

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

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**Submitted by Dialyze Direct**

PRT: Harold Miller (lead), Jeffrey Bailet, MD, and Rhonda Medows, MD  
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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

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

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

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

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

23           In addition to the Committee's sessions with

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

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

11 We have also been exercising our new authority to  
12 provide initial feedback to submitters of proposed models,  
13 which was granted to us by the Bipartisan Budget Act of  
14 2018. Initial feedback, when provided, is given by the  
15 PRTs and is at the discretion of the PRT reviewing  
16 proposal.

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

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

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

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

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

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

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

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



1 of the Secretary's 10 criteria.

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

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

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

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

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

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

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

13   \*           **Committee Member Disclosures**

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

18           Bruce.

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

23           DR. CASALE: Paul Casale, cardiologist and

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

3 I have no disclosures.

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

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

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

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

23 I have no conflicts to disclose.

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

7 I have no conflicts with this proposal.

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

11 I have no disclosures.

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

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

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

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

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

3 CHAIR BAILET: Thank you, everyone.

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

7 Thank you.

8 [Pause.]

9 CHAIR BAILET: Good morning. Good morning,  
10 everyone.

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

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

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

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

6           [Applause.]

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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



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

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

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

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

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

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

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

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

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

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

1 addition to his hat as the head of CMMI.

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

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

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

23           A number of the models that have been advanced by

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

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

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

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

19 CHAIR BAILET: Thank you, Mr. Secretary.

20 [Applause.]

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

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

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

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

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

12 [Applause.]

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

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

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

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

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

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

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

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

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

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

1 as well.

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

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

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

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



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

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

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

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

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

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

7 So thank you for your work.

8 CHAIR BAILET: Thank you, Administrator Verma.

9 [Applause.]

10 MR. BOEHLER: Everybody is leaving me.

11 [Laughter.]

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

14 MR. BOEHLER: It's good.

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

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

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

1 technology, laboratory management services, and health care  
2 analytics.

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

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

11 [Applause.]

12 MR. BOEHLER: Thank you, Jeff.

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

16 [Laughter.]

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

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

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

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

18 The third P is payment for outcomes. We want to  
19 modernize what are outdated payment rules and pay  
20 for results.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

23 I've been personally impressed with the rigor of

1 the PTAC work and appreciate their recommendations.

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

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

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

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

19 CHAIR BAILET: Thank you, Adam.

20 [Applause.]

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

23 [Recess.]



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

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

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

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

17 \* **PRT Report to the Full PTAC**

18 DR. FERRIS: Jeff, thank you very much.

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

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

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

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

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

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

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

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

5 [Laughter.]

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

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

20 CHAIR BAILET: Sure. Okay.

21 DR. FERRIS: Thank you.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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



1 and most importantly, outcomes.

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

11           So, with that overview of the model, I'm going to  
12 move to the summary of the PRT review. You will see of the  
13 10 criteria, the PRT concluded that it did not meet  
14 criterion on 2 and No. 3 and No. 7, and No. 3 is a high  
15 priority.

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

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

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

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

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

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

1 to get right to the nub of this concern.

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

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

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

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

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

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

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

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

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

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

23           So those were our main issues.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

14 Value over volume, met criterion, unanimous.

15 Flexibility, met criterion, unanimous.

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

17 Ability to evaluate, met criterion, unanimous.

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

23 Patient choice, met criterion, unanimous. I



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

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

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

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

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

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

10 And then health information technology met  
11 criterion.

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

15 Thank you.

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

23 [Laughter.]

1 CHAIR BAILET: That's it, Len?

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

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

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

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

16 CHAIR BAILET: Yeah.

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

23 That could be fixed relatively easily. So I

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

4 That's it.

5 CHAIR BAILET: Thank you, Len.

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

10 Bob and then Kavita.

11 \* **Clarifying Questions from PTAC to PRT**

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

15 [Laughter.]

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

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

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

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

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

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

16           CHAIR BAILET: Kavita.

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

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

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

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

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

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

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

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

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

9 CHAIR BAILET: That was cynical.

10 [Laughter.]

11 CHAIR BAILET: Okay. Bruce.

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

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

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

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

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

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



1 different, depending on how the organization is  
2 constructed.

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

13 Grace and then Paul.

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

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

18 DR. TERRELL: So get them ready, okay?

19 DR. FERRIS: Okay.

20 [Laughter.]

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

23 DR. FERRIS: Yeah.

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

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

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

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

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

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

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

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

22           [Laughter.]

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

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

10 DR. TERRELL: For the better.

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

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

23 DR. TERRELL: As a categorical imperative.

1 DR. FERRIS: As a categorical imperative.

2 CHAIR BAILET: All righty. Paul.

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

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

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

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

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

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

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

8 [No response.]

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

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

15 DR. PILGRIM: Thank you very much.

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

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

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

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

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

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

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

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

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

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

23           The APM that we have, importantly, is designed to



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

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

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

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

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

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

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

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

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

14 Thanks.

15 DR. NEDZA: Thank you, Dr. Pilgrim.

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

23 These include observation stays, which is why we

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

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

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

23           The ED observation stays are a very small

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

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

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

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

1 included.

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

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

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

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

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

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

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

23 That said, the development of the safe discharge

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

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

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

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

22           Dr. Pilgrim.

23           DR. PILGRIM: As we conclude our remarks here and

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

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

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

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

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



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

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

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

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

21           Thank you.

22           CHAIR BAILET: Thank you.

23           Now we'll open it up to the Committee.

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

4 CHAIR BAILET: Yeah, yeah. Sure. Please.

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

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

9 DR. BETTINGER: Thanks, Randy.

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

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

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

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

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

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

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

1 reconciliation payments possibly without changing their  
2 processes at all.

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

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

12 I personally have worked in facilities that admit  
13 35 percent of all of the patients, and I've worked in  
14 facilities that admit 12 percent of all the patients. And  
15 artificially applying a benchmark, even risk-adjusted, I  
16 don't think is consistent with the goals.

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

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

23 CHAIR BAILET: Yeah. Len and Grace.

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

5 DR. PILGRIM: Yes.

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

12 DR. BETTINGER: We are open to that transition.

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

18 CHAIR BAILET: Grace.

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

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

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

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

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

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

21 DR. NEDZA: So thank you.

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

1 variation.

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

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

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

22 DR. BETTINGER: Could I make one comment?

23 CHAIR BAILET: Please.

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

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

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

21 CHAIR BAILET: Thank you.

22 Does the Committee have other questions?

23 Bob.



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

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

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

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

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

1 this, and so we encounter that very issue constantly.

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

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

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

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

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

1 there's a lot of abuse of that.

2 DR. PILGRIM: Absolutely.

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

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

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

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

22 DR. BERENSON: All right.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

20 CHAIR BAILET: Kavita and then Paul.

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

23 For the 20 percent or whatever percent, even if -

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

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

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

23           You mentioned already kind of the surprise of



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

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

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

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

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

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

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

15           CHAIR BAILET: Paul.

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

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

1 doesn't is critical for cost savings.

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

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

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

17           DR. CASALE: What?

18           MR. STEINWALD: Just checking.

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

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

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

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

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

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

19           DR. PILGRIM: Yes is the short answer.

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

1 me to ask that question," so --

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

6 DR. PILGRIM: Good point. Thank you.

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

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

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

19 \* **Comments from the Public**

20 MS. MARKS: Okay. Thank you.

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

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

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

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

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

23           Current bundled payment models allow enhanced

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

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

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

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

1 physicians in order for them to reciprocate.

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

8           Thank you.

9           CHAIR BAILET: Thank you, Sandy.

10           The next commenter is Kevin -- is it Biese?

11           MR. BIESE: Biese. Yes, sir.

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

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

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



1 in concert with ACEP.

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

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

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

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

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

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

1 CHAIR BAILET: Thank you, Dr. Biese.

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

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

8 Go right ahead.

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

11 CHAIR BAILET: Yes.

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

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

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

1 as well as reduce cost.

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

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

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

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

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

1 Any other comments on the line, operator?

2 OPERATOR: We have no more comments on the line.

3 CHAIR BAILET: Thank you.

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

6 [No response.]

7 \* **Voting**

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

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

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

23 So please go ahead and vote.

1 [Electronic voting.]

2 \* **Criterion 1**

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

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

15 CHAIR BAILET: Thank you, Sarah.

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

21 Please vote.

22 [Electronic voting.]

23 \* **Criterion 2**

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

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

11 CHAIR BAILET: Thank you, Sarah.

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

21 Please vote.

22 [Electronic voting.]

23 \* **Criterion 3**

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

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

12 CHAIR BAILET: Thank you, Sarah.

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

16 Please vote.

17 [Electronic voting.]

18 \* **Criterion 4**

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



1 not applicable.

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

4           CHAIR BAILET: Thank you, Sarah.

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

8           Please vote.

9           [Electronic voting.]

10 **\*           Criterion 5**

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

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

19           CHAIR BAILET: Thank you.

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

23           Please vote.

1 [Electronic voting.]

2 \* **Criterion 6**

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

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

11 CHAIR BAILET: Thank you, Sarah.

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

17 Please vote.

18 [Electronic voting.]

19 \* **Criterion 7**

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

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

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

7 CHAIR BAILET: Thank you, Sarah.

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

11 Please vote.

12 [Electronic voting.]

13 \* **Criterion 8**

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

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

22 CHAIR BAILET: Thank you.

23 Criterion 9, patient safety. Aim to maintain or

1 improve standards of patient safety.

2 Please vote.

3 [Electronic voting.]

4 \* **Criterion 9**

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

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

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

17 Please vote.

18 [Electronic voting.]

19 \* **Criterion 10**

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

1 members vote not applicable.

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

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

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

14           What?

15           [Speaking off microphone.]

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

18           So you can see the numbers behind you.

19           [Laughter.]

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

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

1 [Electronic voting.]

2 \* **Final Vote**

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

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

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

19 [Speaking off microphone.]

20 \* **Instructions on Report to the Secretary**

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

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

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

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

14 CHAIR BAILET: Thanks, Tim.  
15 Grace.

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

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

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

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

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

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

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



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

4 CHAIR BAILET: Thank you, Grace.  
5 Paul.

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

9 And I agree with Tim and Grace's comments.

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

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

21 CHAIR BAILET: Bruce.

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

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

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

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

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

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

1 locations where they appear to be implementing the model  
2 successfully.

3 CHAIR BAILET: Thank you, Bruce.

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

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

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

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

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

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

14           So, again, I applaud you. Thank you.

15           Len.

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

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

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

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

8 CHAIR BAILET: Thank you, Len.

9 Kavita.

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

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

1 this type of model.

2           And then the final thought I would have is to say  
3 that fixing this issue actually starts even prior to the  
4 kind of thought process of whether to admit a patient. It  
5 actually starts with when someone calls or chooses to call  
6 911, triggering an ambulance that comes out, and for  
7 Medicare to pay for that ambulance visit previously that  
8 had to kind of -- there had to be an actual formal ED visit  
9 that followed.

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

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

20           CHAIR BAILET: Thank you, Kavita. Bob?

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

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

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

1 circumstances.

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

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

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



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

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

11 CHAIR BAILET: All right. Rhonda.

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

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

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

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

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

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

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

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

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

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

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

20           But thank you very much for bringing this  
21 forward.

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

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

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

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

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

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

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

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

7 CHAIR BAILET: Harold.

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

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

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

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

16           CHAIR BAILET: Thank you, Harold. Bruce.

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

23           We've complimented these people on the

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

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

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

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



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

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

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

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

23           There also needs to be a discussion about the

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

4           There are some concerns with the 30-day period in  
5 terms of cost of care, but that could be mitigated by the  
6 amount of risk that's taken and the design feature of the  
7 model that allows a historical aspect. There's also a  
8 design feature of the model that allows different features  
9 and different raps towards risk, and multiple levels of  
10 risk could also mitigate the care risk. Part of the  
11 evaluation of the model also could take into account the  
12 30-day period.           Also, we should include language that  
13 this model, there should be special attention to ER  
14 departments that are in small hospitals and attention to  
15 aspects that are of the model that were raised by the PRT,  
16 in terms of benchmarks and other features should be  
17 considered to make sure that we can lift all the boats and  
18 that all types of hospitals will be included, and that it  
19 really lends itself to an opportunity for rural and  
20 frontier ER departments.

21           But I will go back to the transcript as well.

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

1 Any other wrap-up comments? Bruce.

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

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

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

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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.

1 CHAIR BAILET: Yeah.

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

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

6 \* **Committee Member Disclosures**

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

8 CHAIR BAILET: I have nothing to disclose.

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

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

21 CHAIR BAILET: Thank you, Bob.

22 UNIDENTIFIED SPEAKER: You can keep your seat.

23 CHAIR BAILET: All right. Kavita.

1 DR. TERRELL: Kavita Patel, nothing to disclose.

2 DR. NICHOLS: Len Nichols, nothing to disclose.

3 CHAIR BAILET: Bruce.

4 DR. STEINWALD: Bruce Steinwald, nothing to  
5 disclose.

6 DR. CASALE: Paul Casale, nothing to disclose.

7 MR. MILLER: Harold Miller, nothing to disclose.

8 No conflicts.

9 DR. TERRELL: Grace Terrell, nothing to disclose.

10 DR. FERRIS: Tim Ferris, nothing to disclose.

11 CHAIR BAILET: All right. Thank you. Harold.

12 \* **PRT Report to the Full PTAC**

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

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

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

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

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

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



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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

16           There was no explicit description in the proposal  
17 as to what quality measures would be used and exactly what  
18 the performance levels would be, in terms of returning the  
19 15 percent withhold payment. The concept was certainly  
20 articulated, of using it in that fashion, but there were  
21 not specific standards.

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

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

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

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

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

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

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

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

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

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

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



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

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

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

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

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

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

23           We were also concerned that because of the

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

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

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

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

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

23 But suffice it to say that we spent a fair amount

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

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

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

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

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

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

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

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

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

14 CHAIR BAILET: Len.

15 \* **Clarifying Questions from PTAC to PRT**

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

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

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

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

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

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

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

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

19           DR. FERRIS: Great answer.

20           CHAIR BAILET: Grace.

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



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

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

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

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

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

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

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

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

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

1 look like anything else we've ever seen.

