would also just suggest one could move toward a transition --

DR. PILGRIM: Yes.

DR. NICHOLS: -- where one picked the right peers, start at regional. We're not going to impose national tomorrow, but if you only do historical, yes, everything you said on day one is true. But five years from now, we're not making it to do improvement. That's the fundamental point.

DR. BETTINGER: We are open to that transition.

DR. NEDZA: And there's actually an organization called the ED Benchmarking Alliance that ACEP participates in that's working on a methodology for peer, determining peers for various methods that could inform such a movement.

CHAIR BAILET: Grace.

DR. TERRELL: My question is probably a good follow-up to that.

As I was reviewing your proposal a couple of weeks ago, it was right on after I had spent some time doing some cardiology CME on syncope, so it was perfect

timing to help me think about it from a patient safety point of view, which was discussed earlier.

My specific question, based on my recent personal education, was there are now some really, really good quality criteria for who ought to be admitted -- "ought" -- in an ideal world for syncope and who ought not based on presumed risk.

So, as we are thinking about the quality benchmark movement, separate from the payment movement, there's been a lot of good work done by the emergency physicians, cardiologists and others, on trying to determine what ought to be done for patients when you can categorize those things.

My question for you, because of the patient safety issues that were sort of touched on, is how much of that has actually been focused on -- as you're thinking about financial benchmarks and correlation between what seem to be pretty well known now, established sort of quality metrics on some of these conditions that you chose? So this is just one example of one.

DR. NEDZA: So thank you.

A few things about the syncope, one of the reasons we chose, it was high volume, high cost, high

variation.

We also recognized that there are guidelines, criteria now that aren't widely implemented. I mean, this is a problem we all know, those of us who have been in the quality world, but I think Carolyn Clancy said 58,000 sets of guidelines, and some of them aren't being utilized. I won't say how many, but some aren't.

And so the ability to give financial -- the financial incentives, the care coordination, to ask those questions that we included, like the safe discharge assessment, specifically we thought about in terms of syncope. Is it safe for the person to go home to their home, or are they going to fall again?

The patient safety metrics we've included include tracking post-ED fall rates. As we were trying to think about how we could both measure it and incent people to do the right thing, it's our sense that with the financial incentives in place and the waivers that people will begin to adopt these best practices because now they will have a financial reason to do it and an infrastructure that will encourage them to do it.

DR. BETTINGER: Could I make one comment?

CHAIR BAILET: Please.

DR. BETTINGER: Because I've recognized through all the comments here, there's one point of our original proposal that's been left out, which was really almost a slam-dunk moment for us when it comes to patient safety, that I just wanted to make sure everyone realized.

When we did the initial data analytics that showed what we've been discussing, the tremendous interquartile difference between different hospitals on their admission rates for these four conditions, we also found out at the same time -- and it's in our proposal -- that the post-discharge event problems, whether it is death, hospitalization, or return visit to the ED had no correlation to the admission percentage to the hospital. And that was really what even got us into this proposal to begin with. We realized just because you were admitting 80 percent of your patients didn't mean you were doing any better with your discharge patients than those hospitals that were admitting only 40 percent.

I just wanted to say that because I didn't want to forget that point.

CHAIR BAILET: Thank you.

Does the Committee have other questions?

Bob.

DR. BERENSON: Two, two different kinds of questions.

First, I just want to try to resolve my question about potential conflict with the hospital. So the hypothetical is that a patient comes with chest pain, with a hard score, 4 or 5. Who knows if they actually had a heart attack or didn't? They need to be monitored. They need serial enzymes, and it takes 8 to 12 hours. Under that circumstance, would the hospital still be billing for an observation stay, or is there some option that the patient would be treated in the ED, discharged without billing for what otherwise would be a pretty boilerplate or vanilla observation stay?

DR. PILGRIM: I think it will vary by site. We tried to be general enough so that we didn't overcook and therefore press people into behaviors or outcomes that just weren't applicable to each site.

So I want to address your question as directly as I can. I think it will depend on the clinical protocols that are in place and accepted per cite and on the resources that they have available.

In my day job, I oversee several hundred emergency departments with great teams that take care of

this, and so we encounter that very issue constantly.

We find that every site has its own way of working that problem out, and potential or real conflicts are actually resolved relatively quickly.

And the patients, we live our lives informing patients about what their options are and getting their agreement to go there.

I think you are actually right that there is a potential conflict there. What we find in practicality is that it's almost always worked out on a site-specific basis with the resources and protocols that are in place.

DR. BERENSON: I mean, the part of the conflict I think is a little -- I mean, I've had occasion to review the beneficiary services manual recently. You've got an attending physician who has to essentially put the person either in observation or admit the patient as an inpatient, but then the hospital always has a UR Committee and physician advisors who can come up with a different judgment, and somehow that has to be worked out.

It does seem to me that one of the ways of achieving early savings is to not -- well, one of the very positive things would be -- I would hope that people who don't need to be admitted would not be admitted, and

there's a lot of abuse of that.

DR. PILGRIM: Absolutely.

DR. BERENSON: So that is a behavior effect that you think could come out of this, is that people would be designated more appropriately into either ED-only observation or admission.

DR. PILGRIM: That is absolutely a critical point, and pardon me for -- that is almost the essence of what we tried to create here is that we find right now, we're probably put in more situations of conflict, to use your term, without another model that offers opportunity and resources.

DR. BERENSON: So it does seem to me that that's the real positive of what you're suggesting. It also seems to me that it invites a different opinion from the hospitals whose facility fees will go down. So I just want to be aware that that's what you contemplate happening in some places.

DR. PILGRIM: Yes, which is why the collaborative discussion with the hospital about whether to apply this model in that setting must happen.

DR. BERENSON: All right.

DR. PILGRIM: I don't think an ED group could

ever advisedly simply just do this and not talk to the hospital about those kinds of things.

DR. BERENSON: All right. My second question is a different kind of a question. It raises the issue we've had with many other proposals about when is it appropriate for any particular specialty to be accountable for total cost of care.

So my concrete question is, do you have any data or did the PRT have any data about -- in a 30-day episode, a patient showing up in the ED with one of these four conditions, what percentage of the total spend is from that episode, whether the patient was in the hospital or not, versus all the other stuff that happens?

I mean, my hypothetical again is the patient with chest pain probably has seven conditions, and is it reasonable -- I understand and I applaud you for finding that 20 percent of those people don't have a Part B encounter in 30 days, but 80 percent do. Is it reasonable for you to have accountability for all that spending without really the responsibility or the sort of infrastructure to actually manage those patients? Or at least I didn't see the infrastructure. I didn't see a lot of detail about how you would actually manage the

ambulatory care for patients who don't have a regular source of care and what the communication would be to make sure that you don't have too many cooks spoiling the broth.

So if you could sort of address whether it's even appropriate. I mean, for seven days, I would be very sympathetic. I'm pretty skeptical that you should be accountable for 30 days' worth of spending based on what happened on day zero in the ED, I guess is my question.

DR. NEDZA: We looked at three different ways for the model to save money. The first is inpatient versus discharge, which was about a $9-to-$1 ratio, $1 in outpatient spending. So we felt that just that first part would generate most of the savings.

The second part was really driven -- and the 30 days was driven out of our concerns for patient safety and also the cost of repeat and redundant testing. We had patients who had full chest pain workups discharged from the ED who went on to have heart caths and other things that didn't result in a stent and repeat CT scans, MRIs, a number of things that were also done in the emergency department.

So our feeling was that if the emergency physicians were responsible for coordinating care, not just

about seeing care, but about the communication of what's necessary in the follow-up period, unfortunately a lot of times out outpatient colleagues don't know all the tests we did and the results of those.

So 30 days made sense from an administrative perspective to be in alignment with CMS programs, and surprisingly, the emergency physicians involved in this effort didn't really have many concerns about 30 days as long as they had the right infrastructure because we see patients come back all the time within that 7 or 30 days, or we see patients who had additional testing that may or may not have been necessarily if we had communicated better.

DR. BERENSON: So if I could just follow up, for that 20 percent, where you can't identify a follow-up clinician, are you scheduling that patient to see you in the outpatient department in five days or seven days or something?

DR. PILGRIM: We built the model so that a number of things would be options, and that would be one of them. Telemedicine visits in an option. Hiring additional staff members -- in our group, we hire nurse practitioners, physician assistants very regularly, and repurposing their

role for even home-based care or iterative care back in the emergency department on a more scheduled basis, those are options.

To your infrastructure question and sort of how would this work, that's a good question because envisioning what we're actually doing here is an important part. We have actually found in our own group that we've actually built some infrastructure to do this kind of thing already.

Our probably that was going to rate-limit us is not having the resources to do this, let alone the accountability. We just took it upon ourselves to do this, but at some point, we won't be able to continue.

So I think the key is flexibility because sometimes a telemedicine visit or even a telephonic visit is all that's needed for patients. Sometimes a nurse visit for medication reconciliation is what's needed. So we tried to build this so that the practices would have flexibility about how to do this, and it will vary by condition and by patient, I believe.

CHAIR BAILET: Kavita and then Paul.

DR. PATEL: Thank you. Just a couple of kind of follow-up.

For the 20 percent or whatever percent, even if -

- let's say that changes, which I fully expect it could, depending on where you're at. It might be a larger proportion. It might be a smaller one. Did you happen to look to see, to Tim's point, that sometimes in different integrated structures of governance, there could be variation?

And the reason I'm asking this is because in the waivers, which I think are very appropriate to be able to do telemedicine and be more flexible, there are a number of efforts in primary care to try to take advantage of even existing codes.

I'll just use my own example. We are aggressively through using Maryland's kind of health information exchange system and kind of things that we're adding that I'm personally trying to see our primary care practice add on, where we know that once a patient hits an ED anywhere in the DMV area, we're actually automatically trying to reach out and schedule those TCM visits because, one, it adds revenue. To your number two, that's our number one. And number two, it's hopefully the right thing to do for patients. I wish that order was reversed, but that's what we're trying to do.

You mentioned already kind of the surprise of

that 30-day lag. If you do get some of these waivers and you can advance in this model, I can almost see even more complexity with kind of this overlap that I think you were alluding to.

So just to recap, number one, have you seen any variation? Were you able to do any analyses that looked at different kind of integrations or structures around employment or lack thereof that give you insights into better care coordination?

And then, number two, how could you -- it's great that there are ED docs. I'm not shocked. My own ED docs are, as I am, very frustrated with kind of missed handoffs, but could you move forward and even advance a couple of years and see where there's actually more burden by having ED docs doing TCM visits or ED docs doing CCM visits and things like that?

DR. NEDZA: We were very careful to make a preliminary requirement that there be a conversation between the ED doc and whoever the handoff was going to be with, that there would be a physician-to-physician contact, which is not the norm right now.

So that first step would be to connect that person back into the setting where they should be achieving

their care, their primary care setting, facilitating the specialty follow-up that sometimes doesn't happen, or if they're out of town, doing it with the people who are taking call -- I think we found 5.8 percent of visits took place in a state other than the one where the person resided. Snowbirds, right?

And so the first thing here is to make sure they get reconnected into the system. The waivers are designed to serve as an interim step when that's not going to be -- you know, it's Friday night. It's Monday. They're out of town. There's not room in the schedule to serve as a way for us to do that when no other services are available, so secondary, because we did not want to create another system here that's unnecessary.

CHAIR BAILET: Paul.

DR. CASALE: Yeah. Thank you, and just a couple of comments.

Just one comment around scope, and you mentioned there's no payment specifically for -- you know, payment model for EDs, but I can tell you in my ACO, we would not be successful without the close collaboration with ED. I mean, ED is critical, and as you've already alluded to, the decision-making around who gets in the hospital and who

doesn't is critical for cost savings.

And I have some similar concerns that Bob has around total cost of care. This is probably more from my cardiology hat. As soon as that chest pain patient gets to the cardiologist, they go off and running. You assume -- at least in my experience, I have not seen that the ED physician rein that in. Whether it's appropriate or not, I'm just saying that that often can go, but that's that.

My main question is back to what I had asked Tim, which is around the patient being sure they understand that potentially this is a model in which there are financial incentives for the ED physician. At the same time, there may be higher costs for them, and how would you manage that within this model?

MR. STEINWALD: Well, you are a cardiologist, right?

DR. CASALE: What?

MR. STEINWALD: Just checking.

DR. CASALE: Yeah, yeah. Absolutely, yeah. I'm the one off and running.

DR. NEDZA: We did build in a patient notification in the process in the ED. There's no process measure associated with it because we assumed it needed to

be 100 percent because that's what it's like in other CMS advanced payment models. So we assumed that that was going to be important.

We have been struggling, just as the rest of the health care system has, as payers with the differences when a patient is in a bed next to someone having a similar workup, and one is an observation status and one is an inpatient. So our goal in that, the discussions around the model, in the safe discharge assessment, in the shared decision-making, will be to also continue to inform patients about what their options are and what the potential -- even potential cost is, if necessary.

DR. CASALE: Right. But will that also include the fact that in this model, based on the decision-making, there is the opportunity for the physicians to -- the kind of financial benefit?

DR. NEDZA: Yes. Yeah. Yeah, we have a financial -- yes, definitely.

DR. PILGRIM: Yes is the short answer.

And I would add to Sue's comments that these conversations are increasingly coming to us anyway. The patients will ask us directly: "If I am in the hospital, will I be an inpatient? Because AARP and others have told

me to ask that question," so --

DR. CASALE: Right. No, no. I get that part. It's just that in this model, because you can -- not you, but the ED physician -- can benefit, based on the decision-making separate, as long as that's --

DR. PILGRIM: Good point. Thank you.

CHAIR BAILET: Seeing no other questions, again, I want to thank all of you for the thoughtfulness and all of your efforts creating this model and then working with us to understand and evaluate it and then your comments today and being with us, so thank you again.

So, if you could take a seat, then we're going to have -- we have two folks in the audience who want to make public comments regarding this model. The first is Sandra Marks from the American Medical Association.

So, Sandy, I would ask if you want to make your comments at the microphone, that would be great. Super. Thank you, Sandy.

*** Comments from the Public**

MS. MARKS: Okay. Thank you.

The American Medical Association supports the acute unscheduled care APM proposal and urges PTAC to recommend it to the Secretary.

The model fills an important gap in the current APM portfolio. Decisions that emergency physicians make in diagnosing symptoms and treating patients in EDs can have significant impacts on patient outcomes and on Medicare spending and other payers.

There are many other opportunities to reduce spending through changes in the way emergency care is delivered, but there has been no APM designed specifically for emergency physicians and the contributions they can make to higher-value care delivery.

Emergency physicians face severe and growing time and financial pressures similar to those many other physicians face. The current fee-for-service system allows emergency physicians only a short amount of time to make what are often very high-stakes decisions about patient diagnosis and treatment.

There are no payments to support the time and staffing beyond face-to-face encounters that would help emergency physicians obtain relevant information about patient history and evaluate the timeliness and quality of care a patient would receive in the community if they were discharged from the ED.

Current bundled payment models allow enhanced

services to be delivered to patients who are admitted to the hospital but provide no additional support for patients who are discharged without being admitted. Consequently, when in doubt, the safest decision is to admit the patient to the hospital.

We commend ACEP for developing an APM designed to fix this problem, so emergency physicians will have the resources and incentives to send patients home when it's safe to do so. We think this APM is an important complement to primary care APM, such as CPC+, hospital-based bundled payment programs such as BPCI, and other APMs such as the oncology care model and ACOs, and will help those other APMs to be more successful.

There are many aspects of health care delivery and payment that need to be improved, and no one specialty can fix all of them. We urge you not to penalize this model because it focuses on the types of services that emergency physicians feel they can control, even though, at least as proposed, it does not focus on some other services that are delivered by other physicians.

We believe this model requires emergency physicians to do what they can to ensure care coordination, and other APMs will need to provide the support to other

physicians in order for them to reciprocate.

Finally, there have been other CMMI-supported models, such as one called Bridges to Care, that showed EDs can essentially function as medical homes for patients who do not have one. So there has been some demonstrated success in providing this kind of post-discharge care coordination.

Thank you.

CHAIR BAILET: Thank you, Sandy.

The next commenter is Kevin -- is it Biese?

MR. BIESE: Biese. Yes, sir.

CHAIR BAILET: Thank you. From UNC Health Care and West Health.

DR. BIESE: Thank you so much, and thank you for an excellent conversation.

I'm Kevin Biese. I'm an emergency medicine physician and vice chair of Emergency Medicine at UNC-Chapel Hill and focus on geriatric emergency medicine and lead an accreditation program for recognizing emergency departments as being geriatric appropriate and also run a consortium around the country to improve care of older adults in emergency departments. So this is close to my heart, most of my waking hours, and I do a lot of that work

in concert with ACEP.

Just three comments. One, I think it's really important to remember that hospital admission for frail older adults is often harmful, and so there is a risk to discharging the wrong patient. I make that decision every day, who am I admitting and who am I discharging, but it's not as if it's totally safe to admit them and potentially risky to discharge them. It is often potentially risky to admit them, and that has to be balanced into this equation. It's hard to quantify, but gosh knows there's a lot of data that suggests that, which means that creating a pathway to encourage safe and carefully coordinated transition to a setting other than inpatient admission is wonderful for patient well-being in addition to fiscal considerations, which are obviously profound.

Two is that hawking geriatric emergency departments, I spend a lot of my life working with health care system leadership, talking about how you do this launching educational improvement programs in hospitals around the country. A lot of health care system leadership is interested in finding ways to transition these patients out of -- to discharge them from the ED, to not admit them to the hospital, and so I think that there's an

understanding that sometimes this is neither financially meritorious for some of these marginal cases, especially if they could have prolonged lengths of stay, as well as potentially harmful to admit them. And so this might be -- this might land on a more receptive audience than one might initially think from working across -- with CEOs across the country on this.

And, finally, I just wanted to agree with Dr. Ferris' comment about the Hawthorne effect of this. Right now, as a practicing emergency medicine physician, it feels like I'm mostly incentivized to admit the patient. I feel at risk if I'm discharging them. It's painful I've got to set stuff up, and so that's the way the water flows.

And I think, though, even those this is a limited number of conditions, just really introducing that mindset at a systematic level may spill over profoundly into the way that I think about patients I treat with other conditions that have marginal indications for admission as well as my colleagues' thought processes may have as well.

So I defer to the Committee as to how to best set this up. I'm not an expert in the economics of health care, but I'm tremendously excited about the potential impact this could have on care trajectory.

CHAIR BAILET: Thank you, Dr. Biese.

We have -- no one indicated that they're going to speak on the phone, but I'm asking the operator. Is there anybody on the line that wants to make a public comment?

OPERATOR: Yes, we do. We do have one line from the line of Bing Pao from the EDPMA to now comment through the telephone.

Go right ahead.

DR. PAO: Yes. Hi. This is Dr. Bing Pao. I just want to make sure everybody can hear me.

CHAIR BAILET: Yes.

DR. PAO: I am speaking on behalf of the Emergency Department Practice Management Association, or EDPMA. EDPMA, the trade association representing the business of emergency medicine, our members include physician groups, both large and small. We also represent a number of support organizations, such as billing and coding companies.

Together, our members deliver or directly support emergency care in over half of the emergency physicians throughout the United States.

EDPMA is proud to endorse the acute unscheduled care model. We believe that this model will improve care

as well as reduce cost.

Emergency physicians play an essential role in reducing health care cost by providing quality care and diagnostic testing on a timely basis, so patients can avoid significant downstream health problems and related costs.

To date, however, as has been mentioned multiple times, emergency physicians have not been able to participate in alternative payment models in a meaningful extent, and I think the model that is being presented will provide that opportunity for emergency physicians to participate in alternative payment models as well as being able to merge this model with other alternative payment models.

The model ensures that emergency physicians who are making the initial decisions on inpatient or outpatient care are recognized for making good decisions and encouraging discharge emergency department when appropriate and believe that there are certain safeguards that have been introduced to prevent inappropriate discharges.

Overall, we expect the model to reduce avoidable emissions, EDPMA is happy to endorse the model.

CHAIR BAILET: Thank you. Thank you for your comment.

Any other comments on the line, operator?

OPERATOR: We have no more comments on the line.

CHAIR BAILET: Thank you.

So I turn to my colleagues in the Committee. Are we ready to begin the voting process?

[No response.]

*** Voting**

CHAIR BAILET: I'm seeing I think we're all in on that.

So we're going to begin voting electronically on the 10 criteria starting with Criteria 1. There are now -- for clarity, there are -- Harold, you're not voting, so there are nine of us that will vote. They will be showing up at 10 because of the equipment, as I understand it, and a 1 and a 2 does not meet, 3 and 4 meets, 5 and 6 meets and deserves priority, and then the asterisk is not applicable.

So we're going to go ahead and start to vote with Criteria 1, which is scope, considered a high-priority item aimed to either directly address an issue in payment policy that broadens and expands the CMS APM portfolio or include APM entities whose opportunities to participate in APMs have been limited.

So please go ahead and vote.

[Electronic voting.]

*** Criterion 1**

MS. SELENICH: Okay. So two members voted 6 that is meets and deserves priority consideration. Three members voted 5, meets and deserves priority consideration. One member voted 4, meets; and three members voted 3, meets. Zero members voted 1 or 2, does not meet; and zero members voted not applicable.

A simple majority determines the Committee's recommendation and may roll down until a simple majority is met. In this case, however, we have five members in the meets and deserves priority consideration, so that is the finding of the Committee on this criterion, Criterion 1, meets and deserves priority consideration.

CHAIR BAILET: Thank you, Sarah.

Let's move to Criterion 2, which is quality and cost, also high-priority criteria. Anticipated to improve health care quality at no additional cost, maintain health care quality, while decreasing cost, or both, improve health care quality and decrease cost.

Please vote.

[Electronic voting.]

*** Criterion 2**

MS. SELENICH: Zero members vote that the proposal meets and deserves -- zero members vote 6, meets and deserves priority consideration. One member voted 5, that the proposal meets and deserves priority consideration. Two members voted 4, meets. Five members voted 3, meets. One member voted 2, that the proposal does not meet; and zero members voted 1, does not meet; and zero members voted not applicable.

So the finding of the Committee as we roll down is that the proposal meets Criterion No. 2.

CHAIR BAILET: Thank you, Sarah.

We're going to move to Criterion 3, which is payment methodology. Pay the APM entities with a payment methodology designed to achieve the goals of the PFPM criteria. Addresses in detail through this methodology how Medicare and other payers, if applicable, pay APM entities, how the payment methodology differs from current payment methodologies and why the physician-focused payment model cannot be tested under current payment methodologies. High-priority criteria.

Please vote.

[Electronic voting.]

* **Criterion 3**

MS. SELENICH: So zero members vote 6, that the proposal meets and deserves priority consideration. One member votes 5, that the proposal meets and deserves priority consideration. One member votes 4, the proposal meets the criterion. Four members vote 3, that the proposal meets the criterion. Three members vote 2, that the proposal does not meet the criterion. Zero members vote 1, does not meet; and zero members vote not applicable.

Therefore, the finding of the Committee is that the proposal meets Criterion 3, payment methodology.

CHAIR BAILET: Thank you, Sarah.

Let's go to Criteria 4, value over volume. Provide incentives to practitioners to deliver high-quality health care.

Please vote.

[Electronic voting.]

* **Criterion 4**

MS. SELENICH: So, again, zero members vote 6, meets and deserves priority consideration. Two members vote 5, meets and deserves priority consideration. Five members vote 4, meets. Two members vote 3, meets; and zero members vote 1 or 2, does not meet; and zero members vote

not applicable.

Therefore, the finding of the Committee is that the proposal meets Criterion 4, value over volume.

CHAIR BAILET: Thank you, Sarah.

Criterion 5, flexibility. Provide the flexibility needed for practitioners to deliver high-quality health care.

Please vote.

[Electronic voting.]

* **Criterion 5**

MS. SELENICH: One member votes 6, meets and deserves priority consideration. One member votes 5, meets and deserves priority consideration. Four members vote 4, meets criterion. Three members vote 3, meets criterion; and zero members vote 1 or 2, does not meet; and zero members vote not applicable.

Therefore, the finding of the Committee is that the proposal meets Criterion 5, flexibility.

CHAIR BAILET: Thank you.

Criterion 6, ability to be evaluated. Have evaluable goals for quality of care, cost, and other goals of the PFPM.

Please vote.

[Electronic voting.]

* **Criterion 6**

MS. SELENICH: Zero members vote 6, meets and deserves priority consideration. One member votes 5, meets and deserves priority consideration. Six members vote 4, meets criterion. Two members vote 3, meets criterion. Zero members vote 1 or 2, does not meet criterion; and zero members vote not applicable.

Therefore, the finding of the Committee on this Criterion 6 is that the proposal meets.

CHAIR BAILET: Thank you, Sarah.

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

Please vote.

[Electronic voting.]

* **Criterion 7**

MS. SELENICH: Zero members vote 6, meets and deserves priority consideration. One member votes 5, meets and deserves priority consideration. One member votes 4, meets criterion. Five members vote 3, meets criterion.

Two members vote 2, does not meet criterion; and zero members vote 1, does not meet criterion; and zero members vote not applicable.

Therefore, the finding of the Committee is that the proposal meets Criterion 7, integration and care coordination.

CHAIR BAILET: Thank you, Sarah.

Patient choice. Encourage greater attention to the health of the population served while also supporting the unique needs and preferences of individuals.

Please vote.

[Electronic voting.]

* **Criterion 8**

MS. SELENICH: So zero members vote 6, meets and deserves priority consideration. One member votes 5, meets and deserves priority consideration. Four members vote 4, meets criterion. Four members vote 3, meets criterion. Zero members vote 1 or 2, does not meet criterion; and zero members vote not applicable.

Therefore, the finding of the Committee is that the proposal meets Criterion 8, patient choice.

CHAIR BAILET: Thank you.

Criterion 9, patient safety. Aim to maintain or

improve standards of patient safety.

Please vote.

[Electronic voting.]

* **Criterion 9**

MS. SELENICH: Zero members vote 6, meets and deserves priority consideration. One member votes 5, meets and deserves priority consideration. Four members vote 4, meets criterion. Three members vote 3, meets criterion. One member votes 2, does not meet criterion. Zero members vote 1, does not meet criterion; and zero members vote not applicable.

Therefore, the finding of the Committee is that the proposal meets Criterion 9, patient safety.

CHAIR BAILET: And last, Criterion 10, health information technology. Encourage the use of health information technology to inform care.

Please vote.

[Electronic voting.]

* **Criterion 10**

MS. SELENICH: So zero members vote 5 or 6, meets and deserves priority consideration. Three members vote 4, meets criterion. Six members vote 3, meets criterion. Zero members vote 1 or 2, does not meet criterion; and zero

members vote not applicable.

Therefore, the finding of the Committee is that the proposal meets Criterion 10, health information technology.

CHAIR BAILET: All right. Are we ready to go ahead and make the recommendation to the Secretary? I see everybody nodding affirmatively.

So the way this will work, we will vote electronically, and then we will go around to the individual Committee members to share how they voted. And this is a vote from -- a vote of 1 or 2 means does not meet the criterion. A vote of 2 is recommend the proposed payment model to the Secretary --

What?

[Speaking off microphone.]

CHAIR BAILET: You guys, you're throwing me off my game here. Am I good? Okay, very good.

So you can see the numbers behind you.

[Laughter.]

CHAIR BAILET: I love you guys, honestly. Team work and respect every day here on the PTAC.

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

[Electronic voting.]

* **Final Vote**

MS. SELENICH: So two members vote 4, recommend proposed payment model to the Secretary for implementation as a high priority. Five members vote 3, recommend proposed payment model to the Secretary for implementation. Two members vote 2, recommend proposed payment model to the Secretary for limited scale testing. Zero members vote 1, do not recommend proposed payment model; and zero members vote not applicable.

A two-thirds majority is needed for the recommendation to the Secretary, which is with nine members voting, six. Therefore, the finding of the Committee is that -- as we roll down -- is that the proposed model is recommended to the Secretary for implementation.

CHAIR BAILET: All right. I'd like to -- I guess I would like to start with Tim, for your comments, and just be mindful that as you -- pardon me?

[Speaking off microphone.]

* **Instructions on Report to the Secretary**

CHAIR BAILET: Yeah. So please include -- if you want comments specifically highlighted, this would be a good time to make sure that those go on the record for the

staff to be able to capture those as we go around the room, so starting with you, Tim.

DR. FERRIS: Yes. So I voted 3, recommend -- just lost the slide, but I think I can still function. And I have to say I was on the fence with voting high priority.

I think it -- I was very impressed that the submitters heard what we were saying, and their willingness to adjust and think in their -- the thought with which, the care of thought with which they went through the two-handed issues and the tradeoffs, and I commend them on their diligence in getting this work done -- and as I started off by saying their commitment to making health care better. So that's --

CHAIR BAILET: Thanks, Tim.

Grace.

DR. TERRELL: I voted 4, with highest priority.

So I think that if we can get this right in the emergency departments across the country that we will have solved a lot of the work that we've been tasked to do on PTAC.

So much of my experience as a practicing clinician through the years has been about the response to the emergency department, right? I mean, that's how we

ended up with hospitalists because it was hard for docs to keep doing what they were doing, coming in the outpatient and then going to the emergency department.

I used to want to know who was on call in the emergency department to see if I knew whether I was going to have to get up in the middle of the night a lot because it wasn't necessarily evidence based. It was just based upon the lack of a system.

And what these individuals have done here and the people behind them, they've created an extremely thoughtful way of approaching in what I believe is a safe way. They answered the questions and concerns that the PRT had -- to really start getting into -- if we're able to solve it, then we will have solved quite a bit of what we've been tasked to do. If you look at all the ACO models that are out there, quite a lot of the savings thus far has been from reduced hospitalizations and reduced ED utilization, but it hasn't been with bringing emergency department physicians into that conversation in a meaningful way through an alternative payment model.

So I agree with Sandy Marks and the AMA that this is crucial. I agree with the gentleman from UNC that it's often dangerous to admit someone to the hospital, and this

is just a terrific thought process on the part of these individuals and who all is behind them. And I wish you Godspeed.

CHAIR BAILET: Thank you, Grace.

Paul.

DR. CASALE: So I voted for I recommend for limited scale testing, and I have to tell you I was on the fence between that and for recommendation.

And I agree with Tim and Grace's comments.

I think where I ended up, I still have concerns around the ED physicians taking total cost of care for 30 days. So it's that that I think needs to be fleshed out further, and the other is around the integration and care coordination, which again I think they speak to, but I think there needs to be more definition.

And they're sort of hand-in-hand. If you're going to take 30-day total cost of care, you clearly need a lot of integration and care coordination. I think that part would benefit from the limited testing before going to full implementation.

CHAIR BAILET: Bruce.

MR. STEINWALD: I'm a 3, and I think I'm -- I was very impressed, both with the proposal and also with the

discussion and with the proposer's willingness to consider some modifications that I think we will need to highlight in our report to the Secretary.

One is to remove the artificial distinction between observation stays in the ED and elsewhere.

The second is to consider a transition from historical controls to something that's a benchmark, and we might even want to mention -- I think Dr. Nedza mentioned the ED Benchmarking Alliance or some national activity that's focusing on benchmarking ED services and specifically what should be admitted and what should be not admitted.

And then, third, I think we should emphasize also, given the pushback we've gotten on the misunderstanding of what we mean by limited scale testing, I didn't really want to go there, but also emphasize that this model appears to have sprung expandability potential, both in terms, I assume, in the number of EDs that could participate, but also in the number of conditions that could be added to the four that we'd be starting out with.

And I would recommend that we suggest that there should be a mechanism in the model for explicitly identifying conditions that could be expanded in the

locations where they appear to be implementing the model successfully.

CHAIR BAILET: Thank you, Bruce.

And I agree with your comments. I think this was incredibly thoughtful, the process, the work that you guys did in creating the model and working with us to understand it.

I think the fact that you took the observation conundrum off the table completely, immediately, that's where I personally was hung up on this model, frankly, and so the fact that I voted to recommend it, knowing that that distinction is now going to be -- that would be taken care of.

I think the benchmarking piece is a challenge, and I would hope that there would be a phased approach that as more information comes in and we get more clarity around performance, that that gets standardized rather than facility-specific understanding. We have to start someplace.

So, again, I want to thank the submitters and the emergency medicine physicians who stand beyond you that you represent. This is an incredible -- now that I work, I move from the provider side with 15 hospitals in my

previous life at Aurora Health Care and over a hundred emergency physicians supporting those facilities, and now as a payer supporting payment for the patients who then avail themselves of those facilities. This has been a tremendous challenge for the country, a tremendous expense.

And I agree with your comments about being in the hospital. If you don't need to be there, you shouldn't be there, period, dot, and given the wide variability of admissions right now for patients with these same conditions, we know there's opportunity. And this gives the platform for clinicians and the patients to take another look at where is the best possible place to be to take care of the problems that they're presenting with.