2 MR. MILLER: Okay.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

12 MR. MILLER: Well, our suggestion --

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

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

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

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



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

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

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

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

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

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

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

20           UNIDENTIFIED SPEAKER: You're asking the PRT  
21 questions.

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

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

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

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

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

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

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

17 DR. STEINWALD: Am I up?

18 CHAIR BAILET: You are up, sir.

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

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

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

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

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

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

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

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

8 CHAIR BAILET: Len.

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

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

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

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

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

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

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

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

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

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

11 CHAIR BAILET: We can hear you.

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

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

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



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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

7 DR. MEDOWS: [Off microphone.]

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

9 DR. MEDOWS: [Off microphone.]

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

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

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

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

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

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

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

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

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

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

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



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

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

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

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

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

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

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

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

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

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

21           CHAIR BAILET: Thank you for your comments, Jean.

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

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

2 DR. WASSON: Yeah.

3 MR. MILLER: Thanks for coming.

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

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

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

19 DR. NICHOLS: Who is the payer?

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

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

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

3 CHAIR BAILET: Harold.

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

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

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

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

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

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

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

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

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

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

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

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

18 CHAIR BAILET: Rhonda.

19 DR. WASSON: Does that make sense?

20 CHAIR BAILET: Yes. That was helpful.

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



1 capitation program.

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

6 DR. MEDOWS: Okay.

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

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

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

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

19 DR. ANTONUCCI: Right.

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

23 DR. WASSON: Can I answer this, Jean?

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

2 DR. WASSON: The bottom line is we addressed this

3 after we published this thing called the "What Matters

4 Index." It's showed that asking just five questions of

5 patients can risk adjust, or give you a risk profile

6 prediction model as good as any of the stuff we're spending

7 tons of money on. So what we've done on "How's Your

8 Health" is have what we call the quick-check now up front,

9 that a smartphone, and particularly from Medicaid sites, so

10 that a patient doesn't need to complete all of "How's Your

11 Health." They could, for purposes of reimbursement of the

12 practice, filling out the registry and risk adjust and be,

13 if you will, just asked to do the very short survey up

14 front, which has a max of seven questions. So that would

15 get you what you needed in terms of making sure gaming

16 didn't happen, and also enable the practice to keep track,

17 from a risk perception. If you look at "How's Your Health"

18 you can see how that works. Basically, the more problems

19 of those seven you identify up front, the more it

20 encourages the patient go to deeper. But, you know, for a

21 healthy 35-year-old, they're going to say, "No, I don't

22 want to do, you know, 60 or 50" or whatever the number of

23 questions that would pop up. But if they did 7, they're

1 in.

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

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

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

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

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

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

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

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

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

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

1 addressed.

2 DR. ANTONUCCI: [Off microphone.]

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

10 CHAIR BAILET: Thanks, Rhonda. Len.

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

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

22 DR. NICHOLS: Fifteen.

23 DR. ANTONUCCI: Fifteen.

1 DR. NICHOLS: Okay.

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

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

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

20 CHAIR BAILET: Harold.

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

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

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

8 \* **Comments from the Public**

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

15 OPERATOR: There are no questions at this time.

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

18 \* **Committee Deliberation**

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

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

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

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

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



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

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

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

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

16           CHAIR BAILET: Right.

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

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

1 point? Rhonda and Len, are you -- you're on, so go ahead  
2 then, Len.

3 DR. NICHOLS: I'd like to associate myself with  
4 Harold's remarks. I do think that there's so much  
5 creativity here and yet it's not ready for prime time,  
6 obviously. So when I think about how our recommendations  
7 have been met so far, the best we have gotten, which is  
8 some of what we heard this morning from Adam, well, we like  
9 some of this. We appreciate your hard work and we're going  
10 to incorporate it into, and he explicitly mentioned the  
11 AAFP proposal. I don't know why this isn't a candidate for  
12 at least getting in the mix for these conversations.  
13 Because I'm back to MIPS is not perfect, and meaningful use  
14 is not functional at the small practice level. That's why  
15 MedPAC said what they said, and we all know about EHRs in  
16 the real world is true.

17 So if you've got a way to begin to move down a  
18 different path, admittedly for a subset of the world but a  
19 subset of the world that is truly hemorrhaging people right  
20 now, both patients and providers. So, to me, it ought to  
21 be in the mix, exactly along the lines you just said. It  
22 is worthy of attention to flesh out these details in a beta  
23 testing environment.

1 CHAIR BAILET: Any other comments? Grace, sorry,  
2 and Bruce.

3 DR. TERRELL: So you've mentioned the recent  
4 MedPAC comments on MIPS. American Medical Group  
5 Association, AMGA, of which I'm on the board, so that's the  
6 disclosure, just came out with a recommendation that all  
7 quality should be boiled down to whatever the numbers were,  
8 13 different things that should be what -- I think that was  
9 sort of their alternative to get rid of MIPS. It was like,  
10 just come up with these things, and that's just, that's all  
11 we're going to do. I wasn't part of the group that thought  
12 very deeply about that but was part of the group that  
13 agreed that we would approve that as something to go out  
14 with.

15 Whether you believe that those were the corrects  
16 ones or the right approach or not, it's one more piece of  
17 evidence that what's been out there in the quality world,  
18 people are really starting to question. But there may be  
19 the possibility of having something like that within the  
20 context of the world that is, because most of what our  
21 struggle with this is that it's something entirely  
22 different, that could be -- this could be an additive to  
23 and still be an innovative approach, because of the aspects

1 of it related to simplicity.

2 I mean, the things I loved about this is I'm a  
3 primary care physician and this appealed to me at that  
4 level. I understand all the issues that have been  
5 articulated well. But there could be a solution that's  
6 related to the difference, and the difference as it relates  
7 to a different way of thinking about quality, some  
8 simplicity as it relates to the world that it is, without  
9 basically saying it's an either/or, but there may be  
10 something that's an and.

11 Within that context, I'll go back to the point I  
12 made before Jean spoke, and that we have to think maybe not  
13 so differently about the numbers that we use to vote but  
14 how we communicate what our thought process is, back to the  
15 Secretary. Because I don't think this is going to go away.  
16 I think it's going to get worse, with what we've heard this  
17 morning, from the Secretary, which is they're going to be  
18 sort of still going down their CMMI route, they're going to  
19 really try to pay attention to what we've said. But I  
20 didn't hear they're just going to take what we've got and  
21 just lay it right out, and it's going to be part of what  
22 they do, but I did hear that they find what we do valuable.  
23 So it's going to be mostly important for us to basically

1 say, "We see some real merit in this, okay, and we think it  
2 needs to be thought about and paid attention to."

3 What we're going to have to decide, as a  
4 committee, though, is do we have comfort with this idea of  
5 it's going to get incorporated, you know, in the models,  
6 because in conversations we've had earlier we weren't  
7 terribly comfortable with that.

8 So I think that there are going to be some issues  
9 here for us with the way that we communicate with the  
10 Secretary, that this is going to be a very, very important  
11 proposal to think about. So, anyway.

12 CHAIR BAILET: Bruce.

13 DR. STEINWALD: I wanted to say something I think  
14 similar to -- of course, I'm not sure. We could say  
15 exactly the same thing and it would sound completely  
16 different.

17 DR. TERRELL: It probably would.

18 DR. STEINWALD: Yeah. But it does relate to the  
19 point that Harold raised about how we approach and vote and  
20 ultimately recommend.

21 You know, in your very last sentence in your PRT  
22 report you said that it might be a good idea to incorporate  
23 this, or something like it, into existing primary care

1 models like ACOs and others. And I guess if enough of it  
2 is thought that way, how do we get there through the voting  
3 process, is an important question.

4 CHAIR BAILET: Harold.

5 MR. MILLER: So just to build on all of that, I  
6 guess. So I was raising this before we voted on the  
7 criteria, because we could say some of those things in the  
8 statement about the recommendations but we are supposed to  
9 be evaluating the proposal against the criteria. And at  
10 least I -- and I'll only speak for myself -- originally was  
11 thinking that whenever I said something met the criterion  
12 it was pretty close to being something that turnkey could  
13 be implemented, with the expectation that if we said, "Hey,  
14 meets all the criteria and we recommend implementing it,"  
15 that CMMI would just do it.

16 Well, that ain't going to happen, it appears,  
17 unfortunately. I'm still holding out hope on that. But it  
18 does sound, though, like there is clearly the things that  
19 meet the criteria are ones that will be brought into the  
20 fold for further thought at CMMI.

21 So I guess that's why I raised this, because, to  
22 me, there is now a big difference between saying a proposal  
23 doesn't meet the criterion because it needs some work, or

1 it meets the criterion but needs some work. And so I'm  
2 just saying I think we should all be thinking, whenever we  
3 vote on the criteria, about that distinction, and that  
4 maybe we're not quite prepared yet to figure out exactly  
5 how we would articulate what the dividing line is. But I  
6 know I'm going to be leaning more towards saying something  
7 meets the criterion if I think that it sort of passes that  
8 threshold, than just because it needs a lot of work.

9 CHAIR BAILET: Len.

10 DR. NICHOLS: One last point, and it's pursuant  
11 to Harold. What I would say is we actually -- you're not  
12 going to believe I'm going to say this, Kavita -- we need  
13 one more criterion, and it is creativity. Okay? If we  
14 could give points for creativity, this is really amazing.

15 It's kind of like I remember Bill Clinton being  
16 discovered as never really turning in his exams at Oxford  
17 and never got his degree. So the writer who figured this  
18 out went back to more and more universities and said, "What  
19 was up?" "Oh, he never answered the questions we gave him,  
20 but he was so creative we gave him A's anyway."

21 I mean, this is creative, and we don't have a  
22 criterion for that, and, therefore, it's going to make us  
23 vote. But I like being mindful of that.



1           MR. MILLER: Just a brief add and then we can  
2 move on, but I think your point is well taken, Len. And it  
3 does strike me that there's almost an inverse relationship  
4 between creativity and the scope criterion right now,  
5 because part of what we've been saying all along is, so,  
6 how many people are going to participate in this, and, you  
7 know, how big of an impact is this going to have? The more  
8 creative something is, my guess is just the nature of, you  
9 know, the innovation process is that the smaller the short-  
10 term impact something could potentially have, and the  
11 longer the long-term impact might be.

12           And I do think that I heard what the Secretary  
13 was saying as an interest in more really transformational  
14 kinds of changes. And I heard Adam saying that he wanted  
15 to be thinking about more long-term impacts. So I think  
16 that's another thing that we have to be thinking about is  
17 to what extent something might have bigger long-term  
18 impact, even if in the short run it might only have a  
19 smaller number of potential participants.

20           CHAIR BAILET: So I want to thank the Committee  
21 for this insightful discussion, and Jean, your patience  
22 while we make a little sausage up here. But what I'm  
23 hearing from the Committee are a couple of things. One,

1 we've been fairly rigorous about reviewing models in situ  
2 as they sit and as they've been proposed, although today,  
3 in the previous submitter circumstance, they actually made  
4 some modifications that were material, and we were  
5 accepting of that, and we were able to move forward.

6           We've also been fairly rigorous about saying,  
7 "Look, we try to look at the model holistically. We don't  
8 necessarily agree with having elements of it picked out  
9 that were notable. We're trying to get the model in situ,  
10 the whole model pushed forward." But I'm also hearing a  
11 change today that, in fact, maybe, in certain  
12 circumstances, where there are elements that are so  
13 innovative and so novel, but we could see the potential for  
14 impact, that we want to make sure that those don't get lost  
15 in the overall evaluation process, where we're saying  
16 potentially. We can't recommend it as a model but, my  
17 goodness, there are so many things in here that this  
18 requires further follow-up, and we, as a committee, believe  
19 follow-up is needed, not follow-up to implement but follow-  
20 up to investigate and extract these really key components  
21 of a model, and figure out, can they weave it into a  
22 process that's already in flight, so that this can get out  
23 into the primary care community.

1           And I think that potentially, if we agree, as we  
2 go through our deliberation process, we can incorporate  
3 that in the letter, where we land. Here's where we landed  
4 but here's our overall recommendation, because of this  
5 certain specialness of the components that are included in  
6 this model. I think that's something that we can do today,  
7 depending on, again, how we all vote. But I do think we  
8 have to stay true to the process that we've established,  
9 which is to go through the criteria, which the PRT has  
10 done, and now we, as the Committee, are going to do, and  
11 then I think through the final vote we can have this sort  
12 of cap off this conversation with, well, where do we go  
13 from here, based on where we all landed.

14           Grace, did you have a --

15           So are we, as a committee, are we comfortable at  
16 this point with that sort of framework, to go ahead and  
17 walk through the criteria? Yes? All right.

18       \*           **Voting**

19           CHAIR BAILET: All right. So we're going to  
20 start with Criterion 1, which is scope. Aim to either  
21 directly address an issue in payment policy that broadens  
22 and expands the CMS APM portfolio or include APM entities  
23 whose opportunities to participate in APMs have been

1 limited.

2 [Electronic Voting.]

3 **\* Criterion 1**

4 MS. SELENICH: Okay. So one member voted 6, that  
5 the proposal meets and deserves priority consideration.  
6 One member voted 5, that the proposal meets and deserves  
7 priority consideration. One member voted 4, that the  
8 proposal meets criterion. Four members voted 3, that the  
9 proposal meets the criterion. Two members voted 2, does  
10 not meet criterion. Zero members voted 1, does not meet  
11 criterion; and zero members voted not applicable.

12 A simple majority is needed, and we roll down  
13 until that is met. So the finding of the Committee is that  
14 the proposal meets this criterion.

15 CHAIR BAILET: So let's go to Criterion 2,  
16 quality and -- whoop.

17 DR. FERRIS: I just want to ask. In the past  
18 when there's been a significant distribution, we've -- the  
19 Chair has allowed discussion.

20 CHAIR BAILET: Yes.

21 DR. FERRIS: I can't remember.

22 I did see a significant distribution there, and I  
23 wondered if we should have a discussion.

1           CHAIR BAILET: I think we should have a  
2 discussion and then potentially, depending on how we feel,  
3 we could revote on this criterion. That's the second  
4 widest. I think we've had one other circumstance where  
5 we've had a spread that wide.