So, again, I applaud you. Thank you.

Len.

DR. NICHOLS: So I voted 4 for high-priority recommendation. I took my cue from Dr. Bettinger who made it clear that from the beginning, they were thinking about getting it past CMS, and since we've had no success doing that so far, I thought I would follow your brilliant lead.

That's also why I said high priority because I realize if it's not high priority, we're probably not even going to get a serious look. So I think it's really worth

saying this is -- no, but we've recommended some damn good models before. And we've had some thoughtful applicants before. None beat this group, in my opinion, for how much care you put into it, for the problem that you're addressing, the scope that it really would affect.

I love the Hawthorne effect idea. I think that's true, and I trust these people. So I'd say Godspeed.

CHAIR BAILET: Thank you, Len.

Kavita.

DR. PATEL: I voted No. 3 to recommend, and to be honest, the reason I did that is because I think that we've had feedback from the administration that the kind of category of limited scale testing is actually somewhat murky. So if we had some clarity, I would -- to be perfectly transparent, actually say that because of the issues that have already been raised as well as my concerns about what I see as very inevitable, not even model overlap, but this overlap with kind of existing attempts for better care coordination and fee-for-service, I would have actually said that this is something we should think about meaningfully pilot.

And hearing the Secretary's comments about being willing to do that even in a mandatory way might extend to

this type of model.

And then the final thought I would have is to say that fixing this issue actually starts even prior to the kind of thought process of whether to admit a patient. It actually starts with when someone calls or chooses to call 911, triggering an ambulance that comes out, and for Medicare to pay for that ambulance visit previously that had to kind of -- there had to be an actual formal ED visit that followed.

So there's almost kind of a preventive aspect to this that is incredibly important. To Grace's point, getting this right will help make so many aspects of what patients and caregivers of patients hate about the thought that your kind of ultimate resort is the emergency department.

So I'm hopeful that the message to the Secretary is that this should be considered in line with models for better home-based care, models for better primary care, and ways to get us beyond incremental approaches to value.

CHAIR BAILET: Thank you, Kavita. Bob?

DR. BERENSON: Yeah, I voted 2, mostly for the reasons that Paul very eloquently presented. I don't think ER docs should be accountable for total spending for 30

days. They should be doing a great job in the ED and should be facilitating a handoff. In those circumstances where there's nobody to hand off to, then yes, I think there might be a role, but this is much broader than sort of filling that gap. But, I mean, it goes to sort of the basic issue of when is total cost of care appropriate, and I don't think 30 days is the right way to approach this.

I didn't want to vote, even though I know 2 is -- did you use the word "murky"? Somebody used the word "murky." It may be even nonexistent. I didn't want to vote 1 because I agree with Grace. This is a huge, important area. Since I was practicing, which is now quite a while ago, well, it used to be just standard that the primary care doc and the ER doc had the conversation when the patient hit the ED, and at disposition, either admission or discharge, and then a number of circumstances, because we had that conversation, we didn't have to admit the patient, and I could see that patient at 9 the next morning and the ED doc was comfortable with that as the reasonable disposition. That is -- my understanding is it almost doesn't happen anymore. And so the ED doctor is stuck, and they overly admit because of that, because they are reasonably practicing defensive medicine in those

circumstances.

So I am very sympathetic to what they are trying to accomplish here. I just don't think I see a care model that assures the patient care for 30 days, and what the ED docs' responsibilities are. So I actually think the thing really does need to be developed. It's worthy of developing. It's a shame that CMS so far hasn't considered our limited scale testing option to be viable, but that's what I think is exactly appropriate for this proposal.

CHAIR BAILET: Thank you, Bob. Len, did -- well, you wanted to make a comment before Rhonda?

DR. NICHOLS: I just wanted to pick up on the limited scale testing point, because the way I would phrase it, and I would hope my colleague might agree, is that we don't want to use that word anymore. What we want to do is we say this proposal needs some work. They acknowledge that. They heard us when we said you're not going to get away with historical forever, and they agree you've got to go to blended. But that's got to be worked out and the peer identification sounds like it's non-trivial. It sounds like you're on the case. All that is what I would call technical assistance, preliminary work to get a proposal ready for prime time. We, at one time, called it

limited scale, but we got in trouble for that. So I'd just say purge that and let's talk about CMS should help these people get this ready.

DR. BERENSON: My only response, I'm all for purging. We should use the term "limited scale testing." I think you're talking about some technical fixes. I think my concerns are more conceptual about whether this is really how we want the ED docs to be facilitating improved alternatives to hospitalization, and that's more fundamental.

CHAIR BAILET: All right. Rhonda.

DR. MEDOWS: So I voted number 3 for recommendation, and I did so for several reasons. Number one is that I thought that actually the physicians who are serving in the emergency room, as well as the emergency room care teams, and the populations that are dependent on their care in the emergency room, particularly during times when we don't have adequate ambulatory access elsewhere, really needed to be included in the value-based care and in the population health round. That's just number one.

Two, I want to tell you that I really commend you for coming forward with a model that brings you in with everyone else. Our patients will appreciate this going

forward, if they understand that you understand that things are changing and that they are evolving, and you're right on the bandwagon with us.

I think the goal toward getting people to be where they need to be more appropriately, in terms of their care settings after they've been assessed, after they've been diagnosed, and after a care has been outlined for them is vitally important. I totally do agree that sympathy because of default has been to put someone in the hospital when all else is unclear or the handoff cannot be accomplished, or there isn't a support system at home, we need to do better than that. We should be beyond doing that at this point. And I know that I'm preaching a little bit to the choir here, but it's really important that we recognize that this is totally possible for us to do.

I really appreciated the remarks about the patient discharge assessment, the inclusion of social determinants of care in that assessment. I have to tell you that some of the best ERs that I've been in, either as a patient or the mother of a patient or a doctor have been the ones that have actually done some of this work regardless, without a formal process, without resources, and they've done the work of actually trying to reach out

to the person's primary care physician, et cetera. But there's always that gap, and that gap has grown. We need to reverse that trend.

I also appreciate your comments about making sure that there be a formalized way to tighten the handoff, physician to physician, and the part about the patient choice and education. They need to understand what decision is being provided to them as an option, another way of receiving the care that they need.

I have two comments to include in the comments to the Secretary, and that is when we talk about resources, that's something that needs to be more vetted and it needs to be built upon. There are different ERs, different communities, little tiny hospitals, bigger hospitals. What resources are we going to use to actually make sure that that care coordination occurs, the information occurs, and over what time period?

I understand my colleagues' concerns about, you know, what happens immediately on discharge, 7 days, 30 days, but I think for the ones that have a primary care physician or have a medical home that there still needs to be that time period when somebody is paying attention to what happens during that initial discharge phase. Whether

it's a week or 30 days, we can debate that. Just make sure that they don't get lost.

The other one that I wanted to say is not really limited to the emergency room physicians themselves but to all of us, and that is we need to be concerned about polymanagement and polypharmacy. Right? Everybody wants to be part of this system. That handoff becomes really important. The emergency room physician, at the time of the care in the emergency room, has a unique opportunity to impact positively somebody's care, right then and there, but that handoff needs to occur so that we don't have patients two weeks, three weeks out getting a call from their primary care doc about now we're going to change this, but there's not a disease management company calling them, there's not a health plan calling them. There has to be a coordination. Otherwise, patients get frustrated, and they just throw their hands up in the air, and they go back to their old way of doing it, which is to then come back and visit all of you and say, "I don't know what to do."

But thank you very much for bringing this forward.

CHAIR BAILET: Thank you, Rhonda. I'd like to ask Susan, who has been just scribbling away here, to make

-- if you can summarize what you captured, to make sure that -- oh, Tim, and then Harold. Sorry. And Bruce, it looks like.

DR. FERRIS: Sorry. I just wanted to be on record in response to Bob's total cost of care, and I'm going to go back to the two-armed economist here. And I think while, conceptually, I think total cost of care in this setting is problematic, I believe that there are -- you can design situations in which total cost of care can make sense. And I will say I believe they have designed a situation in which total cost of care makes sense.

And the critical mitigator that I see is how much risk you're taking. If you're taking full downside risk on total cost of care, that would be completely untenable. The fact is the downside risk here is significantly limited.

The second design feature here that mitigates total cost of care is historical control. Now things do change over time but they change sort of slowly, and so using the historical control is a mitigating factor, I believe, in total cost of care.

The third thing that mitigates total cost of care here is the way they structured the ramp toward greater

risk and the multiple levels of risk. That also offers an opportunity to mitigate the highly salient point that Bob made about accepting total cost of care risk when you don't, in fact, control total cost of care.

So I would like just to have those points on record. Thanks.

CHAIR BAILET: Harold.

MR. MILLER: I had one suggestion to include in the report, which I don't think in any fashion conflicts with my recusal on voting and deliberation. We tend to talk about all of these models from the urban perspective and envision emergency departments as being big places with high volumes of people going through them.

But there are a lot of emergency departments around the country that are extraordinarily small, and that are struggling to stay open, and have trouble even attracting the one emergency physician who happens to staff that often times, amazingly enough, I've discovered, in many cases, 24 hours a day for multiple days at a time, who actually essentially lives in the emergency department to provide that care. And I think that as this goes forward, I think basic concept could work in those small emergency departments with those physicians but probably not if it's

simply rolled out in one standard fashion as though it was a large emergency department.

So I think thinking about the issue of the benchmarks and the risks and the calculations and some of the costs associated with that would need some special attention, and I think that in order to have this either not leave out those parts of the country where it would also be desirable to make sure the patients have the ability to go home safely, and not to create any further stress on emergency departments in small hospitals that are actually at risk of closing, that there be some special attention in implementation of the model to make sure that there are opportunities for rural emergency physicians and small rural, frontier and rural emergency departments to participate.

CHAIR BAILET: Thank you, Harold. Bruce.

MR. STEINWALD: To add to what Tim said, actually, he said much more important things than I'm about to say. But to deal with Paul and Bob's concern in the report to the Secretary, I wouldn't cast this as something that needs to be cited in advance of implementing a model, that is the 30-day total cost of care.

We've complimented these people on the

thoughtfulness of their proposal and comprehensiveness. I'm willing to give them the benefit of the doubt. If they believe that the model should be implemented the way that they've designed it, I think we should go with that, but make it clear that part of the evaluation of the model needs to be to examine the period in which ED physicians are going to take responsibility and to see if it needs to be adjusted based on the evidence that the model will produce.

CHAIR BAILET: Thank you, Bruce. So Susan, your pen is smoking. If you could just -- do you want to go ahead?

MS. BOGASKY: I sure will, but I'll also go back to the transcript, just so you know, in terms of I'm getting the details.

So I think the main strengths that I've heard from the PTAC are that it's a very thoughtful and comprehensive proposal, it is a huge, important area of work, it's filling a very important gap, it's in line with the secretarial and CMS priorities, it's an important platform to look at in terms of the best placement of patients. A very major strength of the proposal is the willingness of ACEP to modify based on the PTAC and PRT

concerns, specifically in the area of the observation issue, the ED observation and the non-ED observation.

The willingness of ACEP to consider, in the near or the mid or longer term, a willingness to consider the issue with the episode targets, in terms of thinking about regional versus some other approach and taking into consideration research that's underway, in terms of the benchmarks. And also the important issues with care coordination that were raised by the PRT and the PTAC and the 30-day period.

There is strong expandability in EDs and in conditions. Another strength is nesting with other APMs and other models that are underway at CMS, and care should be taken in looking at that sort of nesting.

Getting this right is important and it fits a very -- it's at the basis, or at the foundation of the work of the PRT, and that was a theme that was repeated. It's a very practically applicable model, that there's a recommendation and we can discuss how this wording will go, in terms of CMS should work with the submitted to refine things that have been identified by PTAC in the model implementation.

There also needs to be a discussion about the

resources used for care coordination, and that would need to be worked out. The handoffs and the coordination are an important aspect of the model.

There are some concerns with the 30-day period in terms of cost of care, but that could be mitigated by the amount of risk that's taken and the design feature of the model that allows a historical aspect. There's also a design feature of the model that allows different features and different raps towards risk, and multiple levels of risk could also mitigate the care risk. Part of the evaluation of the model also could take into account the 30-day period. Also, we should include language that this model, there should be special attention to ER departments that are in small hospitals and attention to aspects that are of the model that were raised by the PRT, in terms of benchmarks and other features should be considered to make sure that we can lift all the boats and that all types of hospitals will be included, and that it really lends itself to an opportunity for rural and frontier ER departments.

But I will go back to the transcript as well.

CHAIR BAILET: That was impressive. Thank you, Susan. That was amazing.

Any other wrap-up comments? Bruce.

MR. STEINWALD: Yeah. You may have said it and I didn't hear it, but we want to make sure that we present this recommendation as something that has substantial scope, that could go far beyond the four conditions that initially would be tested and that could be expanded.

CHAIR BAILET: All right. Again, I want to compliment our efforts today, and seeing that we are done with this proposal we are going to break for 45 minutes, and then reconvene. Again, I want to thank the submitters. Thank you.

[Whereupon, at 11:47 a.m., the meeting was recessed for lunch, to reconvene at 12:30 p.m. this same day.]

AFTERNOON SESSION

[12:38 p.m.]

CHAIR BAILET: All right. If everyone could please take their seats, we are now going to start reviewing our second proposal, An Innovation Model for Primary Care Office Payment, Payment Model IMPC-APM, submitted by Dr. Jean Antonucci. Harold Miller is the lead PRT reviewer. Tim Ferris -- Dr. Ferris and Dr. Kavita Patel are on the review team, so I'm going to turn it over to Harold.

*** An Innovative Model for Primary Care Office Payment. Submitted by Jean Antonucci, MD**

MR. MILLER: Thank you, Jeff.

As Jeff said, this is a proposal for what was described as An Innovative Model for Primary Care Office Payment, from Dr. Jean Antonucci. I want to say --

DR. BERENSON: Disclosures.

MR. MILLER: Oh, disclosures. Oh, disclosures.

CHAIR BAILET: Yeah.

MR. MILLER: Yes, Jeff. What about the disclosures?

CHAIR BAILET: I had too much lunch, I guess. We'll start with Rhonda.

*** Committee Member Disclosures**

DR. MEDOWS: Nothing to disclose, Mr. Chairman.

CHAIR BAILET: I have nothing to disclose.

DR. STEINWALL: I still have nothing to disclosure, Mr. Chairman.

DR. BERENSON: I am going to recuse myself. I have known Jean Antonucci for many years. I've spoken at conferences related to her organization, Ideal Medical Practices, and was involved with talking to her as she was conceiving the payment model. I haven't been too involved recently. But I informed her before even starting to talk to her that if we did chat that I would be recusing myself. So I now feel that I will follow through with that and not participate, and, in fact, I'm going to sit over there somewhere, and see you later.

CHAIR BAILET: Thank you, Bob.

UNIDENTIFIED SPEAKER: You can keep your seat.

CHAIR BAILET: All right. Kavita.

DR. TERRELL: Kavita Patel, nothing to disclose.

DR. NICHOLS: Len Nichols, nothing to disclose.

CHAIR BAILET: Bruce.

DR. STEINWALD: Bruce Steinwald, nothing to disclose.

DR. CASALE: Paul Casale, nothing to disclose.

MR. MILLER: Harold Miller, nothing to disclose. No conflicts.

DR. TERRELL: Grace Terrell, nothing to disclose.

DR. FERRIS: Tim Ferris, nothing to disclose.

CHAIR BAILET: All right. Thank you. Harold.

*** PRT Report to the Full PTAC**

MR. MILLER: As I was saying, this is about the Innovative Model for Primary Care Office Payment. I want to note that this was a proposal that was submitted to us by Jean Antonucci, who is a solo primary care physician in Maine. I think that one of the things that no one quite knew whenever the PTAC process was first created was who was going to be submitting models, but the hope was that they would be coming from practicing physicians, and you don't get a whole lot more practicing physician than the solo primary care physician who develops a model proposal and submits it to us. So I want to commend Jean for doing

that. I will also note that Jean is here today and is losing money by being here, since she practices in a fee-for-service practice.

As Jeff said, so I led the PRT but Kavita Patel and Tim Ferris, who are both physicians and both primary care physicians, served on the PRT with me, which was invaluable, and I appreciate all of their effort, particularly since each of them was leading another PRT simultaneously, and I think Tim was on yet another one beyond this. So some hazardous duty pay for that.

We had lots of questions for Dr. Antonucci. She responded to all of them and we appreciate that, and spent some time with her on the phone, asking some further questions, and used all of that input to prepare the report, the PRT report to the PTAC, which everyone received and which is posted on the website. That is just the opinions of the three PRT members, and is obviously not binding on the whole group.

So this proposal is designed to help primary care practices by providing additional financial resources, reducing administrative burden, and increasing flexibility. It is specifically designed to be feasible for small, independent office-based practices to participate in.

There is really two, at least as we viewed it, two basic components to the payment. One is a risk-stratified, per-beneficiary per-month payment which would replace, essentially, all of the current fees that a primary care physician receives today, not only for office visits but also for minor procedures and tests, and the money could be used for a variety of flexible approaches to care for the patient. There would be two levels of the patient, so it's not a highly differentiated risk stratification. There are basically two levels of payment, one for what would be described as low- and medium-risk patients and one for high-risk patients, and the submitter-proposed payment amounts of $60 and $90 per month, per patient, for those levels. Then the second component of this was a performance-based payment, which would be withholding 15 percent of that per-beneficiary per-month payment and then paying it to the practice only if it met certain performance standards on quality and utilization of hospital services, although the specific performance standard is not defined in the proposal. And there was a reference to the fact that the practice could potentially, in extenuating circumstances, appeal to have that return.

There would be some basic quality standards in terms of having an annual visit with every patient and maintaining office hours and phone access. Quality measurement would be done through a mechanism that is very different than is used in other current payment models of any type, at least in Medicare, by using something called a "How's Your Health" survey, which is that the patients actually fill out, in a 15-minute online survey, and then that provides feedback to the physician about what the patient said. And there is a national website available where these surveys are compiled, so the physician could also compare his performance, for its patients, with other participating practices.

One of the challenges which will come up is that there is nothing that compels the patient to complete this survey, so an issue would be how many patients would fill out the survey, both to provide feedback to the practice as well as to be able to use for the model.

The information from this "How's Your Health" survey would be -- a subset of that would be used to create something called the "What Matters Index," which would be used for the risk stratification, and this would also be very different risk stratification than is typically used

in current payment structures, where there is simply which diagnoses you have and how many diagnoses. But these are issues relative to the patient, such as pain, emotional issues, et cetera, that have been shown to be predictive of hospital admissions and use of other services.

And in this model the patient would explicitly sign up to be part of the practice. There could also be some retrospective attribution based on visiting the practice, but the idea would be fundamentally the patients would decide to be in the practice. And these are just to illustrate how "How's Your Health" is different than typical quality measures used in MIPS and other programs. This is a list of what some of those things are. This is the patient saying did they go to the hospital emergency department, how are their medications working, have they had sick days, what's the kind of access that they had to care.

Just to try to explain this, because this is not the only primary care proposal, certainly not that we've looked at and that exists. We made this chart simply to show what is similar and what is different. And the left-hand column is the current Medicare Comprehensive Primary Care Plus model, the middle column is the alternative

payment model that was submitted by the American Academy of Family Physicians that PTAC reviewed last fall, and the far right is Dr. Antonucci's proposal, which we have labeled, for shorthand, IMPC. And this is not in any fashion meant to represent that CPC+ is a gold standard to compare to or anything. This is simply to show what already exists, because one of the things that the PRT struggled with was to what extent this is a different model than what is already being done.

So you can see, just as a quick overview, CPC+ has three to four different components to the payment. There is still some fee-for-service component included in that. The AAFP model has four components to the payment, and there is still some fee-for-service payment to the practice. The IMPC model that we're discussing today has only really two components to it, the per-beneficiary per-month payment and the 15 percent withhold.

The quality measures and risk adjustment in CPC+ and the AAFP model were all based on typical quality measures that are currently being used. The risk adjustment was done in CPC+ by diagnosis scores. The APC model from AAFP was proposed to use the Minnesota Complexity Assessment Model. This proposal today using the

"How's Your Health" survey for both the quality measures and for the risk adjustment.

We spent a lot of time discussing this, and you can see the conclusions that we drew overall, in terms of how well the proposal, as it is currently described, meets the criteria. We concluded that it did not meet most of the criteria, although two of those were not unanimous decisions.

And I will do as Tim did earlier. I will focus mostly on the key issues and then I'll go more quickly through the individual criteria.

We concluded this had a lot of similarities to the model that we had already recommended, and some of the reasons for approving a model and the need for a different model in primary care would also similarly apply here to the need for more primary care models. And this is significantly simpler than what we approved before, in terms of simply having a monthly payment structure rather than that on top of fee-for-service.

The other side of that, though, is, our one-hand, other-hand point of view from this morning, is that using a totally monthly payment in place of any fee-for-service represents a potential for undertreatment of the patient,

since there would not be a specific payment associated with seeing the patient or doing something explicitly for the patient.

The quality accountability, based on "How's Your Health," had a lot of attractions to it, in that it is moving to patient-reported outcomes, which we thought was a very attractive thing, things that the patient actually cared about. The difficulty is that using it in a payment model requires some degree of similarity in the way the survey is being administered, and it's some assurance that a representative sample of patients are using the survey. And as best as we could tell there was not really a good way of doing that, at least not described in the proposal, to make sure that patients weren't selectively participating.

There was no explicit description in the proposal as to what quality measures would be used and exactly what the performance levels would be, in terms of returning the 15 percent withhold payment. The concept was certainly articulated, of using it in that fashion, but there were not specific standards.

The proposal was for, as I mentioned, $60 per month and $90 per month, per patient payments. We

estimated that that -- and it would depend on the practice and how much they are billing today, but we estimated that that might be as much as tripling the payment to practices, and we were not -- because that was a large increase and we did not have any way of knowing exactly what the characteristics of the patients in the practice would be. We were not able to conclude that Medicare spending would definitely be maintained or decreased with that kind of a proposal.

So our overall conclusion was there were a lot of desirable features and some potentially very important innovations in this model, but there also needed to be a lot of further development of some of those things in order for it to actually be implemented on a broad scale. And I will resist using the word "limited scale" anything here, but to say that we thought that there was a lot of merit to this and the one thing that PTAC should consider is how this might be part of some broader effort to test different models for primary care.

So, briefly, just to go through the 10 criteria, on scope, a majority of us concluded that it did not meet the criterion. That was not unanimous. One of the concerns was about the level of additional development that

would be needed and to what extent this would really be attractive to a lot of primary care practices. We really didn't have any strong evidence that lots and lots of primary care practices would want to participate in this.

On quality and cost, we felt that it did not meet the criterion. This is a little bit more difficult to describe exactly why because, first of all, in terms of quality, the concern was that the fact that this was a monthly payment which could potentially lead to undertreatment of payments, we were not convinced that the quality structure as it was articulated was strong enough to ensure that patients, in some practices -- and this would really be, to a wide extent, an individual practice would choose to do this -- but whether some practices would fail to see patients -- provide adequate access to the patients.

On the cost side, the weaknesses were, as I mentioned earlier, the proposed payment amounts, which would not enable us to really determine definitively that this would save money, and the potential concerns about the ability to measure the impact through the "How's Your Health" tool, because although there are measures in the "How's Your Health" tool for utilization of

hospitalization, et cetera, it is not quite clear how accurate that would be as a mechanism, and there was not anything in the proposal to use other kinds of measures of hospitalization rates.

On the payment methodology, we unanimously agreed it did not meet the criterion. It had a lot of strengths, in terms of flexibility for the practice, et cetera, but we did not see a clear explanation for why the payment amount should be what the payment amounts were. And as I mentioned earlier, there was not really a fully articulated structure for how the quality withhold would actually be awarded and when it would and wouldn't. So the payment methodology really didn't describe, accurately or clearly, when a practice could expect to get its 15 percent back and when it couldn't.

On value over volume, we felt that it did meet that criterion, that this is clearly a model that is not based on -- where revenue is not based on how many services that you deliver, and there is a fairly significant amount of the revenues that would be at risk.

Another interesting feature of the proposal, which has some advantages and disadvantages, is that it proposes that there would be a cap on the number of

patients that a practice could take on, a maximum panel size. The advantage of that is that it avoids a practice simply signing up patients, collecting the per-beneficiary per-month payment but not seeing the patients. The risk, though, that we saw was that that could discourage practices from taking on healthier patients, since the higher payments would be associated with the higher-risk patients.

We unanimously felt that it met the criterion on flexibility, because it is a very flexible payment. It is a monthly payment that is not tied to specific services, and it is a risk-adjusted payment, so there would be more money and more flexibility for patients who needed more service, although there was no assurance as to exactly how the higher amount would be used.

We did not reach complete consensus on ability to be evaluated. In some respects, this could be evaluated compared to other practices, in terms of overall spending, et cetera. What would be difficult would be that there would be essentially completely different quality measures being collected here and a completely different risk stratification structure, based on information that would be collected for these practices but not for other

practices, and vice versa. So it would be very difficult to determine whether another practice was similar to one of these practices or not. But a minority view was that the more innovative the payment mode, the more difficult it's going to be to evaluate, and so it's going to be challenging if we try to strictly say how clearly can this be evaluated.

Integration and care coordination, we thought that this could certainly enable the primary care practice to do more to care coordinate if it wanted to but there was nothing specifically in the model that assured that that would happen, and again, it would depend a bit on how reliably the patients were responding to the "How's Your Health" survey.

We felt that this could potentially encourage more physicians to enter and remain in primary care, but the concern was that the cap on panel size, in the short run, could actually reduce patients' access to primary care, because practices could participate in this model and see fewer patients than they are seeing today and still receive adequate payment. So that led us to conclude that this did not meet the criterion on patient choice.

We were also concerned that because of the

concern about the potential for undertreatment of the patient with a per-beneficiary per-month payment, we were concerned that there was no description in the model about how patients would be informed about this, and given assurance to the patient that they would still be seen.

Patient safety, we felt that it did not meet the criterion, again for similar reasons, because we were concerned that the protections for access and for quality assurance were not adequate to ensure that some patients were not being left behind.

We did think that it met the health information technology criterion because it's using an online mechanism for patient-reported outcomes, which would be a very unique addition to the suite of models that exists out there.

So, Mr. Chairman, that concludes the PRT report from me. Let me see if Kavita or Tim have anything to add to that.

DR. PATEL: Thank you, Harold. That was pretty comprehensive. It might be helpful for the PTAC to know that the three of us went pretty deep, thanks to Dr. Antonucci, on the "How's Your Health" model, because it was hard to really understand it.

But suffice it to say that we spent a fair amount

of time with Dr. Antonucci actually getting us into a non-PHI-related portal, and it's incredibly -- the depth of it, and its potential are so incredible that as we were kind of going through this as a PRT, we thought that this -- I will speak for myself -- I thought that this proposal offered some really interesting, important, I'll call them building blocks or pieces that we felt like should be, despite some of the drawbacks we've identified, that are worthy of consideration. And potentially we've always voted on things and thought about things and it's kind of in totality, but I would encourage the PTAC to kind of think about some of those building elements, because there are very good ones here.

DR. FERRIS: Great. Thanks, Harold. That was a terrific summary, and I agree with your comments, Kavita.

Two points, and I think they're just building off a little bit of what you said, Harold. But in reflecting on this, one of the things that constantly comes up is where in the process of development is a particular model that's submitted to PTAC? And we've struggled with this and I'll try to avoid the limited scale reference as well.

But I do think it may be instructive for the rest of the PTAC at least to hear where I thought this model

fell in that development process, which was because Dr. Antonucci has done this model in her practice, and therefore, to me that's alpha testing, and alpha testing is practicable in a single instance to actually turn the crank and make it work. What is next in that development process is a beta testing process, and in a beta testing process you're really looking at what it is, not in terms of its practical, internal workings but how does it work in the field. And that's where so many of the comments that Harold made about our concerns, we just don't have information about.

I will also say, to continue that scale, that we also talked here about some models, about sort of the tweaking phase, like just a few things that need tweaking. So feel comfortable about the beta testing but actually there's a few technical items that need to be fixed. Then comes implementation, and I will point out, these things are never done. So we just got a raft of changes to the next gen in our ACO. So we're still changing these models as they go. So just to put this in context where I saw this submission.

The second comment, I guess it's again a framing thing, but it is unfortunate that many of our concerns are

related to fairness and avoidance of abuse. And in alpha testing situation you don't have to worry about those things. But in our responsibility on PTAC, we do have to worry about those things. In fact, that's probably our primary responsibility. And so I recognize that in the hands of an ethical, skilled, and devoted primary care doctor, such as, I'm sure, Dr. Antonucci is, this could be a terrific model. But our responsibilities include a substantial level of comfort that a recommended model will almost always result in higher-value care. And this model, laudatory as it is, did not provide that assurance to me.

So I just wanted to add those two comments, and thank you, Harold.

CHAIR BAILET: Len.

*** Clarifying Questions from PTAC to PRT**

DR. NICHOLS: I'm really glad you did that, because I wanted to go there anyway, and I guess what I wanted -- maybe I'll just try to refine the question for the PRT, and obviously Dr. Antonucci, when she comes up.

What struck me was there were a number of elements about which you had legitimate concern, almost all of which point to the hypothetical of a possibly less-than-fully ethical and committed and dedicated.

So I have two questions for the PRT. Did you sketch out what would need to be done if you had decided to recommend going forward, in other words, a continuum of issues? Did you map a pathway to getting to a beta test model? And number two, maybe there's a way to think about a criterion for selecting participation by physicians that would alleviate some of the worry about those people that we know exist in certain states, that shall be unnamed. And so the question really is, can you think of a pathway forward and can we think of a screening criterion to minimize the risk for beta testing?

MR. MILLER: Well, I'll start and then Tim can go on, and I want to commend Tim, thank him for adding that, because I think that was a critical piece of this.

We did not do what you're suggesting, partly because we're not allowed to provide that. But I would say, personal opinion in this particular case, is I think that this is sufficiently dramatically innovative that it really is not something that you could just sort of sit around in our spare time in an afternoon and say, "How do you fix this?"

But I would add, potentially, and I will see if Tim and Kavita would agree with this, is that I think that

figuring out how to fix some of these things could have benefit well beyond this model, because some of the issues that came up with respect to this are, so how do you get the patients to respond, is going to be true with anything where we're talking about patient-reported outcomes. Everybody keeps talking about outcomes, and we need more outcome measures, and then we don't have them, and why don't we have them? Well, that's one of the reasons why we don't have them is because it's difficult to get that.

So to some extent I would argue that for some things like that, putting the burden on one particular applicant with one particular aspect of this would probably be too much, that it would make more sense to say, "Hey, we're going to need things like this, and we ought to start using some of these beta tests to figure out some of those things," and then use them more broadly. That would be sort of my thought about that. I don't know if Tim or Kavita want to add to that.

DR. FERRIS: Great answer.

CHAIR BAILET: Grace.

DR. TERRELL: So as I was listening to you all talk, I kept being surprised at your thought process, not that I disagreed with it but because the things that were

coming out of your mouth sounded like something that would be coming out of somebody else's mouth, and vice versa. And so I want you to explain yourselves a little better to help me with this.

MR. MILLER: You mean we're merging into one another? Is that what you're saying?

DR. TERRELL: Well, it scared me so I want to kind of get over this.

So one of the things that I heard was that the quality -- this was so different in terms of evaluating quality, relative to anything else that we have. And you made illusion to the fact that that's true if things were different. But aren't we supposed to be about innovation and looking at different things as opposed to something that's like everything else?

So that just seemed to surprise me that you all sort of ended up there. So I'm just going to make you sort of -- I want to make you flesh it out in a minute.

The other one was really related to this issue of simplicity, as you were comparing it to the others, and you sort of gave -- you know, yep, this is great because it's simpler, but gosh, it's simpler and it doesn't have all these other things, therefore we're scared of it, because,

you know, it's just a payment on a monthly basis, and so, therefore, people might cheat, or they might not give good care. Well, there's data out there, and maybe you know the data better than I do, where there have been people that have been paid just on a per-member per-month basis. Typically they've been part of a large capitated system where there's checks and balances in place. But you all, what you just said kind of just dismissed that as being risky because people might do the cheat that's in capitation, which is not provide adequate care, right? Okay.

So I guess my point is, you, Mr. Small Rural Practice Dude, okay, just gave a report that is about simplicity and innovation, and in a practice that isn't like most of the more complex models that we get out of -- you know, out of the societies and, you know, larger groups like Tim's small organization in Massachusetts, or Kavita's in Maryland.

So what's it going to take for you? And I'm being provocative now so we can be respectful later. But I need some clarity on what's good enough for small rural practice, the solo provider, that brings a model that has simplicity and innovation in it, but it doesn't happen to

look like anything else we've ever seen.