6           So, Tim, did you want to --

7           DR. FERRIS: I'll launch?

8           CHAIR BAILET: Yeah.

9           DR. FERRIS: Yeah.

10           I took in all the comments. I think my approach  
11 to this was that I was not going to change the frame in  
12 which I voted and have voted in the past about criteria,  
13 but that in the written portion of the -- of our  
14 communication, we would express all the things that --

15           CHAIR BAILET: Yeah.

16           DR. FERRIS: -- we had expressed.

17           But I'm -- maybe it's my own feelings about  
18 process, but in-flight changes to an established process, I  
19 find problematic because we have not thought through the  
20 implications of those in-flight process changes, so that  
21 was just the way I voted.

22           CHAIR BAILET: Len.

23           DR. NICHOLS: So I appreciate the integrity of

1 your processes internal, but I would say in this case, I do  
2 believe it's worth deviating because the creativity  
3 dimension, which is not reflected in our 10 criteria, is so  
4 great here.

5           So I take your point, and it's the way we ought  
6 to behave and the way I hope to behave the rest of my life.  
7 But today, for this vote, I'm going to give them the  
8 benefit of the doubt because I think if we don't, they  
9 won't -- no matter what we write, Tim, the letter will be  
10 perceived differently. Maybe it's not going to matter, but  
11 at least it will come with a positive vote.

12           DR. FERRIS: I actually -- having been a  
13 recipient of this kind of information, both qualitative and  
14 quantitative, I pay much more attention to the qualitative  
15 than the quantitative. I don't personally look at the  
16 votes.

17           DR. NICHOLS: Yes, but if you were there, we'd  
18 already be in a different place. And you're not, so --

19           CHAIR BAILET: Okay. Grace and then Harold.

20           DR. TERRELL: I was the 6 on this, but I'll say  
21 that, even though we don't have to.

22           The reason is if you actually take that sentence  
23 up there outside of everything else, there is a specific

1 real issue in primary care for which I believe there has to  
2 be some solutions that come out of the world to fix. And  
3 so this doesn't say anything about whether it meets the  
4 other nine criteria. It just says that it's an aim to  
5 directly address a really important issue and to broaden  
6 the approaches to it, which kind of gets to the criteria.

7 I have noticed in some other proposals that we've  
8 seen -- and so this is just an observation -- that I have  
9 seen some other rankings where No. 1 has been voted on as  
10 meets or meets with high priority, and then there's been --  
11 by PRTs and/or PTAC at the PTAC level, and then underneath,  
12 after that, we don't -- it never reaches that. There will  
13 be some noes, or there will be some low scores.

14 So that tells me something that we need to be  
15 thinking about, and that is, this is really what I believe  
16 Congress had in mind, which was to have thoughtful people  
17 who are out there doing it think about really important  
18 issues and try to come up with ways of addressing it. And  
19 they're not all going to be perfect. In fact, many of  
20 them, most of them, if not all of them, are not going to be  
21 perfect.

22 But I think that we should be paying attention to  
23 our own patterns of voting when we see this, which we've

1 seen a lot, which is that we see that this has been  
2 identified appropriately as a really important scope  
3 priority issue for which we later on start seeing, "Okay.  
4 But it doesn't do this. It doesn't do this. It doesn't do  
5 this." This says something that we need to be paying  
6 attention to.

7 CHAIR BAILET: Harold.

8 MR. MILLER: Jeff, you're losing your voice.

9 CHAIR BAILET: I know. You guys are poking me  
10 today.

11 MR. MILLER: Well, first of all, if you voted 6  
12 on that, I voted 6, and so there's something wrong with our  
13 voting system.

14 DR. TERRELL: Oh.

15 CHAIR BAILET: Wait. Is that true?

16 MR. MILLER: Well, I pushed this little 6 button  
17 here over on the far right. So any --

18 CHAIR BAILET: Then we need to revote.

19 DR. TERRELL: Yeah.

20 MR. MILLER: Well, we may need to, but the  
21 Russians may be involved here. Jean may have a -- because  
22 I've heard the Russians tried to get in through Maine.

23 CHAIR BAILET: All right. Let's stay on the



1 reservation.

2 MR. MILLER: Wait, wait, wait.

3 So, second of all, I would just say, at least my  
4 reason for voting for that was because I think this does  
5 broaden and expand the CMS APM portfolio in fairly  
6 significant ways by doing things very differently, and I'm  
7 more convinced, having heard the presentation, that it  
8 would include entities whose opportunities to participate  
9 have been limited.

10 Finally, to Tim's point, I in general support  
11 that point. I don't think we should be doing stuff on the  
12 fly. However, we got some significant new information this  
13 morning as to what the official in-public position is of  
14 the Department of Health and Human Services and CMI as to  
15 how it's going to approach our recommendations, and so I  
16 think it would be problematic for the applicants that we  
17 are voting on today not to try to take that into  
18 consideration.

19 Yes, I think we probably should be going back and  
20 rethinking our categories, and I think it's going to be  
21 problematic when we get to the recommendation categories  
22 because those recommendation categories no longer make any  
23 sense. But I do think that we should try as best as we

1 can, personal opinion, today to make sure that how we are  
2 voting is consistent with the direction that we've heard.

3 CHAIR BAILET: I agree.

4 So, Harold, because you raise the issue, I think  
5 we just should go through the process of revoting to make  
6 sure we captured the intent, if both you and Grace voted  
7 and it's not reflected here. Let's just go ahead, please,  
8 if we could, and revote on Criterion 1.

9 DR. PATEL: Just revote?

10 CHAIR BAILET: Yeah, just revote.

11 [Electronic Voting.]

12 \* **Criterion 1**

13 MS. SELENICH: Okay. So two members voted 6,  
14 meets and deserves priority consideration. One member  
15 voted 5, meets and deserves priority consideration. Zero  
16 members voted 4, meets. Five members voted 3, meets. One  
17 member voted 2, does not meet. Zero members voted 1, does  
18 not meet. Zero members voted not applicable.

19 Therefore, the finding of the Committee is that  
20 the proposal meets Criterion 1, scope.

21 CHAIR BAILET: All right. So let's go ahead, and  
22 could we move on to the second criterion? I think we  
23 should.

1           Second criterion is quality and cost, high  
2 priority. Anticipated to improve health care quality at no  
3 additional cost, maintain health care quality while  
4 decreasing cost, or both improve health care quality and  
5 decrease cost.

6           Please vote.

7           [Electronic Voting.]

8   \*       **Criterion 2**

9           MS. SELENICH: Zero members voted 5 to 6, meets  
10 and deserves priority consideration. Zero members voted 4,  
11 meets. Three members voted 3, meets. Five members voted  
12 2, does not meet. One member voted 1, does not meet. Zero  
13 members voted not applicable.

14           Therefore, the finding of the Committee is that  
15 the proposal does not meet Criterion 2, quality and cost.

16           CHAIR BAILET: Thank you, Sarah.

17           Criterion 3, payment methodology. Pay the APM  
18 entities with a payment methodology designed to achieve the  
19 goals of the PFPM criteria. Addresses in detail through  
20 this methodology how Medicare and other payers, if  
21 applicable, pay APM entities, how the payment methodology  
22 differs from current payment methodologies, and why the  
23 physician-focused payment model cannot be tested under

1 current payment methodologies. High priority.

2 Please vote.

3 [Electronic Voting.]

4 \* **Criterion 3**

5 MS. SELENICH: So zero members voted 6, meets and  
6 deserves priority consideration. One member voted 5, meets  
7 and deserves priority consideration. Zero members voted 4,  
8 meets. Two members voted 3, meets. Six members voted 2,  
9 does not meet. Zero members voted 1, does not meet; and  
10 zero members voted not applicable.

11 Therefore, the finding of the Committee is that  
12 the proposal does not meet Criterion 3, payment  
13 methodology.

14 CHAIR BAILET: Thank you, Sarah.

15 Criterion 4 is value over volume. Provide  
16 incentives to practitioners to deliver high-quality health  
17 care.

18 Please vote.

19 [Electronic Voting.]

20 \* **Criterion 4**

21 MS. SELENICH: One member voted 6, meets and  
22 deserves priority consideration. Zero members voted 5,  
23 meets and deserves priority consideration. Five members

1 voted 4, meets. Two members voted 3, meets. One member  
2 voted 2, does not meet. Zero members voted 1, does not  
3 meet; and zero members voted not applicable.

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

6 CHAIR BAILET: Thank you, Sarah.

7 Flexibility is the fifth criterion. Provide the  
8 flexibility needed for practitioners to deliver high-  
9 quality health care.

10 Please vote.

11 [Electronic Voting.]

12 \* **Criterion 5**

13 MS. SELENICH: One member voted 6, meets and  
14 deserves priority consideration. One member voted 5, meets  
15 and deserves priority consideration. Four members voted 4,  
16 meets. Two members voted 3, meets. One member voted 2,  
17 does not meet. Zero members voted 1, does not meet; and  
18 zero members voted not applicable.

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

21 CHAIR BAILET: Thank you.

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

1 of the PFPM.

2 Please vote.

3 [Electronic Voting.]

4 \* **Criterion 6**

5 MS. SELENICH: Zero members voted 5 or 6, meets  
6 and deserves priority consideration. Zero members voted 4,  
7 meets. Four members voted 3, meets. Five members voted 2,  
8 does not meet. Zero members voted 1, does not meet; and  
9 zero members voted not applicable.

10 Therefore, the finding of the Committee is that  
11 the proposal does not meet Criterion 6, ability to be  
12 evaluated.

13 MR. MILLER: Can we --

14 CHAIR BAILET: Yeah. My inclination is to at  
15 least have a conversation about this because I'll just --  
16 maybe I'll start the conversation, Harold.

17 I voted did not meet, and the reason, part of it  
18 was in the discussion around the withhold and the lack of  
19 specificity around how to -- you know, what performance  
20 metrics are going to be tracked for that withhold to be  
21 paid. So it was -- it's not that it couldn't include those  
22 kinds of elements. It just didn't, and again, I'm taking  
23 the approach of the Committee in the past that we look at

1 this as it sits. So that's how I voted, and it looks like  
2 Harold and then Len have comments.

3 Harold.

4 MR. MILLER: So I'm voting consistently with how  
5 I did on the PRT, which is that I thought that any very  
6 innovative proposal is going to be challenging to evaluate,  
7 which doesn't mean that it can't be evaluated. It just  
8 means it's going to be more challenging to be evaluated.

9 And we've never really talked about exactly how  
10 to rate this criterion. I mean, I think the issue is could  
11 this be done in the standard simplistic way that one  
12 evaluates things by taking the same numbers that everybody  
13 reports and saying is there a statistically significant  
14 difference based on claims data. The answer is no.

15 Could one go in and find out whether or not people  
16 who are part of these practices feel that they are getting  
17 very different care than people in other practices do?  
18 Yes.

19 Would that be more challenging and expensive to  
20 do? Yes.

21 Does the Innovation Center spend a lot of money  
22 on evaluations? Yes, it does, and I think that it could do  
23 that perfectly well here, which is why I voted that it

1 meets.

2 CHAIR BAILET: Paul.

3 DR. CASALE: Yeah. The way I thought of this,  
4 you know, a lot of times when we're looking at this, we're  
5 often thinking about can we evaluate the cost and payment  
6 reduction part, and to be honest, sometimes we, I think,  
7 give a little shorter trip to the quality side.

8 In this one, I feel like we can track the quality  
9 in a very interesting and innovative way and evaluate that,  
10 and yes, there may be more concerns on the cost side. But  
11 that's where I landed on meets because I thought the  
12 quality side would be -- could be evaluated.

13 CHAIR BAILET: Len and then Tim.

14 DR. NICHOLS: So I -- maybe I take a narrow view  
15 of the word "evaluation," but I think of this almost  
16 completely about can you measure what you care about and  
17 can you find a control group. If you can do those two  
18 things, you can evaluate anything, in my opinion. In my  
19 opinion, the answer is yes in both of these questions.

20 I would take your criticism, Jeff, as criticism  
21 of the payment model, not of the evaluability of the  
22 proposal, and to my mind, no, if you're not using these  
23 tools, you're not going to be completely comparable because



1 you're not going to have that data on other people. It's a  
2 beta test evaluation, but it's an evaluation, I would  
3 submit, a stepped-wedge design where you get a bunch of  
4 practices. They're all ultimately the control group.  
5 They're all ultimately the target group, and you phase them  
6 in over time, and you can construct and evaluate.

7           It's not perfect, but it's been done in  
8 epidemiology since -- I don't know -- penicillin. So I'm  
9 pretty sure it's been around a while.

10           So I think it's a perfectly valid technique, and  
11 it will get you to the point of was there a difference,  
12 given that every one of these practices also has an EHR.  
13 You can do correlates with the usual suspects, and to me,  
14 that's what you want.

15           CHAIR BAILET: Tim.

16           DR. FERRIS: It is interesting how we -- you  
17 know, it's one word, "evaluation," and so many different  
18 people, all of whom do evaluations, can think about that  
19 word so differently.

20           I do interpret the word "evaluation" as in not an  
21 experiment because it is, as so many people have pointed  
22 out here, very easy to design an experiment that evaluates  
23 this, but an experiment means actually constructing a

1 control group and constructing an intervention group. And  
2 it is absolutely possible to do this.

3 But in typical sense, the evaluation in a CMS  
4 payment model involves not the construction of -- the  
5 active enrollment in construction, but actually using  
6 available information that they have at their fingertips.

7 Given the specific nature of the data collection  
8 process in this around quality metric, I don't see how you  
9 could do that without constructing an experiment. That's  
10 not to say an experiment isn't possible and in fact  
11 desirable and would be an evaluation of a beta test,  
12 precisely as you said, Len. That's not how I interpret  
13 this question.

14 DR. TERRELL: This is limited scale testing, not  
15 an experiment?

16 DR. CASALE: What did you say?

17 DR. FERRIS: So, actually, I have been forbidden  
18 to use the term --

19 DR. TERRELL: I just said is a limited scale  
20 testing, which happens to be one of our criteria right now.  
21 It's not an experiment.

22 DR. FERRIS: Yeah.

23 So, actually, I do consider it an experiment, but

1 I think I've been forbidden from using the term "limited  
2 scale testing."

3 DR. TERRELL: Yeah.

4 CHAIR BAILET: Okay. Do we want to revote, or  
5 are we good with -- no. I hear -- like I said, we're going  
6 to go ahead and revote one more time with feeling, please.

7 Criterion 6.

8 [Electronic Voting.]

9 \* **Criterion 6**

10 MS. SELENICH: So zero members voted 5 or 6,  
11 meets and deserves priority consideration. One member  
12 voted 4, meets. Four members voted 3, meets. Four members  
13 voted 2, does not meet. Zero members voted 1, does not  
14 meet. Zero members voted not applicable.

15 Therefore, the finding of the Committee is that  
16 the proposal meets Criterion 6, ability to be evaluated.

17 CHAIR BAILET: You have to love the process,  
18 don't you?

19 [Laughter.]

20 CHAIR BAILET: Very good. All right. Very good.  
21 Moving right along.

22 Criterion 7, integration and care coordination.

23 Encourage greater integration and care coordination among

1 practitioners and across settings where multiple  
2 practitioners or settings are relevant to delivering care  
3 to the population treated under the PFPM.

4 Please vote.

5 [Electronic Voting.]

6 \* **Criterion 7**

7 MS. SELENICH: So zero members voted 5 or 6,  
8 meets and deserves priority consideration. Zero members  
9 voted 4, meets. Three members voted 3, meets. Six members  
10 voted 2, does not meet. Zero members voted 1, does not  
11 meet. Zero members voted not applicable.

12 Therefore, the finding of the Committee is that  
13 the proposal does not meet Criterion 7, integration and  
14 care coordination.

15 MR. MILLER: I'm just curious. Have we ever  
16 actually found any proposal that we thought met this  
17 criterion? Maybe --

18 DR. TERRELL: Yes.

19 DR. CASALE: Oh, yeah.

20 CHAIR BAILET: Thanks for asking, Harold.

21 Okay. Very good. Criterion 8, patient choice.  
22 Encourage greater attention to the health of the population  
23 served while also supporting the unique needs and

1 preferences of individual patients.

2 [Electronic Voting.]

3 **\* Criterion 8**

4 MS. SELENICH: Zero members voted 6, meets and  
5 deserves priority consideration. One member voted 5, meets  
6 and deserves priority consideration. Zero members voted 4,  
7 meets. Six members voted 3, meets. Two members voted 2,  
8 does not meet. Zero members voted 1, does not meet; and  
9 zero members voted not applicable.

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

12 CHAIR BAILET: Thanks, Sarah.

13 Criterion 9, patient safety. Aim to maintain or  
14 improve standards of patient safety.

15 Please vote.

16 [Electronic Voting.]

17 **\* Criterion 9**

18 MS. SELENICH: One member voted 6, meets and  
19 deserves priority consideration. Zero members voted 5,  
20 meets and deserves priority consideration. Zero members  
21 voted 4, meets. Two members voted 3, meets. Six members  
22 voted 2, does not meet. Zero members voted 1, does not  
23 meet; and zero members voted not applicable.

1           Therefore, the finding of the Committee is that  
2 the proposal does not meet Criterion 9, patient safety.

3           CHAIR BAILET: Last criterion, 10, health  
4 information technology. Encourage the use of health  
5 information technology to inform care.

6           Please vote.

7           [Electronic Voting.]

8   \*       **Criterion 10**

9           MS. SELENICH: Zero members voted 6, meets and  
10 deserves priority consideration. One member voted 5, meets  
11 and deserves priority consideration. One member voted 4,  
12 meets. Seven members voted 3, meets. Zero members voted 1  
13 or 2, does not meet; and zero members voted not applicable.

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

17           CHAIR BAILET: Grace.

18           DR. TERRELL: I just want to go back to Criterion  
19 9, since I was the outlier on 6, to give my rationale for  
20 why I thought it was a high criteria for patient safety.

21           My thought process, which apparently none of the  
22 rest of you had -- so that's good, but it might be useful -  
23 - is that patient-reported outcomes to my way of thinking

1 is probably the greatest and best potential there is out  
2 there for patient safety that we know, but it's very, very  
3 rarely integrated in a meaningful way into the thought  
4 process around patient safety.

5 I actually went through during the deliberations  
6 and did that How's My Health criteria, and it really is  
7 putting some real high-quality patient in control way of  
8 actually thinking about your health.

9 To my mind, that's not typically -- patient-  
10 reported outcomes is not typically tied nearly as much as  
11 it should be to the patient safety aspect of the criteria  
12 that we do.

13 So I get where everybody else was because it was  
14 -- you know, there was issues that were brought up, but I  
15 do think that that's something that we might ought to be  
16 thinking about in the future if we get other patient-  
17 reported outcomes as another creative methodology as to  
18 whether that ought to be thought about within the context  
19 of patient safety, which I don't think it typically is.

20 CHAIR BAILET: Thank you, Grace.

21 So we are at the point where we could have more  
22 dialogue or we could then come through -- we can begin the  
23 process of actually voting on the recommendation, and I

1 guess I'll throw out there I feel like we should move  
2 forward with that process.

3 And if you could flash the -- yeah, I'm going to  
4 try and get this right this time.

5 MR. MILLER: Jeff, can I --

6 CHAIR BAILET: Yeah.

7 MR. MILLER: I hate to disagree with you on that,  
8 but I think we ought to talk about what we mean by No. 2  
9 and whether we're using No. 2 before we vote because it  
10 seemed to me pretty clear last time, people were  
11 interpreting that differently, and I'm not sure how we  
12 should interpret that.

13 So we could vote and then talk about it and then  
14 revote again.

15 CHAIR BAILET: Yeah.

16 MR. MILLER: But I just wondered whether that  
17 might --

18 CHAIR BAILET: Well, and that's a -- Harold, I  
19 know this is going to surprise you, but that's exactly what  
20 I was about to say --

21 MR. MILLER: It doesn't surprise me, Jeff.

22 CHAIR BAILET: -- Harold.

23 So let me define -- let me flash back to the



1 Committee our definition of what 2 meant when we created  
2 this voting. A vote of 2 means recommend proposed payment  
3 model to the Secretary for limited scale testing of the  
4 proposed payment model. This category may be used when  
5 PTAC determines a proposal meets all or most of the  
6 Secretary's criteria, but lacks sufficient data, one, to  
7 estimate potential cost savings and/or impacts of the  
8 payment model and/or, two, specify key parameters in the  
9 payment model, such as risk adjustment or stratification,  
10 and PTAC believes the only effective way to obtain those  
11 data would be through implementation of the payment model  
12 in a limited number of settings. So that was our agreed  
13 collective consciousness on how we attributed a limited  
14 scale on No. 2 when we established this criterion.

15 Len.

16 DR. NICHOLS: Thank you for reminding us of how  
17 well we articulated that, but I will remind all of us, they  
18 don't care. And what they heard in limited scale testing  
19 was lower priority, too much work.

20 So I just think it's a kiss of death. To me, you  
21 either say implementation and write the letter very nicely,  
22 or you say don't do it and write the letter very nicely.  
23 Either way, you write the letter very nicely, appropriately

1 nuanced, but I think 2 is the kiss of death because they've  
2 said it's been used, an excuse to say no, and we've --  
3 they've already done it. So it's crazy to send it forward  
4 with that label.

5 CHAIR BAILET: So Harold, Bruce, Paul, and then  
6 Tim.

7 MR. MILLER: So I think, again -- this, I think  
8 will be -- we'll have to articulate after we decide how we  
9 voted. We'll have to articulate what the recommendation  
10 statement is, but I think we should -- the confusion I  
11 believe was that limited scale was also believed to somehow  
12 be limited impact, and so it seems to me that if we agree  
13 that we should not vote for something in No. 2, if we think  
14 it will only ever have limited impact, then that -- and we  
15 clarified that in the recommendations, that might be okay  
16 because my concern would be if we said, "Hey, we think this  
17 is ready to go for implementation." That would be wrong.  
18 I don't think we should say we're not voting for No. 2 at  
19 all and give ourselves only the choice of not recommending  
20 or recommending for implementation, but it does seem to me  
21 at this point that we have to be clear about what we mean  
22 by No. 2 and maybe add some additional phrases to that that  
23 said that we recommended that because of the reasons that

1 Jeff said and that we believe that it would have  
2 significant impact, et cetera, et cetera, et cetera.

3 CHAIR BAILET: Okay. Bruce and then Paul.

4 MR. STEINWALD: Well, if 2 is the kiss of death,  
5 I guess 1 is a real smooth, right?

6 [Laughter.]

7 MR. STEINWALD: All right. So I guess I'm trying  
8 to figure out where to fit my own opinion, and I like what  
9 you said at the end of your PRT report, that this would be  
10 a suitable model for implementation within an existing  
11 structure, not standalone.

12 And if we don't want any kisses or smooches, then  
13 that leads to 3, but we just have to explain what we mean  
14 by 3. It's not standalone, but it's what we say it is.

15 DR. NICHOLS: Bruce, can I ask what possible  
16 existing framework could you work this into? Another trace  
17 of CPC+?

18 MR. STEINWALD: Well, simplistically --

19 DR. NICHOLS: I would do that, but would you?

20 MR. STEINWALD: Well, I would find a collection  
21 of ACOs that were big enough and willing enough to  
22 incorporate something like this within their own framework.

23 DR. NICHOLS: [Speaking off microphone.]

1 MR. STEINWALD: Well, I know, but, I mean, that's  
2 -- what did they say here? That's what they said, and  
3 either that or some other structure that works even better.

4 CHAIR BAILET: Okay. Paul.

5 DR. CASALE: Just a couple comments, and, Len, I  
6 acknowledge what you just said, but I have to respectfully  
7 disagree around like you can't consider the limited -- I  
8 mean, there's been a lot of water under the bridge since  
9 we've developed all of that. I think we're in a -- I think  
10 in a different place, and hopefully, you know, the  
11 administration is as well.

12 And then I worry that if -- you know, as I'm  
13 thinking to go to 3, I feel like it's -- there's been other  
14 models that have been clearly 3's, and now they're sort of  
15 -- we're just putting all of these in the bucket in order  
16 for them to pay attention.

17 So I guess I'm not so challenged by this, the  
18 limited testing or concern that that necessarily means it's  
19 the kiss of death.

20 CHAIR BAILET: So we have Rhonda. Please.

21 DR. MEDOWS: So, Mr. Chairman, you can tell me if  
22 this is an inappropriate question, but we had another  
23 candidate come in and make a proposal. And the proposal

1 had some components of it that we thought were actually  
2 kind of smart, kind of cool, and a little bit new, but  
3 their proposal was not completely developed. And we saw  
4 the train coming. We knew this was coming, and we gave the  
5 candidate the opportunity to make a decision about whether  
6 or not they wanted us to complete this vote or not.

7           Are we past that point, and do we want to at  
8 least give the applicant a chance to decide if she wants us  
9 to do that?

10           Let me just finish.

11           My rationale for even bringing it up is that we  
12 are all g patient-reported outcomes, that piece of it,  
13 actually looking at quality a different way, in a way that  
14 matters to patients. My concern is that we don't want that  
15 to be harmed or tainted.

16           There are other pieces of it that I'm hearing  
17 from the conversation that need more development. Maybe  
18 I'm wrong; maybe I'm right. Usually, I'm right, but we'll  
19 go with that.

20           I'm just saying let's be considerate. You should  
21 have the opportunity to decide if you want us to complete  
22 this process or whether or not you want to take what we've  
23 already said and come back another day.

1           Just to be fair, we offered it to someone else.

2           CHAIR BAILET: So that's great, Rhonda, and I  
3 thank you for raising that. I don't think we're past the  
4 opportunity to pose that question, if that's what we'd like  
5 to do.

6           I'd like to hear from Harold and Len and then  
7 turn it -- yeah, absolutely, then turn it to the proposer.

8           Please, Harold.

9           MR. MILLER: So I would certainly support  
10 Rhonda's suggestion if -- I mean, I think we could  
11 certainly offer.

12           I guess I would say, though, there is nothing  
13 that prevents an applicant who we don't recommend their  
14 proposal from bringing back a new proposal and having us  
15 consider it later.

16           My concern in this particular case is that I  
17 think that it is not reasonable to expect the applicant to  
18 fix the things that we are concerned about without  
19 substantial technical assistance, which we are not able to  
20 provide, and the only reasonable way to do that is through  
21 CMMI.

22           And so I think that, in my personal opinion, if  
23 one believes that something like -- primary care needs to

1 be fixed. I think primary care needs to be fixed, and it  
2 needs to be fixed soon. And I don't think that it fixes  
3 primary care soon to ask one solo primary care doctor to go  
4 off and see if she can come up with a better proposal. So  
5 I think that's the issue.

6 I do think we should give her the choice, but my  
7 personal feeling is that this needs to get to CMS, and CMS  
8 needs to start doing something with it ASAP.

9 DR. NICHOLS: So thank you for raising this,  
10 Rhonda, because I had the exact same thought about 45  
11 minutes ago, and then I thought exactly what Harold said.

12 Jean can't do this. I'm all for letting --  
13 giving her the choice, but I don't think she can fix what  
14 we know CMMI is going to demand.

15 So the only way to make this work is to command  
16 CMS resources, and that's the way it should work because  
17 this is so creative. We should try to make this work in a  
18 beta testing way a couple years down the road.

19 CHAIR BAILET: Grace.

20 DR. TERRELL: I missed part of the conversation  
21 for biological reasons.

22 But now that I'm back, part of what --

23 MR. MILLER: You were out consulting with your

1 philosophers, weren't you?

2 DR. TERRELL: That's right. We're going from  
3 philosophy to biology.

4 But now that I'm back, Len, what you were talking  
5 about at the time was limited scale testing and the fact  
6 that they told us we're not going to go down that route,  
7 and we've all had all that.

8 I think that that needs to be tied back to a  
9 point you've made for as long as you've been on this  
10 Committee about the resources that are out there with  
11 respect to, in this case, a small solo provider in a rural  
12 setting versus other levels of resources.