MR. MILLER: Okay.

DR. TERRELL: So expliquer s'il vous plait.

MR. MILLER: So I'll start. First of all, I want to say that I am glad to have escaped having any kind of philosopher from the 17th century as part of this comment.

So two things. I guess on your second point, there have been broad scale test uses of primary care capitation in the past, which have failed miserably. The state of Oklahoma, for example, years ago, had a primary care capitation program in its Medicaid program and it literally set it up, operated it for a while, and then took it back down and went back to fee-for-service, because there were so many complaints about physicians not seeing the patients.

So you're absolutely right. I personally think it's a model that makes a lot of sense, but as Tim said, the challenge that we have is whether or not one could simply launch the model broadly in Medicare without worrying about those things. That then leads to the second question, is we would probably have been a whole lot more comfortable with that if there had been more traditional -- not to say that they're better, but more traditional

measures of quality that one could say, yes, we clearly see that these patients, there's not been some abrupt break in the quality approach. But the measures that were in there were not like that, and they were innovative.

And so, in some sense, the proposal -- and I will confess, I was the, you know, let's not argue against it on evaluation because this is so innovative in two different directions that the two different directions essentially weaken the ability to ensure that the other one is -- you know, so if you said, "Well, we're going to measure quality differently but people are still going to get paid, fee-for-service, so we know, you know, exactly what they're doing, and everything like that," then that would have been a little bit stronger on that case. You know, if there had been traditional quality measures and we're using primary care capitation it would have been stronger.

But because, not undesirably from the physician's perspective, it leaped to change both of those things, the problem for us became how could we be sure that those, as Tim described them, some of those, you know, less ethical practices wouldn't violate? But that's kind of my interpretation. Tim and Kavita can weigh in on that.

DR. FERRIS: First let me say, that was a great

question, very excellently worded and completely appropriate, so I'm glad you asked it. I also think I completely agree with Harold's answer.

I want to try to respond by reflecting, in a little bit more detail, on the quality measure side of this, because I think it's fairly straightforward on the primary care cap thing. But the quality measure side of this, the issues associated, which Harold mentioned, but I just want to provide a little bit more detail on that, it is a sought-after ideal in quality measurement to actually have patient-reported outcomes as the defining set of measures. It makes so much more sense than the stuff that we do now. But as soon as you imply that you are going to use that, in some way, in an assurance way, rather than in an improvement way -- like in an improvement setting, you don't have to worry about all the assurance statistical validity fairness issues. But as soon as you start using that in a context where that is your only buttress against abuse, that becomes problematic. And, honestly, the science of adjusting data collection and adjusting patient-reported outcomes for performance is only in its very infancy. It's just recently we even thought that that might be something that we should be doing.

So there are researchers working on this now, but the sampling frames, the response frames, the modality by which you collect the information, we know that pretty big swings occur when you just slightly change the sampling frames, when you slightly change data collection modalities. And this proposal contained no details at all about those issues, because, frankly, that's what a beta test would collect.

So I hope that responds, and we can go into even more detail about what's in "How's Your Health." "How's Your Health," I think, is a terrific instrument. I was first introduced to it well over a decade ago. Before reviewing this proposal I personally did not know how far it has come in terms of its comparative performance. It's come a long way, but it is not there yet, in terms of the kind of rigor that would be required in any federal payment program that one could think of as reasonably -- as providing reasonable assurance.

DR. TERRELL: Before we go on, then, so what I'm hearing is too soon or not flushed out enough, alpha, beta, and all that. This gets us to the larger issue that we have, because the other thing you said is there's really good pieces of this that need to be thought about. So on

the context of what we do on the PTAC side, where we get things at different levels of development, from different places of experience, whether it's a solo practitioner or, you know, a society of specialist with thousands of people represented, like we did this morning, what can we do, from a process point of view, such that good ideas, when they are at the alpha stage, get embedded, per the conversation that we heard this morning with the officials, into the process to improve the health care system? Which is sort of what, I guess, the other the question that you all were asked, is what are we going to do to make that happen --

MR. MILLER: Well, our suggestion --

DR. TERRELL: -- as opposed to just voting down things?

MR. MILLER: -- our suggestion here was, the way at least we tried to figure out how to sort of cut that Gordian knot was to say if, in fact, you could try this, in a beta testing mode, inside a larger primary care model, such that you were not putting primary care physicians everywhere else in the position of it's either this model or nothing, but that there's other things you could do so that you would be more likely -- again, this is me speaking and I'll see if Tim and Kavita agree with it -- so that you

would really have the committed folks who wanted to be in this for the right reasons, to help try to flesh out all those details, that that might be one way of getting there. That having it as a freestanding model sort of separately, that everybody would apply for or not apply for, et cetera, would make it much more difficult to do that than if you said, "Here's three different kind of things and this is for the practices that" whatever characteristics one might do to sort of say, "Let's try this on more than one, but less than 10,000 at once," so that we could see how to make some of those things work. At least that's kind of where, at least, I was coming down.

DR. TERRELL: So, Mr. Chairman, based on that, I think that when we're thinking about the way that we write letters to the Secretary in the future, if we have something that we may not recommend -- and this may not be the case. We may end up recommending this one -- but yet that there's clear merit to components of it, and now that we're so afraid and frightened away of the limited scale testing option, we need to have the ability in our communications back to the Secretary that says this is at the alpha level and it ain't ready yet, or whatever, but we see these things and you need to pay attention to them, and

you need to figure out how to -- please figure out how to take that into your thought process as we're sort of continuing to provide insight to the federal process from, you know, folks that have boots on the ground, if you will.

CHAIR BAILET: Right. I look at it as we're conveying information, a recommendation, and included in that the strength of our recommendation as we've done in the past. We've included the strengths and the shortcomings of these proposals, and I think when we had something that we think is incredibly important and impactful, we highlight that as well. So we'll be sure, in the construct of the document --

MR. MILLER: I just want to add one, I guess, and we can debate this more later, but while it's sort of -- while it's on the table, I think there's a difference between saying there's a component of this model that we like and you should think about trying to use it for something else, and saying this model has different components than other ones do and it needs to be sort of tested as a whole to figure out how those things work, so that potentially some of those things could be use otherwise. Because I'd be concerned if somebody said, "Okay, we're just going to go run a 'How's Your Health'

test somewhere," without trying to link it to the kinds of payment changes.

Because I do think that, in my opinion, again, about this proposal, the combination of the two innovations was problematic for our evaluation of it, but was a strength from the model's perspective because it said not only are you going to have a completely different way of being evaluated, you're also going to have a completely different way of being paid in order for you to be able to do well on that, and vice versa. And that's something, I think, we have to keep in mind, whether those two things are really linked together, joined at the hip, and need to go forward together, or whether they are really separable or not. We can talk about that more as we go along.

DR. PATEL: There's a lot more we could say but I feel like if we actually go through some of our comments, because we brought up some of these issues.

CHAIR BAILET: Yeah. Well, so where, I mean, you know --

UNIDENTIFIED SPEAKER: You're asking the PRT questions.

CHAIR BAILET: Right. Right. Exactly. So I've got Bruce, Len, and Rhonda teed up to ask the PRT

questions. But are you saying that the PRT report-out has not been completed?

DR. PATEL: Oh, I'm sorry. I meant Dr. Antonucci's part. I mean, she's had a lot of thoughtful interactions.

MR. MILLER: It would be good to hear from her soon.

DR. PATEL: I feel like some of this is stealing a little bit from -- because kind Len's point and Grace's point, I mean, there's our opinions. And the only thing I just want to -- I know others have questions.

DR. NICHOLS: We need to shape you for the next discussion.

DR. PATEL: That's right. I was going to say something, just about what Grace asked. But okay, go ahead.

DR. STEINWALD: Am I up?

CHAIR BAILET: You are up, sir.

DR. STEINWALD: I'm up. All right. So in the issue of stinting, and again forgive me if something about this is in there and I missed it, but did you give any thought or discussion to what's often called concierge medicine in the private sector? Because, you know, there

you're substituting monthly fees for fee-for-service fees in a primary care setting. And my impression, there are a lot of issues with concierge medicine so I'm not endorsing it. But the one thing that -- impression that I have gotten from what I've read is that we worry less about stinting because of the expanded access of the patient to the primary care doctor and the limitation on the panel of patients that a doctor sees in a concierge practice.

So, Grace had contrasted, or raised the issue of, well, what happens under a fully capitated system, and I'm raising another model to ask if it's relevant to this discussion.

MR. MILLER: Well, I would say one key difference is that in concierge medicine practices the patient is paying. This would be Medicare would be paying for the service, so there's a little bit of a difference there. And I don't know what concierge medicine practices have in terms of a quality -- I don't know that many of them do. They basically make a promise and the patient gets to decide whether or not they're getting it or not, as opposed to reporting. But I think those are the differences. I mean, we can discuss whether or not those are critical or not, but I think that is a big difference between what is

happening in the private sector, and this would be Medicare paying.

DR. PATEL: The point I was going to make to Grace's point ties in a little bit of this. Something that we talked about extensively at the PRT was -- and Harold has it in kind of our similar criterion around flexibility and patient choice -- but to Grace's question about how do you make this work for a solo doc, or even a rural -- it doesn't have to be solo docs but a rural practice, and then also with concierge care, we thought a lot about the patient kind of beneficiary, what Medicare has promised a beneficiary that they have rights to, but then patient access.

So if I'm the only doctor in a setting that then chooses to be, even on a voluntary basis, in this model, that there are aspects of this which might not appeal and would probably put a patient into a position of not having that access. The same goes for a concierge style practice, where patients to date have options whether or not they choose to be in a concierge practice. So we've found the potential for a lack of optionality, so that could be very problematic. You can eliminate some of that by what Harold had suggested, with kind of implementing this even within -

- it doesn't have to be a large urban practice but just within a place where an alternative -- whether that's an alternative for the physician or an alternative to the patient what exists. And I think that that was, I'll say for myself, if we could overcome a lot of these other flaws or issues in order to get to yes, that was still that was potentially a significant barrier.

CHAIR BAILET: Len.

DR. NICHOLS: So I realize we want to get to the good doctor, but this is such a fascinating discussion and I think it's so relevant, both to this ultimate vote but everything we've done and everything we may do in the future. So I guess I wanted to probe a little bit.

I love the two-dimensionality of if only one thing was moving it would be more comfortable. But let's talk about quality measures in the real world. MedPAC just basically said, forget MPS, because they, like a lot of people around this table, know how, shall we say, variable the quality of the EHR data is actually at this moment flowing to CMS, upon which payment is about to be made. Do we really think this "How's Your Health" stuff is worse than meaningful use?

And so what I'm getting to here is, you know,

this is a situation where it's so creative, and that's the thing that I'm obviously attracted to, as were you. It's so creative, I just hate to kill it without a pathway forward. And I agree with you completely, it should be integral to the proposal, not where we like this little thing and that little thing.

So my question is, why not try a kind of beta test where you have -- I assume this person has EHRs. They're out there everywhere -- and go ahead and collect the EHR data, and do your study of the implications and similarities and correlations and so forth, and let's do this on a step-wedge evaluation basis. No, you can't compare it to anything else, but you can compare it to itself in the past, and I think you could possibly design something -- not tomorrow but two years from now, maybe -- that would really build upon this in a completely, in my view, with fidelity toward the creativity of this proposal.

MR. MILLER: I will suggest that's probably a discussion for later, when we're deliberating on this. But I like the idea of beta test. The people on Security Boulevard seem not to, so we'll have to deal with that. But I do think it would be useful, when we hear from Dr. Antonucci and her colleagues, about what do we know about

how good "How's Your Health" is relative to other quality measures, and I think they are going to talk about that.

CHAIR BAILET: All right. Well, thank you for your efforts, PRT committee, and Harold, for leading it, and I'd like now to invite Dr. Antonucci up to the table to provide her prepared remarks and answer questions for the Committee. Welcome.

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

DR. ANTONUCCI: Hi, folks. Can you hear me?

CHAIR BAILET: We can hear you.

DR. ANTONUCCI: Okay. Thank you. You guys are great. This has been a great discussion. I came prepared to be politely eviscerated, so this is a great discussion. I think I have a lot of answers to some of the things you brought up, but I rehearsed for 10 minutes and so I'll have to be respectful about time.

I also think that we have, on the phone, or I hope we do, John Wasson, who is the originator of "How's Your Health," who can speak far better than I can, but I'm going to try and answer some of your questions.

I'm mostly going to read to you, because that keeps me organized. It feels a little funny to me. Can we

back up, also? Let's stop the Dr. Antonucci. We could just do Jean, okay, because it takes a lot of syllables to say Dr. Antonucci, and we might need some minutes.

In real life I'm sort of hopelessly shy and quirky, and so I'm going to read to be organized. I often say that I didn't speak until I was 16 at all, and that was to meet boys, of course. And now what I speak about is primary care.

And so I'm delighted to be here. You guys are great. I would like to thank the staff who answers really dumb questions very graciously. Thank you very much. You guys work really hard.

So I think that I submitted a proposal, you know, because I'm kind of desperate in primary care. We really need to do something in primary care, and I think that we keep doing more of the same. We do the same thing over and over again. And sometimes we know what needs to be done but we can't get it to happen. You know, there's that Churchill statement also, about Americans will always do the right thing after they've done everything else.

And so I have had my own practice for 13 ½ years. I also had worked, employed by a hospital. I worked in an FQHC and I worked in a VA. And now I work in a practice

that is very innovative. I have, I believe -- and I will warn you that I switch from "I" to "we," not because there's more than one of me or I'm pompous. There are a lot of doctors and people who stand behind me, who helped me write the proposal, and dozens and dozens of docs all over the country who have been using "How's Your Health" and are doing what I'm doing. And I think we know that in primary care people are leaving, daily, because primary care is so bad. So one of the reasons I'm here is to see if I can do anything to improve the sustainability for primary care and for our patients.

Many of us really don't feel well represented by our professional organizations, so it sounds unpleasant to talk like this. I was really embarrassed by the AAFP's proposal to you. I watched the whole hearings. And I felt like it was just we'll do MIPS and we'll tweak it and please give us more money, and I was really embarrassed by that. And so in the PRT proposal, in my feedback it basically said, well, you're just asking for a raise. And, well, so I gulped. I think that we're not asking for a raise. We are drastically underpaid, but we're asking to be paid for the work we do, and we're asking to be paid more fairly, and we're asking to reduce the burden

associated with payment. So that is, indeed, why my model has two parts to it. The burden of payment is great.

And despite Kavita's comment earlier about using transitional care codes and CCM codes, I'd like to look CMS in the eye and say, "Please, no more codes. Please, God, these codes and their rules and the $32 I have to give back and the babysitting TCM for 30 days before you can submit it." I mean, these things are just insulting to primary care.

And I know that, also, you know, we live in this world where this world tolerates orthopedics being paid three to five times what I can possibly make. So being told primary care is asking for a raise, yeah, it might look like that, but I think that there are grounds to pay primary care better but also differently. I know there's not a lot of evidence that says if you pay primary care more you get better results, but there's lots of evidence that says if there's good primary care, it does benefit society, and you get results.

So what I wanted to do while I'm here is (a) remind you, or tell you that it's not just me as a solo family doc in rural Maine. There are a lot of people like me. And to be obnoxious, I think we have the goods. I

have seen every patient, for the last 13 years, on time, the day they call or the next day, with very few exceptions, and I have superb quality and cost measures. But I get cut out of lots of measures. You know, I couldn't be in CPC+ even if it was in my territory. You can't be in some initiatives if you're a small practice.

And so I have what you want, and I think the country needs that. I love the idea that one of you, perhaps Len, maybe many of you, were saying, "How do we find a path forward?" because that's what I came to ask you. How you can you help me find a path forward?

I want to correct a few little mistakes. I found a document on the site called the "analysis," having to go with my proposal. In one place it said I was a concierge practice. I am so not a concierge practice, okay? I take Medicaid and I don't limit it and I've done it from the beginning. I live in the oldest state in the Union and I live in a very old, very poor part of my state, and there's a lot of opioid crisis where I live. I'm a Suboxone provider. So I am not a concierge practice. I'd probably have one patient, if that.

Also, in the analysis, I just wanted to correct that it said something about Ideal Medical Practices.

That's a nonprofit helped found, and it called that a PCMH. I am a PCMH Level 3. I have tortured myself through that thing, twice, but I might as well tell you, I am a PCMH Level 3. It's worthless but it's me. I did that.

I also would like to say -- and I know you're from Rhode Island. Is that correct?

DR. MEDOWS: [Off microphone.]

DR. ANTONUCCI: Uh oh. Then I'm wrong.

DR. MEDOWS: [Off microphone.]

DR. ANTONUCCI: Oh. Oh, okay. Well, thank you. I did make the assumption it was Providence, Rhode Island, because Rhode Island is put out, in the analysis and in lots of places, as this great place that has done all this great work for primary care, and that ain't so. Rhode Island has systematically killed all of its really bright, shining star little practices. I was a little worried I might accidentally be insulting some of your work or something. I was very nervous about that. I am so glad to hear that you're from someplace else.

So, okay. So what I want to do is in the next few minutes just see if I can kind of defend my proposal and answer a few questions, and we get to figure out if there's any way forward, and in any case, thank you. I got

to visit some friends outside Washington and lose a lot of money, and I'd like to thank my PRT for not bringing up Immanuel Kant. Thank you very much, because I was a biology major.

So the proposal is centered around this technology, "How's Your Health," as well as the capitation payment part, which I'll get to. "How's Your Health" -- and thank you for delving deeply into it. Kavita said that she got well into it. I spent half an hour and I thought I'd barely introduced people to it. It is very sophisticated, although it looks simple. There's a wealth of data in there. It's been around for a long time. It's very well-tested. It's free, which is a wonderful price. It is very future-facing. It improves the value of the services we provide to patients and it reduces the measurement burden, some of the inefficiencies and costs and constraints around our current measurement paradigm.

The technology of "How's Your Health," I think you kind of got this already, but I'll tell you again. When a patient takes a survey, which takes about 15 minutes, the physician immediately gets results, and you get an immediate feedback about the patient's wants or needs, or what they misunderstood. You know, you might

have Bob Berenson take the survey and you get this thing back saying that he's never had his cholesterol checked. I sit there and I say, "My God, I'm a horrible doctor." And then I look in his chart. He has too had his cholesterol checked. So I have to tell him that we did this, remember, and this is your results, or you don't need it again. You get that immediately, although you get a practice-wide aggregate if you log in. You get very meaningful information about gaps of quality and care, so you can stratify and follow on services for the patients, and it's very efficient.

I think one of the concerns I heard about "How's Your Health" technology was that it wasn't evidence-based, and John Wasson has years and years of work around this, and I'll let him talk about it. There's plenty of evidence behind it. And what I heard from you folks repeatedly, especially today, was this business of about the data. Do you make patients take it? Which patients do you make take it? How many numbers do you have to have? How new is the science of patient-reported outcomes measures, which we call PROMs, because it's easier.

John has data about this that's very good, and so a few things to throw at you, although it may be a little

hard, maybe, to wrap your head around. The stability of the data is very good if even 30 people, 30 patients take the survey. That's not that 30 is a goal. That's really true because of the kinds of questions that are asked, that are global to every patient. They're not just diabetic questions and so forth.

One does shoot for having every patient in your practice do "How's Your Health." That's not ever going to be realistic, but you can start with getting information about your practice and beginning to measure putting physicians into tertiles if you have as few as 30 patients. And John can talk more about that. I'm not like a data hound and, you know, p-values make get upset. I don't do statistics stuff but I respect the fact if you want that kind of data, if you're paying someone and you're measuring quality, you need that kind of serious work to be done, and John has done that.

So the other thing, besides data and "How's Your Health" is I wanted to address a little bit the other unique part of the proposal, or the scary part, the part about capitation and physicians gaming the system. I don't see how, in my proposal, physicians can provide less care and do well, because it's the patient's voice that it's

measuring here. Patients are reporting access and care. You can't meet the benchmarks if it's the patient's voice.

This is not capitation like any other form we've seen. We know that patients' perceptions of access affect their health-seeking behaviors. When you ask the patient whether or not they have good access, and that's one of your quality benchmarks -- and there are some other benchmarks -- and that's how you're being paid, I don't see -- I can be naïve -- that you can game that system, that physicians are going to take that money and not provide care, because it's the patient's voice, and that's one of the very unique things.

There are some other quality benchmarks but I want to be really clear about the capitation part. And we hear capitation looks scary, a lot of physicians don't like it. I think that for primary care it is the way to go. I don't know anything about specialists and I don't care. I do not care about your problems. I'm sorry. Someday I maybe will.

But I think the capitation, for primary care, capitation is where you need to be headed, but I don't think you can game this system when it's the patient's voice.

And so then let me try and address just a few other things I think you raised and then wrap up. With regard to scope, I failed that. I failed most of my criteria. I know dozens and dozens and dozens of practices who would jump at this. I have names already of 30 practices. But I did not have, I guess, the wherewithal to get them on the phone, or to write to you. But just with what I know, most physicians love this, especially the small practices, that get -- thank you; I got the one-minute sign. I don't think you gave that sign to the ER people.

Anyway, I think scope, this appeals to small practices and there are lots of people that would jump at it. I answered the concern about payment. I'll talk faster. I don't meant to be disrespectful. I'm sorry.

I think there are no concerns about reduced access. Patients are measuring. With regard to choice, I absolutely get that. I thought a lot about the snowbirds and stuff. I don't think every patient in a practice has to be in this. I think we do have to tell patients that there is a program. Patients have the right to go anyplace they want, and they may only be able to be in a program six months of the year in my practice. And someone raised a

logistical question about that. But patients get choice. They don't have to be in the program if they're in my practice, and there would be some things to talk about, about what if a patient goes somewhere else for primary care. But I think all that is solvable. I've thought about that.

With regards to continuity and care coordination, "How's Your Health" measures who is in charge, and care coordination follows from continuity. There aren't really any good measures in the literature about care coordination. I don't think there are any. And I think that we do address that in "How's Your Health."

So I actually think I meet all your criteria, maybe with some fine tuning. And I think I, and many of my colleagues with small practices have what you want, and I would like your help in going forward. I think history calls. Primary care is a mess. We desperately need to do something about primary care. I'm delighted that you're willing to think about this at all, and if you can tell me how to go forward, please do. Otherwise, thanks.

CHAIR BAILET: Thank you for your comments, Jean.

MR. MILLER: Jeff, can we see if John Wasson is on the phone? Is he? Is he? Okay.

CHAIR BAILET: Yeah, he's on the phone. Len.

DR. WASSON: Yeah.

MR. MILLER: Thanks for coming.

CHAIR BAILET: Hi, John. We can hear you. We're going to get to you in just a minute. Thank you.

DR. NICHOLS: Just one question, and then maybe we'll have some more. But when you talk about the path forward, have you approached insurers to see how they would feel about starting this party on their own?

DR. ANTONUCCI: Well, yes and no. I'm capitated by one payer, because I showed them my data, which was How's Your Health data. They -- I showed them what payers like, which is money. I showed them my data on hospital admissions, ER visits. And I have been capitated at $30 a month for years now. I can do it because I'm low overhead. Most practices couldn't do it at $30 per payment per month, per patient per month. I don't have a way to approach insurers, sir. No insurer will talk to me.

DR. NICHOLS: Who is the payer?

DR. ANTONUCCI: It's called Martin's Point, in Maine. They're only maybe in Maine and New Hampshire.

MR. MILLER: Martin's Point is a small plan. It's up in Maine.

DR. ANTONUCCI: I have no way to approach insurers.

CHAIR BAILET: Harold.

MR. MILLER: So Jean and John are on the phone. I think one of the big concerns is this issue of how do you get enough patients to respond to the survey, not for a statistically valid look at a practice retrospectively that wasn't being paid based on the measures, but based on when it's tied to the payment, so that you ideally are getting as many patients as possible, that you're not having a situation where all of the problematic patients somehow manage not to be able to get to the terminal to fill out their survey, et cetera.

So I'm wondering if you could just talk a bit about how you think that might be addressed if there were to be a model implemented at some point that did have payment tied to "How's Your Health." Now if there are examples already, somewhere in the country, where somebody has done that, that would be very helpful to hear about. But if that's not the case, if you could talk about how you might sort of make sure that there was a big enough, you know, representative sample of patients large enough to be able to do that.

DR. ANTONUCCI: There are examples, and basically you do it before a preventive visit, if at all possible. I have some troubles with that and do it somewhat unconventionally. John will tell you about that. Lots and lots of people have used it, and it's just a part of your practice, that people do it before they come in. But John -- are you there, John?

DR. WASSON: Yeah. I guess let me just deal with this from the full practice assurance questions that came up, and, you know, underserving, et cetera. When a patient completes "How's Your Health," they automatically can forward it to the office, and it goes not only in the way Jean has described but the additional piece is it goes into a searchable registry.

And so right there, if I were building an incentive system, I would be asking that if a practice has patients who are going to be paid, they would complete the survey on an annual or bi-annual basis, and you'd be able then to compare the registry, year by year, in a report, to see if you'd have attrition, unnecessary attrition. And in that way you could make sure, using the measures, if everyone is still on board and measuring, you can be sure that your measures of access, et cetera, that might change

over time, are not being impacted by a selection bias. The major issue here is selection bias.

So that would be the mechanism. Now how do patients do it? You have to remember, first and foremost, it's designed as a service for the patients. So if you looked at Jim Bloomer's practice, for example, in Maine, or Lynn Ho's, or Jean, in a more limited sense, because she doesn't do it on everybody, they, in essence, have made it part of their annual -- when you're coming in, please complete "How's Your Health." And seeing a patient's interest, because it's not a survey that goes to some office and some insurance company and they never get results, they get immediate results in their hands the minute they've completed. They can get a personal health record to take with them elsewhere, et cetera, et cetera.

So because it's a service, it isn't a tough sell, and most of these practices can get up in the high, you know, above 60 to 70 to 80 percent uptake by patients rather quickly. So that's what we've observed.

MR. MILLER: So if I could just add a quick follow-up question. So you're then suggesting that it would be essentially a performance expectation by the practice that it have, I mean, ideally, every patient

filling out the survey, and potentially having that tied to the payment somehow?

DR. WASSON: Yeah. I have always -- you know, I didn't write the proposal so I don't know what Jean wrote. But yeah, I think that there should be an expectation, if Practice A came on in the first year, they should be expected to get some percent of their patients to compete "How's Your Health," a minimal percent, and it should escalate thereafter. And then I would have to get rid of the gaming potential, which we haven't observed over time. We've had these practices for decades.

If gaming were happening, you could have them report back on their registry, here are all the patients we've been paid for. If they haven't done "How's Your Health" it would show up as an absence from the registry, and you could then have a disincentive, shall we say, for that.

CHAIR BAILET: Rhonda.

DR. WASSON: Does that make sense?

CHAIR BAILET: Yes. That was helpful.

DR. MEDOWS: Please don't go away. I have a question for you and Jean. I just need some clarity. So if a patient doesn't do the survey, are they in the

capitation program.

DR. ANTONUCCI: Sure, if they want to be. Any patient who wants to be in it with a participating physician could be in the program. Most patients don't refuse to do the survey. They might forget.

DR. MEDOWS: Okay.

DR. ANTONUCCI: They might not have an opportunity. But, of course, they could be in the program.

DR. MEDOWS: But you're assessing to use the survey as a way to kind of risk adjust what that capitation payment would be. So if you had it, you could figure that out. Right?

DR. ANTONUCCI: Right. Okay. So you're asking me a question now. I better think about how can I know which risk group they're in if they haven't taken the survey.

DR. MEDOWS: Well, you're proposing to use it to adjust it, right?

DR. ANTONUCCI: Right.

DR. MEDOWS: Based on the complexity and the need of the patient and that kind of stuff. Right? So you would --

DR. WASSON: Can I answer this, Jean?

DR. MEDOWS: Sure. Please. I'm not Jean, but --

DR. WASSON: The bottom line is we addressed this after we published this thing called the "What Matters Index." It's showed that asking just five questions of patients can risk adjust, or give you a risk profile prediction model as good as any of the stuff we're spending tons of money on. So what we've done on "How's Your Health" is have what we call the quick-check now up front, that a smartphone, and particularly from Medicaid sites, so that a patient doesn't need to complete all of "How's Your Health." They could, for purposes of reimbursement of the practice, filling out the registry and risk adjust and be, if you will, just asked to do the very short survey up front, which has a max of seven questions. So that would get you what you needed in terms of making sure gaming didn't happen, and also enable the practice to keep track, from a risk perception. If you look at "How's Your Health" you can see how that works. Basically, the more problems of those seven you identify up front, the more it encourages the patient go to deeper. But, you know, for a healthy 35-year-old, they're going to say, "No, I don't want to do, you know, 60 or 50" or whatever the number of questions that would pop up. But if they did 7, they're

in.

DR. MEDOWS: So I was actually thinking that there were two different questions that had a side question about gaming. So I understand the value of a patient-reported outcome survey, and using that, talking about measures that matter to them. I understand that. I don't have any issues with that.

I think separately is the part about it being tied to the capitation payment itself. Right? So even if they only did seven of the questions, that's some information. But I want to make sure that the people who get risk adjusted up, that's actually tied to the science of a survey being done and showing that they have an increased risk to justify that. That's one separate thing.

The next part of my question, since I have the microphone, Mr. Chairman, is the part about the capitation payment itself. There is a statement in the PRT report, and you kind of talked about it a little, tiny bit in your proposal, about the total cap payment would be higher than the current costs, on average, of what you get paid now.

DR. ANTONUCCI: Higher than the current reimbursement, not cost.

DR. MEDOWS: Okay. That's a very good point,

reimbursement now. And so what is being -- what are you being paid for that's different, that justifies that higher reimbursement? Talk about that. That would be really helpful.

DR. ANTONUCCI: Right. So if understand you correctly, and you can just jump in, there is a great many things that we do for patients now that we're not being paid for, because we're paid fee-for-service. Yet I use the phrase "touches." How many touches does a patient need? The high-risk patients need lots of touches. They need the follow-up phone calls, all these things that we know make a difference. And so we're not being paid for them. That's what I think we should be paid for.

DR. MEDOWS: That and probably some of the social services and some of the family outreach and all that kind of thing.

DR. ANTONUCCI: We can go on and on. That's correct.

DR. MEDOWS: So, I mean, we can talk about whether or not it's a higher capitation or whether or not it's just that the family medicine or the primary care, the fee schedule needs to be adjusted the right way as well. Right? Two parts of this, about how that could be

addressed.

DR. ANTONUCCI: [Off microphone.]

DR. MEDOWS: I know you're trying to tie to value, and thank you for doing that, but I'm thinking that we're answering several questions. It's not just about how to incorporate the patient's voice, it's not just about doing the value, but it's also about fair pay for services that a primary care physician provides. Is that right? Okay. Just checking. Just making sure. Thank you.

CHAIR BAILET: Thanks, Rhonda. Len.

DR. NICHOLS: So this may be a little granular, so maybe John, feel free to chime in if you need to. But I'm really curious, picking up on Rhonda's point. At the moment, what fraction of your patients are what we will call low risk, and what fraction are high risk, and how does that vary across the practices that John may know about?

DR. ANTONUCCI: I think it's -- there's some data, and maybe, John, I got it from you. It's true for my practice. I think it's pretty widespread that roughly 15 percent are high risk in any practice.

DR. NICHOLS: Fifteen.

DR. ANTONUCCI: Fifteen.

DR. NICHOLS: Okay.

DR. ANTONUCCI: I wanted to sneak something in here for a minute. There is this concern about capping panel size, well, could it reduce access to care, and yet capping panel size is a protection with capitation, to not just take lots of money and provide care. I have to be really clear about what's happening now. We're between a rock and a hard place. I see now that panel sizes aren't capped, but on a practical basis, the number of hours in a day is capped. And so you can have a lot of patients that belong to you and they're being sent to the ER for UTIs. Right?

So I don't see a big concern about capping the panel size. I get what the concern is, but I don't think it has any practical significance.

DR. NICHOLS: Well, one might think about a world in which different kinds of practices would have different caps. I mean, that's part of the beta testing world that we're talking about.

CHAIR BAILET: Harold.

MR. MILLER: This is more just an observation, but it had not occurred to me before that one could make the higher payment for high-risk patients contingent on

people having filled out the survey to justify that, which those are the patients who, in fact, one would most want to have the survey filled out for in some fashion. And then John talked about trying to track them once they were identified. So it's just an observation.

CHAIR BAILET: Thank you, Harold. Jean, thank you.

*** Comments from the Public**

CHAIR BAILET: What we'd like to do now, Jean, if you could return to your seat we're going to open it up for folks to make public comments. We have one person who has registered, but I don't believe they're on the phone. I'm going to ask the operator, is there an individual signed on to make a public comment? Operator?

OPERATOR: There are no questions at this time.

CHAIR BAILET: Thank you. Any other comments from the Committee or are we ready to -- Harold.

*** Committee Deliberation**

MR. MILLER: I guess I feel compelled. I would like to proceed to the vote, but before that I think we -- I personally think we need to have a bit of discussion as a reflection of all we've done today and what we do going forward, about how we vote. Because I think we have been,

in many cases, saying whether something meets a criterion or not, based on whether or not we think the proposal is fixable or not. We don't want brand new proposals, so we have said we don't want to say we're passing on something because somehow it could be changed into something completely different. But we've never quite articulated where's the threshold of sort of how much would have to be done to be able to make one comfortable with it.

So if one takes the extreme point of view, and you say, well, a proposal doesn't have all of the various details worked out such that one could be confident that implementing it as written would be a perfect thing, then if you're taking the strict point of view you would say doesn't meet the criterion, because it's not all articulated them.

We have, I think, more generally, taken the view, when we've voted on these things, that we thought that it met something if, in fact, it had problems such that we thought that they could be fixed -- I think the discussion this morning was relatively easily, or something like that.

And I guess as I'm thinking about this proposal, and potentially others that might come along, on the innovation issue, is that just like it's harder to evaluate

something, the more innovative it is, it seems to me it's also harder to get all the details worked out in the proposal, the more innovative it is. And the more there is the need for the beta testing process that Tim raised earlier, if you said, "Hey, this is a really simple change from what exists today, but they haven't really thought through any of the details on it," you'd say, "Well, that really ought to go back and get done." But if you say, "Boy, this is a really innovative thing and it's going to have to be beta tested," and some of those issues which, to me, is why we were talking about limited scale testing in Medicaid, so some of those things are just plain are not going to be able to be worked out unless you actually do something in practice.

So I guess my personal feeling at the moment is -- and I just thought it might be useful to talk about this before we all vote -- is that I'm really leaning towards saying that if I think that a proposal, the basic structure, makes sense, but that a variety of details, which could be big in some cases, would need to be worked out, but that they would have to be worked out in practice, that that, to me, means that it could meet the criterion, because I'm seeing whether it's payment methodology or

whatever else, that I think that the structure is there, as opposed to others I think we've seen, where I would not say that. I would say that the whole structure was just plain wrong and it needed to be rethought. It wasn't a matter of figuring out how you could get the patients to fill out the survey or whatever else. It was just plain wrong.

So I just thought it might be useful, Jeff, you know, and it's up to you and the will of the rest of the folks, just to talk about that just a tad before we decide to vote, because, in a sense, you know, when we're all attaching these numbers to things, the question is sort of what do those numbers mean. And we have not been doing what I thought we had originally intended to do, is that whenever there are differing points of view about some of those things that we stop and talk about them --

CHAIR BAILET: Right.

MR. MILLER: -- you know, and then decide what to do. So anyway, that's just -- I wanted to raise that because I do feel like this proposal has gone into levels of innovation that I think are desirable in thinking, and that raise sort of questions for us that we've not quite confronted before.

CHAIR BAILET: So do we want to discuss Harold's

point? Rhonda and Len, are you -- you're on, so go ahead then, Len.

DR. NICHOLS: I'd like to associate myself with Harold's remarks. I do think that there's so much creativity here and yet it's not ready for prime time, obviously. So when I think about how our recommendations have been met so far, the best we have gotten, which is some of what we heard this morning from Adam, well, we like some of this. We appreciate your hard work and we're going to incorporate it into, and he explicitly mentioned the AAFP proposal. I don't know why this isn't a candidate for at least getting in the mix for these conversations. Because I'm back to MIPS is not perfect, and meaningful use is not functional at the small practice level. That's why MedPAC said what they said, and we all know about EHRs in the real world is true.

So if you've got a way to begin to move down a different path, admittedly for a subset of the world but a subset of the world that is truly hemorrhaging people right now, both patients and providers. So, to me, it ought to be in the mix, exactly along the lines you just said. It is worthy of attention to flesh out these details in a beta testing environment.

CHAIR BAILET: Any other comments? Grace, sorry, and Bruce.

DR. TERRELL: So you've mentioned the recent MedPAC comments on MIPS. American Medical Group Association, AMGA, of which I'm on the board, so that's the disclosure, just came out with a recommendation that all quality should be boiled down to whatever the numbers were, 13 different things that should be what -- I think that was sort of their alternative to get rid of MIPS. It was like, just come up with these things, and that's just, that's all we're going to do. I wasn't part of the group that thought very deeply about that but was part of the group that agreed that we would approve that as something to go out with.

Whether you believe that those were the corrects ones or the right approach or not, it's one more piece of evidence that what's been out there in the quality world, people are really starting to question. But there may be the possibility of having something like that within the context of the world that is, because most of what our struggle with this is that it's something entirely different, that could be -- this could be an additive to and still be an innovative approach, because of the aspects

of it related to simplicity.

I mean, the things I loved about this is I'm a primary care physician and this appealed to me at that level. I understand all the issues that have been articulated well. But there could be a solution that's related to the difference, and the difference as it relates to a different way of thinking about quality, some simplicity as it relates to the world that it is, without basically saying it's an either/or, but there may be something that's an and.

Within that context, I'll go back to the point I made before Jean spoke, and that we have to think maybe not so differently about the numbers that we use to vote but how we communicate what our thought process is, back to the Secretary. Because I don't think this is going to go away. I think it's going to get worse, with what we've heard this morning, from the Secretary, which is they're going to be sort of still going down their CMMI route, they're going to really try to pay attention to what we've said. But I didn't hear they're just going to take what we've got and just lay it right out, and it's going to be part of what they do, but I did hear that they find what we do valuable. So it's going to be mostly important for us to basically

say, "We see some real merit in this, okay, and we think it needs to be thought about and paid attention to."

What we're going to have to decide, as a committee, though, is do we have comfort with this idea of it's going to get incorporated, you know, in the models, because in conversations we've had earlier we weren't terribly comfortable with that.

So I think that there are going to be some issues here for us with the way that we communicate with the Secretary, that this is going to be a very, very important proposal to think about. So, anyway.

CHAIR BAILET: Bruce.

DR. STEINWALD: I wanted to say something I think similar to -- of course, I'm not sure. We could say exactly the same thing and it would sound completely different.

DR. TERRELL: It probably would.

DR. STEINWALD: Yeah. But it does relate to the point that Harold raised about how we approach and vote and ultimately recommend.

You know, in your very last sentence in your PRT report you said that it might be a good idea to incorporate this, or something like it, into existing primary care

models like ACOs and others. And I guess if enough of it is thought that way, how do we get there through the voting process, is an important question.

CHAIR BAILET: Harold.

MR. MILLER: So just to build on all of that, I guess. So I was raising this before we voted on the criteria, because we could say some of those things in the statement about the recommendations but we are supposed to be evaluating the proposal against the criteria. And at least I -- and I'll only speak for myself -- originally was thinking that whenever I said something met the criterion it was pretty close to being something that turnkey could be implemented, with the expectation that if we said, "Hey, meets all the criteria and we recommend implementing it," that CMMI would just do it.

Well, that ain't going to happen, it appears, unfortunately. I'm still holding out hope on that. But it does sound, though, like there is clearly the things that meet the criteria are ones that will be brought into the fold for further thought at CMMI.

So I guess that's why I raised this, because, to me, there is now a big difference between saying a proposal doesn't meet the criterion because it needs some work, or

it meets the criterion but needs some work. And so I'm just saying I think we should all be thinking, whenever we vote on the criteria, about that distinction, and that maybe we're not quite prepared yet to figure out exactly how we would articulate what the dividing line is. But I know I'm going to be leaning more towards saying something meets the criterion if I think that it sort of passes that threshold, than just because it needs a lot of work.

CHAIR BAILET: Len.

DR. NICHOLS: One last point, and it's pursuant to Harold. What I would say is we actually -- you're not going to believe I'm going to say this, Kavita -- we need one more criterion, and it is creativity. Okay? If we could give points for creativity, this is really amazing.

It's kind of like I remember Bill Clinton being discovered as never really turning in his exams at Oxford and never got his degree. So the writer who figured this out went back to more and more universities and said, "What was up?" "Oh, he never answered the questions we gave him, but he was so creative we gave him A's anyway."

I mean, this is creative, and we don't have a criterion for that, and, therefore, it's going to make us vote. But I like being mindful of that.

MR. MILLER: Just a brief add and then we can move on, but I think your point is well taken, Len. And it does strike me that there's almost an inverse relationship between creativity and the scope criterion right now, because part of what we've been saying all along is, so, how many people are going to participate in this, and, you know, how big of an impact is this going to have? The more creative something is, my guess is just the nature of, you know, the innovation process is that the smaller the short-term impact something could potentially have, and the longer the long-term impact might be.

And I do think that I heard what the Secretary was saying as an interest in more really transformational kinds of changes. And I heard Adam saying that he wanted to be thinking about more long-term impacts. So I think that's another thing that we have to be thinking about is to what extent something might have bigger long-term impact, even if in the short run it might only have a smaller number of potential participants.

CHAIR BAILET: So I want to thank the Committee for this insightful discussion, and Jean, your patience while we make a little sausage up here. But what I'm hearing from the Committee are a couple of things. One,

we've been fairly rigorous about reviewing models in situ as they sit and as they've been proposed, although today, in the previous submitter circumstance, they actually made some modifications that were material, and we were accepting of that, and we were able to move forward.

We've also been fairly rigorous about saying, "Look, we try to look at the model holistically. We don't necessarily agree with having elements of it picked out that were notable. We're trying to get the model in situ, the whole model pushed forward." But I'm also hearing a change today that, in fact, maybe, in certain circumstances, where there are elements that are so innovative and so novel, but we could see the potential for impact, that we want to make sure that those don't get lost in the overall evaluation process, where we're saying potentially. We can't recommend it as a model but, my goodness, there are so many things in here that this requires further follow-up, and we, as a committee, believe follow-up is needed, not follow-up to implement but follow-up to investigate and extract these really key components of a model, and figure out, can they weave it into a process that's already in flight, so that this can get out into the primary care community.

And I think that potentially, if we agree, as we go through our deliberation process, we can incorporate that in the letter, where we land. Here's where we landed but here's our overall recommendation, because of this certain specialness of the components that are included in this model. I think that's something that we can do today, depending on, again, how we all vote. But I do think we have to stay true to the process that we've established, which is to go through the criteria, which the PRT has done, and now we, as the Committee, are going to do, and then I think through the final vote we can have this sort of cap off this conversation with, well, where do we go from here, based on where we all landed.

Grace, did you have a --

So are we, as a committee, are we comfortable at this point with that sort of framework, to go ahead and walk through the criteria? Yes? All right.

*** Voting**

CHAIR BAILET: All right. So we're going to start with Criterion 1, which is scope. Aim to either directly address an issue in payment policy that broadens and expands the CMS APM portfolio or include APM entities whose opportunities to participate in APMs have been

limited.

[Electronic Voting.]

*** Criterion 1**

MS. SELENICH: Okay. So one member voted 6, that the proposal meets and deserves priority consideration. One member voted 5, that the proposal meets and deserves priority consideration. One member voted 4, that the proposal meets criterion. Four members voted 3, that the proposal meets the criterion. Two members voted 2, does not meet criterion. Zero members voted 1, does not meet criterion; and zero members voted not applicable.

A simple majority is needed, and we roll down until that is met. So the finding of the Committee is that the proposal meets this criterion.

CHAIR BAILET: So let's go to Criterion 2, quality and -- whoop.

DR. FERRIS: I just want to ask. In the past when there's been a significant distribution, we've -- the Chair has allowed discussion.

CHAIR BAILET: Yes.

DR. FERRIS: I can't remember.

I did see a significant distribution there, and I wondered if we should have a discussion.

CHAIR BAILET: I think we should have a discussion and then potentially, depending on how we feel, we could revote on this criterion. That's the second widest. I think we've had one other circumstance where we've had a spread that wide.

So, Tim, did you want to --

DR. FERRIS: I'll launch?

CHAIR BAILET: Yeah.

DR. FERRIS: Yeah.

I took in all the comments. I think my approach to this was that I was not going to change the frame in which I voted and have voted in the past about criteria, but that in the written portion of the -- of our communication, we would express all the things that --

CHAIR BAILET: Yeah.

DR. FERRIS: -- we had expressed.

But I'm -- maybe it's my own feelings about process, but in-flight changes to an established process, I find problematic because we have not thought through the implications of those in-flight process changes, so that was just the way I voted.

CHAIR BAILET: Len.

DR. NICHOLS: So I appreciate the integrity of

your processes internal, but I would say in this case, I do believe it's worth deviating because the creativity dimension, which is not reflected in our 10 criteria, is so great here.

So I take your point, and it's the way we ought to behave and the way I hope to behave the rest of my life. But today, for this vote, I'm going to give them the benefit of the doubt because I think if we don't, they won't -- no matter what we write, Tim, the letter will be perceived differently. Maybe it's not going to matter, but at least it will come with a positive vote.

DR. FERRIS: I actually -- having been a recipient of this kind of information, both qualitative and quantitative, I pay much more attention to the qualitative than the quantitative. I don't personally look at the votes.

DR. NICHOLS: Yes, but if you were there, we'd already be in a different place. And you're not, so --

CHAIR BAILET: Okay. Grace and then Harold.

DR. TERRELL: I was the 6 on this, but I'll say that, even though we don't have to.

The reason is if you actually take that sentence up there outside of everything else, there is a specific

real issue in primary care for which I believe there has to be some solutions that come out of the world to fix. And so this doesn't say anything about whether it meets the other nine criteria. It just says that it's an aim to directly address a really important issue and to broaden the approaches to it, which kind of gets to the criteria.

I have noticed in some other proposals that we've seen -- and so this is just an observation -- that I have seen some other rankings where No. 1 has been voted on as meets or meets with high priority, and then there's been -- by PRTs and/or PTAC at the PTAC level, and then underneath, after that, we don't -- it never reaches that. There will be some noes, or there will be some low scores.

So that tells me something that we need to be thinking about, and that is, this is really what I believe Congress had in mind, which was to have thoughtful people who are out there doing it think about really important issues and try to come up with ways of addressing it. And they're not all going to be perfect. In fact, many of them, most of them, if not all of them, are not going to be perfect.

But I think that we should be paying attention to our own patterns of voting when we see this, which we've

seen a lot, which is that we see that this has been identified appropriately as a really important scope priority issue for which we later on start seeing, "Okay. But it doesn't do this. It doesn't do this. It doesn't do this." This says something that we need to be paying attention to.

CHAIR BAILET: Harold.

MR. MILLER: Jeff, you're losing your voice.

CHAIR BAILET: I know. You guys are poking me today.

MR. MILLER: Well, first of all, if you voted 6 on that, I voted 6, and so there's something wrong with our voting system.

DR. TERRELL: Oh.

CHAIR BAILET: Wait. Is that true?

MR. MILLER: Well, I pushed this little 6 button here over on the far right. So any --

CHAIR BAILET: Then we need to revote.

DR. TERRELL: Yeah.

MR. MILLER: Well, we may need to, but the Russians may be involved here. Jean may have a -- because I've heard the Russians tried to get in through Maine.

CHAIR BAILET: All right. Let's stay on the

reservation.

MR. MILLER: Wait, wait, wait.

So, second of all, I would just say, at least my reason for voting for that was because I think this does broaden and expand the CMS APM portfolio in fairly significant ways by doing things very differently, and I'm more convinced, having heard the presentation, that it would include entities whose opportunities to participate have been limited.

Finally, to Tim's point, I in general support that point. I don't think we should be doing stuff on the fly. However, we got some significant new information this morning as to what the official in-public position is of the Department of Health and Human Services and CMI as to how it's going to approach our recommendations, and so I think it would be problematic for the applicants that we are voting on today not to try to take that into consideration.

Yes, I think we probably should be going back and rethinking our categories, and I think it's going to be problematic when we get to the recommendation categories because those recommendation categories no longer make any sense. But I do think that we should try as best as we

can, personal opinion, today to make sure that how we are voting is consistent with the direction that we've heard.

CHAIR BAILET: I agree.

So, Harold, because you raise the issue, I think we just should go through the process of revoting to make sure we captured the intent, if both you and Grace voted and it's not reflected here. Let's just go ahead, please, if we could, and revote on Criterion 1.

DR. PATEL: Just revote?

CHAIR BAILET: Yeah, just revote.

[Electronic Voting.]

* **Criterion 1**

MS. SELENICH: Okay. So two members voted 6, meets and deserves priority consideration. One member voted 5, meets and deserves priority consideration. Zero members voted 4, meets. Five members voted 3, meets. One member voted 2, does not meet. Zero members voted 1, does not meet. Zero members voted not applicable.

Therefore, the finding of the Committee is that the proposal meets Criterion 1, scope.

CHAIR BAILET: All right. So let's go ahead, and could we move on to the second criterion? I think we should.

Second criterion is quality and cost, high priority. Anticipated to improve health care quality at no additional cost, maintain health care quality while decreasing cost, or both improve health care quality and decrease cost.

Please vote.

[Electronic Voting.]

* **Criterion 2**

MS. SELENICH: Zero members voted 5 to 6, meets and deserves priority consideration. Zero members voted 4, meets. Three members voted 3, meets. Five members voted 2, does not meet. One member voted 1, does not meet. Zero members voted not applicable.

Therefore, the finding of the Committee is that the proposal does not meet Criterion 2, quality and cost.

CHAIR BAILET: Thank you, Sarah.

Criterion 3, payment methodology. Pay the APM entities with a payment methodology designed to achieve the goals of the PFPM criteria. Addresses in detail through this methodology how Medicare and other payers, if applicable, pay APM entities, how the payment methodology differs from current payment methodologies, and why the physician-focused payment model cannot be tested under

current payment methodologies. High priority.

Please vote.

[Electronic Voting.]

* **Criterion 3**

MS. SELENICH: So zero members voted 6, meets and deserves priority consideration. One member voted 5, meets and deserves priority consideration. Zero members voted 4, meets. Two members voted 3, meets. Six members voted 2, does not meet. Zero members voted 1, does not meet; and zero members voted not applicable.

Therefore, the finding of the Committee is that the proposal does not meet Criterion 3, payment methodology.

CHAIR BAILET: Thank you, Sarah.

Criterion 4 is value over volume. Provide incentives to practitioners to deliver high-quality health care.

Please vote.

[Electronic Voting.]

* **Criterion 4**

MS. SELENICH: One member voted 6, meets and deserves priority consideration. Zero members voted 5, meets and deserves priority consideration. Five members

voted 4, meets. Two members voted 3, meets. One member voted 2, does not meet. Zero members voted 1, does not meet; and zero members voted not applicable.

Therefore, the finding of the Committee is that the proposal meets Criterion 4, value over volume.

CHAIR BAILET: Thank you, Sarah.

Flexibility is the fifth criterion. Provide the flexibility needed for practitioners to deliver high-quality health care.

Please vote.

[Electronic Voting.]

* **Criterion 5**

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

Therefore, the finding of the Committee is that the proposal meets Criterion 5, flexibility.

CHAIR BAILET: Thank you.

Criterion 6, ability to be evaluated. Have evaluable goals for quality of care, cost, and other goals

of the PFPM.

Please vote.

[Electronic Voting.]

*** Criterion 6**

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

Therefore, the finding of the Committee is that the proposal does not meet Criterion 6, ability to be evaluated.

MR. MILLER: Can we --

CHAIR BAILET: Yeah. My inclination is to at least have a conversation about this because I'll just -- maybe I'll start the conversation, Harold.

I voted did not meet, and the reason, part of it was in the discussion around the withhold and the lack of specificity around how to -- you know, what performance metrics are going to be tracked for that withhold to be paid. So it was -- it's not that it couldn't include those kinds of elements. It just didn't, and again, I'm taking the approach of the Committee in the past that we look at

this as it sits. So that's how I voted, and it looks like Harold and then Len have comments.

Harold.

MR. MILLER: So I'm voting consistently with how I did on the PRT, which is that I thought that any very innovative proposal is going to be challenging to evaluate, which doesn't mean that it can't be evaluated. It just means it's going to be more challenging to be evaluated.

And we've never really talked about exactly how to rate this criterion. I mean, I think the issue is could this be done in the standard simplistic way that one evaluates things by taking the same numbers that everybody reports and saying is there a statistically significant difference based on claims data. The answer is no.

Could one go in an find out whether or not people who are part of these practices feel that they are getting very different care than people in other practices do? Yes.

Would that be more challenging and expensive to do? Yes.

Does the Innovation Center spend a lot of money on evaluations? Yes, it does, and I think that it could do that perfectly well here, which is why I voted that it

meets.

CHAIR BAILET: Paul.

DR. CASALE: Yeah. The way I thought of this, you know, a lot of times when we're looking at this, we're often thinking about can we evaluate the cost and payment reduction part, and to be honest, sometimes we, I think, give a little shorter trip to the quality side.

In this one, I feel like we can track the quality in a very interesting and innovative way and evaluate that, and yes, there may be more concerns on the cost side. But that's where I landed on meets because I thought the quality side would be -- could be evaluated.

CHAIR BAILET: Len and then Tim.

DR. NICHOLS: So I -- maybe I take a narrow view of the word "evaluation," but I think of this almost completely about can you measure what you care about and can you find a control group. If you can do those two things, you can evaluate anything, in my opinion. In my opinion, the answer is yes in both of these questions.

I would take your criticism, Jeff, as criticism of the payment model, not of the evaluability of the proposal, and to my mind, no, if you're not using these tools, you're not going to be completely comparable because

you're not going to have that data on other people. It's a beta test evaluation, but it's an evaluation, I would submit, a stepped-wedge design where you get a bunch of practices. They're all ultimately the control group. They're all ultimately the target group, and you phase them in over time, and you can construct and evaluate.

It's not perfect, but it's been done in epidemiology since -- I don't know -- penicillin. So I'm pretty sure it's been around a while.

So I think it's a perfectly valid technique, and it will get you to the point of was there a difference, given that every one of these practices also has an EHR. You can do correlates with the usual suspects, and to me, that's what you want.

CHAIR BAILET: Tim.

DR. FERRIS: It is interesting how we -- you know, it's one word, "evaluation," and so many different people, all of whom do evaluations, can think about that word so differently.

I do interpret the word "evaluation" as in not an experiment because it is, as so many people have pointed out here, very easy to design an experiment that evaluates this, but an experiment means actually constructing a

control group and constructing an intervention group. And it is absolutely possible to do this.

But in typical sense, the evaluation in a CMS payment model involves not the construction of -- the active enrollment in construction, but actually using available information that they have at their fingertips.

Given the specific nature of the data collection process in this around quality metric, I don't see how you could do that without constructing an experiment. That's not to say an experiment isn't possible and in fact desirable and would be an evaluation of a beta test, precisely as you said, Len. That's not how I interpret this question.

DR. TERRELL: This is limited scale testing, not an experiment?

DR. CASALE: What did you say?

DR. FERRIS: So, actually, I have been forbidden to use the term --

DR. TERRELL: I just said is a limited scale testing, which happens to be one of our criteria right now. It's not an experiment.

DR. FERRIS: Yeah.

So, actually, I do consider it an experiment, but

I think I've been forbidden from using the term "limited scale testing."

DR. TERRELL: Yeah.

CHAIR BAILET: Okay. Do we want to revote, or are we good with -- no. I hear -- like I said, we're going to go ahead and revote one more time with feeling, please.

Criterion 6.

[Electronic Voting.]

* **Criterion 6**

MS. SELENICH: So 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. Zero members voted 1, does not meet. Zero members voted not applicable.

Therefore, the finding of the Committee is that the proposal meets Criterion 6, ability to be evaluated.

CHAIR BAILET: You have to love the process, don't you?

[Laughter.]

CHAIR BAILET: Very good. All right. Very good. Moving right along.

Criterion 7, integration and care coordination. Encourage greater integration and care coordination among

practitioners and across settings where multiple practitioners or settings are relevant to delivering care to the population treated under the PFPM.

Please vote.

[Electronic Voting.]

* **Criterion 7**

MS. SELENICH: So zero members voted 5 or 6, meets and deserves priority consideration. Zero members voted 4, meets. Three members voted 3, meets. Six members voted 2, does not meet. Zero members voted 1, does not meet. Zero members voted not applicable.

Therefore, the finding of the Committee is that the proposal does not meet Criterion 7, integration and care coordination.

MR. MILLER: I'm just curious. Have we ever actually found any proposal that we thought met this criterion? Maybe --

DR. TERRELL: Yes.

DR. CASALE: Oh, yeah.

CHAIR BAILET: Thanks for asking, Harold.

Okay. Very good. Criterion 8, patient choice. Encourage greater attention to the health of the population served while also supporting the unique needs and

preferences of individual patients.

[Electronic Voting.]

* **Criterion 8**

MS. SELENICH: Zero members voted 6, meets and deserves priority consideration. One member voted 5, meets and deserves priority consideration. Zero members voted 4, meets. Six members voted 3, meets. Two members voted 2, does not meet. Zero members voted 1, does not meet; and zero members voted not applicable.

Therefore, the finding of the Committee is that the proposal meets Criterion 8, patient choice.

CHAIR BAILET: Thanks, Sarah.

Criterion 9, patient safety. Aim to maintain or improve standards of patient safety.

Please vote.

[Electronic Voting.]

* **Criterion 9**

MS. SELENICH: One member voted 6, meets and deserves priority consideration. Zero members voted 5, meets and deserves priority consideration. Zero members voted 4, meets. Two members voted 3, meets. Six members voted 2, does not meet. Zero members voted 1, does not meet; and zero members voted not applicable.

Therefore, the finding of the Committee is that the proposal does not meet Criterion 9, patient safety.

CHAIR BAILET: Last criterion, 10, health information technology. Encourage the use of health information technology to inform care.

Please vote.

[Electronic Voting.]

* **Criterion 10**

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

Therefore, the finding of the Committee is that the proposal meets Criterion 10, health information technology.

CHAIR BAILET: Grace.

DR. TERRELL: I just want to go back to Criterion 9, since I was the outlier on 6, to give my rationale for why I thought it was a high criteria for patient safety.

My thought process, which apparently none of the rest of you had -- so that's good, but it might be useful -- is that patient-reported outcomes to my way of thinking

is probably the greatest and best potential there is out there for patient safety that we know, but it's very, very rarely integrated in a meaningful way into the thought process around patient safety.

I actually went through during the deliberations and did that How's My Health criteria, and it really is putting some real high-quality patient in control way of actually thinking about your health.

To my mind, that's not typically -- patient-reported outcomes is not typically tied nearly as much as it should be to the patient safety aspect of the criteria that we do.

So I get where everybody else was because it was -- you know, there was issues that were brought up, but I do think that that's something that we might ought to be thinking about in the future if we get other patient-reported outcomes as another creative methodology as to whether that ought to be thought about within the context of patient safety, which I don't think it typically is.

CHAIR BAILET: Thank you, Grace.

So we are at the point where we could have more dialogue or we could then come through -- we can begin the process of actually voting on the recommendation, and I

guess I'll throw out there I feel like we should move forward with that process.

And if you could flash the -- yeah, I'm going to try and get this right this time.

MR. MILLER: Jeff, can I --

CHAIR BAILET: Yeah.

MR. MILLER: I hate to disagree with you on that, but I think we ought to talk about what we mean by No. 2 and whether we're using No. 2 before we vote because it seemed to me pretty clear last time, people were interpreting that differently, and I'm not sure how we should interpret that.

So we could vote and then talk about it and then revote again.

CHAIR BAILET: Yeah.

MR. MILLER: But I just wondered whether that might --

CHAIR BAILET: Well, and that's a -- Harold, I know this is going to surprise you, but that's exactly what I was about to say --

MR. MILLER: It doesn't surprise me, Jeff.

CHAIR BAILET: -- Harold.

So let me define -- let me flash back to the

Committee our definition of what 2 meant when we created this voting. A vote of 2 means recommend proposed payment model to the Secretary for limited scale testing of the proposed payment model. This category may be used when PTAC determines a proposal meets all or most of the Secretary's criteria, but lacks sufficient data, one, to estimate potential cost savings and/or impacts of the payment model and/or, two, specify key parameters in the payment model, such as risk adjustment or stratification, and PTAC believes the only effective way to obtain those data would be through implementation of the payment model in a limited number of settings. So that was our agreed collective consciousness on how we attributed a limited scale on No. 2 when we established this criterion.

Len.

DR. NICHOLS: Thank you for reminding us of how well we articulated that, but I will remind all of us, they don't care. And what they heard in limited scale testing was lower priority, too much work.

So I just think it's a kiss of death. To me, you either say implementation and write the letter very nicely, or you say don't do it and write the letter very nicely. Either way, you write the letter very nicely, appropriately

nuanced, but I think 2 is the kiss of death because they've said it's been used, an excuse to say no, and we've -- they've already done it. So it's crazy to send it forward with that label.

CHAIR BAILET: So Harold, Bruce, Paul, and then Tim.

MR. MILLER: So I think, again -- this, I think will be -- we'll have to articulate after we decide how we voted. We'll have to articulate what the recommendation statement is, but I think we should -- the confusion I believe was that limited scale was also believed to somehow be limited impact, and so it seems to me that if we agree that we should not vote for something in No. 2, if we think it will only ever have limited impact, then that -- and we clarified that in the recommendations, that might be okay because my concern would be if we said, "Hey, we think this is ready to go for implementation." That would be wrong. I don't think we should say we're not voting for No. 2 at all and give ourselves only the choice of not recommending or recommending for implementation, but it does seem to me at this point that we have to be clear about what we mean by No. 2 and maybe add some additional phrases to that that said that we recommended that because of the reasons that

Jeff said and that we believe that it would have significant impact, et cetera, et cetera, et cetera.

CHAIR BAILET: Okay. Bruce and then Paul.

MR. STEINWALD: Well, if 2 is the kiss of death, I guess 1 is a real smooth, right?

[Laughter.]

MR. STEINWALD: All right. So I guess I'm trying to figure out where to fit my own opinion, and I like what you said at the end of your PRT report, that this would be a suitable model for implementation within an existing structure, not standalone.

And if we don't want any kisses or smooches, then that leads to 3, but we just have to explain what we mean by 3. It's not standalone, but it's what we say it is.

DR. NICHOLS: Bruce, can I ask what possible existing framework could you work this into? Another trace of CPC+?

MR. STEINWALD: Well, simplistically --

DR. NICHOLS: I would do that, but would you?

MR. STEINWALD: Well, I would find a collection of ACOs that were big enough and willing enough to incorporate something like this within their own framework.

DR. NICHOLS: [Speaking off microphone.]

MR. STEINWALD: Well, I know, but, I mean, that's -- what did they say here? That's what they said, and either that or some other structure that works even better.

CHAIR BAILET: Okay. Paul.

DR. CASALE: Just a couple comments, and, Len, I acknowledge what you just said, but I have to respectfully disagree around like you can't consider the limited -- I mean, there's been a lot of water under the bridge since we've developed all of that. I think we're in a -- I think in a different place, and hopefully, you know, the administration is as well.

And then I worry that if -- you know, as I'm thinking to go to 3, I feel like it's -- there's been other models that have been clearly 3's, and now they're sort of -- we're just putting all of these in the bucket in order for them to pay attention.

So I guess I'm not so challenged by this, the limited testing or concern that that necessarily means it's the kiss of death.

CHAIR BAILET: So we have Rhonda. Please.

DR. MEDOWS: So, Mr. Chairman, you can tell me if this is an inappropriate question, but we had another candidate come in and make a proposal. And the proposal

had some components of it that we thought were actually kind of smart, kind of cool, and a little bit new, but their proposal was not completely developed. And we saw the train coming. We knew this was coming, and we gave the candidate the opportunity to make a decision about whether or not they wanted us to complete this vote or not.

Are we past that point, and do we want to at least give the applicant a chance to decide if she wants us to do that?

Let me just finish.

My rationale for even bringing it up is that we are all g patient-reported outcomes, that piece of it, actually looking at quality a different way, in a way that matters to patients. My concern is that we don't want that to be harmed or tainted.

There are other pieces of it that I'm hearing from the conversation that need more development. Maybe I'm wrong; maybe I'm right. Usually, I'm right, but we'll go with that.

I'm just saying let's be considerate. You should have the opportunity to decide if you want us to complete this process or whether or not you want to take what we've already said and come back another day.

Just to be fair, we offered it to someone else.

CHAIR BAILET: So that's great, Rhonda, and I thank you for raising that. I don't think we're past the opportunity to pose that question, if that's what we'd like to do.

I'd like to hear from Harold and Len and then turn it -- yeah, absolutely, then turn it to the proposer.

Please, Harold.

MR. MILLER: So I would certainly support Rhonda's suggestion if -- I mean, I think we could certainly offer.

I guess I would say, though, there is nothing that prevents an applicant who we don't recommend their proposal from bringing back a new proposal and having us consider it later.