13 And one of the things that we may want to make  
14 clear to the Secretary in the letter is if we go down the  
15 route of limited scale testing, my personal bias is I don't  
16 care what they say about it, if that's what I think it  
17 needs. I like the definition that's out there. I'm going  
18 to vote in that direction.

19 We may need to make the argument, since there has  
20 been a focus from this administration on the desire to do  
21 something, for limited, rural, small providers, that if  
22 you're going to actually say that and you're actually going  
23 to ask their opinion and they actually give it to you, then



1 you actually ought to probably do some limited scale  
2 testing, dudettes.

3           So it's something that within the context of  
4 where your head was going earlier, which was despair. I  
5 just want you to get out of it and go back to who you  
6 usually are, which is to rail, rail against the night, and  
7 to really go with where this relates to technical  
8 assistance and all of that because I do think that those  
9 issues are related, which is part of the criteria this  
10 administration has versus what its actual at least verbally  
11 stated goals are with respect to that.

12           MR. MILLER: And I believe that Grace was just  
13 trying to get points on her depression screening measure  
14 for having counseled you on that.

15           CHAIR BAILET: All right.

16           DR. NICHOLS: So I'll just say I'm glad biology  
17 let you come back just in time.

18           CHAIR BAILET: Okay.

19           DR. NICHOLS: But I would also say --

20           CHAIR BAILET: Go ahead. I'm sorry, Len.

21           DR. NICHOLS: I agree it's more intellectually  
22 honest to say limited scale testing. I just remember being  
23 given quite some length of time saying we'll never do that.

1 So I'm happy to vote for that over nothing.

2 I do think if we vote don't recommend, it won't  
3 be seriously read, so we've got to do something on this  
4 side of the table, and so --

5 CHAIR BAILET: So my personal opinion -- and  
6 maybe with a modicum, a dash of chairmanship thrown in -- I  
7 think we should vote. I think we should remain consistent  
8 with our process to date. I think we have lots of degrees  
9 of freedom to put information in the letter about how we  
10 feel collectively about the model relative to how we land  
11 on the vote, which is not determined yet, and then use  
12 that letter and the relationships that we're building with  
13 the administration to make sure that several things are  
14 heard, which we have CMMI leadership in the room. They're  
15 here in the room, staff.

16 This is an issue that's not new. We talked about  
17 it two meetings ago about primary care challenges and how  
18 every day primary care, the programs get washed away, and  
19 physicians leave and abandon the practice, and they can't  
20 get new people to fill these positions, particularly in  
21 stressed, smaller communities.

22 So we can incorporate all of that in the letter.  
23 So I guess I would -- Len, my point of view is potentially

1 different than yours relative to a does not recommend does  
2 not mean that it goes in -- I think we still have degrees  
3 of freedom -- what we put in the letter, if that's where we  
4 land, on what our overarching recommendation is, what we  
5 should do with this model, and the components therein. So  
6 I think we have that opportunity.

7 I welcome other comments before we vote, and I  
8 guess even before that, just to be respectful of our former  
9 process that was offered other candidates, I guess, Jean,  
10 to you specifically, if you are sitting here and thinking  
11 that you would prefer us not to move forward, this would be  
12 a good time to share that with us.

13 DR. ANTONUCCI: I think that I would ask you to  
14 move forward. Someone said correctly that I don't have the  
15 resources to solve the questions that you asked of me.

16 CHAIR BAILET: Right.

17 DR. ANTONUCCI: This is a great discussion. You  
18 guys are great.

19 CHAIR BAILET: Thank you.

20 So I think we're ready to vote. What we're going  
21 to do is we're going to vote electronically first, and then  
22 we're going to go around the room -- and I'm going to start  
23 with Rhonda -- and talk about how we voted and move

1 forward.

2 [Electronic Voting.]

3 \* **Final Vote**

4 MS. SELENICH: Zero members voted for recommend  
5 proposed model to the Secretary for implementation as a  
6 high priority. One member voted 3, recommend proposed  
7 payment model for implementation. Six members voted 2,  
8 recommend proposed payment model to the Secretary for  
9 limited scale testing. Two members voted 1, do not  
10 recommend proposed payment model; and zero members voted  
11 not applicable.

12 A two-thirds majority is needed. That rolls down  
13 to 2. So the finding of the Committee is to recommend the  
14 proposed payment model to the Secretary for limited scale  
15 testing.

16 \* **Instructions on Report to the Secretary**

17 DR. MEDOWS: So I voted 1, do not recommend  
18 proposed payment model to the Secretary, and I did so  
19 because I thought that the proposal was incomplete in  
20 significant areas, both in terms of quality and cost as  
21 well as the payment model itself.

22 I do recommend that in the letter to the  
23 Secretary that the comment include an emphasis on the

1 importance we felt that the patient-reported outcomes be  
2 incorporated and as a possible alternative way to do risk  
3 assessment, ID, and stratifications that need more -- have  
4 more complex care needs.

5           And I also thought that we needed to talk more  
6 earnestly about our approach to how we are making these  
7 recommendations to the Secretary.

8           And if I could be quite frank, my concern is that  
9 if we voted for it to be recommended, knowing that there  
10 were some holes in it, that it would not serve the  
11 candidate or PTAC or the public well, simply to try to do  
12 something that we think would try to push CMS to look at  
13 something. Quite frankly, I just don't honestly believe  
14 that that is the case. I think it would be better to  
15 actually speak to the parts that we believe are strong or  
16 promising or innovative and that there are things that  
17 actually involve in better patient care.

18           I think what's missing are the pieces where we  
19 had -- we did not have information about which quality  
20 benchmarks could actually be used to resolve the withholds.  
21 The capitation payments itself and the risk adjustment  
22 needed further work. I know we talked about people being  
23 concerned about clinicians gaming a cap payment, but we

1 also have to think about it on the reverse way as well. If  
2 the cap payments are meant to try to help recoup some of  
3 the losses from lower reimbursement for more complex  
4 patients, if those more complex patients do not complete  
5 this survey, they will be -- I am assuming default to the  
6 lower cap payment, and they still -- a primary care  
7 physician would still not reap the reimbursement, the pay  
8 that is needed to cover that care.

9 I think it needs to be completed, and I think it  
10 needs to be more thought out. And that's my humble  
11 opinion. Sorry to disappoint you all.

12 CHAIR BAILET: Thank you, Rhonda.

13 DR. PATEL: I voted No. 2, and that was mainly --  
14 I'll credit Grace persuaded me that it's completely  
15 accurate that I would not have voted No. 2 because I didn't  
16 think limited scale is something that would be kind of  
17 taken in by the administration, but I feel like there's no  
18 other category that reflects that there are indeed pretty  
19 significant flaws, which I think could be overcome with  
20 more work. That work should not be put on the backs of the  
21 submitter by him- or herself or even if it was a large  
22 organization. I think this is something that should be  
23 done because it's a priority, particularly in primary care,

1 by the administration.

2           So I would just ask that in the -- I think others  
3 have said this, but some reflection in our comments to the  
4 Secretary around any association with limited scale to not  
5 be actually subject to the definition that you had read, so  
6 that they know that it's something different. So that  
7 hopefully will get captured.

8           DR. NICHOLS: So I voted 2 because I was shamed  
9 into intellectual honesty by my colleagues. I was trying  
10 to game the system and get a 3 up there to push us over the  
11 edge because I just fear if you don't give them a good,  
12 strong push, it won't go very far.

13           I agree with Rhonda. It's incomplete, but I am  
14 pretty sure -- and I think Jean just confirmed -- she can't  
15 fix this. We need professional help to do that.

16           What I am struck by, A, is the incredible  
17 creativity of this proposal and how consistent and, indeed,  
18 up to until this moment, maybe uniquely consistent with  
19 what Adam laid out this morning. We all remember the four  
20 P's, but he also said what works -- transparent, simple  
21 accountability. This is that, and what I really love is  
22 simple because I'm a simple guy, but also, that's what  
23 primary care needs and what we actually ought to be

1 focusing on.

2           And so I think appropriately defined, redefined,  
3 clarified limited scale testing really means, in my mind,  
4 in addition to the words you said, use CMS resources to  
5 develop the pieces of this that need work and then do the  
6 beta test.

7           CHAIR BAILET: So I voted 1, not to recommend,  
8 and I don't know. I'm worried about your telepathic  
9 skills, Rhonda, because a lot of the challenges you had  
10 with this, I have as well. So I don't necessarily want to  
11 repeat them, but I do think -- I think this is a watershed  
12 moment for the PTAC and the CMS leadership who were here  
13 with us today. I think there's an opportunity for us to  
14 navigate what we're experiencing because to some degree  
15 we're using the lens of the past, and I'm not saying that  
16 we have any tangible reason to -- demonstrable reason  
17 that's concrete to make us change, but I think the frame  
18 has changed.

19           I think that there's receptivity on the other end  
20 to work more closely with us, and I think that this model  
21 needs refinement. I think that this model -- even just the  
22 withhold, I mean, working with physicians, when you  
23 withhold payment and you can't tell them what's the



1 mechanism for them to earn that back, that is a significant  
2 challenge. So I think the model needs work.

3 I think that CMS is interested in building  
4 primary care based on their comments that they've shared  
5 with us, coming forward with a model. I think this gets to  
6 a particular niche for primary care, which is what happens  
7 to practices that are in smaller communities with less  
8 infrastructure. I think this model has a lot of unique  
9 elements that will fill that gap and inspire and  
10 incorporate and support those physicians who practice in  
11 those environments.

12 But I don't think it's ready to recommend, but I  
13 hope -- I know we will capture the strengths of this model  
14 in our letter to the Secretary.

15 Bruce.

16 MR. STEINWALD: Okay. I was the 3.

17 [Laughter.]

18 MR. MILLER: That was really a smooch, Bruce, I  
19 tell you.

20 MR. STEINWALD: It's already been defined as  
21 intellectual dishonesty, so I might as well own up.

22 [Laughter.]

23 MR. STEINWALD: I'm not sure I believe any

1 differently that those that voted 2.

2           But, you know, it's not just because we've gotten  
3 this negative feedback on anything that we've recommended  
4 for limited scale testing in the past. It's also because  
5 of the feedback that we've gotten tends to have accentuated  
6 the negative. We write a report. We identify a number of  
7 positive things, a number of negative things, and what we  
8 get back in the letter -- and maybe times are changing --  
9 is highlighted, the negative.

10           So regardless of what particular category we  
11 recommend in, I think in our discussion, we need to make it  
12 clear what we mean by limited scale testing. And we also  
13 need to accentuate the positives that so many people have  
14 identified in this proposal and really, really highlight  
15 them in our letter to the Secretary.

16           CHAIR BAILET: Paul.

17           DR. CASALE: Okay. Process of elimination, I  
18 must be a 2, which I am, for limited scale testing.

19           Yeah. So I think, as I think through the payment  
20 part -- and yeah, there's a lot of issues, but I think  
21 they're all fixable. And I think the quality side is very  
22 creative and innovative, and to what Len said, which was  
23 exactly what I heard this morning, the simplicity, you have

1 simplicity, transparency, accountability. I mean, that's  
2 here. Again, fixing -- and it's got most of the P's of  
3 those four P's, if not all the P's.

4 So, in my mind, I think there's been enough work  
5 done in primary care models, et cetera, that I think we can  
6 fix the cost parts, and then we can add in this patient-  
7 reported outcome piece, which I think would be a big leap  
8 forward.

9 MR. MILLER: I voted for 2, limited scale  
10 testing, because I think that this model is perfectly,  
11 exactly what it is that we meant wherever we said limited  
12 scale testing, which is that it needs to be done on a small  
13 scale initially to be able to refine the methodology  
14 sufficiently, to be able to move it forward for broader  
15 scale implementation, and that the only way to make those  
16 refinements is to in fact implement it in some practices  
17 because you do not find out how well it is that you can get  
18 patients to answer a survey that they need to answer unless  
19 you're actually doing it. And you can't do it if you're  
20 not paying the practice appropriate to be able to do that,  
21 et cetera. So the whole thing has to be done in a beta  
22 testing model site to do that.

23 I think I want to make sure, at least from my

1 perspective, that the issue is that it's not to me a bad  
2 payment model. It is not a problematic payment structure.  
3 It needs to have details worked out that cannot be worked  
4 out to anybody's satisfaction, in my opinion, without  
5 implementing it.

6 That's very different than us saying that we  
7 think that the payment model has lots of problems with it  
8 and it needs to be redone.

9 If there were problems with the payment per se  
10 that had to be redone, I would say, "Jean, you should go  
11 take and redo your proposal," but I don't think that's the  
12 case here.

13 I don't think the notion of having a withhold is  
14 a bad thing. I think the withhold is perfectly fine.  
15 People will disagree about whether withholds are a good  
16 thing or not, but I think it's a perfectly fine thing to  
17 do. I think it's a perfectly fine and wonderful thing to  
18 do to pay capitation. I think it's a wonderful thing to do  
19 to have a risk-adjusted capitation. I think it's a  
20 wonderful thing to do to have a simple structure that's  
21 based on the actual patient needs rather than HCCs, for  
22 God's sake, which we know don't work, and yet they continue  
23 to show up everywhere as the default mechanism. And it's

1 time to move beyond that.

2           So I think it's a wonderful thing that there's  
3 all that, but the fact that it is that innovative means  
4 that there is a variety of details that need to be worked  
5 out.

6           And when I say that I don't think that it's  
7 something that Jean could work out, I don't mean that  
8 because she's a small primary care physician. I think it's  
9 important to say that. I don't think that we're somehow  
10 giving a pass to every small practice that brings in a  
11 model and say, "Oh, we know you couldn't do it." I don't  
12 think that's the issue.

13           I think the issue is nobody could do this unless  
14 they had resources to be able to support the delivery of  
15 care difficulty, and so if some large integrated system  
16 wanted to do it, sure, they could do it. They could pay  
17 their practices this way and do all this kind of stuff  
18 because they could put the money into it, but you can't do  
19 that for most of the country. And I don't think that we  
20 should have payment models dependent on having big, wealthy  
21 institutions doing things because they have the money.

22           So I think that this fits perfectly into the  
23 category of saying that CMS should do it and do it on a

1 limited scale in order to be able to move it more broadly.