My concern in this particular case is that I think that it is not reasonable to expect the applicant to fix the things that we are concerned about without substantial technical assistance, which we are not able to provide, and the only reasonable way to do that is through CMMI.

And so I think that, in my personal opinion, if one believes that something like -- primary care needs to

be fixed. I think primary care needs to be fixed, and it needs to be fixed soon. And I don't think that it fixes primary care soon to ask one solo primary care doctor to go off and see if she can come up with a better proposal. So I think that's the issue.

I do think we should give her the choice, but my personal feeling is that this needs to get to CMS, and CMS needs to start doing something with it ASAP.

DR. NICHOLS: So thank you for raising this, Rhonda, because I had the exact same thought about 45 minutes ago, and then I thought exactly what Harold said.

Jean can't do this. I'm all for letting -- giving her the choice, but I don't think she can fix what we know CMMI is going to demand.

So the only way to make this work is to command CMS resources, and that's the way it should work because this is so creative. We should try to make this work in a beta testing way a couple years down the road.

CHAIR BAILET: Grace.

DR. TERRELL: I missed part of the conversation for biological reasons.

But now that I'm back, part of what --

MR. MILLER: You were out consulting with your

philosophers, weren't you?

DR. TERRELL: That's right. We're going from philosophy to biology.

But now that I'm back, Len, what you were talking about at the time was limited scale testing and the fact that they told us we're not going to go down that route, and we've all had all that.

I think that that needs to be tied back to a point you've made for as long as you've been on this Committee about the resources that are out there with respect to, in this case, a small solo provider in a rural setting versus other levels of resources.

And one of the things that we may want to make clear to the Secretary in the letter is if we go down the route of limited scale testing, my personal bias is I don't care what they say about it, if that's what I think it needs. I like the definition that's out there. I'm going to vote in that direction.

We may need to make the argument, since there has been a focus from this administration on the desire to do something, for limited, rural, small providers, that if you're going to actually say that and you're actually going to ask their opinion and they actually give it to you, then

you actually ought to probably do some limited scale testing, dudettes.

So it's something that within the context of where your head was going earlier, which was despair. I just want you to get out of it and go back to who you usually are, which is to rail, rail against the night, and to really go with where this relates to technical assistance and all of that because I do think that those issues are related, which is part of the criteria this administration has versus what its actual at least verbally stated goals are with respect to that.

MR. MILLER: And I believe that Grace was just trying to get points on her depression screening measure for having counseled you on that.

CHAIR BAILET: All right.

DR. NICHOLS: So I'll just say I'm glad biology let you come back just in time.

CHAIR BAILET: Okay.

DR. NICHOLS: But I would also say --

CHAIR BAILET: Go ahead. I'm sorry, Len.

DR. NICHOLS: I agree it's more intellectually honest to say limited scale testing. I just remember being given quite some length of time saying we'll never do that.

So I'm happy to vote for that over nothing.

I do think if we vote don't recommend, it won't be seriously read, so we've got to do something on this side of the table, and so --

CHAIR BAILET: So my personal opinion -- and maybe with a modicum, a dash of chairmanship thrown in -- I think we should vote. I think we should remain consistent with our process to date. I think we have lots of degrees of freedom to put information in the letter about how we feel collectively about the model relative to how we land on the vote, which is not determined yet, and then use that letter and the relationships that we're building with the administration to make sure that several things are heard, which we have CMMI leadership in the room. They're here in the room, staff.

This is an issue that's not new. We talked about it two meetings ago about primary care challenges and how every day primary care, the programs get washed away, and physicians leave and abandon the practice, and they can't get new people to fill these positions, particularly in stressed, smaller communities.

So we can incorporate all of that in the letter. So I guess I would -- Len, my point of view is potentially

different than yours relative to a does not recommend does not mean that it goes in -- I think we still have degrees of freedom -- what we put in the letter, if that's where we land, on what our overarching recommendation is, what we should do with this model, and the components therein. So I think we have that opportunity.

I welcome other comments before we vote, and I guess even before that, just to be respectful of our former process that was offered other candidates, I guess, Jean, to you specifically, if you are sitting here and thinking that you would prefer us not to move forward, this would be a good time to share that with us.

DR. ANTONUCCI: I think that I would ask you to move forward. Someone said correctly that I don't have the resources to solve the questions that you asked of me.

CHAIR BAILET: Right.

DR. ANTONUCCI: This is a great discussion. You guys are great.

CHAIR BAILET: Thank you.

So I think we're ready to vote. What we're going to do is we're going to vote electronically first, and then we're going to go around the room -- and I'm going to start with Rhonda -- and talk about how we voted and move

forward.

[Electronic Voting.]

*** Final Vote**

MS. SELENICH: Zero members voted for recommend proposed model to the Secretary for implementation as a high priority. One member voted 3, recommend proposed payment model for implementation. Six members voted 2, recommend proposed payment model to the Secretary for limited scale testing. Two members voted 1, do not recommend proposed payment model; and zero members voted not applicable.

A two-thirds majority is needed. That rolls down to 2. So the finding of the Committee is to recommend the proposed payment model to the Secretary for limited scale testing.

*** Instructions on Report to the Secretary**

DR. MEDOWS: So I voted 1, do not recommend proposed payment model to the Secretary, and I did so because I thought that the proposal was incomplete in significant areas, both in terms of quality and cost as well as the payment model itself.

I do recommend that in the letter to the Secretary that the comment include an emphasis on the

importance we felt that the patient-reported outcomes be incorporated and as a possible alternative way to do risk assessment, ID, and stratifications that need more -- have more complex care needs.

And I also thought that we needed to talk more earnestly about our approach to how we are making these recommendations to the Secretary.

And if I could be quite frank, my concern is that if we voted for it to be recommended, knowing that there were some holes in it, that it would not serve the candidate or PTAC or the public well, simply to try to do something that we think would try to push CMS to look at something. Quite frankly, I just don't honestly believe that that is the case. I think it would be better to actually speak to the parts that we believe are strong or promising or innovative and that there are things that actually involve in better patient care.

I think what's missing are the pieces where we had -- we did not have information about which quality benchmarks could actually be used to resolve the withholds. The capitation payments itself and the risk adjustment needed further work. I know we talked about people being concerned about clinicians gaming a cap payment, but we

also have to think about it on the reverse way as well. If the cap payments are meant to try to help recoup some of the losses from lower reimbursement for more complex patients, if those more complex patients do not complete this survey, they will be -- I am assuming default to the lower cap payment, and they still -- a primary care physician would still not reap the reimbursement, the pay that is needed to cover that care.

I think it needs to be completed, and I think it needs to be more thought out. And that's my humble opinion. Sorry to disappoint you all.

CHAIR BAILET: Thank you, Rhonda.

DR. PATEL: I voted No. 2, and that was mainly -- I'll credit Grace persuaded me that it's completely accurate that I would not have voted No. 2 because I didn't think limited scale is something that would be kind of taken in by the administration, but I feel like there's no other category that reflects that there are indeed pretty significant flaws, which I think could be overcome with more work. That work should not be put on the backs of the submitter by him- or herself or even if it was a large organization. I think this is something that should be done because it's apriority, particularly in primary care,

by the administration.

So I would just ask that in the -- I think others have said this, but some reflection in our comments to the Secretary around any association with limited scale to not be actually subject to the definition that you had read, so that they know that it's something different. So that hopefully will get captured.

DR. NICHOLS: So I voted 2 because I was shamed into intellectual honesty by my colleagues. I was trying to game the system and get a 3 up there to push us over the edge because I just fear if you don't give them a good, strong push, it won't go very far.

I agree with Rhonda. It's incomplete, but I am pretty sure -- and I think Jean just confirmed -- she can't fix this. We need professional help to do that.

What I am struck by, A, is the incredible creativity of this proposal and how consistent and, indeed, up to until this moment, maybe uniquely consistent with what Adam laid out this morning. We all remember the four P's, but he also said what works -- transparent, simple accountability. This is that, and what I really love is simple because I'm a simple guy, but also, that's what primary care needs and what we actually ought to be

focusing on.

And so I think appropriately defined, redefined, clarified limited scale testing really means, in my mind, in addition to the words you said, use CMS resources to develop the pieces of this that need work and them do the beta test.

CHAIR BAILET: So I voted 1, not to recommend, and I don't know. I'm worried about your telepathic skills, Rhonda, because a lot of the challenges you had with this, I have as well. So I don't necessarily want to repeat them, but I do think -- I think this is a watershed moment for the PTAC and the CMS leadership who were here with us today. I think there's an opportunity for us to navigate what we're experiencing because to some degree we're using the lens of the past, and I'm not saying that we have any tangible reason to -- demonstrable reason that's concrete to make us change, but I think the frame has changed.

I think that there's receptivity on the other end to work more closely with us, and I think that this model needs refinement. I think that this model -- even just the withhold, I mean, working with physicians, when you withhold payment and you can't tell them what's the

mechanism for them to earn that back, that is a significant challenge. So I think the model needs work.

I think that CMS is interested in building primary care based on their comments that they've shared with us, coming forward with a model. I think this gets to a particular niche for primary care, which is what happens to practices that are in smaller communities with less infrastructure. I think this model has a lot of unique elements that will fill that gap and inspire and incorporate and support those physicians who practice in those environments.

But I don't think it's ready to recommend, but I hope -- I know we will capture the strengths of this model in our letter to the Secretary.

Bruce.

MR. STEINWALD: Okay. I was the 3.

[Laughter.]

MR. MILLER: That was really a smooch, Bruce, I tell you.

MR. STEINWALD: It's already been defined as intellectual dishonesty, so I might as well own up.

[Laughter.]

MR. STEINWALD: I'm not sure I believe any

differently that those that voted 2.

But, you know, it's not just because we've gotten this negative feedback on anything that we've recommended for limited scale testing in the past. It's also because of the feedback that we've gotten tends to have accentuated the negative. We write a report. We identify a number of positive things, a number of negative things, and what we get back in the letter -- and maybe times are changing -- is highlighted, the negative.

So regardless of what particular category we recommend in, I think in our discussion, we need to make it clear what we mean by limited scale testing. And we also need to accentuate the positives that so many people have identified in this proposal and really, really highlight them in our letter to the Secretary.

CHAIR BAILET: Paul.

DR. CASALE: Okay. Process of elimination, I must be a 2, which I am, for limited scale testing.

Yeah. So I think, as I think through the payment part -- and yeah, there's a lot of issues, but I think they're all fixable. And I think the quality side is very creative and innovative, and to what Len said, which was exactly what I heard this morning, the simplicity, you have

simplicity, transparency, accountability. I mean, that's here. Again, fixing -- and it's got most of the P's of those four P's, if not all the P's.

So, in my mind, I think there's been enough work done in primary care models, et cetera, that I think we can fix the cost parts, and then we can add in this patient-reported outcome piece, which I think would be a big leap forward.

MR. MILLER: I voted for 2, limited scale testing, because I think that this model is perfectly, exactly what it is that we meant wherever we said limited scale testing, which is that it needs to be done on a small scale initially to be able to refine the methodology sufficiently, to be able to move it forward for broader scale implementation, and that the only way to make those refinements is to in fact implement it in some practices because you do not find out how well it is that you can get patients to answer a survey that they need to answer unless you're actually doing it. And you can't do it if you're not paying the practice appropriate to be able to do that, et cetera. So the whole thing has to be done in a beta testing model site to do that.

I think I want to make sure, at least from my

perspective, that the issue is that it's not to me a bad payment model. It is not a problematic payment structure. It needs to have details worked out that cannot be worked out to anybody's satisfaction, in my opinion, without implementing it.

That's very different than us saying that we think that the payment model has lots of problems with it and it needs to be redone.

If there were problems with the payment per se that had to be redone, I would say, "Jean, you should go take and redo your proposal," but I don't think that's the case here.

I don't think the notion of having a withhold is a bad thing. I think the withhold is perfectly fine. People will disagree about whether withholds are a good thing or not, but I think it's a perfectly fine thing to do. I think it's a perfectly fine and wonderful thing to do to pay capitation. I think it's a wonderful thing to do to have a risk-adjusted capitation. I think it's a wonderful thing to do to have a simple structure that's based on the actual patient needs rather than HCCs, for God's sake, which we know don't work, and yet they continue to show up everywhere as the default mechanism. And it's

time to move beyond that.

So I think it's a wonderful thing that there's all that, but the fact that it is that innovative means that there is a variety of details that need to be worked out.

And when I say that I don't think that it's something that Jean could work out, I don't mean that because she's a small primary care physician. I think it's important to say that. I don't think that we're somehow giving a pass to every small practice that brings in a model and say, "Oh, we know you couldn't do it." I don't think that's the issue.

I think the issue is nobody could do this unless they had resources to be able to support the delivery of care difficulty, and so if some large integrated system wanted to do it, sure, they could do it. They could pay their practices this way and do all this kind of stuff because they could put the money into it, but you can't do that for most of the country. And I don't think that we should have payment models dependent on having big, wealthy institutions doing things because they have the money.

So I think that this fits perfectly into the category of saying that CMS should do it and do it on a

limited scale in order to be able to move it more broadly.

I think the thing -- the clarification I would like to make sure that we state in here is that we do not think that this would have limited impact, that this could have significant impact if it works properly. We don't know that. We don't know that by anything else, and it's certainly clear that all the other models haven't been having significant impact either, even though they had high expectations attached to them.

So I don't think that it's anything for us to say that we're sure that this is going to have a big impact, but I think that the notion that this could have a very significant opportunity for primary care to be able to deliver care differently, to keep primary care physicians in practice, et cetera, it makes it worth doing that and doing it through the multiple steps that would have to be done to be able to do that. And I think that we have to get to the point where we're willing to do models in multiple stages because the more innovative they are, the more stages are going to have to be done.

And everybody wants to have gazillions of dollars of savings immediately, and I don't think that that's a reasonable expectation for a lot of these things.

So that's my long-winded explanation for why I voted for No. 2.

CHAIR BAILET: Thank you, Harold.

Grace.

DR. TERRELL: I voted for No. 2, and I think you've all heard in previous dialogue a lot of my reasoning behind that.

As we are writing this letter to the Secretary, I think that one of the things that is crossing my mind is given what we heard this morning about Adam's four P's, this would be perhaps a good place for us to use our criteria, limited scale testing, and pressure-test them against those four P's in the dialogues.

We can go through our 10 criteria, and we can make our points that have all come up. But because there's been conflict between our understanding of the way to evaluate this and their belief about its validity -- and since they provided a different framework from which they're thinking about the world this morning, that I think that this particular proposal, to Len's point perfectly, could match from that point of view. The place and space to do it will be within the context of our framework of limited scale.

So if we can end the way we write this up, focus on the limited scale as it relates to those four P's, I think that this will be an opportunity that may help us move along beyond the perceived conflict we have right now.

CHAIR BAILET: Thank you, Grace.

Tim.

DR. FERRIS: So I was a 2. In the interest of expediency, I would refer to my two points at the opening. You can get them from the transcript about beta testing and about assurances.

And, in closing, I'd like to associate myself with Dr. Antonucci's comment about you guys are great.

[Laughter.]

CHAIR BAILET: Okay. But before we break, we have Audrey here, who has been flying through. She's already to go ahead and give us a summary, Audrey. It's your time to shine.

MS. McDOWELL: All right. So I'll begin with a disclaimer. This is my very first PRT, so I'll ask for a little bit of grace.

So I'll begin by summarizing the key points that I heard and the strengths and weaknesses, and then I also want to flag that there are three places where the full

PTAC had a different vote or conclusion regarding the criteria in comparison to the PRT, and so I want to just make sure that I get some additional insights regarding the reasons for the differences, so we can include that in the report to the Secretary.

So in terms of key points that I heard, one of the things that they're emphasizing is that the Committee believes that -- and voted that we're recommending that the implementation needs to be done on a small scale or a limited scale to provide an opportunity for refinement before being able to do more broad implementation. That there are flaws that the Committee believes could be overcome with additional work, but that the goal would be to use CMS resources to do that refinement rather than putting burden on the submitter. That in the letter to the Secretary and communications to the Secretary, part of what needs to be done is we need to clarify what is being meant by limited scale testing in the context of the recommendation, and part of what we want to do is perhaps use this as an opportunity to focus on the meaning of limited scale as it relates to the four p's that were outlined during the earlier discussion with senior leadership.

That we also want to make sure that we accentuate the positives of this proposal in the letter to the Secretary, and that the Committee also does not think that this proposal can only have a limited impact. We have no way of necessarily knowing for sure, but that we do think it could potentially have a significant impact in addressing some of the concerns relating to primary care.

Additionally, we want to also highlight a couple of the points that were raised earlier in the discussion that were raised by the PRT participants earlier. Tim had raised concerns relating to -- I believe we said beta testing and assurances, so we'll also make sure that those are included, and we'll go back and make sure when we double-check the transcript for those.

Relating to major strengths, we want to make sure that we emphasize that this particular proposal is considered to reflect a lot of creativity, particularly relating to providing a different way of thinking about quality and simplicity.

The proposal also -- we believe -- the Committee believe it's consistent with the goals that were outlined earlier by senior leadership relating to transparency, simplicity, and accountability, and also that, again, it

has most, if not all, of the four P's, and again, that there is a belief that it should be possible to fix many of the concerns that were raised relating to some of the payment issues. And there's also a belief that there are a lot of strengths related to the inclusion of patient-reported outcomes.

In terms of some of the key weaknesses that were raised, concerns were expressed about incompleteness related to not identifying in the proposal which specific quality benchmarks would be used, concerns about capitation payments, and the potential for higher-risk patients potentially not to complete the survey, and that that might affect whether or not a practice would then get the higher capitation payments for those patients and how that would potentially affect the payment to the primary care practice.

Additionally, concerns regarding the need to clarify the mechanism for how a primary care practice would be able to learn back the withhold.

And, finally, that one of the limitations related to the innovativeness of the proposal means that there are a variety of details that need to be worked out, and that

it also will require multiple stages for implementation. So there's kind of a tradeoff there.

Are there any additional concerns? I guess there are also some additional comments that we want to make sure that we highlight -- let's see. That we want to include some language in the letter to the Secretary about the way in which we're making our recommendations and also that there are concerns relating to the way that we're doing risk adjustment.

And I need to go back to the transcript and make sure that we capture the details related to that.

Are there any other things that were missed in terms of major themes?

DR. NICHOLS: I don't think you missed anything.

MS. McDOWELL: Okay.

DR. NICHOLS: But I think it might be worth -- just on that second to last point, I think what we wanted to make sure was that we conveyed what we're saying now as limited scale testing is not what leadership thought it was when we met with them the first time. I don't remember exactly when that was, but we just need to make that explicit, I believe, in the letter: And what we mean by this is this and not what you all thought it was. And I

think we'll be okay if we do that.

MS. McDOWELL: Okay . And so, if you don't mind, I have three criteria that I would like to just get some additional language from the Committee regarding the reasons for why the Committee voted differently than the PRT did.

The first one on scope. The PRT voted that it did not meet, and the Committee voted that it meets the criteria. So I don't know if there are any specific thoughts on that.

DR. MEDOWS: So I have one. I think what we were looking at is not just primary care as a whole but primary care of a solo or small practice, particularly in rural parts of the country.

MS. McDOWELL: Okay.

DR. MEDOWS: So that's a group that actually needs to be represented in alternative payment models.

MR. MILLER: I also think that the nature of the proposal has potential impacts beyond this primary care, sort of the notion of needing to do something more on how to do patient-reported outcomes. We've cut across other areas, and so its scope would go beyond this in terms of the methodology issues. So that's another reason why the

impact could be larger than it might appear by simply doing it in a small number of primary care practices.

CHAIR BAILET: Bruce, did you want to make a comment?

MR. STEINWALD: Back to Len's point about what we mean by limited scale testing, I don't have a clear sense of whether the Committee believes what the PRT report said at its last paragraph, that it ought to be implemented within another existing structure, or do we not need to be that specific?

It sounded to me like a good idea. I'm not sure, Len, in your response to it, thought within an ACO was sensible.

DR. NICHOLS: I don't see this as an ACO. I see it as another form of primary care. So it's more CPC+ track 7(B) or something. I'm happy to have it embedded in that language. I don't mind that paragraph. To me, that's kind of being prescriptive. I would rather leave it open because if the only way to get it is to make it CPC 7(B), I'm for it. If we actually would acknowledge the uniqueness of it and the potential of it, you could imagine as one of a number of things going in this other direction. I want to get away from the meaningful use measures, and

this thing does it. CPC+ does not.

CHAIR BAILET: Kavita and Harold.

DR. PATEL: Just to build on that, we already heard from Adam today, and we've heard previously that it sounds like they're launching something around primary care inevitably. So I would not be prescriptive such -- I mean, it almost be like, e.g., CPC, ACOs, or another primary care model, just because I can easily see, depending on what that model looks like, that this could be one of the beta-tested, you know, kind of how it is a supply and settings within that model.

MR. MILLER: Well, I would just like to suggest that maybe the way the wording we say is something that is not prescriptive but describes what some of the benefits would be. So it could be done -- we might say it could be done as part of CPC.

I think there's two reasons for that. One is we've heard that, understandably, it's hard to launch whole new things, and so it may be easier to sort of add something onto an existing model.

The second thing is -- I raised this earlier -- I am somewhat concerned because -- I don't think this would happen, but I would be concerned if the only model that

CMS put out was this, and all of a sudden, you had every primary care practice in the country thinking that it either had to be in this or nothing, which would then make it very difficult to do it kind of on a testing scale like this. And I think having it be part of something that's broader that would say you can do this other thing, but if you really want to be innovative you could do this, it seems to me we'd get the right people into it.

So I guess I would suggest, if everybody would agree, that we sort of -- we talk about that as a specific option, that we don't say we think that's the only way it could be done, but that there would be some advantages. And we don't think it would be problematic to do it. I don't think it would be problematic to say it's Track 17 of CPC+. It may or may not be, but I don't think there's any other reasonable option, anyway, truthfully.

CHAIR BAILET: All right. Bob, I know you wanted to make some comments.

DR. BERENSON: Yeah, just a couple. I've been quite for too long, so I wanted to --

First, I thought you all did a great job, and. Jean, in particular, you did a great job. So I just wanted to say that.

I wanted to just comment on a couple of things I heard during the discussion, not about the proposal, but about capitation, just to clarify two points. And the background is that I practiced under Primary Care Capitation, outside of an ACO. I think it's a viable model, including for rural docs in particular, if it's done right, and that's the challenge.

And to go against my caricature, which is that there's always a fee-for-service option, to Rhonda's point that maybe we would consider new codes, I think this is an area where you can't do it in fee-for-service.

As anybody here who has practiced primary care knows -- and it was documented by Rich Baron in a New England Journal article a few y ears ago -- you're doing dozens of one-minute activities all day long. How do you build for a one-minute activity? I mean, the transaction costs, the copayment you have to collect. All of that stuff can't be done fee-for-service, and so whether it's CPC+, which is partial capitation, or this, which is total capitation, I think for primary care, you got to go to some form of capitation.

And then the final point I wanted to make, Harold pointed to the Oklahoma data, which said that Medicaid

capitation resulted in stinting, and Bruce talked about, but then there's concierge practices. And you could add direct primary care, which is the current sort of model du jour, seems to be well accepted at least by affluent patients who are able to do that.

We have this tendency to look at the incentives in a payment model and decide what the potential behavior can be, like stinting, completely ignoring the payment level, the generosity of the payment.

So from personal experience and anecdotes, if you pay me a Medicaid level of capitation, I'm going to stint on services. I can't pay my costs. If you pay me a concierge level of capitation. I'm going to do great, but then how does an insurance -- how does a payer actually justify that? The challenge is to find the sweet spot, which is that the payment is enough. You do need some measurement. You need some of that stuff, but it is just impossible.

And, in fact, there was an HHS task force 25 years ago in the heyday of HMO gatekeeper payment, which concluded that it is impossible to judge whether incentives are too strong. That was what they were asked to do because the left wanted to ban sort of capitation and these

kinds of things, and they said, "We can't do it." And they actually listed six factors that would determine what the behavior might be, and they led with the generosity of the payment. So it makes it much more complicated.

So I just wanted to say that. This is very challenging, but it is absolutely worth trying to figure out how to do capitation for primary care docs. Done.

CHAIR BAILET: Thank you, Bob.

Harold.

MR. MILLER: I don't think we've got to Audrey's other points she needed to -- there were two other areas where you said that we voted differently. I just to make sure you got clarification there.

MS. McDOWELL: That's correct. On ability to be evaluated, the PRT said does not meet, but the full PTAC voted that it meets the criterion.

MR. MILLER: And that was nip and tuck.

DR. NICHOLS: But it had to do, I believe, with accepting the proposition that for this proposal, beta testing evaluation is the right model. It is not -- and I think that's what sort of won the day. So go back to Tim's beta testing dissertation, and you'll find the details there.

MR. MILLER: I would just also note I think the issue is what do you mean by evaluation, and I think the question is could you figure out whether this is working in improving care. The answer is yes.

Could you get statistically significant stuff? And I think the issue ends up being too many of the evaluations that are being done -- this is just a side comment on my part. Too many evaluations are being done on things that have so little impact that everybody is worried about the statistical significance of the $36 that ACOs saved nationally last year. You know, big whoopy.

So the issue is if this actually has a big impact, it will not be that hard to determine that it's there. It's only if it's a small impact. So I think that's going to be one of the other issues in the evaluation, is exactly how much of an impact are you trying to detect.

DR. FERRIS: I don't want to give the impression, at least from my perspective, that a P value is the key issue here, in my understanding of the evaluation issue.

My understanding is about fairness, and that's got nothing to do with P values. So I just wanted to clarify it from my perspective.

DR. NICHOLS: Well, as long as we're clarifying perspectives, I'll just say to me, the difference in a beta evaluation and a full-scale evidence is generalizability. You can prove impact with beta. You can't generalize, therefore, to implement nationwide, which you could from a full one. That's really what it --

CHAIR BAILET: Audrey.

MS. McDOWELL: All right. And the last one, where there was a discrepancy on patient choice, the PRT concluded that it does not meet, and the PTAC, the full PTAC, concluded that it meets the criterion.

DR. PATEL: [Speaking off microphone.]

MS. McDOWELL: The full PTAC voted six, that it meets; two, that it does not meet; and one, that it meets with priority consideration.

MR. MILLER: So I would say there's a couple of factors that went into that. One was the concern about whether it would expand or reduce access to primary care. So if it is done on a limited scale, then I'm not worried about that because it's not going to do that. So I think that's a question. To me, it's jumping ahead to the recommendation, but I don't think if it's done on a limited scale.

And the second issue was to what extent are the patients being informed about what they're choosing, and I think that that is sufficiently easily solvable that before the patient signs up that they could be -- that I don't think that one votes against it just because the proposal didn't articulate that. I think it's articulated, but that would be my answer as to why I tilt it back over.

Other people can say whether they agree with that or not, I guess.

DR. PATEL: I'll just support that Dr. Antonucci's answer about patients -- you could be in one practice with one doctor, and someone could opt into the program or just say, "No, thank you. I will stick with what I've got," and that that physician would then still provide that other care model to that patient. So that's another rationale for why the discrepancy.

CHAIR BAILET: Grace.

DR. TERRELL: So the question, maybe some of our scholars like Bob can answer or not.

But all the concerns that have been out there in the past with respect to full capitation, has there ever been a patient-reported outcomes type of link to that to sort of take care of the potential concerns people have

about stinting through which there's data? Because to my mind, the creativity and the innovation that are in this, I agree with you. I think full cap for primary care, if done right, is a wonderful solution. I agree with you about the amounts make a difference in terms of the generosity of the payment.

But the aspect of actually also linking it to patient-reported outcomes, to my mind, is genius, and I just wondered if there's data out there to support that in the past from some of the stuff that --

DR. BERENSON: Not that I'm aware of. I actually thought Jean did a great job of explaining the rationale.

I mean, if you're being stinted, you probably are able to report that you're being -- if you're being shipped to -- I mean, this probably doesn't happen in rural practices as much because you can't just refer everybody out.

But in an urban practice, that is the reason 30 years ago, they came up with these risk pools based on total cost of care, because of concern that the primary care doc would just refer everybody and not provide any services.

But I would think that the right patient-reported

outcomes would capture that. So I think it's a very promising approach.

DR. TERRELL: So based on that, I think as we're writing up, Audrey, the report, emphasizing the new innovative nature of basically the issues that people have had concern about in the past with respect to full capitation and behaviors have never been linked in this innovative way before might be a very important thing for us to state or emphasize as we are sort of making our points to the Secretary.

CHAIR BAILET: Tim.

DR. FERRIS: One friendly amendment to that. So there is quite a bit of research, and actually, Dr. Wasson mentioned it, correlating HRAs of which How's Your Health is a type of health risk assessment, is a type of HRA.

There's a lot of research correlating HRAs with outcomes. Using an HRA in the context of stratification and making sure that that stratification is fair is, I would say, not well studied. I'm not aware of anything, of any data that directly does that.

And there's a big difference between comparing our squares and variance explained -- and there is quite a bit of research on that -- to taking it this next step in

payment models. So I would just say that's quite specifically the piece of work that would need to be done here.

CHAIR BAILET: Thank you, Tim, and thank the Committee for the incredible discussion. I think we've come a long way.

We'll work with Angela as we draft this letter to make sure that we cast it in the appropriate spirit.

Pardon?

MR. MILLER: Audrey.

CHAIR BAILET: I said Audrey. But I said Andrea by mistake?

Audrey, my apologies.

MS. McDOWELL: I answer to anything that's in the room.

CHAIR BAILET: Yeah. Well, I hear you. I hear you. It's been a long day, and it's not over yet.

So I'll tell you what we're going to do. I want to first thank Dr. Antonucci, Jean, for bringing this proposal forward, for hanging in there with us, for serving your community and helping give a helping hand to primary care across the country, so thank you for that. Appreciate everybody's hanging, hanging through this conversation, and

I recommend taking a 10-minute break, and we will reconvene for our last proposal. Thank you.

[Recess.]

CHAIR BAILET: I'm going to go ahead and get started.

[Pause.]

*** APM for Improved Quality and Cost in Providing Home Hemodialysis to Geriatric Patients Residing in Skilled Nursing Facilities. Submitted by Dialyze Direct**

CHAIR BAILET: So we still don't have Len Nichols, but we are -- we're going to go ahead and get going, and hopefully by the time we get done with the conflicts, Len will be back.

So the third proposal today is the Alternative Payment Model for Improved Quality and Cost in Providing Home Hemodialysis to Geriatric Patients Residing in Skilled Nursing Facilities, submitted by Dialyze Direct. Harold Miller is the lead reviewer. Myself and Dr. Rhonda Medows were on the PRT.

*** Disclosures**

CHAIR BAILET: I'll start with disclosures, starting with myself. I have nothing to disclose, and

maybe I'll start, Rhonda, with you, and we can come around the room.

DR. MEDOWS: I have no disclosures.

DR. BERENSON: I have no disclosures.

DR. PATEL: Kavita Patel, no disclosures.

MR. STEINWALD: Bruce Steinwald, no disclosures.

DR. CASALE: Paul Casale, no disclosures.

MR. MILLER: Harold Miller, no disclosures or conflicts.

DR. TERRELL: Grace Terrell, no disclosures.

DR. FERRIS: Tim Ferris, no disclosures.

CHAIR BAILET: And our esteemed colleague Len Nichols is working his way to the microphone to declare whether he has something to disclose on the Dialyze Direct proposal.

DR. NICHOLS: I lost five bucks in the vending machine, but I have no conflicts of interest.

[Laughter.]

CHAIR BAILET: All right. Harold is the lead reviewer. Harold, I'm going to turn it over to you, please.

*** PRT Report to the Full PTAC**

MR. MILLER: Thank you, Jeff. And thank you,

Jeff and Rhonda Medows, for serving on the PRT with me. Both Jeff and Rhonda are physicians, and we always make sure we have at least one physician on the PRT.

We worked on this project over the -- proposal over the summer and asked a lot of questions about it, which the folks from Dialyze Direct responded to all of our many questions several times -- thank you -- and we had a discussion on the phone with them, and we provided some preliminary feedback to them and then used all of that input, as well as some data analysis that was done for us and a discussion with a clinical expert to prepare our PRT report, which I will try to outline for you. Fasten your seat belts because this is a little challenging to follow some of this.

So this proposal is designed for patients who are in skilled nursing facilities. There are -- and who have end-stage renal disease and who need dialysis. There are two different kinds of patients in skilled nursing facilities: patients who are there on a long-term basis, who are residents of the facility, where Medicare is simply paying for health care if they need health care, but somebody else is paying -- the patient or Medicaid or someone is paying for their nursing home stay; and then

there are patients who are there on a short-term where Medicare is paying for their stay in the nursing home. And I say that because that distinction is going to be critical for some of the discussion later on about the various criteria.

And the purpose of the proposal is to encourage the patients in the nursing facilities who need dialysis to be able to get dialysis in the nursing facility rather than having to be transported to an off-site dialysis facility and to get more frequent dialysis, meaning five days a week, generally, rather than three days per week.

Also, the method of dialysis that they would be receiving in the nursing home would technically be considered home hemodialysis as opposed to what is typically done in a dialysis center. It would be staff-assisted, though, home hemodialysis in the nursing facility. So rather than what would ordinarily be viewed as home hemodialysis where the patient themselves or the patient's family members are assisting them to be able to hook up the equipment, et cetera, there would be staff in the nursing facility to be able to do all of that.

Interesting characteristics of this proposal is that there's no actual change proposed to the way Medicare

pays for the dialysis treatments themselves. The only change in the payment model is for the nephrologist who is caring for the patient, and there are two specific payments proposed for that. One is a one-time bonus payment, if you will, of $500 for providing education to a patient who uses this service about -- so that they understand what the service is, et cetera. And the second is a payment equal to 90 percent of any savings resulting from the patient avoiding transportation costs to see the nephrologist in their -- so the nephrologist would see the patient in the skilled nursing facility rather than in the nephrologist's office.

This is somewhat complicated to follow because -- so if you're getting your dialysis at a dialysis facility, the expectation is that the nephrologist will see you in the dialysis facility. If you are getting home hemodialysis, the expectation is that you will go to see the nephrologist in their office, and the requirement is that you see the nephrologist in their office at least once a month.

So the issue would be if the nephrologist comes to see the patient in the nursing facility rather than having the patient have to go to the nephrologist, that if

there were payments being made for transportation, ambulance transportation for the patient to go to the nephrologist's office, and the nephrologist went to the skilled nursing facility instead, the nephrologist would get 90 percent of the savings from the avoided transportation costs.

Now, that structure raises some interesting challenges, as you'll see. So we reviewed this and concluded that -- almost unanimously across the board that the proposal did not meet the majority of the criteria, including none of the high-priority criteria of the Secretary's criteria. I'll try to hit the high points here as usual on the key issues and then go through more quickly in terms of the individual criteria.

We felt that this -- what the goal of the proposal was was very meritorious, that today, if a patient is in a nursing facility and the nursing facility itself does not have an on-site dialysis center, the nursing home patient is typically transported by ambulance to a dialysis center, which is a lengthy, unpleasant, and potentially dangerous process in some sense, because accidents can happen, et cetera, in transport. And so being able to get dialysis in the nursing facility rather than a dialysis

center would be a desirable thing.

Moreover, patients in many cases are much better off being able to get more frequent dialysis, five days a week rather than three days a week, because it gives them much more stable, shorter treatments. There are also benefits to the patient in the nursing facility from not having to leave the nursing facility entirely for an entire day for three days a week. So all of those things are good things that would happen if that was available.

There's no change proposed in the Medicare payment. Medicare pays for every dialysis session. If the patient was receiving more frequent dialysis in the nursing facility, Medicare would be paying more. It would be paying for five treatments a week rather than three treatments a week.

However, if the patient is being transported by ambulance to the dialysis center and if Medicare is paying for the ambulance to the dialysis center, then if the patient is not being transported to the dialysis center, Medicare wouldn't be paying for the ambulance transportation.

So in the circumstance in which a patient is today being transported to a dialysis -- off-site dialysis

center by ambulance and Medicare is paying for the ambulance -- I'll just use sort of rough numbers. Let's just say for round numbers, just for ease of understanding, Medicare would pay about $250 per dialysis session in the dialysis center three times a week. It would probably be paying about $250 each way for the ambulance treatment each time that they go. So that would mean that on three days a week Medicare would be paying $500 for transportation and $250 for a dialysis session, or $750 per day three times a week.

If the patient was getting more frequent dialysis in the nursing facility at $250 per session but not having to be transported, Medicare would be paying more, $750 -- I'm sorry, $1,250 for the five dialysis sessions, but nothing for the transportation. So in that circumstance, there would be significant savings to Medicare.

So all of that is important to understand because that's sort of -- the premise of the model is that the patient is able to get more frequent dialysis in a more convenient location and Medicare spends less.

However, whether Medicare pays for the ambulance or not depends on the reason why the patient is in the nursing facility, and I will say we struggled a bit to be

able to get clarity about exactly what Medicare policies are on all of this because it is somewhat confusing. There are issues associated with medical necessity of transportation. There are issues associated with eligible sites of transportation. There are also issues of eligibility for more frequent dialysis. But I'll get to that all in a second.

So, as we understand it, if you are a long-term resident of a skilled nursing facility where Medicare is not paying for your nursing home stay and you need medically necessary ambulance transportation to a dialysis center, Medicare would pay for that. The assumption is that most of these patients, because they are in nursing facilities, would need ambulance transportation to a dialysis center. But it is not absolutely certain in all cases that would be true. It has to be medically necessary. So in those cases, the patient -- there would be a savings to Medicare if the patient could get more frequent dialysis in the nursing facility.

However, if the patient is on a short-term skilled nursing facility stay and they go to the dialysis center, the transportation, our understanding is, would be paid -- is not paid separately by Medicare, but would be a

cost chargeable to the skilled nursing facility and covered by the Medicare payment to the skilled nursing facility, which means that in that case Medicare would not be saving any money on ambulance transportation by doing that.

It appears from what we have heard from the applicant that most of the patients participating in this model currently, because they are actually doing this model, would be in the second category, would be in the short-term skilled nursing facility stay category. So, therefore, that raises a question about whether or not this actually does save money for Medicare because if there is no savings on transportation, then more frequent dialysis would be more spending.

Now, if you just limit your look at savings to transportation, that's what I just described. There are other potential benefits from more frequent dialysis such as potentially fewer hospitalizations due to fewer complications; potentially shorter skilled nursing facility stays, which would mean that Medicare would be paying for fewer days, et cetera. There is no mechanism in this model to assure that that would happen. There is not any definitive evidence that that would happen. There is believed to benefit from more frequent dialysis, but there

is not exactly a lot of research on nursing facility patients getting more frequent dialysis because, in fact, most of them don't. So it's hard to say for sure what's going to happen with that.

The payment model doesn't address any of the barriers that exist in the current payment system to delivering this service. We were told by the applicant that the cost to them of delivering this service in the nursing facility would be higher than the current amount that Medicare would pay. And, in fact, it would be -- the cost would be about 50 percent more than what Medicare would pay. So, in theory, the only way it could be done would be if they were able to cross-subsidize it in some fashion. And, moreover, it only would seem to be workable even at that level of subsidy if there were a sufficient volume of patients in the nursing facility because you have to put staff in the nursing facility, because this is staff-assisted home hemodialysis. You have to have a certain number of staff in the nursing facility to be able to do that. And, therefore, you have to have a certain number of patients to be able to get enough money to cover that fixed cost.

Sorry for all that detail, but that's sort of

critical to understanding this whole thing. So that's sort of the basic thrust of all this as key issues.

Now, I'll get into some other issues associated with what is actually being proposed in the payment model, but the fundamental conclusion from this was that we were not convinced that this model as proposed would, in fact, save money for Medicare.

Now, just to talk about the individual criteria, so on scope, the majority of us felt that this did not meet the scope for a couple of reasons. One was we thought that it certainly fills a gap in terms of there are no sort of nursing home facility dialysis-oriented models, and there aren't enough models for nephrologists. But there are a relatively small number of nursing facilities currently in the country that have the minimum volume of patients who need -- ESRD patients who need dialysis to be able to make this economically viable. So it's not that you could do this in every nursing facility. It would only be a small -- we estimated it would be less than 1 percent of the nursing facilities in the country.

On quality and cost, this is a somewhat challenging thing also. If you are in the nursing facility on a long-term basis and you need dialysis on a long-term

basis and you could get more frequent dialysis on a long-term basis, that would probably be a good thing in general. There are some risks of getting more frequent dialysis, but, in general, it would be believed to be better to be able to get more frequent dialysis.

If you're in a nursing facility for a short-term stay, it's less clear because if you were on dialysis before and going to a dialysis center and now you're in the nursing facility for a short-term stay and you could get more frequent dialysis while you're in the nursing facility for the short-term stay, but then you would leave the nursing facility and go back home and not be able to do home hemodialysis yourself and have to go back to a three-day-a-week regimen at the off-site center, you would be suddenly getting for a short period of time more frequent dialysis and then going back to less frequent dialysis, which could potentially cause a variety of challenges for the patients, for transitions or changing medications, et cetera, which could potentially be problematic.

Then the problem with the payment methodology, as I mentioned, is that -- there's no change in the actual payment for the service itself, even though it does not appear to be financially viable under current Medicare

payments. The payment changes are only aimed at the nephrologist. The key thing is the notion that the nephrologist would get 90 percent of any savings from avoiding ambulance transportation to the nephrologist's office, but we do not believe that Medicare pays for ambulance transportation to a nephrologist's office. It only pays for medically necessary transportation at all, and a physician's office is not an eligible site. Medicare will pay for ambulance transportation to a dialysis center or to a hospital but not to a physician's office.

So if it's the case that Medicare is paying for that, it's not because the policy says that they should. It's simply because somehow people are managing to get paid for that. But it would be hard to say that you're assuring a nephrologist that they're going to get a bunch of savings from something that Medicare doesn't pay for.

The second piece of the component payment is this $500 bonus payment to the nephrologist which would seem to basically create a bias for the nephrologist to have to recommend this particular service whether or not it makes sense for the patient or not. It's not $500, as we understand it, for simply educating the patient about options. It's $500 if the patient uses this particular

service. There is no payment -- the payment is not affected in any fashion by quality or outcomes. There is no accountability for any savings, et cetera. It's simply the change -- those two changes in payment.

Okay. A little faster from this. Value over volume, certainly it would be beneficial to be able to deliver this service, so we felt that it met that criterion.

Flexibility, we debated this a lot and concluded that it did not meet the criterion because it's not clear that it gives the nephrologist a whole lot more flexibility given the restrictions. It's only available in certain circumstances, it only works in certain cases, et cetera, so it wasn't clear that it really provided a whole lot of flexibility.

Ability to be evaluated, we felt that it could be evaluated.

We did not feel that the proposal, as is often the case with many of our proposals that we get, addressed the issue of integration and care coordination. There certainly would be opportunities for better care coordination with the skilled nursing facility if dialysis was being done there rather than off site, but there was

nothing described explicitly as to how that would be done.

We did feel that it gave patients another choice because the ability to get more frequent dialysis in the nursing home is a choice that most patients do not have today. So that would be an advantage from the patient's perspective.

Conversely, though, we were very concerned about the patient safety issues because there could be some -- there are some risks associated with more frequent dialysis, and there would be these transition problems that would occur for patients who would suddenly be getting more frequent dialysis in the nursing facility in a short-term stay and then not being able to get it afterwards. And it would be less likely that the nephrologist would be seeing the patients less frequently if they were only seeing them once a month rather than seeing them multiple times in the dialysis center.

And, finally, we did not feel it met the HIT requirements because there was no real discussion at all about how HIT was going to be used.

So, with that, let me see whether Rhonda or Jeff have anything that they want to add or correct about what I said.

DR. MEDOWS: I have no edits, no corrections. Comprehensive as usual. I'm actually more anxious to hear from the applicant themselves. I think there are certain issues that you want to help us understand.

CHAIR BAILET: Well done, Harold. Thank you.

*** Clarifying Questions from PTAC to PRT**

CHAIR BAILET: So do the Committee members have clarifying questions for us at this point? Bob?

DR. BERENSON: If I have this right, the real --

MR. MILLER: If you have it right, you get lots of points, because it was hard.

DR. BERENSON: No, just what you've said, not what they're going to say.

That is, patients who are in a nursing home for a SNF stay, that benefit mostly, they're the ones who disproportionately need dialysis. Is that part right?

MR. MILLER: No. The sense was, though, that what is happening is that those are the patients who are getting it today. So it's not -- there's nothing about the --

DR. BERENSON: Getting what?

MR. MILLER: Getting the dialysis in these nursing facilities are mostly -- I think their number they

can tell you themselves, but it was about 60 percent or more of the patients who were getting --

DR. BERENSON: Okay, because I believe there are some nursing homes that specialize in SNF patients, so they probably have the volume to justify -- I mean, this is just --

MR. MILLER: Yes, and we were told also that this is also apparently attractive to hospitals who now feel that they can discharge a patient to a skilled nursing facility that can do dialysis rather than having to discharge them to a place where they --

DR. BERENSON: The point I was going to ask about is this would -- my understanding -- and I may be wrong on this -- is that the average SNF stay is about 30 days, which happens to be the time that there's no co-payments, and that this would like be a benefit for one month for those patients.

MR. MILLER: That's the concern, is that the majority of the patients would get it for a very short period of time.

DR. BERENSON: Okay. Thank you.

CHAIR BAILET: Len?

DR. NICHOLS: So I was intrigued with this notion

of the dialysis den. How big does it have to be? And if it's that big, how much does it lower the cost?

MR. MILLER: Well, their number was that they needed about eight patients to make it financially viable, although financially viable appears to be a combination of Medicare and other non-Medicare patients being able to pay the bills for it. And some patients might be -- and, again, they can clarify this. Some patients might be in the den, and some patients might be actually getting bedside treatment. But I think the majority of patients would be getting it in a -- in a room that would be set up with dialysis equipment in it. So that's the issue.

So the nursing facility would have to have space and, you know, whatever, but they're using home hemodialysis equipment, so it's essentially designed to be something that anybody could use in their own home. So it's not something that would require all kinds of special hook-ups. Again, I think they can clarify that.

CHAIR BAILET: But they do deploy a staff. They do deploy a staff.

MR. MILLER: They would have a staff there, so there's an employed staff that there have to be enough payments coming in for enough patients to add up to cover

that. So they were saying that they felt that they needed to have eight people per facility and two facilities nearby to be staffed by the same group of people.

CHAIR BAILET: Any other -- Bruce?

MR. STEINWALD: Yeah, a question. I see in their response to questions they have 30 sites operational and contracts in a bunch more in several states. And this is a question perhaps as much for them. You said in your review that it's actually more expensive to provide this in nursing home dialysis than in center dialysis, the way it's typically done, three days a week.

MR. MILLER: Well, there's two separate points here. One is how expensive it is to do the dialysis and how much Medicare pays. So the issue -- on the Medicare side, the issue would be if you're getting -- if you're getting more frequent dialysis anywhere, if you're getting it five days a week -- and Medicare pays by the dialysis session, so if you get it five days a week, Medicare pays more.

The cost is a separate issue. It appears that they don't think that they can do it at the Medicare payment rate per dialysis session.

One other thing I should -- worth highlighting

here is that the assumption is also that most or all of the patients who are in the nursing facility who need dialysis would qualify for a Medicare payment for more frequent dialysis. That's a MAC, Medicare administrative contractor, decision as to whether or not they are, and there is apparently some issues going on with that right now in terms of the MACs trying to change the rules, the MACs not approving as many patients as before, and so the belief from the applicant is that most of the patients would meet the criteria because they are sick patients and they're in a nursing home, et cetera, and so, therefore, more frequent -- they would qualify for more frequent dialysis. But it is currently dependent -- there's no proposed change to this. It's dependent on having the current rules for whether the patient is eligible for more frequent dialysis continued to persist in the future.

MR. STEINWALD: Thanks. I guess we can wait for the proposer to explain more about the relationship with the skilled nursing facilities and what their interest is in participating in the model.

CHAIR BAILET: Paul?

DR. CASALE: Just a question around that education bonus of $500. Is that for patients who are

enrolled, or is it educating patients to get them enrolled? That was one. And, second, how did -- any insight on how they came up with $500?

MR. MILLER: No.

DR. CASALE: No to the --

MR. MILLER: Well, to all of that. You should -- you should ask them. I would say it is not -- it is not clear in the proposal. We did not try to pin this down, so you should ask them. My understanding or my impression is that it's a $500 bonus to the nephrologist if the patient decides to use this service on the premise that the nephrologist has helped them understand the benefits of it. And the $500 was intended in some fashion to make up for the loss of the education payment that the nephrologist gets if a patient is actually on home-home hemodialysis because they would ordinarily need to educate the patient about how to do that, and they would get paid for that. So the idea here is that you would get sort of the same thing, but whether or not anybody determined whether that was the right number or not, I'm not sure.

CHAIR BAILET: All right. So we're going to go ahead then and have our applicants come up, and if you have prepared remarks, that's -- we're going to restrict those

to ten minutes as best we can, and then obviously the Committee has a lot of questions.

MR. MILLER: You will not --

CHAIR BAILET: So if you could introduce yourselves, that would be great.

MR. MILLER: -- in any fashion if you disagree with things that I said in the spirit of clarification.

[Pause.]

CHAIR BAILET: All right. Very good. So Allen, Dr. Kaufman, do you want to -- okay. Very good.

One clarifying question. You have another member on the phone with you?

MR. ROTHENBERG: He is just listening, Dr. Nathan Levin.

CHAIR BAILET: Okay. Very good.

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

MR. ROTHENBERG: I would like to thank the Committee for considering our application. I think that the recent misunderstanding of our model, and I wanted to explain our model, first of all, by a short story, how I got into dialysis, that will explain this focus on dialysis.

So the story starts with a woman by the name of Margaret Schneck. She happened to be my mother-in-law. She was admitted to Mount Sinai Hospital in New York a few years ago when she was told her kidney failed and she had multiple issues that derived from the fact that she never took care of her kidneys.

She stayed in the hospital for two months, very expensive hospitalization, which typically happens to a crash dialysis patient. When she was released, she moved into my home, 62 years old, and she was assigned to a local dialysis clinic, run by one of the larger dialysis organizations. Her slot was 5:00 in the morning. She would wake up at 4, we would drive 40 minutes. She would be there for about four to five hours, we would pick her up around 10:00. She will come home and stay in bed until the next day. She would be completely wiped. And she was on multiple blood pressure medications, very frequently rehospitalized, and had many -- she suffered from depression because of it. She didn't see any reason to live.

When I found out about home dialysis I reached out to the dialysis facility and I asked them about it. Even though they advertised for it, they really tried to

persuade me away from it. When the found out that I'm persistent and I'm planning on going to a competition, they agreed to train me to be the caregiver for my mother-in-law.

Within about three to four weeks I was trained, and within a month of her being on that more frequently dialysis she was able to drop an additional 13 kilograms of water, which is about 26 pounds, that traditional dialysis was not able to remove. Her blood pressure medication went down from 4 to 0. She was able to travel. Her recovery time went down from almost a full day to about a half hour. Her life completely changed.

When she went back for a scheduled open heart surgery for a valve replacement, the doctor in the hospital asked her, "Who are you? Where do you come from? What did you do to yourself?" and she said, "I did home dialysis." And the doctor said, "I never heard about it." And to date, many doctors don't even know about this particular modality.

In the United States there are 500,000 dialysis patients, over 500,000. There are only about 1 to 2 percent on home dialysis. What shocked me at that time is that in the state of New Jersey, where I live, out of

13,000 dialysis patients there are 94 on home dialysis, and it's not because they don't want it. It's because there are barriers to entry, and the barriers for this modality is, first, you need to find a really dedicated caregiver that's willing to commit to do it without taking off.

Second, doctors feel more comfortable when the patient comes to the dialysis clinic. They have nurses taking care of that patient and he doesn't have to be worried about getting phone calls, answering questions. Ninety-five percent of nephrologists that were surveyed around the country said if their family member would need dialysis they would recommend home dialysis, but that is not the case to their patients.

That's the time that I founded Dialyze Direct, with the mission to look at who are the patients that will benefit the most out of this particular modality. And the patients that benefit the most are the patients that actually cost to the system the most, and they are the patients that are the most frail and have specific needs that traditional dialysis does not address. Those are the patients that live in the nursing homes. Nobody likes to be in the nursing home and nobody likes to be on dialysis.

These patients are being shipped from the nursing

home to the dialysis clinic. They're long term or short term. And while in the dialysis clinic, if something goes a bit wrong or if something is a bit off, nobody takes responsibility. These patients are being shipped right to the acute care hospital.

A paper that was published recently, in the last few months, looked at state by state and incident dialysis patients, patients that started dialysis and they live in the nursing home. The average patient spent about 30 to 40 nights in the hospital a year. That's a real cost to the system.

Dialyze Direct went and created a model of coordination of care in the nursing home, where our staff, our trained staff, licensed staff, are going into the nursing home and providing this care to these patients. These patients are now, we know, every change of medication. Instead of a paper that sometimes goes between the dialysis clinic and the nursing home, they meet face-to-face with the nurses to take care of these patients. We provide the care for these patients during dialysis, and what we see is that dialysis-related hospitalizations dropped so far by over 60 percent, that's significant, compared to the USRDS data as far as hospitalizations.

One more phenomenon that we see is that patients that are on Permcath around the country are very prone to infection. That's the access for the dialysis. Every preparation, specifically the ones in the nursing home, a very large majority of them are on Permcath because their veins are too weak. We see a dramatic, almost 100 percent reduction of infection rate with these patients. That drops hospitalizations as well.

So we resolved the issue of the barrier of patients having the ability to have the caregiver, because our caregivers are there. As far as having dialysis in the nursing home, we do not need hundreds of patients. We need about 10 percent of the patient population in the building. So if a building has 100 patients, 8 to 10 patients, that's what we have.

We are right now over 50 buildings. We keep growing rapidly. And I can tell you that most of our buildings, the census is 8 to 10 patients, and we have some waiting lists on them from the discharge planners from the hospital.

We do treat patients that are long term, and we do treat patients that are short term. I will tell you that the managed care on the Medicaid side, and state by

state, and the managed care on Medicare Advantage, they see the cost of these patients, they consider them to be a very high cost, and they are paying the amount that we said that we need just to break even, just over to break even. So it is the right thing for these patients, and they see how to save that money.

The only barrier that we didn't overcome with this model is the physician. A physician does not have an incentive to come to the nursing home, and the reason for it is the physician goes to the dialysis center, they have multiple patients at a time, they can see 20 to 30 patients at a time, depending on the amount of stations, and they just sweep by, and they did their visit.

So when we originally went and were recommended by somebody in CMS, based on the outcomes that they saw on CROWNWeb at the time, to meet with CMMI, CMMI noticed that the main barrier that we have is the physician, and that's why we were referred to the PTAC at the time.

Our model, we did not focus right now on increasing the payment to our treatment, but we focused on the main barrier for these physicians. When they do home dialysis, they do get this extra payment of $500. We do not charge for training, which, in typical home dialysis

patients we would get paid separately for the training and the physician will get paid for the training. The physician doesn't train but he oversees the training. Over here, because it's our staff, we are not going to charge for the training.

But the overall savings to the system is the better coordination of care. Besides the actual medications that we see -- and trust me, there are a lot of -- nursing homes never send any information to the dialysis center and patients are coming to the dialysis center after they had a blood pressure medication and then when it drops a bit more, they are in dialysis, they end up in the hospital. We even provide IV therapy for the vancomycin, for example, that a patient would need. He would not need a separate IV therapy. They do it on site.

Our patients were able to do rehab on a daily basis as opposed to dialysis patients that cannot do it on a daily basis, because they are too tired. Our recovery time -- with this modality the recovery time is about 30 to 60 minutes, and that's research-based. One of the less -- Dr. Kaufman will speak about the modality and how big is the savings so far, and the outcomes that are known to very big studies that were done around the country with that.

I will tell you also that one of the research students that was published showed direct correlation from reduction of recovery time to hospitalizations, and the fact that we are reducing it from almost a full day to a half hour to an hour, that alone is a huge savings.

So these patients are coming from the lowest socioeconomic. Like you said, many of them are Medicaid patients. They are there on the long term. They don't have a chance with the regular treatment. They are being looked at as the outliers, and as a matter of fact, the system is almost incentivizing them to go to the hospital every 30 days because then they are not considered on the census of that particular dialysis clinic so they don't even affect the star rating, so considered transient.

We only focus on the real sick that cost the most. If regular dialysis patients are 1 percent of Medicare population -- they cost 7 percent of the budget -- the 65 and older on dialysis are 20 percent, and as they get sicker and sicker, it gets much stiffer. So we are targeting the main reasons for hospitalizations, which the root cause for it is the fluid overload.

I think -- any questions? Our team is ready to answer.

CHAIR BAILET: Thank you. Len, Kavita, Tim, and Grace.

DR. NICHOLS: Thanks for starting with a story. That was very helpful.

I would like to ask about the model. You mentioned the target of the physician. But one of the things that's curious to me, as an economist, is where the savings sort of end up. And I guess the question really is why not build in a shared savings or some kind of shared risk for the hospitalization ED stuff into your larger system? That would seem to make it much more likely to be viable for you, you could share it with the SNF, whatever.

MR. ROTHENBERG: I think it's a very good question, and the answer to it is as follows. We treat these patients, some of them for a short time, some of them for a longer time. We are not responsible for the full care for these patients. There are other providers and other stakeholders to take care of these patients.

What we measure is the dialysis-related hospitalizations. As an example, a patient could have many other issues, but the things that are related to dialysis that typically take X amount percentage of his hospitalizations, which is very high in the dialysis

patients, those are the ones that we see huge successes and we can monitor that, and provide those types of outcomes.

But as far as overall care for these patients, we are not responsible for it. It's very different than, for example, an ACO or a primary care that's really in charge of the whole care for these patients. We only take care of the dialysis part. We help to manage the other chronic diseases, because when you take that particular part of the care, if you address that part of the care, ultimately the human body handles better other diseases as well that derive from the complications.

DR. NICHOLS: Yeah. All I was getting at was that I think the appeal of the model to CMS -- forget us -- the appeal of the model to CMS will be maybe there's a shared coordination arrangement with the other providers, in the ecosystem of these patients. You identified, focus on managing the dialysis portion of it, but the savings right now would seem to me to be redounding to either the MA plan, the MCO if it's Medicaid, or the SNF or somebody, or the hospital.

And so, fundamentally, it would seem there's a much more elaborate model that one could develop here, that would take advantage of what you're doing.

MR. ROTHENBERG: I just want to add two things that I realized that I missed. First, in the past year, CMS went and took action about this modality in the nursing home. On the nursing home side, they went and published a state operating manual that demanded the nursing home to educate patients about the possibility of having it onsite, and if a patient elects to have it, then nursing home has to provide documentation that either they help to move them to a facility that has it or they provide it onsite. On the dialysis side, they went and published, this month, guidance to provide home dialysis in the nursing home. This is where CMS sees a huge benefit for these patients.

The next thing that I will tell you, the idea over here of us providing this model, it's not for Dialyze Direct. We truly believe, and what we see so far and how the industry goes, and how this directly helps these patients, we hope that every single provider, dialysis provider around the country -- we cannot handle the whole country -- will take from that, and we are not even looking to do that -- will take that and do it everywhere else. It's simple to learn and to adopt and to do, if we show that we overcome those particular barriers.

So this is the opportunity to really make it more

available. There are 75,000 dialysis patients in the SNF right now, according to CMS. We believe it's more because the short-terms are not really calculated in that. So it's about 10 to 15 percent of the dialysis population in total. And there are 7,000 nursing homes that will take care of these patients. We see, right now, in the Midwest, for example, you would have -- I mean, Dialyze Direct purchased, yesterday, a company in Illinois that has 400 patients just in Chicago alone in the nursing homes. So it is there. The issue is what are the incentives of these physicians?

CHAIR BAILET: Kavita.

DR. PATEL: You sort of answered it. I was trying to understand kind of the denominator. Can you tell me a little bit more about -- you mentioned the, kind of, I'll say, staffing ratios of what assistance might be required. What would that entail if you actually tried to do this, because at least in the nursing homes I've worked in and have worked with, they wouldn't be able to necessarily meet some of those thresholds, even if there was a very attractive kind of alternative payment model.

So do you think this is going to be limited to skilled nursing facilities of a certain size, or do you

have a sense of what that might be in terms of market uptick for this?

MR. ROTHENBERG: Sure. So first of all, the nursing home that we feel is the right nursing home to start with are not the ones that are 40 or 50 beds, unless there are specifically vent units, that they have a specialty. The nursing homes that we have, most of them, the average nursing home size, which they are about 100 beds and up. I can tell you that we have, to date, over 200 facilities that have already signed up with us, waiting for us to go in there. There is a huge push and need from the nursing home asking for this particular service.

What Dialyze Direct offers them, it is our staff, not the nursing home staff. We spend one caregiver to two or three patients, depends on if you have four patients or six patients. Until this month we only did four patients in a room at the same time in the den setting. CMS took away that restriction and now we are doing six or eight, depends if it's a very large nursing home. When a patient has need as far as a vent patient, a patient that has isolation needs, a patient that has an injury and cannot be moved, that will be on the bedside. It will be one to one.

DR. PATEL: Do you mind -- this is just a follow-

up. This is more of a comment. It feels like -- and I'll speak just for myself, but you are identifying almost all the flaws, especially with your mother-in-law's story, in doing what I think is the right thing for patients, that are somewhat regulatory, somewhat just this arcane nature, the way we pay for medicine, and then, quite frankly, it sounds like the business model for a nephrologist, whether that's an employed nephrologist or an independent solo nephrologist, really is not viable in a patient-centered world. The way you describe it's kind of forcing this function.

And the struggle that I have is that it's hard to think about this as a payment model. It feels, to me, like this more needs to be a conversation with, frankly, the very people who were here earlier today, the Secretary, the head of CMS, and the head of CMMI, to say, "Come on. This is ridiculous. We have some tangible barriers that could be overcome with some of the changes and the fee schedule, relaxation of some of these regulations," and, quite frankly, the way we pay for Medicare benefits in the nursing home setting. And my only kind of statement is that I think that might go a lot further than creating a model where I think there are some significant gaps.

CHAIR BAILET: Tim.

DR. FERRIS: So I'm going to pick up where Kavita left off and approach it a little bit more from a conceptual level.

My summary would be that you have identified, through your personal encounter and then through figuring out what the ecosystem is around home dialysis, a better model of care, a model that because it exists now -- and I'm talking about the care model first. I'll get to the financial model. But the care model, it is clearly, unequivocally a better care model.

It exists now, which means that the possibility -- there may be barriers, but as Kavita was saying, there are barriers in everything we do in health care. Nothing is ideal. And it seems to me that you are -- you said yourself you are rapidly growing, which means, actually, whatever barriers that exist, you are finding ways to overcome those barriers, in fact. And there is an information gap, but that information gap is present with any new technology.

And so it seems to me that the incentive that's being sought here is the incentive of how do we disseminate a proven, better model of care, and what are the finances

associated with that dissemination and more rapid adoption, so that more people can take advantage of that?

I would say traditionally, in economic terms -- and I recognize physicians practicing economics is probably a bad idea -- that, in general, it's a fairly simple solution and that generally doesn't involve necessarily alternative payment mechanisms. It involves just paying what is necessary to get the job done, to incent people to get the work done. So I'm thinking about new codes. I'm thinking about properly valuing codes. But I don't necessarily move to the place of a new payment model when I think about I want something that's relatively new, maybe not so new, but clearly better, and I want that more widely adopted.

So it's sort of just a frame in which I think about dissemination of technology, adoption of technology, and maybe you could respond to that.

MR. ROTHENBERG: Sure. Two things I would like to say. We believe that the success of this model and the success of the outcomes that will really save cost, really relies on the continuity of care. And the person that knows the patients the best is the person that has history with the patient. Right now, many of the physicians that

see these patients don't want to continue to see the patient while he is in the nursing home, because they don't have the incentives.

If we want to save money, to the government and the payer, is by encouraging this continuity of care, and it will not happen unless there is a payment model that will target that. Ultimately, yes, we feel that we are saving a lot of money to Medicare for the acute care stay, tremendously, and the transportation, when the transportation is warranted. But we targeted what we feel is the biggest barrier to really have the best outcomes for these patients. When you bring in a physician from the outside, yes, we manage to circumvent and go around this barrier, but that's not really the right, the best way in order to get the best outcomes. You're bringing in somebody new that never cared for this patient, starting from zero, and that's the reason why we are pushing for that.

CHAIR BAILET: Grace.

DR. TERRELL: So my background is I'm a general internist. I trained at Wake Forest, which has done a lot of work in the past, as a major center for end-stage renal disease, and a lot of work on peritoneal dialysis, and was

a medical director of a nursing home, where I couldn't stand to get an end-stage renal disease patient in because I just would end up hating the nephrologist I was dealing with. And then also I was over a Medicare shared savings program where we were able to get our benchmark and our savings much around bringing our cost down from whatever the benchmark was, $70,000 for end-stage renal, to about $50,000, by putting in some basic things, not this, that were about medical home and whole-person care.

So, number one, I love you guys, applaud you for what you're doing, but I have a few concerns based on my experience, that I just want to sort of flesh out with you. First of all, are you just talking about vascular dialysis.

MR. ROTHENBERG: Hemodialysis.

DR. TERRELL: Yeah. You're not doing any peritoneal dialysis at all, because there's a lot of that done at the homes. So just a series of little interrelated questions.