2 I think the thing -- the clarification I would  
3 like to make sure that we state in here is that we do not  
4 think that this would have limited impact, that this could  
5 have significant impact if it works properly. We don't  
6 know that. We don't know that by anything else, and it's  
7 certainly clear that all the other models haven't been  
8 having significant impact either, even though they had high  
9 expectations attached to them.

10 So I don't think that it's anything for us to say  
11 that we're sure that this is going to have a big impact,  
12 but I think that the notion that this could have a very  
13 significant opportunity for primary care to be able to  
14 deliver care differently, to keep primary care physicians  
15 in practice, et cetera, it makes it worth doing that and  
16 doing it through the multiple steps that would have to be  
17 done to be able to do that. And I think that we have to  
18 get to the point where we're willing to do models in  
19 multiple stages because the more innovative they are, the  
20 more stages are going to have to be done.

21 And everybody wants to have gazillions of dollars  
22 of savings immediately, and I don't think that that's a  
23 reasonable expectation for a lot of these things.

1           So that's my long-winded explanation for why I  
2 voted for No. 2.

3           CHAIR BAILET: Thank you, Harold.

4           Grace.

5           DR. TERRELL: I voted for No. 2, and I think  
6 you've all heard in previous dialogue a lot of my reasoning  
7 behind that.

8           As we are writing this letter to the Secretary, I  
9 think that one of the things that is crossing my mind is  
10 given what we heard this morning about Adam's four P's,  
11 this would be perhaps a good place for us to use our  
12 criteria, limited scale testing, and pressure-test them  
13 against those four P's in the dialogues.

14           We can go through our 10 criteria, and we can  
15 make our points that have all come up. But because there's  
16 been conflict between our understanding of the way to  
17 evaluate this and their belief about its validity -- and  
18 since they provided a different framework from which  
19 they're thinking about the world this morning, that I think  
20 that this particular proposal, to Len's point perfectly,  
21 could match from that point of view. The place and space  
22 to do it will be within the context of our framework of  
23 limited scale.

1           So if we can end the way we write this up, focus  
2 on the limited scale as it relates to those four P's, I  
3 think that this will be an opportunity that may help us  
4 move along beyond the perceived conflict we have right now.

5           CHAIR BAILET: Thank you, Grace.

6           Tim.

7           DR. FERRIS: So I was a 2. In the interest of  
8 expediency, I would refer to my two points at the opening.  
9 You can get them from the transcript about beta testing and  
10 about assurances.

11           And, in closing, I'd like to associate myself  
12 with Dr. Antonucci's comment about you guys are great.

13           [Laughter.]

14           CHAIR BAILET: Okay. But before we break, we  
15 have Audrey here, who has been flying through. She's  
16 already to go ahead and give us a summary, Audrey. It's  
17 your time to shine.

18           MS. McDOWELL: All right. So I'll begin with a  
19 disclaimer. This is my very first PRT, so I'll ask for a  
20 little bit of grace.

21           So I'll begin by summarizing the key points that  
22 I heard and the strengths and weaknesses, and then I also  
23 want to flag that there are three places where the full



1 PTAC had a different vote or conclusion regarding the  
2 criteria in comparison to the PRT, and so I want to just  
3 make sure that I get some additional insights regarding the  
4 reasons for the differences, so we can include that in the  
5 report to the Secretary.

6           So in terms of key points that I heard, one of  
7 the things that they're emphasizing is that the Committee  
8 believes that -- and voted that we're recommending that the  
9 implementation needs to be done on a small scale or a  
10 limited scale to provide an opportunity for refinement  
11 before being able to do more broad implementation. That  
12 there are flaws that the Committee believes could be  
13 overcome with additional work, but that the goal would be  
14 to use CMS resources to do that refinement rather than  
15 putting burden on the submitter. That in the letter to the  
16 Secretary and communications to the Secretary, part of what  
17 needs to be done is we need to clarify what is being meant  
18 by limited scale testing in the context of the  
19 recommendation, and part of what we want to do is perhaps  
20 use this as an opportunity to focus on the meaning of  
21 limited scale as it relates to the four p's that were  
22 outlined during the earlier discussion with senior  
23 leadership.

1           That we also want to make sure that we accentuate  
2 the positives of this proposal in the letter to the  
3 Secretary, and that the Committee also does not think that  
4 this proposal can only have a limited impact. We have no  
5 way of necessarily knowing for sure, but that we do think  
6 it could potentially have a significant impact in  
7 addressing some of the concerns relating to primary care.

8           Additionally, we want to also highlight a couple  
9 of the points that were raised earlier in the discussion  
10 that were raised by the PRT participants earlier. Tim had  
11 raised concerns relating to -- I believe we said beta  
12 testing and assurances, so we'll also make sure that those  
13 are included, and we'll go back and make sure when we  
14 double-check the transcript for those.

15           Relating to major strengths, we want to make sure  
16 that we emphasize that this particular proposal is  
17 considered to reflect a lot of creativity, particularly  
18 relating to providing a different way of thinking about  
19 quality and simplicity.

20           The proposal also -- we believe -- the Committee  
21 believe it's consistent with the goals that were outlined  
22 earlier by senior leadership relating to transparency,  
23 simplicity, and accountability, and also that, again, it

1 has most, if not all, of the four P's, and again, that  
2 there is a belief that it should be possible to fix many of  
3 the concerns that were raised relating to some of the  
4 payment issues. And there's also a belief that there are a  
5 lot of strengths related to the inclusion of patient-  
6 reported outcomes.

7           In terms of some of the key weaknesses that were  
8 raised, concerns were expressed about incompleteness  
9 related to not identifying in the proposal which specific  
10 quality benchmarks would be used, concerns about capitation  
11 payments, and the potential for higher-risk patients  
12 potentially not to complete the survey, and that that might  
13 affect whether or not a practice would then get the higher  
14 capitation payments for those patients and how that would  
15 potentially affect the payment to the primary care  
16 practice.

17

18           Additionally, concerns regarding the need to  
19 clarify the mechanism for how a primary care practice would  
20 be able to learn back the withhold.

21           And, finally, that one of the limitations related  
22 to the innovativeness of the proposal means that there are  
23 a variety of details that need to be worked out, and that

1 it also will require multiple stages for implementation.  
2 So there's kind of a tradeoff there.

3 Are there any additional concerns? I guess there  
4 are also some additional comments that we want to make sure  
5 that we highlight -- let's see. That we want to include  
6 some language in the letter to the Secretary about the way  
7 in which we're making our recommendations and also that  
8 there are concerns relating to the way that we're doing  
9 risk adjustment.

10 And I need to go back to the transcript and make  
11 sure that we capture the details related to that.

12 Are there any other things that were missed in  
13 terms of major themes?

14 DR. NICHOLS: I don't think you missed anything.

15 MS. McDOWELL: Okay.

16 DR. NICHOLS: But I think it might be worth --  
17 just on that second to last point, I think what we wanted  
18 to make sure was that we conveyed what we're saying now as  
19 limited scale testing is not what leadership thought it was  
20 when we met with them the first time. I don't remember  
21 exactly when that was, but we just need to make that  
22 explicit, I believe, in the letter: And what we mean by  
23 this is this and not what you all thought it was. And I

1 think we'll be okay if we do that.

2 MS. McDOWELL: Okay . And so, if you don't mind,  
3 I have three criteria that I would like to just get some  
4 additional language from the Committee regarding the  
5 reasons for why the Committee voted differently than the  
6 PRT did.

7 The first one on scope. The PRT voted that it  
8 did not meet, and the Committee voted that it meets the  
9 criteria. So I don't know if there are any specific  
10 thoughts on that.

11 DR. MEDOWS: So I have one. I think what we were  
12 looking at is not just primary care as a whole but primary  
13 care of a solo or small practice, particularly in rural  
14 parts of the country.

15 MS. McDOWELL: Okay.

16 DR. MEDOWS: So that's a group that actually  
17 needs to be represented in alternative payment models.

18 MR. MILLER: I also think that the nature of the  
19 proposal has potential impacts beyond this primary care,  
20 sort of the notion of needing to do something more on how  
21 to do patient-reported outcomes. We've cut across other  
22 areas, and so its scope would go beyond this in terms of  
23 the methodology issues. So that's another reason why the

1 impact could be larger than it might appear by simply doing  
2 it in a small number of primary care practices.

3 CHAIR BAILET: Bruce, did you want to make a  
4 comment?

5 MR. STEINWALD: Back to Len's point about what we  
6 mean by limited scale testing, I don't have a clear sense  
7 of whether the Committee believes what the PRT report said  
8 at its last paragraph, that it ought to be implemented  
9 within another existing structure, or do we not need to be  
10 that specific?

11 It sounded to me like a good idea. I'm not sure,  
12 Len, in your response to it, thought within an ACO was  
13 sensible.

14 DR. NICHOLS: I don't see this as an ACO. I see  
15 it as another form of primary care. So it's more CPC+  
16 track 7(B) or something. I'm happy to have it embedded in  
17 that language. I don't mind that paragraph. To me, that's  
18 kind of being prescriptive. I would rather leave it open  
19 because if the only way to get it is to make it CPC 7(B),  
20 I'm for it. If we actually would acknowledge the  
21 uniqueness of it and the potential of it, you could imagine  
22 as one of a number of things going in this other direction.  
23 I want to get away from the meaningful use measures, and

1 this thing does it. CPC+ does not.

2 CHAIR BAILET: Kavita and Harold.

3 DR. PATEL: Just to build on that, we already  
4 heard from Adam today, and we've heard previously that it  
5 sounds like they're launching something around primary care  
6 inevitably. So I would not be prescriptive such -- I mean,  
7 it almost be like, e.g., CPC, ACOs, or another primary care  
8 model, just because I can easily see, depending on what  
9 that model looks like, that this could be one of the beta-  
10 tested, you know, kind of how it is a supply and settings  
11 within that model.

12 MR. MILLER: Well, I would just like to suggest  
13 that maybe the way the wording we say is something that is  
14 not prescriptive but describes what some of the benefits  
15 would be. So it could be done -- we might say it could be  
16 done as part of CPC.

17 I think there's two reasons for that. One is  
18 we've heard that, understandably, it's hard to launch whole  
19 new things, and so it may be easier to sort of add  
20 something onto an existing model.

21 The second thing is -- I raised this earlier -- I  
22 am somewhat concerned because -- I don't think this would  
23 happen, but I would be concerned if the only model that

1 CMS put out was this, and all of a sudden, you had every  
2 primary care practice in the country thinking that it  
3 either had to be in this or nothing, which would then make  
4 it very difficult to do it kind of on a testing scale like  
5 this. And I think having it be part of something that's  
6 broader that would say you can do this other thing, but if  
7 you really want to be innovative you could do this, it  
8 seems to me we'd get the right people into it.

9           So I guess I would suggest, if everybody would  
10 agree, that we sort of -- we talk about that as a specific  
11 option, that we don't say we think that's the only way it  
12 could be done, but that there would be some advantages.  
13 And we don't think it would be problematic to do it. I  
14 don't think it would be problematic to say it's Track 17 of  
15 CPC+. It may or may not be, but I don't think there's any  
16 other reasonable option, anyway, truthfully.

17           CHAIR BAILET: All right. Bob, I know you wanted  
18 to make some comments.

19           DR. BERENSON: Yeah, just a couple. I've been  
20 quite for too long, so I wanted to --

21           First, I thought you all did a great job, and.  
22 Jean, in particular, you did a great job. So I just wanted  
23 to say that.



1           I wanted to just comment on a couple of things I  
2 heard during the discussion, not about the proposal, but  
3 about capitation, just to clarify two points. And the  
4 background is that I practiced under Primary Care  
5 Capitation, outside of an ACO. I think it's a viable  
6 model, including for rural docs in particular, if it's done  
7 right, and that's the challenge.

8           And to go against my caricature, which is that  
9 there's always a fee-for-service option, to Rhonda's point  
10 that maybe we would consider new codes, I think this is an  
11 area where you can't do it in fee-for-service.

12           As anybody here who has practiced primary care  
13 knows -- and it was documented by Rich Baron in a New  
14 England Journal article a few years ago -- you're doing  
15 dozens of one-minute activities all day long. How do you  
16 build for a one-minute activity? I mean, the transaction  
17 costs, the copayment you have to collect. All of that  
18 stuff can't be done fee-for-service, and so whether it's  
19 CPC+, which is partial capitation, or this, which is total  
20 capitation, I think for primary care, you got to go to some  
21 form of capitation.

22           And then the final point I wanted to make, Harold  
23 pointed to the Oklahoma data, which said that Medicaid

1 capitation resulted in stinting, and Bruce talked about,  
2 but then there's concierge practices. And you could add  
3 direct primary care, which is the current sort of model du  
4 jour, seems to be well accepted at least by affluent  
5 patients who are able to do that.

6           We have this tendency to look at the incentives  
7 in a payment model and decide what the potential behavior  
8 can be, like stinting, completely ignoring the payment  
9 level, the generosity of the payment.

10           So from personal experience and anecdotes, if you  
11 pay me a Medicaid level of capitation, I'm going to stint  
12 on services. I can't pay my costs. If you pay me a  
13 concierge level of capitation. I'm going to do great, but  
14 then how does an insurance -- how does a payer actually  
15 justify that? The challenge is to find the sweet spot,  
16 which is that the payment is enough. You do need some  
17 measurement. You need some of that stuff, but it is just  
18 impossible.

19           And, in fact, there was an HHS task force 25  
20 years ago in the heyday of HMO gatekeeper payment, which  
21 concluded that it is impossible to judge whether incentives  
22 are too strong. That was what they were asked to do  
23 because the left wanted to ban sort of capitation and these

1 kinds of things, and they said, "We can't do it." And they  
2 actually listed six factors that would determine what the  
3 behavior might be, and they led with the generosity of the  
4 payment. So it makes it much more complicated.

5 So I just wanted to say that. This is very  
6 challenging, but it is absolutely worth trying to figure  
7 out how to do capitation for primary care docs. Done.

8 CHAIR BAILET: Thank you, Bob.

9 Harold.

10 MR. MILLER: I don't think we've got to Audrey's  
11 other points she needed to -- there were two other areas  
12 where you said that we voted differently. I just to make  
13 sure you got clarification there.