Second is, a lot of the work in the past on peritoneal dialysis has been because it could be done easily at home, and I think the rationale for what you're talking about here is that it is a nursing home. This these people's home, but we know that they're more complex.

They can't be at home. They need skilled care. So as it relates to that, how much thought have you put into what a non-nursing home home is like in terms of the resources, many of which, as you articulated well, are not adequate for this population, and what is actually needed and needed from a measurement standpoint in terms of resource. Has Medicare done that for you?

And then I guess my final concern, or at least I'd like you to talk about it, we talked about this being a better model of care, but I really almost winced when you said "but we're not going to take total care, because these patients are complex and others are involved."

I would like for you to comment on this within the context of my understanding of a really good model, which is about a specialty medical home where you do take total care, because I think that the people that I've seen in nephrology who have done it best basically take these patients and they become the primary provider. It has always seemed to me that the problem is that they don't like to do that in the nursing home, because it's awful. But as a medical director, my concern was that if they weren't doing that, the rest of the people on call were going to kill the patient, because they weren't used to

thinking about them being an end-stage renal patient when it came to that call in the middle of the night as it related to potassium or whatever.

So partly this is, I want you to think about what you all have relative to other alternatives within your specialty, and just explain to me why you got to this as opposed to some of that, because I know that work has been done.

MR. ROTHENBERG: So I will divide my answer between me and Alice Hellebrand. Alice Hellebrand is our Chief Nursing Officer. She is also the President of American Nephrology Nurse Association, and she will address the second part.

The first part, PD. Patients in the nursing home are cared for, but since the access for PD is close to the groin and there are issues with diapers and other things, as far as infection it is an issue for these particular patients, and that's the reason why we do not offer PD. There is one program in the country that does it, has a very small model. Rogosin Institute somewhere in New York has a small model that worked in one particular nursing home, but anybody else that tried that part really was not that successful.

DR. TERRELL: It's more of an outcomes issue.

MR. ROTHENBERG: Right. It's more of an outcomes issue.

I would like Alice to explain about your answer as far as the nursing home. I would tell you that in the nursing homes that we operate, it's not only that we just take care of dialysis and go. Besides the fact that our dietician goes and sees every single supplement the patient gets and they know that no new supplements are being given unless it runs by us as well. We know about any change of medication that we said. But also, we are there. So when they want to admit a patient, we first look at it, is it because maybe they just drank too much? Maybe we have to dialyze them instead of the afternoon, in the morning?

So there is definitely more coordination of care on that part, but Alice, maybe you could speak more.

MS. HELLEBRAND: As a nurse I'd like to point out, you know, the challenges with a nephrologist, and, you know, having some conflicts there. But I also want to say that when we first came into this, and coming from dialysis, you know, the majority of the skilled nursing home staff or owners of the skilled nursing home did not want to accept dialysis patients, and we found that they

were ending their life in not the best situation in an acute care hospital, because no one would take them because of the understanding of their special needs and high comorbidities.

Because we're in the skilled nursing home and we're collaborating with the staff that's onsite, and we're providing the education and the understanding of how to care for these patients when we are not providing that direct dialysis, they are more accepting from those patients. And not only, as Josh said, that we are bringing in our dieticians but we are also bringing in our social workers, and our social workers are actually talking to the patients and helping them to adjust to two totally horrible situations that these patients are in. No one grows up and says, "I want to live in a skilled nursing home," and I have never, in my over 30 years of being in dialysis, have ever had someone say, "I want to be a dialysis patient." And I will preface that by also saying that I don't know many nephrologists who say, "I'm going to medical school and I want to go into a skilled nursing home," which is really one of our barriers to success in this, and that's why we are proposing this model.

So our collaboration is improving the day-to-day

lives of these patients. I can't say that they're going to live longer. You know, we like to think that even dialysis cures the flu. It does not. I want to put that out there. But what we're trying to do what we have accomplished is giving these patients a better life and a better understanding within the medical community.

DR. TERRELL: So within the context of your concern about not considering taking on the total cost of care, I think most specialties don't need to take on the total cost of care. I just wonder if within the context of actually owning, if you will, an end-stage renal disease patient, if this is actually a specialty that could and should, because of the potential that's out there, and why you basically, specifically said you didn't want to do that.

MR. ROTHENBERG: So because we are in a different facility that has different -- they have interests that some aligned with us, but they have their own staff and their own interests. And they're really responsible for that care.

We are contributing as much as possible for this care, but there is a conflict over here that we could not take complete care for these patients because they are the

ones responsible primarily for everything.

But what we did put inside is that although we are not responsible, there are things that they have to report to us before they change. Like you said, the middle-of-the-night call and changing, nobody is prescribing any new medication until they show up in the morning. If it is that life-saving, they should be in the hospital.

And we see that that type of corroboration helps, but they still want to be in charge of that part. We will not have customers as far as nursing homes if we would say we want to take charge of this whole -- of the whole care of these patients.

CHAIR BAILET: Bob.

DR. BERENSON: I probably missed this, but I'm trying to do some quick studying on the internet about CPT codes and things like that. Now, now.

So did you say that the nephrologist who you want to incentivize to go to the nursing home would actually be doing the training?

MR. ROTHENBERG: No.

DR. BERENSON: No, all right.

MR. ROTHENBERG: It would not be the training.

It's just instead of the training, where they would get --

DR. BERENSON: Right.

MR. ROTHENBERG: And right now, they're being incentivized to oversee the training. They never train.

DR. BERENSON: Right.

MR. ROTHENBERG: But to oversee the training for home dialysis, in the clinic, they would go home-home by $500. We're trying to -- we can --

DR. BERENSON: So there is a CPT code for the physician --

MR. ROTHENBERG: Yes, yes.

DR. BERENSON: -- to oversee the training?

MR. ROTHENBERG: Yes, correct.

DR. BERENSON: And then there's a separate payment for the clinic --

MR. ROTHENBERG: Correct.

DR. BERENSON: -- that does the training. Is that right?

MR. ROTHENBERG: Correct, correct.

DR. BERENSON: So wouldn't there be an opportunity to just extend, create a new code for training in the nursing home, not just at home, for overseeing training in the nursing home?

MR. ROTHENBERG: But there's no training. You're eliminating the training. It's our staff.

DR. BERENSON: Because it's not in the home?

MR. ROTHENBERG: Because it's staff-assisted, it's our staff. Our staff are trained. They're not training for this particular patient.

DR. HELLEBRAND: Right. We're not using the person who's developing -- providing the care is not the husband, wife, friend, whatever.

DR. BERENSON: I see. So I got it.

DR. HELLEBRAND: It is dialysis --

DR. BERENSON: So there is no training necessary.

DR. HELLEBRAND: It is dialysis professionals.

DR. BERENSON: So then you can't justify overseeing the training.

MR. ROTHENBERG: Right. There is money available should that patient -- would have been -- gone home, but we are bringing out staff to provide it. So that's why we're trying to say there's --

DR. HELLEBRAND: There's code.

MR. ROTHENBERG: Correct.

DR. BERENSON: All right. So that's helpful to understand that barrier.

The second one I have is, as you described the economics of all of this, that nephrologists are more than happy to see 20 patients in a center, getting $237 per month or something that I just quickly looked at --

MR. ROTHENBERG: $280.

DR. BERENSON: And that's supposedly based on resources and actual costs, which is practice expenses and work, which sounds like it's exorbitant for what they're doing, and that the practice expenses and work would go up if you're seeing only a few patients in a nursing home, so that, again, another HCPCS code or CPT code that pay at a higher level for seeing a patient in a nursing home would be a potential solution. Is that not something that --

MR. ROTHENBERG: I think that will be way too complicated, as with all the -- with all the codes they right now have to deal with as far as -- you see a patient when they go to a center. They expect -- in order for them to get the full monthly capture rate, they have to see the patient four times a month. So they come once a week, and they see all the patients per shift.

And for a home patient, they see them once a month. So those codes are there. To start to have now a separate code to something that it is home dialysis, but

it's not really home dialysis that has to be -- it's a different model because right now, it's just bundled up.

DR. BERENSON: No. It would have to be designated as --

MR. ROTHENBERG: And we were told --

DR. BERENSON: But you are in a whole new payment model. That strikes me as pretty complex also as opposed to --

MR. ROTHENBERG: Well, we think --

DR. BERENSON: -- there's a CPT code for -- how many times does a nephrologist have to go to the nursing home to supervise the dialysis?

MR. ROTHENBERG: At least once a month.

DR. NICHOLS: So, Josh, you just started to say we were told it was too complicated to add a new code.

MR. ROTHENBERG: Correct. And where we were directed, when we're directed to PTAC from CMMI, it was because of that, and --

DR. BERENSON: Did you ever go to CM? I mean, did you ever go to the people in charge of the fee schedule?

MR. ROTHENBERG: We were --

DR. BERENSON: Who are they? Who are these

people who told you?

MR. ROTHENBERG: It was a whole committee of CMMI, and then it was like six, seven people around there in the room. And they said, "This is great, and if you tell us this is your problem right now and we see why it is, go to PTAC" --

DR. BERENSON: So you started at CMMI?

MR. ROTHENBERG: Yes.

DR. BERENSON: Okay.

MR. ROTHENBERG: That's what it is. We started at CMMI, and they said go to PTAC to see if you can get this --

DR. BERENSON: Okay. Now I'm getting it. Now I'm getting it.

[Laughter.]

DR. HELLEBRAND: Your world is as complicated as ours.

DR. BERENSON: You know, there's 9,000 codes in the Medicare Fee Schedule. There's 9,000. They're not all active at all times, but there's -- there's actually 9,500 that I just had to work through to do 2.0.

The point is the nephrologist doesn't need to know 9,000 codes. If a nephrologist has a specialty in

going to the SNF to do dialysis, they'll learn what the three codes are or whatever it is, the Rutkin value, the extra work that's associated with the fact that you do not have any economies of scale because there's fewer patients, and this doesn't strike me as a payment model. This strikes me as the need for some targeted coding to solve a problem, is I guess my initial thinking on this.

I'm done.

CHAIR BAILET: Thank you, Bob.

Harold.

MR. MILLER: So I'd like to reorient just a little bit here because I think we -- all the questioning so far has been primarily about is it good to be doing what Dialyze Direct is doing, and I think what they're doing makes perfect sense. And once the PRT sort of struggled through that, we thought, sure, it basically makes sense.

The question is about whether it's always the best thing, but in general, the best thing. And then people sort of leaped over and sort of just accepted the assumption that the nephrologist needed an incentive, and then Bob started talking about trying to create codes.

So I'd like to sort of focus, though, on that part in the middle because, I mean, that to me is what this

is all about. The question is, Does the nephrologist need something different, and what is that something different that they need? And that's the thing -- that's all we are talking about here. We're not in the position of saying is Dialyze Direct a good program. You're not asking for different payment for the dialysis. We have nothing to do with that.

All you're proposing here is a model to pay the nephrologists differently, and what you've proposed -- I'm surprised you would say creating a code is complicated when you're talking about trying to calculate 90 percent of the savings on transportation when the transportation isn't even covered.

But I'd like you to sort of articulate more clearly. What exactly do you think the barrier is for the nephrologist? Why do you think this proposal that you have made for the change directly solves that? Because I'm not convinced that it does. What other options you considered, and why you rejected them in favor of this one, and why you think that this actually works when we didn't think that it would work.

So I'd like to just focus very specifically on that. Let's assume -- don't tell me about why Dialyze

Direct is a good thing. I accept that. What I want to understand is if the nephrologist is the barrier, which apparently it hasn't been too much so far, but if the nephrologist is the barrier, what exactly is the -- what's your analysis of the causes of the barrier? Because there is currently concern about nephrologists not wanting to do home dialysis, and I don't think that would be solved by what you're proposing.

It's because -- back to Bob's issue is -- they get paid less for a home dialysis patient than they do for a center dialysis patient, a slightly smaller amount. They would be -- it's a disadvantage for them today to see the patients in their office. It would be even more challenging for them to have to go to nursing homes to be able to do that.

Is that the barrier, and what do you think your thing does to solve that? What did you consider alternatives, and why do you think it actually works? That to me is the nub of what we have to decide today.

MR. ROTHENBERG: Let me give it a true.

We believe that the barrier is to have the patient continue with the same nephrologist that they have until now. The nephrologist doesn't have -- every

nephrologist is asking, "What is in there for me? Why would I want to go to the nursing home if I can have them come to my center, to the center I'm associated with?"

MR. MILLER: So can you just stop there for a second? So what is the nephrologists doing in those circumstances? Are they saying to the patient, "No, no, no. You don't want to do this"? What is the thing that's happening that you're trying to overcome?

MR. ROTHENBERG: Okay. Two things happen. Either they say go find a nephrologist that will take care of this patient, or they will try to persuade the patient to just continue, come to the center. And then it's patient choice. We just tell the patient the facts. It's his choice to decide if that's what he wants, but if the patient wants, he would have to give up his nephrologist, which is we feel detrimental to the success. When I speak for the success, I speak about outcomes and about ultimately saving the cost, the overall coast.

When we will go to nephrologists and say there's a different payment for this and you would get paid, these incentives over here, that you will get paid per patient in addition to your monthly capture rate that you get regardless, that will make -- we believe will make the

nephrologist -- when we see evidence to say, "Okay. Now I understand that I do have incentives over here."

MR. MILLER: Can you explain to me why you believe that what -- you would do that? Have you talked to nephrologists --

MR. ROTHENBERG: Yes.

MR. MILLER: -- and they said, "You give us $500, man, and we'll send all of our patients your way"?

MR. ROTHENBERG: It was "Put us on your payroll. Give us something for coming in there and doing it, and if there's incentives, we will do that." Yes.

MR. MILLER: Wait, wait, wait. Pause here. "Put us on your payroll," that's not a $500 one-time bonus?

MR. ROTHENBERG: Well, they have few patients. The point is, the idea is that what is in for me. I need to see an incentive to come in there.

MR. MILLER: But what I'm saying to understand, really specifically, is you've proposed a one-time $500 bonus for something the nephrologist is going to have to do on potentially a long-term basis, not for the short-term patients. For the short-term patients, I can kind of understand it, potentially, but for a long-term patient, one time, $500, you're telling me is enough to convince a

nephrologist. Or have you promised them some very large amount from this 90 percent of things that doesn't exist, and do they believe that there is some continuing payment coming from that?

MR. ROTHENBERG: Okay. We did not speak to them about the transportation part.

As far as the $500, yes, because they're looking at it that this model can grow more, and there's more patients that's coming. And it's just additional money that they can get. This is basically what that -- that's the feedback that we got. The idea is to say, "Listen, there is incentives for a nephrologist to have" -- or for home dialysis. Obviously, somebody thought that that $500 is worth it.

The reason why they do not offer it is not because of the $500. The reason why they do not offer it is because they feel that they feel more comfortable with the nurses taking care of the patients. Plus, they feel that when the patient is home, they have to be more available to answer the phone calls as opposed to when the nurses are there, they're taking care. We took care of that part.

But the incentives of the $500 does not exist

there. So we wanted to show that you're still going to get that part, and you can grow your practice with that as well.

Allen?

DR. KAUFMAN: Let me just answer. I just would like to make one other point.

You know, the majority of patients, maybe 60 percent, are short-term transient patients, coming and going for some kind of rehabilitation situation. They might average about a month and a half or 6 weeks or something like that, that they say in there.

So if you look at the model, the education model, the extra $500 model -- so let's just say a patient becomes a home dialysis patient for a two-month period of time, and then they're gone. Remember that, though, this is the majority of patients coming and going.

So a physician will have a Medicare monthly capitation rate of about $250 a month. It could be $260. I think it is in New York. So it's $250 a month. He gets that twice. Well, you've now effectively doubled his capitation fee at least for the short-term patients.

MR. MILLER: Could you tell me about the long-term patients, though, please?

DR. KAUFMAN: Well, but here's -- let me just say about it. So here's -- this is where it becomes efficiency of scale a bit. If I'm a physician and I'm coming into the nursing facility and I'm seeing the short-term patients because I'm incentivized to do it, for me, it means nothing if I see another two patients that are living there day in and day out, you know, forever.

So once you get a physician to come into a facility, then it becomes efficiencies of -- once I'm making a trip to that facility, because I get certain benefits, it's nothing to me to go and see the patients that are living there, and by ratio, in general, is going -- it's about 60 percent for the short-term and about 40 percent for the long-term patients.

So I think that's -- you look at the overall picture. Overall, it's a net plus for the physician.

MR. MILLER: Let me just ask one follow-up question, and then I'll shut up.

So Medicare, thanks to the Chronic Care Act, is going to be doing telehealth, telemedicine visits for nephrologists now.

DR. KAUFMAN: Right.

MR. MILLER: Do you think that that's going to

solve the problem, and will you be able to do that, such that you don't need to incentivize them anymore because they'll be able to see the patient at least every two months in the two-month window by telemedicine, by some kind -- because you would have the capability, I would assume, to set something like that up for the more easily to do that. Do you think that that's going to make a difference?

DR. KAUFMAN: Well, let me answer that. First of all, every technology that's developed or utilized, we're going to try to utilize and try to get the most out of it. You know, we're going to try to figure out how it works.

However, on the one hand, we're talking about the -- a minimal requirement to see a patient, and on the other hand, you have to act like a doctor. And you have to see patients as often as you have to see them. That's a separate thing. I know we're talking about the economics and the fiscal thing, and you have to see home patients once a month. But it may not be appropriate to see a skilled nursing facility patient once a month. You may decide to come twice a month or three times a month, whatever the thing demands.

We absolutely will use telehealth if it's a tool

that will help in any way, but I just don't see it as actively as solving this problem because these are the -- you know, telehealth in a home-based --

MR. MILLER: Well, just to be clear, the reason why I'm asking is because -- you're not quite addressing -- I mean, I understand the issue now if how this could be very lucrative for the nephrologist for the short-term patients. I'm trying to go with the long-term patients, where I think there's a lot of potential value here. But a one-time $500 thing ain't going to do that, from my perspective.

So it seems to me like you're saying, all of a sudden, now I have to -- even the nephrologist has to have lots of short-term SNF patients to make this work.

But if in fact they can do now a larger number of those visits by telemedicine, then the penalty of them having to see the patient every month goes down, which would make it a little bit better for them to do the long-term care patient. So I just wondered if you'd been thinking about that.

DR. KAUFMAN: Yep. Yes, we have, and we are going to utilize every tool available.

MR. ROTHENBERG: As soon as that's available.

I would also say that it's estimated the dialysis population to grow in the next 10 years by over 30 percent. Most of them are the elderly population because we live longer as well, and there's a big flow of baby boomers that have diabetes and other diseases that will cause deterioration of the kidney and ultimately ESRD.

There is not enough doctors and enough nurses and enough slots to treat for those patients. This is something that the more it's incentivized, will free more slots in the community, and it will help to care for these patients as well.

DR. KAUFMAN: Just one last point. The fastest-growing demographic within the dialysis world is the elderly patients. That's the most rapid-growing demographic in the world, and it's just going to have its impact in the next decade or so. It will be really clear what happens.

DR. HELLEBRAND: And, unfortunately, that is the population that receives the least amount of medical care and certainly the oversight from the nephrologist. So any incentivizing that we can do to get the nephrologist in there to help us to care for these patients is a benefit on any level, whether we approve this model or not. But there

is that barrier to access of having the nephrologist engaged and seeing a platform why the home patient, who's home, who is very well, healthy, probably does not need that much oversight. They receive this payment. It does not take a lot of their resources to care for this patient because they usually walk, talk. They're healthy in all, but yet there's no incentive for the patient that is utilizing more of the resources, more of their time that's residing in the skilled nursing home. And that's how we came up with this model.

CHAIR BAILET: So we have Paul, then Tim, and then I have a comment. So go ahead, Paul.

DR. CASALE: Great.

So I was just going to push a little bit more on this total cost of care, which I know you've been asked a couple of times. As you probably know, the renal physicians came with their model, and we asked them specifically because they did want to accept total cost of care responsibility. And they said that when patients go on dialysis, the nephrologist -- and you can speak to this -- often becomes, not that they take over the primary car, but they become their principal physician.

And so I understand this dynamic around the

medical director of the nursing home and all of that, but it would seem to me much more attractive as a physician-focused payment model if in this actually incorporated total cost of care into the model as opposed to this sort of transactional one that you're proposing.

MR. ROTHENBERG: I agree. However, like I said before, we have customers -- we would not have customers as far as nursing homes if we will dictate to them that that's what they want. They would not accept that because the dynamics of the nursing home. We're talking about the nursing home part.

DR. CASALE: Yeah. Again, I don't know all the dynamics, but I'm just saying from a --

MR. ROTHENBERG: I understand.

DR. CASALE: You've repeatedly said that it's hard to get the nephrologists sort of engaged. They need an incentive. Well, in a total cost of care model, I think there would be a lot of incentive, given the fact that -- just all the reasons why you say your program reduces hospitalizations. The ER visit does much better care of patients. That would be reflected financially in a total cost of care model.

MR. ROTHENBERG: Right.

DR. FERRIS: The question I have is very specific and just reflects my ignorance about this, and I'm trying to understand some of the financial dynamic.

So Dialyze Direct provides dialysis services; is that correct?

MR. ROTHENBERG: Mm-hmm. Correct.

DR. FERRIS: So is there a regulatory barrier for Dialyze Direct to just pay the incentive to the nephrologist?

MR. ROTHENBERG: Yes.

DR. KAUFMAN: Do you want to answer that?

We'll let our regulatory guy answer.

MR. PAULL: Yeah, there is.

Essentially, what you're describing would implicate significant risks with the anti-kickback statute primarily for the reason that included in the physician's monthly rate already is his services that he's supposed to provide care for that patient, and he's already being reimbursed for it through those codes.

In the situation where then we were paying the physician something on top of it, it would be -- that would say extremely likely that the OIG would view that as being remuneration in exchange for patient referrals from the

physician.

DR. FERRIS: So --

MR. PAULL: If we switched to that model, I would quit my job that day.

DR. FERRIS: Yeah. So just to follow up on this, because we've been brainstorming a little bit here, so apologies to you guys for our brainstorming, but it seems to me that the OIG problem -- and again, my ignorance, so please help me here -- would go away if they didn't bill the alternative.

I'm not sure I -- like couldn't a waiver under specific circumstances also be a solution? So there are ways to go after a waiver situation which will allow under the condition of dialysis being delivered in a nursing home that you get a safe harbor for a payment that incents the -- because it's clearly in CMS's interest because CMS wins big for that waiver, right? They get the benefits, all the benefits that you have talked about, and the cost is not borne by them. The cost is borne by you, and you did state earlier that you just bought a company, a new company, which suggests to me that you're not in the red.

So I'm just going after solutions here, but it seems to me that an incentive for a safe harbor provision

that said in the case where the nephrologist needs to go to make a visit to a SNF, that that's a safe harbor from the anti-kickback statute, which I will just say there are lots of exceptions and exemptions from anti-kickback statutes under very specific conditions. So it would not set a precedent to suggest that one be applied here.

MR. PAULL: So I won't speak in terms of the financial viability of that type of arrangement. I'll leave that for Josh.

But what I could say is that you're right that there are certain situations that the OIG has provided safe harbors for certain arrangements.

I can't speak in terms of the OIG's process and how complicated that might be in terms of creating one of those for this very specific type of situation. I would say that it could be also possible that the OIG would be hesitant to create a safe harbor in the situation because the very dynamic would potentially invite abuse, where you do have a provider that is directly funneling payments to, I guess, the purest definition of what a referral source is in the eyes of the OIG.

That being said, I don't work for the OIG, but I guess being a regulatory attorney and my experience with

the AKS and federal agencies and everything with that, I would see that there could be some hesitation there.

MR. ROTHENBERG: And as far as our model, as far as for us to bear the cost as is we are bearing the cost and we are creating all the savings for CMS and for the thing, I know there's not enough money out there to also pay the nephrologists as well on a per-patient basis.

CHAIR BAILET: Rhonda.

DR. MEDOWS: I'm just a little slow. It took me a while to finally -- now I get it. Okay. So you need an incentive payment to get a nephrologist to partner with you to take care of patients.

MR. ROTHENBERG: And continue the care.

DR. MEDOWS: Right. In the nursing home.

MR. ROTHENBERG: Correct.

DR. MEDOWS: But you're talking to the PTAC, which is pretty much under a direction to find a way to either improve quality while keeping the cost flat or reducing the cost while keeping the quality maintained. Those are our two driving principles coming forward.

So a straightforward incentive to get the nephrologist to participate without any ties to it, not going to pass muster. It's almost like you need to have

some kind of a quality outcome ties to that $500 or whatever it is, and it could be something that they were going to be doing, anyway, right? Their performance. But it's almost like there has to be something tied to it. It can't just be a flat $500 for you to participate. Do you - -

MR. ROTHENBERG: I understand what you're saying.

DR. MEDOWS: Yeah.

And then when you were talking about the short-term incentives, why somebody would want to do it, totally got it. It took me forever. Finally got it. Thank you. Thank you. Thank you.

Longer term, I'm understanding that the benefit to the nephrologist would not only be the $500, but it would also be that your service would be of such level, of subpar, that actually you would be managing quite a bit for the patient care as opposed to when you provide similar care to somebody are home, right?

MR. ROTHENBERG: Correct.

DR. MEDOWS: The nephrologist gets called less frequently because they have not only your service, but they have a nursing home staff around them as well.

MR. ROTHENBERG: Correct.

DR. MEDOWS: So you're trying to find something to get them in the door.

MR. ROTHENBERG: Correct. And with saving them money.

DR. MEDOWS: But it's got to be tied. So the only problem is we got to tie it to something. It can't just be a straight-up incentive.

MR. ROTHENBERG: I understand what you're saying.

DR. MEDOWS: It has to be tied to something, and I think that's part of what's missing in the way that the proposal is going. We are taking what you have said and what you have presented and what the nephrologist has presented in terms of overall it's better for patients to have hemodialysis more frequently and to have it at a setting where they don't have to get into an ambulance and go out and be exposed to cooties, which is a technical term for diseases all over the place, that kind of thing, but that's technical --

CHAIR BAILET: Rhonda, is that right up there with bug juice?

DR. MEDOWS: Yes, it is.

CHAIR BAILET: Okay, very good.

DR. MEDOWS: Right. So I'm admitting that --

MR. MILLER: There's going to be a quality measure for no cooties coming up in MIPS.

DR. MEDOWS: Right. But there's got to be something. You understand that incentive has to be tied to something more definitively, and is there a way to look at the model that you're proposing to tie it to something? Because we can't just say give them $500 so they'll participate because we think this is a better way to provide care. It has to be give them $500 -- it's better model of care, and this is what they're going to achieve. It has to be -- do you understand what I'm saying? There has to be a quality outcome at least tied to it. Does that make sense?

That's my humble opinion, and they may disagree.

DR. KAUFMAN: I just want to say one thing and just in the world that we live in right now. I totally get the quality outcome discussion that we're having.

There is one problem. The problem is that as of today, there are no -- nobody has quality outcomes for skilled nursing facility dialysis patients in America. We are working on that, and it's a whole nother discussion, which we will come out with later on.

But the problem is that all of the great work

that the RPA does, that they have their quality outcomes, that they have their algorithms, that they know how to do -- they know how to measure a doctor's performance, potentially, is all based upon end-stage renal disease, the general population.

The nursing home population is completely different from the -- it's the 15 percent of the dialysis population that is the sickest, the most comorbidity.

If I can have a skilled nursing facility patient that I'm taking care of for a year and they have two hospitalizations, is that great? Is that terrible? It's terrible if it's a home dialysis patient that's in his private home. That's awful. It may be great for a skilled nursing facility patient who otherwise would be four or five times in a hospital during the year. So the problem is to even start with that quality outcome business, you have to make quality outcomes.

By the way, within our model, using Medicare billing as guidelines for hospitalizations, we do plan to have -- we looked at the power -- to reach a -- we did a power analysis of how many patients do we need to see to have a 85 or 90 percent chance of finding a meaningful difference between more frequent dialysis patients and

patients who are on conventional dialysis paired for the nursing him. So we have a model, as we explained within our model. It will choose about a 5-to-1 ratio of our basic group, which will be it needs about 300 patients. We'll have about 1,500 paired patients using Medicare billing to track hospitalizations of the two paired groups.

And this will actually be one of the first ways to judge outcomes. So the problem is this is the problem, but we are where we are. And we're in the current date of time, and we're like doing the best we can with the tools that we have. But I can't make up tools that we don't have so far, which we will have, but not today. But not today. Not today. We can't.

CHAIR BAILET: Thank you, Ron.

And I'd like to -- because I was on the PRT. I applaud the work that you're doing. You're taking care of some of the most vulnerable of the vulnerable amongst the end-stage renal patients, and that's notable.

I just go back to the work that we're trying to do here relative to evaluating a proposal and making a recommendation to the Secretary about an alternative payment model, a physician-focused alternative payment model.

I understand the clinical benefits of more frequent dialysis. It wasn't lost on me. I've seen dialysis patients struggle with recovery. It pretty much saps them, and they're offline for quite a while. And the fact that they're able to go through this process with not only better, stable vitals, but a better state of mind. And they can actually live their life more completely instead of having these cycles of essentially brown-outs, if you will, are great.

But if I look at it through the lens of a model, the model that you have proposed, the backbone of the model is savings generated by transportation, and I think as we have explored this multiple times and we've had discussions today, but we've also had multiple discussions -- Dr. Kaufman, we chatted with you a bit as well -- that really isn't -- when the smoke clears out of the room, that's really not the Willie Sutton. That's not where the money is.

The money could be where you're pointing out, hey, these folks don't end up in the hospital. That's not a small amount of savings if that can be validated. The challenge is it's not embedded in your model, and we don't have the statistical information to prove it out. So for

us to make a recommendation on the model based on the savings, I think that's a soft spot in my own mind. I'll speak for myself.

Tim, you wanted to make a comment there?

DR. FERRIS: Just --

CHAIR BAILET: Because I'm not done, but --

DR. FERRIS: No, no.

CHAIR BAILET: No, no. Please go ahead. No. Please, Tim.

DR. FERRIS: [Speaking off microphone.]

CHAIR BAILET: All right. So I have a -- I'm challenged. I'm challenged there. We're talking about providing some kind of incentive payment to the clinician to get them into the home because they don't want to go to the skilled nursing facility when they can go to a dialysis center and they can see 15, 20 patients, and they're now going to have to go travel to a different place with different resources, right? It's not going to be a resource-rich environment, and they're going to see a smaller number of patients.

So, financially, it's going to be more challenging for them. Clinically, it could be more challenging because they don't have all of the depth of the

support, but the model as it's constructed, as it's proposed, what I'm struggling with is I don't know what I'm recommending. I don't know what I'm recommending, and I think what you're hearing from the Committee members is we're probing, and I don't have anything to hold onto yet, and that's a challenge I have and maybe I'm -- we can vote. You know, we can go through the criteria. We can vote and we can come up with a recommendation. But I struggle with I don't know what we're recommending. So I'll leave it at that and let Tim jump in there.

DR. FERRIS: I think along those lines, what I heard was there is a very real problem that they are trying to address, and maybe in the spirit of the comments we heard this morning, from the Secretary, the Administrator, and the Director of CMMI, that it sounds like they were referred to us. Without predicting what we're going to do, we may be saying we're not the right place for this.

I think it would be unfortunate if the result was the ping pong ball. A better outcome here would be if there was actually some dialogue between us and the right, as Bob was pointing out, the right group to think about this problem.

And I'm going to be optimistic here, but it is

possible that through the articulation or the endorsement of the problem, and the endorsement of a solution, maybe not solution as proposed but identifying the problem as a real problem, we might help the American public by elevating this discussion to the right place within CMS. I'm understanding that may be an optimistic --

CHAIR BAILET: And Tim, where I'm going, where I'm going to land is we've been here once before. My concern is if this Committee goes through and completes our process, and we vote, and it comes down where we're not going to recommend this model -- and I'm not suggesting that that's where we're going to end up, but I'm just -- worst case, it creates a deeper hole. And what I want to create is optionality for you.

And so what Tim is suggesting is perhaps -- I'm throwing this out -- we could pause the process. You could withdraw your proposal, which allows us not to have to vote on it. We then can take advantage of the relationships that we have and see if we can solve this issue directly in a way that does not require creation of an alternative payment model, and all of the, what we have been told, the 18-month pipeline for building it out and implementing it and getting it out. So I'm just throwing that out there as

a question.

MS. SELENICH: [Off microphone.]

CHAIR BAILET: A statutory change issue. What is this?

MS. SELENICH: [Off microphone.]

CHAIR BAILET: Oh. Well, my point is they have the opportunity at this point to withdraw their proposal. Is that correct?

MS. SELENICH: [Nods in affirmative.]