14 MS. McDOWELL: That's correct. On ability to be  
15 evaluated, the PRT said does not meet, but the full PTAC  
16 voted that it meets the criterion.

17 MR. MILLER: And that was nip and tuck.

18 DR. NICHOLS: But it had to do, I believe, with  
19 accepting the proposition that for this proposal, beta  
20 testing evaluation is the right model. It is not -- and I  
21 think that's what sort of won the day. So go back to Tim's  
22 beta testing dissertation, and you'll find the details  
23 there.

1           MR. MILLER: I would just also note I think the  
2 issue is what do you mean by evaluation, and I think the  
3 question is could you figure out whether this is working in  
4 improving care. The answer is yes.

5           Could you get statistically significant stuff?  
6 And I think the issue ends up being too many of the  
7 evaluations that are being done -- this is just a side  
8 comment on my part. Too many evaluations are being done on  
9 things that have so little impact that everybody is worried  
10 about the statistical significance of the \$36 that ACOs  
11 saved nationally last year. You know, big whoopy.

12           So the issue is if this actually has a big  
13 impact, it will not be that hard to determine that it's  
14 there. It's only if it's a small impact. So I think  
15 that's going to be one of the other issues in the  
16 evaluation, is exactly how much of an impact are you trying  
17 to detect.

18           DR. FERRIS: I don't want to give the impression,  
19 at least from my perspective, that a P value is the key  
20 issue here, in my understanding of the evaluation issue.

21           My understanding is about fairness, and that's  
22 got nothing to do with P values. So I just wanted to  
23 clarify it from my perspective.

1 DR. NICHOLS: Well, as long as we're clarifying  
2 perspectives, I'll just say to me, the difference in a beta  
3 evaluation and a full-scale evidence is generalizability.  
4 You can prove impact with beta. You can't generalize,  
5 therefore, to implement nationwide, which you could from a  
6 full one. That's really what it --

7 CHAIR BAILET: Audrey.

8 MS. McDOWELL: All right. And the last one,  
9 where there was a discrepancy on patient choice, the PRT  
10 concluded that it does not meet, and the PTAC, the full  
11 PTAC, concluded that it meets the criterion.

12 DR. PATEL: [Speaking off microphone.]

13 MS. McDOWELL: The full PTAC voted six, that it  
14 meets; two, that it does not meet; and one, that it meets  
15 with priority consideration.

16 MR. MILLER: So I would say there's a couple of  
17 factors that went into that. One was the concern about  
18 whether it would expand or reduce access to primary care.  
19 So if it is done on a limited scale, then I'm not worried  
20 about that because it's not going to do that. So I think  
21 that's a question. To me, it's jumping ahead to the  
22 recommendation, but I don't think if it's done on a limited  
23 scale.

1           And the second issue was to what extent are the  
2 patients being informed about what they're choosing, and I  
3 think that that is sufficiently easily solvable that before  
4 the patient signs up that they could be -- that I don't  
5 think that one votes against it just because the proposal  
6 didn't articulate that. I think it's articulated, but that  
7 would be my answer as to why I tilt it back over.

8           Other people can say whether they agree with that  
9 or not, I guess.

10           DR. PATEL: I'll just support that Dr.  
11 Antonucci's answer about patients -- you could be in one  
12 practice with one doctor, and someone could opt into the  
13 program or just say, "No, thank you. I will stick with  
14 what I've got," and that that physician would then still  
15 provide that other care model to that patient. So that's  
16 another rationale for why the discrepancy.

17           CHAIR BAILET: Grace.

18           DR. TERRELL: So the question, maybe some of our  
19 scholars like Bob can answer or not.

20           But all the concerns that have been out there in  
21 the past with respect to full capitation, has there ever  
22 been a patient-reported outcomes type of link to that to  
23 sort of take care of the potential concerns people have

1 about stinting through which there's data? Because to my  
2 mind, the creativity and the innovation that are in this, I  
3 agree with you. I think full cap for primary care, if done  
4 right, is a wonderful solution. I agree with you about the  
5 amounts make a difference in terms of the generosity of the  
6 payment.

7 But the aspect of actually also linking it to  
8 patient-reported outcomes, to my mind, is genius, and I  
9 just wondered if there's data out there to support that in  
10 the past from some of the stuff that --

11 DR. BERENSON: Not that I'm aware of. I actually  
12 thought Jean did a great job of explaining the rationale.

13 I mean, if you're being stinted, you probably are  
14 able to report that you're being -- if you're being shipped  
15 to -- I mean, this probably doesn't happen in rural  
16 practices as much because you can't just refer everybody  
17 out.

18 But in an urban practice, that is the reason 30  
19 years ago, they came up with these risk pools based on  
20 total cost of care, because of concern that the primary  
21 care doc would just refer everybody and not provide any  
22 services.

23 But I would think that the right patient-reported

1 outcomes would capture that. So I think it's a very  
2 promising approach.

3 DR. TERRELL: So based on that, I think as we're  
4 writing up, Audrey, the report, emphasizing the new  
5 innovative nature of basically the issues that people have  
6 had concern about in the past with respect to full  
7 capitation and behaviors have never been linked in this  
8 innovative way before might be a very important thing for  
9 us to state or emphasize as we are sort of making our  
10 points to the Secretary.

11 CHAIR BAILET: Tim.

12 DR. FERRIS: One friendly amendment to that. So  
13 there is quite a bit of research, and actually, Dr. Wasson  
14 mentioned it, correlating HRAs of which How's Your Health  
15 is a type of health risk assessment, is a type of HRA.

16 There's a lot of research correlating HRAs with  
17 outcomes. Using an HRA in the context of stratification  
18 and making sure that that stratification is fair is, I  
19 would say, not well studied. I'm not aware of anything, of  
20 any data that directly does that.

21 And there's a big difference between comparing  
22 our squares and variance explained -- and there is quite a  
23 bit of research on that -- to taking it this next step in



1 payment models. So I would just say that's quite  
2 specifically the piece of work that would need to be done  
3 here.

4 CHAIR BAILET: Thank you, Tim, and thank the  
5 Committee for the incredible discussion. I think we've  
6 come a long way.

7 We'll work with Angela as we draft this letter to  
8 make sure that we cast it in the appropriate spirit.

9 Pardon?

10 MR. MILLER: Audrey.

11 CHAIR BAILET: I said Audrey. But I said Andrea  
12 by mistake?

13 Audrey, my apologies.

14 MS. McDOWELL: I answer to anything that's in the  
15 room.

16 CHAIR BAILET: Yeah. Well, I hear you. I hear  
17 you. It's been a long day, and it's not over yet.

18 So I'll tell you what we're going to do. I want  
19 to first thank Dr. Antonucci, Jean, for bringing this  
20 proposal forward, for hanging in there with us, for serving  
21 your community and helping give a helping hand to primary  
22 care across the country, so thank you for that. Appreciate  
23 everybody's hanging, hanging through this conversation, and

1 I recommend taking a 10-minute break, and we will reconvene  
2 for our last proposal. Thank you.

3 [Recess.]

4 CHAIR BAILET: I'm going to go ahead and get  
5 started.

6 [Pause.]

7 \* **APM for Improved Quality and Cost in Providing**  
8 **Home Hemodialysis to Geriatric Patients Residing**  
9 **in Skilled Nursing Facilities. Submitted by**  
10 **Dialyze Direct**

11 CHAIR BAILET: So we still don't have Len  
12 Nichols, but we are -- we're going to go ahead and get  
13 going, and hopefully by the time we get done with the  
14 conflicts, Len will be back.

15 So the third proposal today is the Alternative  
16 Payment Model for Improved Quality and Cost in Providing  
17 Home Hemodialysis to Geriatric Patients Residing in Skilled  
18 Nursing Facilities, submitted by Dialyze Direct. Harold  
19 Miller is the lead reviewer. Myself and Dr. Rhonda Medows  
20 were on the PRT.

21 \* **Disclosures**

22 CHAIR BAILET: I'll start with disclosures,  
23 starting with myself. I have nothing to disclose, and

1 maybe I'll start, Rhonda, with you, and we can come around  
2 the room.

3 DR. MEDOWS: I have no disclosures.

4 DR. BERENSON: I have no disclosures.

5 DR. PATEL: Kavita Patel, no disclosures.

6 MR. STEINWALD: Bruce Steinwald, no disclosures.

7 DR. CASALE: Paul Casale, no disclosures.

8 MR. MILLER: Harold Miller, no disclosures or  
9 conflicts.

10 DR. TERRELL: Grace Terrell, no disclosures.

11 DR. FERRIS: Tim Ferris, no disclosures.

12 CHAIR BAILET: And our esteemed colleague Len  
13 Nichols is working his way to the microphone to declare  
14 whether he has something to disclose on the Dialyze Direct  
15 proposal.

16 DR. NICHOLS: I lost five bucks in the vending  
17 machine, but I have no conflicts of interest.

18 [Laughter.]

19 CHAIR BAILET: All right. Harold is the lead  
20 reviewer. Harold, I'm going to turn it over to you,  
21 please.

22 \* **PRT Report to the Full PTAC**

23 MR. MILLER: Thank you, Jeff. And thank you,

1 Jeff and Rhonda Medows, for serving on the PRT with me.  
2 Both Jeff and Rhonda are physicians, and we always make  
3 sure we have at least one physician on the PRT.

4           We worked on this project over the -- proposal  
5 over the summer and asked a lot of questions about it,  
6 which the folks from Dialyze Direct responded to all of our  
7 many questions several times -- thank you -- and we had a  
8 discussion on the phone with them, and we provided some  
9 preliminary feedback to them and then used all of that  
10 input, as well as some data analysis that was done for us  
11 and a discussion with a clinical expert to prepare our PRT  
12 report, which I will try to outline for you. Fasten your  
13 seat belts because this is a little challenging to follow  
14 some of this.

15           So this proposal is designed for patients who are  
16 in skilled nursing facilities. There are -- and who have  
17 end-stage renal disease and who need dialysis. There are  
18 two different kinds of patients in skilled nursing  
19 facilities: patients who are there on a long-term basis,  
20 who are residents of the facility, where Medicare is simply  
21 paying for health care if they need health care, but  
22 somebody else is paying -- the patient or Medicaid or  
23 someone is paying for their nursing home stay; and then

1 there are patients who are there on a short-term where  
2 Medicare is paying for their stay in the nursing home. And  
3 I say that because that distinction is going to be critical  
4 for some of the discussion later on about the various  
5 criteria.

6           And the purpose of the proposal is to encourage  
7 the patients in the nursing facilities who need dialysis to  
8 be able to get dialysis in the nursing facility rather than  
9 having to be transported to an off-site dialysis facility  
10 and to get more frequent dialysis, meaning five days a  
11 week, generally, rather than three days per week.

12           Also, the method of dialysis that they would be  
13 receiving in the nursing home would technically be  
14 considered home hemodialysis as opposed to what is  
15 typically done in a dialysis center. It would be staff-  
16 assisted, though, home hemodialysis in the nursing  
17 facility. So rather than what would ordinarily be viewed  
18 as home hemodialysis where the patient themselves or the  
19 patient's family members are assisting them to be able to  
20 hook up the equipment, et cetera, there would be staff in  
21 the nursing facility to be able to do all of that.

22           Interesting characteristics of this proposal is  
23 that there's no actual change proposed to the way Medicare

1 pays for the dialysis treatments themselves. The only  
2 change in the payment model is for the nephrologist who is  
3 caring for the patient, and there are two specific payments  
4 proposed for that. One is a one-time bonus payment, if you  
5 will, of \$500 for providing education to a patient who uses  
6 this service about -- so that they understand what the  
7 service is, et cetera. And the second is a payment equal  
8 to 90 percent of any savings resulting from the patient  
9 avoiding transportation costs to see the nephrologist in  
10 their -- so the nephrologist would see the patient in the  
11 skilled nursing facility rather than in the nephrologist's  
12 office.

13           This is somewhat complicated to follow because --  
14 so if you're getting your dialysis at a dialysis facility,  
15 the expectation is that the nephrologist will see you in  
16 the dialysis facility. If you are getting home  
17 hemodialysis, the expectation is that you will go to see  
18 the nephrologist in their office, and the requirement is  
19 that you see the nephrologist in their office at least once  
20 a month.

21           So the issue would be if the nephrologist comes  
22 to see the patient in the nursing facility rather than  
23 having the patient have to go to the nephrologist, that if

1 there were payments being made for transportation,  
2 ambulance transportation for the patient to go to the  
3 nephrologist's office, and the nephrologist went to the  
4 skilled nursing facility instead, the nephrologist would  
5 get 90 percent of the savings from the avoided  
6 transportation costs.

7           Now, that structure raises some interesting  
8 challenges, as you'll see. So we reviewed this and  
9 concluded that -- almost unanimously across the board that  
10 the proposal did not meet the majority of the criteria,  
11 including none of the high-priority criteria of the  
12 Secretary's criteria. I'll try to hit the high points here  
13 as usual on the key issues and then go through more quickly  
14 in terms of the individual criteria.

15           We felt that this -- what the goal of the  
16 proposal was was very meritorious, that today, if a patient  
17 is in a nursing facility and the nursing facility itself  
18 does not have an on-site dialysis center, the nursing home  
19 patient is typically transported by ambulance to a dialysis  
20 center, which is a lengthy, unpleasant, and potentially  
21 dangerous process in some sense, because accidents can  
22 happen, et cetera, in transport. And so being able to get  
23 dialysis in the nursing facility rather than a dialysis

1 center would be a desirable thing.

2           Moreover, patients in many cases are much better  
3 off being able to get more frequent dialysis, five days a  
4 week rather than three days a week, because it gives them  
5 much more stable, shorter treatments. There are also  
6 benefits to the patient in the nursing facility from not  
7 having to leave the nursing facility entirely for an entire  
8 day for three days a week. So all of those things are good  
9 things that would happen if that was available.

10           There's no change proposed in the Medicare  
11 payment. Medicare pays for every dialysis session. If the  
12 patient was receiving more frequent dialysis in the nursing  
13 facility, Medicare would be paying more. It would be  
14 paying for five treatments a week rather than three  
15 treatments a week.