CHAIR BAILET: Okay. So I just want to make sure. See, this is my team that keeps me between the fence line here, so I just --

MR. ROTHENBERG: We thought, originally, that we fit more to the CMMI, overall, for the whole model. We were surprised they sent us to PTAC, and that's what I said originally.

CHAIR BAILET: Yeah.

MR. ROTHENBERG: I could be now that there is new direction. It is, but somebody has to tell --

CHAIR BAILET: Right, and again, I'm not washing out -- I'm not trying to wash out all of the good work that we've done --

MR. ROTHENBERG: No, I understand.

CHAIR BAILET: -- and I'm not throwing in the towel, you know. I'm just making a suggestion and I'll stop there. Len?

DR. NICHOLS: Well, I first want to ask Sarah, if they were to withdraw, could we still write a letter? I get the statutory charge issue, but it seems to me write a letter, because, if I remember correctly, one of the three Adam mentioned this morning was the live ESRD proposal that came before, that we recommended. And I would just say, in the spirit of, there's a panoply of options. This is a specific population that is not being addressed, in general, for which you could imagine Plan 7(B), my favorite little thing. I'm just saying it seems to me we have standing, if you will, to comment, because the proposal came before us. We have another lawyer that is consulting.

CHAIR BAILET: In a caucus. A caucus here. Please, bear with us.

MR. ROTHENBERG: As long as we don't have a protest in the back of the room.

CHAIR BAILET: Please. Go ahead, Len.

DR. NICHOLS: I'll offer, and maybe ask -- here's what I think happened, for what it's worth. CMMI heard nephrology needs a payment. CMMI didn't want to do the

code business, or didn't direct you to the code people, for whatever reason. You, God bless you, went home, came back with a payment for the doc and a shared savings thing, because that's what you think you've got to do to get it past us, and here you're trapped with a shared savings thing that's not really the focus of the whole thing.

So I submit they did their job --

CHAIR BAILET: Oh.

DR. NICHOLS: -- and they were given --

CHAIR BAILET: Yeah.

DR. NICHOLS: -- well-intentioned, not good advice, and the solution here is to use our ability to comment on the nature of the population you're addressing to get the conversation at a higher level, at the right level of HHS.

MR. ROTHENBERG: And then we can really discuss the whole model --

DR. NICHOLS: Bingo.

MR. ROTHENBERG: -- not just the physicians.

DR. NICHOLS: Exactly. Right. But for the first time --

MR. ROTHENBERG: That's why we were like, why do have to go to the physician, but that's what they told us

to do.

DR. NICHOLS: Trust me. Welcome to my world.

CHAIR BAILET: So, Len --

DR. NICHOLS: Well, I was going to ask the question is, can we do this?

CHAIR BAILET: Well, so they're working on that, but Paul and Harold, if you want to go ahead.

DR. CASALE: Yeah. I was just going to, because I think, Len, I was thinking exactly the same. From the comments that were made this morning, and clearly CKD was called out, that it is one of the things they're working on, and we know that they've alluded to bringing in RPA for their discussion. So it seems like it's an opportunity where that is going on, and wouldn't it make sense, as you said, if we can provide a letter to elevate this into that discussion, because, as you just said, they're not going to do 10 different models, certainly, and it would be an opportunity to bring this into that conversation.

CHAIR BAILET: Harold.

MR. MILLER: So I'm having a bit of trouble. I'm happy to go along with it but I'm having a bit of trouble understanding what the great problem is with evaluating this. I don't think -- I think it has, as we said in the

PRT report, some positive things that we could say about it and then say that it's not a good payment methodology and it's not an alternative payment model, and then write a letter to say that.

I mean, I think the fact that we would recommend that it's not an alternative payment model does not mean that we're recommending that nothing should be done. We can say this is not an alternative payment model but we think something should be done.

Now we could skip over all the voting and everything, I guess, if we wanted to, or do it quickly by -- we could use the non-applicable route, which we've used before. I'm not a big fan of the non-applicable route, because, I mean, I think that the issue is the criteria are applicable. I just think that it's going to fail, at least from my perspective, a bunch of the criteria. But I think it gets us to writing the letter to say what needs to be done. And I just don't see a problem with us saying no, we're not recommending this as an alternative payment model but we are saying that we think that there is an opportunity here that needs to be addressed.

CMS could create -- I mean, you haven't talked about how you would operationalize this bonus anyway, but

it would be probably be a code that somebody would build. So, mean, you know, it would just be some code. So they could create a code if they thought that it was a desirable thing to do. It would not be unheard of to say, you know, nephrologists are allowed to bill $500 for a $500 payment whenever a patient goes to this thing, but it would get to the point that Rhonda was raising, would be that there would be some definition of what this thing is that everybody views as desirable, that you want to reward the nephrologist for.

And the problem is right now we don't -- I'm troubled that we don't have that, and I think if I were CMS and I would be looking at this I would be saying I would be a whole lot more interested in doing this for long-term nursing facility patients, and I would be interested in doing this maybe differently for the short-term facility patients. So I'm not getting lots of churn with people trying to get more $500 payments just by getting more people into a SNF. So I think a lot of work has to be done along those lines.

I think, as Rhonda pointed out, it's not -- I think, to me, that fundamentally it's not a physician-focused payment model. This is basically something that

some other entity is going to be doing and it wants to throw $500 at the nephrologist so that they don't stand in the way. That, to me, is not a physician-focused payment model. That's a physician buy-off model, or something like that. But it's not a physician-focused payment model. So I think we could say good problem, needs a solution, not this, and becoming, after a careful, detailed review. That's my thought.

CHAIR BAILET: Yeah, we do have guidance. So we can't write a letter offline. We have to deliberate, come to our conclusions, and we have to create a --

DR. NICHOLS: Then I follow Harold's suggestion.

CHAIR BAILET: So the process is --

DR. NICHOLS: The best outcome is to vote.

CHAIR BAILET: -- we go through, we follow our process --

DR. NICHOLS: -- write a letter, try to get the conversation we talked about.

CHAIR BAILET: Yeah. Okay. So that means we're at the point now where we'd like you guys to -- again, thank you for coming and presenting. We're not done yet but we're going to see if there are some folks on the phone who want to comment. We could have questions amongst

ourselves, and then we're going to go ahead and vote on the criteria, and then we're going to vote on the recommendation. Okay.

MR. ROTHENBERG: And we concur with the previous doctor that you guys are doing a great job.

CHAIR BAILET: Oh, thank you. Yeah, if it was easy everybody would be doing it. Kavita.

DR. PATEL: Just so I can understand, I, at least, kind of side with like -- I'm concerned. Are we still going to offer them a chance to withdraw the application, knowing we cannot write a letter. I understand that. What, are we going to talk to anybody about?

CHAIR BAILET: Well, look --

DR. PATEL: I feel like we're delaying it maybe a little bit, but not that much.

CHAIR BAILET: So, Kavita, if they withdraw that does not preclude them -- us facilitating them going to speak to someone.

DR. PATEL: Correct.

CHAIR BAILET: It doesn't preclude any of us going to speak to --

DR. PATEL: Correct.

CHAIR BAILET: -- leadership. But we're not going to write a letter to the Secretary --

DR. PATEL: Okay.

CHAIR BAILET: -- unless we do it here and go through our process.

DR. PATEL: So can I just, for transparency sake, just restate that if we were to not vote, for whatever reason, because someone withdrew, a rock landed on your head, I don't know, all of the things that could happen in the next five minutes, all we would be doing is potentially delaying something, if submitters were to take some of this feedback and think about what we've said and reflect on it, and potentially resubmit it later.

CHAIR BAILET: That's an option. They have that option as well.

DR. PATEL: That would be one. The second option would be to go ahead and to deliberate for the purpose of, not knowing how everybody individually is going to vote, but I would still be pressed to keep my vote with some of the caveats that I made as comments to our submitters, and that could potentially create a perception of, at least in my case, that I didn't think was sufficient. So that seems like the other potential here. So I'm just trying to weigh

the pros and cons of both of those decisions.

CHAIR BAILET: Okay. So Harold and then Len.

MR. MILLER: The law says that we are to make recommendations to the Secretary, comments and recommendations to the Secretary on proposals that we got. The laws says nothing about the categories. We invented the bloody categories that we vote on, and we can invent a different category if we want. We invented a different category called non-applicable a while back. If we want to invent a different category here -- we can go through evaluating based on the criteria and then we can say we're voting to send a letter to the Secretary saying, you know -- and Sarah can tell me if I'm wrong, but we're making comments and recommendations to the Secretary.

I think the thing that people are concerned about is they don't want a statement that we voted to say not recommend. We don't have to vote not recommend. We can vote to send a letter of comments to the Secretary saying that we think it's a problem and it needs to have an action, and I think that's a perfectly legitimate thing to do, and then we're following the process. It's just that we've invented yet another category.

I think we have to go and we have to rethink all

the categories anyway, because nobody understands what limited scale testing is or why we're doing it, and nobody understands what any of the other things are. So we've got to do that, so we might as well just start here and create yet another one. Okay.

CHAIR BAILET: Harold, I'm actually going to double down on your comment, because it's been recommended one of the categories we could -- I'm going to throw out a straw model here -- would be we recommend for further evaluation, or further development. So, Len, you had -- Grace, go ahead and then Len.

DR. TERRELL: Just a quick comment. I am inferring, perhaps not correctly but I suspect I am, that we think, at least from our conversation, that they have correctly identified a real problem, okay, but we are not necessarily thinking that we're going to think that this is the solution. Okay. So the problem we have is that we're trying to figure out, within the context of what you're talking about, how to say that to the Secretary, which is, "Yep, they nailed it. There's a problem. Nope, maybe we don't necessarily think this is a physician-focused payment model." Okay.

So the category may be, yep, they nailed it.

There's a problem. You need to go fix this, dude. And, you know, whether it needs to be in CMMI or whether it needs to be a code recommendation as it relates to, you know, sort of the typical way that CMS would deal with it, I don't see that that's something that we can't comment on, so long as we basically say we recognize that they have correctly, appropriately identified a significant problem that needs to be fixed. We think that these are some of the ways that we suggest. You think about it. What's wrong with that category?

CHAIR BAILET: I think we have the latitude to create categories, as Harold has said --

DR. TERRELL: Okay.

CHAIR BAILET: -- and if that's the will of the Committee, if that's where we think we want to land, I'd like to arrive at the landing zone before we go through --

DR. TERRELL: Right.

CHAIR BAILET: -- the voting process. Sarah? Yeah, please.

MS. SELENICH: So you can create new categories. As you know, the ones that you've set up, you've set up. I would add that in the past you have allowed public comment -- I know you're going to have that tomorrow -- on your

practices and procedures. And in an earlier meeting you all discussed remaining consistent with your current sort of processes. So I just wanted to mention that.

MR. MILLER: Well, we consistently said before we had a consistent, non-applicable recommendation, did we not?

CHAIR BAILET: Exactly. We did.

MR. MILLER: So we could, and I think we actually did that without public comment.

CHAIR BAILET: And we could -- but a non-applicable --

MR. MILLER: I was saying if we wanted to be -- do something that we had done before, we did non-applicable. But I'm saying we did non-applicable on the spot without having public comment, and then we later on institutionalized, Ann, am I -- do I remember correctly? It was done at the meeting and then we later on agreed to adopt it into our formal voting options, but we scrambled that day to add that to the list of things to do, if I'm remembering correctly.

CHAIR BAILET: Len and then Grace.

DR. NICHOLS: So, you know, we've had now a physician play economist and I'm going to be an economist

playing a lawyer, for fun. Okay? If I remember sort of some of the legal decisions I've been forced to read in my life, there is this concept of something without prejudice, and it has to do with, in a sense, passing the decision down the chain, but not indicating which way you would have ruled if you'd been forced to rule. And sometimes it's remanded with that, so that kind of thing.

So the notion here that's in all our heads, is how do we use the one lever we have, which is a letter to the Secretary, to ensure the highest likelihood this conversation takes place, that we all believe should take place, and it seems to me it's perfect valid, and, indeed, desirable, in our letter to say these people were sent to us by CMMI and the model they came up with was designed to solve the problem they have, in some sense, already solved, but along the way of solving it they discovered the barrier, which the physician-focused model would help overcome.

Now, I think it is a physician-focused model. I don't think it's a physician-focused model we would design nor recommend wholeheartedly. But it is enough of a physician-focused model to engender the letter. I just feel like we've already recommended 10 models that got

either rejected or delayed and transmogrified, so rejecting it doesn't feel smart. Saying it's not applicable is disingenuous. And so I like the idea of saying this conversation should continue without prejudice, and lay out the fact of how we think that conversation should take place, and leave it to the Secretary, who is the only creature we can actually advise, leave it to the Secretary to figure out how to engender that conversation.

DR. NICHOLS: Grace.

DR. TERRELL: I think the problem is the category of non-applicable is something that if we had just a different word. Because if you think about what the non-applicability has to do with it, it had to do specifically with the issue of is it a physician-focused payment model.

But I would say that there is a potential other distinction between ones that get here, and one of them is there may be some things that are just not applicable because they're not applicable. They're not physician-focused payment models. They're just something else that landed in our lap, okay?

And then there's another thing that's out there, which is, okay, maybe it's in our purview, but we just think that there is a problem that is stronger than says

that it's not recommended. It's about there is a problem out there that is absolutely important that they identified.

And a lot of these things that we've actually rejected are not recommended. In many respects I has that characteristic. Right? I mean, I can't think of a single person who has come to us. They've all been thoughtful in many different but their own ways, to basically say, "I see a problem. You know, Congress said that there was a place that I could bring the problem, and it would be deliberated on." And then, unfortunately, the way we've got it categorized now is either non-applicable or don't recommend, but there's been no focus on the fact that there are some really important problems that we still need to make sure that somebody is thinking about.

So is there another word?

CHAIR BAILET: Yeah.

DR. TERRELL: Is there another word that could be used that would essentially allow us to do that in a way that it's still within our purview --

CHAIR BAILET: Okay.

DR. TERRELL: -- because it's applicable to the fact that they are finding problems.

CHAIR BAILET: I think we could untie the Gordian Knot here by actually recommending for other attention, or for further development. So we're recommending it, but we're recommending it for other attention, because we are required to evaluate the model against the 10 Secretary's criteria. We haven't gone through that process, but we have to do that. And so I think we should do that, and then let's get to the output. But I don't think, until we do that, I think that's the next step. That's my recommendation, if the Committee would indulge me.

DR. NICHOLS: So your suggestion is other attention --

CHAIR BAILET: Right, other attention --

DR. NICHOLS: -- or further development.

CHAIR BAILET: -- or further development. I mean, I'm going to leave it to the -- I mean, we can hash that out. I've got Rhonda and Harold. Rhonda?

DR. MEDOWS: Can I just make a motion that we write a letter to the Secretary, somebody second it, we all vote, and then we send the letter?

CHAIR BAILET: You mean without going through the criteria? I think we have -- I thought we --

MS. PAGE: Whatever that letter says we have to

deliberate in public.

CHAIR BAILET: -- we have to deliberate. We have to evaluate it against the --

MS. PAGE: In public.

CHAIR BAILET: -- in public.

MS. PAGE: Whatever that letter says we have to deliberate in public.

CHAIR BAILET: Right.

UNIDENTIFIED SPEAKER: [Off microphone.]

DR. NICHOLS: Well, I'm -- I understand we would deliberate in public. I'm clear on what everybody is saying. I mean, the law says we are supposed to evaluate against a criteria, so I think the safest thing is for us to evaluate against the criteria. I like Jeff's suggestion. I would just take out the word "other." I mean, it merits attention.

CHAIR BAILET: Yeah.

MR. MILLER: And we can explain what kind of attention we think it merits. I think the issue is we don't necessarily believe that the best thing is, at least as a first line of defense, is that they should go back and try to create the kind of model that would fit into the category that we ordinarily do. I mean, what we're saying

is they ought to go to CM and see whether they think that there's something different that could be done, to the fee schedule or whatever else, and then after all of that's done, if it turns out that there's something better, bring it back here. But the point is they shouldn't continue to cycle with us until those other things.

So I'd just say -- we're saying to the Secretary it deserves attention, you know. And then if somebody sends them back to us, it will have been hopefully with some information as to why nothing else worked.

DR. MEDOWS: Mr. Chairman, can I call the question, please?

CHAIR BAILET: Please.

DR. MEDOWS: Let's vote.

*** Voting**

CHAIR BAILET: I'm right with you, Rhonda. I'd like to go through the criteria. Let's go. Clickers in hand. Our expert, the man behind it is going to go ahead and get this thing teed up. We're going to vote on the first criteria, and we all know what that is. Scope, aim to either directly address an issue and payment policy that broadens and expands the CMS and APM portfolio or includes APM entities whose opportunities to participate in APMs

have been limited.

Please vote.

[Electronic Voting.]

*** Criterion 1**

CHAIR BAILET: Can I just make -- are you required to read all the zeroes? You are. Very good. Okay.

MS. SELENICH: We read them for the transcription and also for the folks on the phone.

CHAIR BAILET: Got it.

MS. SELENICH: There's also a lag for livestreaming.

CHAIR BAILET: Thank you.

MS. SELENICH: So zero members voted 5 or 6 for meets and deserves priority consideration. Zero members voted 4, meets; three members voted 3, meets; four members voted 2, does not meet; three members voted 1, does not meet; and zero members voted not applicable. We rolled down, and in this case the majority is 6. A simple majority is 6, so the finding of the Committee is that the proposal does not meet Criterion 1, Scope.

CHAIR BAILET: Thank you.

Criterion 2 is quality and cost. Anticipated to

improve health care quality at no additional cost, maintain health care quality while decreasing cost, or both, improve health care quality and decrease cost. High priority. Please vote.

[Electronic Voting.]

* **Criterion 2**

MS. SELENICH: Zero members vote 5 or 6, meets and deserves priority consideration; zero members vote 4, meets; two members vote 3, meets; four members vote 2, does not meet; three members vote 1, does not meet; and one member votes not applicable. The finding of the Committee is that the proposal does not meet Criterion 2.

CHAIR BAILET: Criterion 3, payment methodology. Pay the APM entities with a payment methodology designed to achieve the goals of the PFPM criteria. Addresses in detail through this methodology how Medicare and other payers, if applicable, pay APM entities, how the payment methodology differs from current payment methodologies, and why the physician-focused payment model cannot be tested under current payment methodologies.

Please vote.

[Electronic Voting.]

* **Criterion 3**

MS. SELENICH: Zero members vote 5 or 6, meets and deserves priority consideration; zero members vote 3 or 4, meets; one member votes 2, does not meet; seven members vote 1, does not meet; and two members vote not applicable. Therefore, the finding of the Committee is that the proposal does not meet Criterion 3, payment methodology.

CHAIR BAILET: Thank you. Value over volume. Provide incentives to practitioners to deliver high-quality health care.

Please vote.

[Electronic Voting.]

*** Criterion 4**

MS. SELENICH: Zero members vote 5 or 6, meets and deserves priority consideration; two members vote 4, meets; six members vote 3, meets; one member votes 2, does not meet; one member votes 1, does not meet. Therefore, the finding of the Committee is that the proposal meets Criterion 4.

CHAIR BAILET: Thank you. Flexibility. Provide flexibility needed for practitioners to deliver high-quality health care.

[Electronic Voting.]

*** Criterion 5**

MS. SELENICH: Zero members vote 5 or 6, meets and deserves priority consideration; zero members vote 4, meets; six members vote 3, meets; four members vote 2, does not meet; zero members vote 1, does not meet; zero members vote not applicable. Therefore, the finding of the Committee is that the proposal meets Criterion 5, flexibility.

CHAIR BAILET: Thank you. Ability to be evaluated is the sixth criterion. Have evaluable goals for quality of care, cost, and any other goals of the PFPM.

[Electronic Voting.]

* **Criterion 6**

MS. SELENICH: Zero members vote 5 or 6, meets and deserves priority consideration; zero members vote 4, meets; four members vote 3, meets; four members vote 2, does not meet; one member votes 1, does not meet; and one member votes not applicable. Therefore, the finding of the Committee is that the proposal does not meet Criterion 6, ability to be evaluated.

CHAIR BAILET: Thank you, Sarah. Criterion 7 is integration and care coordination. Encourage greater integration and care coordination among practitioners and across settings where multiple practitioners or settings

are relevant to delivering care to populations treated under PFPM.

Please vote.

[Electronic Voting.]

* **Criterion 7**

MS. SELENICH: Zero members vote 5 or 6, meets and deserves priority consideration. Zero members vote 4, meets. Five members vote 3, meets. Two members vote 2, does not meet. Three members vote 1, does not meet. Zero members vote not applicable.

Therefore, the finding of the Committee is the proposal does not meet Criterion 7.

CHAIR BAILET: Thank you.

Patient choice. Encourage greater attention to the health of the population served while also supporting the unique needs and preferences of individual patients.

Please vote.

* **Criterion 8**

[Electronic Voting.]

MS. SELENICH: One member votes 6, meets and deserves priority consideration. One member votes 5, meets and deserves priority consideration. Two members vote 4, meets. Six members vote 3, meets. Zero members vote 1 or

2, does not meet; and zero members vote not applicable.

Therefore, the finding of the Committee is the proposal meets Criterion 8, patient choice.

CHAIR BAILET: Patient safety. Aim to maintain or improve standards of patient safety.

[Electronic Voting.]

*** Criterion 9**

MS. SELENICH: One member votes 6, meets and deserves priority consideration. One member votes 5, meets and deserves priority consideration. One member votes 4, meets. Four members votes 3, meets. Two members vote 2, meets; and one member votes 1, does not meet.

CHAIR BAILET: We want --

MS. SELENICH: Oh, two members vote 2, does not meet; and then one member votes 1, does not meet. Zero members vote not applicable.

So the finding of the Committee, although you may want to discuss this further, is that the proposal meets Criterion 9, patient safety.

CHAIR BAILET: Do we want to discuss it, or do we want to move on?

[No response.]

CHAIR BAILET: I think we're going to move on to

Criterion 10, which is health information technology. Encourage use of health information technology to inform care.

[Electronic Voting.]

*** Criterion 10**

MS. SELENICH: Zero members vote 5 or 6, meets and deserves priority consideration. Zero members votes 4, meets. Two members vote 3, meets. Six members vote 2, does not meet. Two members vote 1, does not meet; and zero members vote not applicable.

Therefore, the finding of the Committee is the proposal does not meet Criterion 10, health information technology.

CHAIR BAILET: Thank you, Sarah.

So we are ready to make the recommendation and vote. So we're going to go ahead and do that now.

We need to spend one minute on renumbering these puppies here.

So could we add five, then? Could we add just a fifth? That would be the easiest to just --

DR. CASALE: [Speaking off microphone.]

MS. SELENICH: Yeah. I was going to say, I don't think we can --

DR. CASALE: [Speaking off microphone.]

MS. SELENICH: Right. So if it's fine with the Committee, if we can use --

DR. CASALE: I was suggesting that since there's consensus that not applicable is not applicable, just substitute the merit's attention for the not applicable. Then people want to vote on the others.

MR. MILLER: I would move that we consider for the voting process, when we vote the zero button, that we are voting as though we are voting the statement being merits, consider whatever. What's the phrase?

CHAIR BAILET: Recommend for -- well, I had recommend for other attention, and you said --

MR. MILLER: Recommend attention.

CHAIR BAILET: Recommended --

MR. MILLER: So I would move that we -- that we are for the purpose of this vote striking the words "not applicable" and substituting the words --

CHAIR BAILET: "Recommend for attention"?

MR. MILLER: "Recommend for attention."

DR. MEDOWS: Second.

CHAIR BAILET: All right.

DR. NICHOLS: [Speaking off microphone.]

CHAIR BAILET: There is no star.

MS. SELENICH: It's zero on your voting pads.

CHAIR BAILET: All right. So --

MR. MILLER: We have to take a vote, Jeff.

CHAIR BAILET: We are going to take a vote.

You know, Harold, I'd be lost without you.

[Laughter.]

MS. SELENICH: Just a quick clarifying question. So, currently, the way this is set up, you need a two-thirds vote, and we've been rolling down the categories. If you all do not reach a two-thirds vote --

MR. MILLER: No, no, no. We have to vote on the motion.

MS. SELENICH: Oh, yeah.

MR. MILLER: We don't need two-thirds.

CHAIR BAILET: We are going to vote on the motion. We have a second. All in favor?

[Chorus of ayes.]

CHAIR BAILET: Any opposed?

[No response.]

CHAIR BAILET: Motion carries.

Please continue, Sarah.

MS. SELENICH: So part of that process is are we

going to roll down to this recommend for attention vote.

MR. MILLER: I would suggest we see what the votes are, and then we should decide how we will interpret that.

CHAIR BAILET: Yeah. I guess we'll cross that bridge. All right. Here we go.

MR. MILLER: I would suggest we can make a motion that we suspend our normal rules for rolling down for the purpose of this vote.

CHAIR BAILET: Let's go. I don't think we need to.

So are we ready to go? All right. Hit it.

[Electronic Voting.]

*** Final Vote**

MS. SELENICH: So zero members vote 4, recommend proposed payment model for implementation as a high priority. Zero members votes 3, recommend proposed payment model for implementation. Zero members vote 2, recommend proposed payment model for limited scale testing. One member votes do not recommend proposed payment model, and nine members vote recommend for attention.

Therefore, the finding of the Committee is to recommend the model for attention.

MR. STEINWALD: I'm sorry. I remembered "further development" or something. "Attention" --

CHAIR BAILET: Yeah. So it's "for attention." Yeah. Because I think -- so do you want to -- should we --

MR. MILLER: Can I just suggest too that -- and maybe everybody agrees -- the phrase should be "recommends the proposal for attention," not "the model for attention"?

CHAIR BAILET: Yeah.

MS. SELENICH: So "recommends the proposal for attention."

CHAIR BAILET: Yeah. Do we have a motion -- a second for that?

DR. MEDOWS: Second.

CHAIR BAILET: All in favor?

[Chorus of ayes.]

CHAIR BAILET: All right. So we've got the new language, Sarah?

MS. SELENICH: Yes.

CHAIR BAILET: Very good. So that's what we just voted on.

Bruce, do you want a revote because --

MR. STEINWALD: Yes.

CHAIR BAILET: Yes, I think we should revote.

Please. Could we revote? We're going to revote because Bruce didn't -- he needs to -- he wants his vote to reflect what he believes, so he took a nap, so let's --

Okay, very good. One more time with feeling. We're going to go ahead and vote. Please.

The language, Sarah, please? Read the language back.

MS. SELENICH: The language for what we're substituting the not applicable category for is "recommend the proposal for attention."

CHAIR BAILET: Okay. Let it rip. There we go. All right. Because I think it's important for the vote to reflect the collective consciousness of the group, and it's unanimous.

[Electronic Voting.]

*** Final Vote**

MS. SELENICH: So zero -- I'll do it quickly. Zero members vote 4 -- recommendation categories 1, 2, 3, and 4, and 10 -- everyone voted for recommend the proposal for attention.

*** Instructions on Report to the Secretary**

CHAIR BAILET: So we have spent a lot of time getting here. The next step is -- since we all -- you all

voted 10, so we don't have to declare personally.

Sally, you have been writing feverishly. It would be nice for you to share what we already have said, and then we can fill in any gaps that we think we want to make sure get incorporated in the letter. Does that work, Sally?

DR. STEARNS: Sounds good.

All right. So the discussion of this model showed substantial enthusiasm for the underlying care model of facilitating more frequent dialysis in nursing home settings, particularly the care model that enables nursing home participants to avoid risks and costs of transport and to potentially achieve better health outcomes.

The discussion identified the barrier of a nephrologist willingness to follow patients into the nursing home, despite the value of enabling many patients to continue to receive care from the same nephrologist with the benefits of MFD.

Okay. And it was also noted that MFD in nursing home has benefits in terms of improvement health outcomes, including the possibility of reduced hospitalization.

In terms of concerns on the model, the main concern was that the model is not a true physician-focused

payment model because it involves a payment to nephrologist -- or simply because it involves a payment to nephrologist. The proposed shared savings pertain -- as laid out in the proposal pertain only to transportation, and the savings may be particularly questionable for some groups such as short-stay SNF patients.

So the proposal did not have -- or did not involve broader potential for shared savings by including other components of care or attention to total cost of care that might be affected.

So, in summary, the PTAC feels that the problem merits attention. It is not clear, however, that the submitters should try to develop a physician-focused payment model. Instead, it would be desirable to facilitate attention by HHS leadership through further discussion

DR. MEDOWS: Is this the addendum?

CHAIR BAILET: Yeah. This is -- right. This is the time when we can pile on. So Len and then Rhonda.

DR. NICHOLS: So, Sally, I'm not sure I -- well, I would not support saying that this is not a physician-focused payment model.

I think we should say this is not an ideal

physician-focused payment model for the problem that it was designed.

I also think we should acknowledge in the letter that they came to us because they were sent to us by CMMI, and that given everything we talked about, which I'm sure the transcript will flesh out, but also, I want to go back to -- I think it was Josh who talked about the new requirements, regulations in the nursing home industry to provide these inside services. That says CMS is already moving, and therefore, we're just trying to get this chassis attached to that conversation. And, therefore, I think it is a physician-focused payment model, and I wouldn't want to say it's not because I'm just afraid that will lead to it being discarded right away.

CHAIR BAILET: Rhonda.

DR. MEDOWS: Can we include some language around the quality piece, an acknowledge that while there is data that substantiates the improvements in dialysis patients outside of the nursing home, but there does not exist yet the baseline data for SNF patients on home dialysis? That is to be explored.

CHAIR BAILET: Grace.

DR. TERRELL: I agree with Rhonda with respect to

the quality aspects needed to be fleshed out in general, as was articulated well by the applicants.

I am somewhat skeptical, however, that peritoneal dialysis is always a -- should be excluded in a model of care that involves somebody in a nursing home, and so some of the things that I think needs to be thought about broadly with respect to quality may be more than just what a dialysis company itself might know. There may be evidence that greatly supports that. I just don't know. So I think there needs to be a broad conversation about quality.

With respect to the fact that we need to say that this is a problem that they accurately identified, I think that there should be some specific language with respect to how we think this attention by the Secretary should be thought through, whether a code, a simple code, and therefore going straight to CMS would be the way to go versus a waiver, which was talked about by the applicants as the way to go. So if we put language in there that sort of follows them, think about these things, please, that would be useful.

Finally, they continue to make the point that a nursing home would not want them to take care of the total

cost of care. You mentioned the total cost of care, Sally, and it's because the entity that brought this forward, I think, is very specific in what it's doing, which is providing dialysis for nursing homes.

However, that just is because of the way nursing homes are paid versus what you all were paid for now. We need to make sure as we're talking and articulating about what we think could be done better as they are thinking through what this problem is, is to make sure that it's not only about facility fees versus procedure fees versus total cost of care fees versus physician-focused payment fees, but that the problem itself needs to be thought about comprehensively as the way all these types of things currently dysfunctionally interrelate with one another.

And they actually identified a new problem for me, which is because they are a dialysis company, the total cost of care is a barrier for them to even provide. So that ought to be thought through as well by CMS.

CHAIR BAILET: Harold.

MR. MILLER: I think it's important to say that we think there are two different populations here that need to be examined separately -- the long-term nursing population and the short-term SNF patient. And that if

examination of those two populations leads back to one model or one approach that works for them, fine, but I think that the needs of the populations, the payment methods that exist today for each of them, et cetera, are all so different that they just have to be looked at separately. And I think to me that was one of the weaknesses of this proposal, was it just sort of blended them all together and didn't make that distinction.

So I think that when this greater attention occurs, it's important that they be looked at separately, and I raise that particularly because I think it may be different people may be looking at that, at CMS, and need to be thinking about those different pieces.

And, again, if it comes back to one approach, fine, but I think that the people who know each of those separate components and what's associated with them should look at them separately and decide what makes sense to do.

CHAIR BAILET: Thank you.

Rhonda -- oh, very good. See, I'm surprised I caught that.

This has been a long day.

[Laughter.]

CHAIR BAILET: So I want to thank first the

applicants. You guys have put a lot of work into preparing. I remember, if you people who were looking at the transcript, Dr. Kaufman, you know, that conversation that we've had, I mean, you guys have really leaned in. We appreciate your patience with us, as we have refined our process. And we're here to support the clinical community and make recommendations to the Secretary, and I think we landed in a great spot. And I want to compliment my colleagues around the table here for sticking with it because it was high level of engagement that led us to the solution, and I think we actually did a nice job, if I would say so myself.

Thank you, and I guess, do I have a motion to adjourn?

DR. FERRIS: Motion.

DR. MEDOWS: Please.

CHAIR BAILET: Second?

DR. MEDOWS: Second.

CHAIR BAILET: All in favor.

[Chorus of ayes.]

CHAIR BAILET: Meeting is adjourned.

[Whereupon, at 6:11 p.m., the meeting was recessed, to reconvene Friday, September 7, 2018.]