16           However, if the patient is being transported by  
17 ambulance to the dialysis center and if Medicare is paying  
18 for the ambulance to the dialysis center, then if the  
19 patient is not being transported to the dialysis center,  
20 Medicare wouldn't be paying for the ambulance  
21 transportation.

22           So in the circumstance in which a patient is  
23 today being transported to a dialysis -- off-site dialysis



1 center by ambulance and Medicare is paying for the  
2 ambulance -- I'll just use sort of rough numbers. Let's  
3 just say for round numbers, just for ease of understanding,  
4 Medicare would pay about \$250 per dialysis session in the  
5 dialysis center three times a week. It would probably be  
6 paying about \$250 each way for the ambulance treatment each  
7 time that they go. So that would mean that on three days a  
8 week Medicare would be paying \$500 for transportation and  
9 \$250 for a dialysis session, or \$750 per day three times a  
10 week.

11           If the patient was getting more frequent dialysis  
12 in the nursing facility at \$250 per session but not having  
13 to be transported, Medicare would be paying more, \$750 --  
14 I'm sorry, \$1,250 for the five dialysis sessions, but  
15 nothing for the transportation. So in that circumstance,  
16 there would be significant savings to Medicare.

17           So all of that is important to understand because  
18 that's sort of -- the premise of the model is that the  
19 patient is able to get more frequent dialysis in a more  
20 convenient location and Medicare spends less.

21           However, whether Medicare pays for the ambulance  
22 or not depends on the reason why the patient is in the  
23 nursing facility, and I will say we struggled a bit to be

1 able to get clarity about exactly what Medicare policies  
2 are on all of this because it is somewhat confusing. There  
3 are issues associated with medical necessity of  
4 transportation. There are issues associated with eligible  
5 sites of transportation. There are also issues of  
6 eligibility for more frequent dialysis. But I'll get to  
7 that all in a second.

8           So, as we understand it, if you are a long-term  
9 resident of a skilled nursing facility where Medicare is  
10 not paying for your nursing home stay and you need  
11 medically necessary ambulance transportation to a dialysis  
12 center, Medicare would pay for that. The assumption is  
13 that most of these patients, because they are in nursing  
14 facilities, would need ambulance transportation to a  
15 dialysis center. But it is not absolutely certain in all  
16 cases that would be true. It has to be medically  
17 necessary. So in those cases, the patient -- there would  
18 be a savings to Medicare if the patient could get more  
19 frequent dialysis in the nursing facility.

20           However, if the patient is on a short-term  
21 skilled nursing facility stay and they go to the dialysis  
22 center, the transportation, our understanding is, would be  
23 paid -- is not paid separately by Medicare, but would be a

1 cost chargeable to the skilled nursing facility and covered  
2 by the Medicare payment to the skilled nursing facility,  
3 which means that in that case Medicare would not be saving  
4 any money on ambulance transportation by doing that.

5           It appears from what we have heard from the  
6 applicant that most of the patients participating in this  
7 model currently, because they are actually doing this  
8 model, would be in the second category, would be in the  
9 short-term skilled nursing facility stay category. So,  
10 therefore, that raises a question about whether or not this  
11 actually does save money for Medicare because if there is  
12 no savings on transportation, then more frequent dialysis  
13 would be more spending.

14           Now, if you just limit your look at savings to  
15 transportation, that's what I just described. There are  
16 other potential benefits from more frequent dialysis such  
17 as potentially fewer hospitalizations due to fewer  
18 complications; potentially shorter skilled nursing facility  
19 stays, which would mean that Medicare would be paying for  
20 fewer days, et cetera. There is no mechanism in this model  
21 to assure that that would happen. There is not any  
22 definitive evidence that that would happen. There is  
23 believed to benefit from more frequent dialysis, but there

1 is not exactly a lot of research on nursing facility  
2 patients getting more frequent dialysis because, in fact,  
3 most of them don't. So it's hard to say for sure what's  
4 going to happen with that.

5           The payment model doesn't address any of the  
6 barriers that exist in the current payment system to  
7 delivering this service. We were told by the applicant  
8 that the cost to them of delivering this service in the  
9 nursing facility would be higher than the current amount  
10 that Medicare would pay. And, in fact, it would be -- the  
11 cost would be about 50 percent more than what Medicare  
12 would pay. So, in theory, the only way it could be done  
13 would be if they were able to cross-subsidize it in some  
14 fashion. And, moreover, it only would seem to be workable  
15 even at that level of subsidy if there were a sufficient  
16 volume of patients in the nursing facility because you have  
17 to put staff in the nursing facility, because this is  
18 staff-assisted home hemodialysis. You have to have a  
19 certain number of staff in the nursing facility to be able  
20 to do that. And, therefore, you have to have a certain  
21 number of patients to be able to get enough money to cover  
22 that fixed cost.

23           Sorry for all that detail, but that's sort of

1 critical to understanding this whole thing. So that's sort  
2 of the basic thrust of all this as key issues.

3 Now, I'll get into some other issues associated  
4 with what is actually being proposed in the payment model,  
5 but the fundamental conclusion from this was that we were  
6 not convinced that this model as proposed would, in fact,  
7 save money for Medicare.

8 Now, just to talk about the individual criteria,  
9 so on scope, the majority of us felt that this did not meet  
10 the scope for a couple of reasons. One was we thought that  
11 it certainly fills a gap in terms of there are no sort of  
12 nursing home facility dialysis-oriented models, and there  
13 aren't enough models for nephrologists. But there are a  
14 relatively small number of nursing facilities currently in  
15 the country that have the minimum volume of patients who  
16 need -- ESRD patients who need dialysis to be able to make  
17 this economically viable. So it's not that you could do  
18 this in every nursing facility. It would only be a small -  
19 - we estimated it would be less than 1 percent of the  
20 nursing facilities in the country.

21 On quality and cost, this is a somewhat  
22 challenging thing also. If you are in the nursing facility  
23 on a long-term basis and you need dialysis on a long-term

1 basis and you could get more frequent dialysis on a long-  
2 term basis, that would probably be a good thing in general.  
3 There are some risks of getting more frequent dialysis,  
4 but, in general, it would be believed to be better to be  
5 able to get more frequent dialysis.

6           If you're in a nursing facility for a short-term  
7 stay, it's less clear because if you were on dialysis  
8 before and going to a dialysis center and now you're in the  
9 nursing facility for a short-term stay and you could get  
10 more frequent dialysis while you're in the nursing facility  
11 for the short-term stay, but then you would leave the  
12 nursing facility and go back home and not be able to do  
13 home hemodialysis yourself and have to go back to a three-  
14 day-a-week regimen at the off-site center, you would be  
15 suddenly getting for a short period of time more frequent  
16 dialysis and then going back to less frequent dialysis,  
17 which could potentially cause a variety of challenges for  
18 the patients, for transitions or changing medications, et  
19 cetera, which could potentially be problematic.

20           Then the problem with the payment methodology, as  
21 I mentioned, is that -- there's no change in the actual  
22 payment for the service itself, even though it does not  
23 appear to be financially viable under current Medicare

1 payments. The payment changes are only aimed at the  
2 nephrologist. The key thing is the notion that the  
3 nephrologist would get 90 percent of any savings from  
4 avoiding ambulance transportation to the nephrologist's  
5 office, but we do not believe that Medicare pays for  
6 ambulance transportation to a nephrologist's office. It  
7 only pays for medically necessary transportation at all,  
8 and a physician's office is not an eligible site. Medicare  
9 will pay for ambulance transportation to a dialysis center  
10 or to a hospital but not to a physician's office.

11           So if it's the case that Medicare is paying for  
12 that, it's not because the policy says that they should.  
13 It's simply because somehow people are managing to get paid  
14 for that. But it would be hard to say that you're assuring  
15 a nephrologist that they're going to get a bunch of savings  
16 from something that Medicare doesn't pay for.

17           The second piece of the component payment is this  
18 \$500 bonus payment to the nephrologist which would seem to  
19 basically create a bias for the nephrologist to have to  
20 recommend this particular service whether or not it makes  
21 sense for the patient or not. It's not \$500, as we  
22 understand it, for simply educating the patient about  
23 options. It's \$500 if the patient uses this particular

1 service. There is no payment -- the payment is not  
2 affected in any fashion by quality or outcomes. There is  
3 no accountability for any savings, et cetera. It's simply  
4 the change -- those two changes in payment.

5           Okay. A little faster from this. Value over  
6 volume, certainly it would be beneficial to be able to  
7 deliver this service, so we felt that it met that  
8 criterion.

9           Flexibility, we debated this a lot and concluded  
10 that it did not meet the criterion because it's not clear  
11 that it gives the nephrologist a whole lot more flexibility  
12 given the restrictions. It's only available in certain  
13 circumstances, it only works in certain cases, et cetera,  
14 so it wasn't clear that it really provided a whole lot of  
15 flexibility.

16           Ability to be evaluated, we felt that it could be  
17 evaluated.

18           We did not feel that the proposal, as is often  
19 the case with many of our proposals that we get, addressed  
20 the issue of integration and care coordination. There  
21 certainly would be opportunities for better care  
22 coordination with the skilled nursing facility if dialysis  
23 was being done there rather than off site, but there was



1 nothing described explicitly as to how that would be done.

2           We did feel that it gave patients another choice  
3 because the ability to get more frequent dialysis in the  
4 nursing home is a choice that most patients do not have  
5 today. So that would be an advantage from the patient's  
6 perspective.

7           Conversely, though, we were very concerned about  
8 the patient safety issues because there could be some --  
9 there are some risks associated with more frequent  
10 dialysis, and there would be these transition problems that  
11 would occur for patients who would suddenly be getting more  
12 frequent dialysis in the nursing facility in a short-term  
13 stay and then not being able to get it afterwards. And it  
14 would be less likely that the nephrologist would be seeing  
15 the patients less frequently if they were only seeing them  
16 once a month rather than seeing them multiple times in the  
17 dialysis center.

18           And, finally, we did not feel it met the HIT  
19 requirements because there was no real discussion at all  
20 about how HIT was going to be used.

21           So, with that, let me see whether Rhonda or Jeff  
22 have anything that they want to add or correct about what I  
23 said.

1 DR. MEDOWS: I have no edits, no corrections.  
2 Comprehensive as usual. I'm actually more anxious to hear  
3 from the applicant themselves. I think there are certain  
4 issues that you want to help us understand.

5 CHAIR BAILET: Well done, Harold. Thank you.

6 \* **Clarifying Questions from PTAC to PRT**

7 CHAIR BAILET: So do the Committee members have  
8 clarifying questions for us at this point? Bob?

9 DR. BERENSON: If I have this right, the real --

10 MR. MILLER: If you have it right, you get lots  
11 of points, because it was hard.

12 DR. BERENSON: No, just what you've said, not  
13 what they're going to say.

14 That is, patients who are in a nursing home for a  
15 SNF stay, that benefit mostly, they're the ones who  
16 disproportionately need dialysis. Is that part right?

17 MR. MILLER: No. The sense was, though, that  
18 what is happening is that those are the patients who are  
19 getting it today. So it's not -- there's nothing about the  
20 --

21 DR. BERENSON: Getting what?

22 MR. MILLER: Getting the dialysis in these  
23 nursing facilities are mostly -- I think their number they

1 can tell you themselves, but it was about 60 percent or  
2 more of the patients who were getting --

3 DR. BERENSON: Okay, because I believe there are  
4 some nursing homes that specialize in SNF patients, so they  
5 probably have the volume to justify -- I mean, this is just  
6 --

7 MR. MILLER: Yes, and we were told also that this  
8 is also apparently attractive to hospitals who now feel  
9 that they can discharge a patient to a skilled nursing  
10 facility that can do dialysis rather than having to  
11 discharge them to a place where they --

12 DR. BERENSON: The point I was going to ask about  
13 is this would -- my understanding -- and I may be wrong on  
14 this -- is that the average SNF stay is about 30 days,  
15 which happens to be the time that there's no co-payments,  
16 and that this would like be a benefit for one month for  
17 those patients.

18 MR. MILLER: That's the concern, is that the  
19 majority of the patients would get it for a very short  
20 period of time.

21 DR. BERENSON: Okay. Thank you.

22 CHAIR BAILET: Len?

23 DR. NICHOLS: So I was intrigued with this notion

1 of the dialysis den. How big does it have to be? And if  
2 it's that big, how much does it lower the cost?

3 MR. MILLER: Well, their number was that they  
4 needed about eight patients to make it financially viable,  
5 although financially viable appears to be a combination of  
6 Medicare and other non-Medicare patients being able to pay  
7 the bills for it. And some patients might be -- and,  
8 again, they can clarify this. Some patients might be in  
9 the den, and some patients might be actually getting  
10 bedside treatment. But I think the majority of patients  
11 would be getting it in a -- in a room that would be set up  
12 with dialysis equipment in it. So that's the issue.

13 So the nursing facility would have to have space  
14 and, you know, whatever, but they're using home  
15 hemodialysis equipment, so it's essentially designed to be  
16 something that anybody could use in their own home. So  
17 it's not something that would require all kinds of special  
18 hook-ups. Again, I think they can clarify that.

19 CHAIR BAILET: But they do deploy a staff. They  
20 do deploy a staff.

21 MR. MILLER: They would have a staff there, so  
22 there's an employed staff that there have to be enough  
23 payments coming in for enough patients to add up to cover

1 that. So they were saying that they felt that they needed  
2 to have eight people per facility and two facilities nearby  
3 to be staffed by the same group of people.

4 CHAIR BAILET: Any other -- Bruce?

5 MR. STEINWALD: Yeah, a question. I see in their  
6 response to questions they have 30 sites operational and  
7 contracts in a bunch more in several states. And this is a  
8 question perhaps as much for them. You said in your review  
9 that it's actually more expensive to provide this in  
10 nursing home dialysis than in center dialysis, the way it's  
11 typically done, three days a week.

12 MR. MILLER: Well, there's two separate points  
13 here. One is how expensive it is to do the dialysis and  
14 how much Medicare pays. So the issue -- on the Medicare  
15 side, the issue would be if you're getting -- if you're  
16 getting more frequent dialysis anywhere, if you're getting  
17 it five days a week -- and Medicare pays by the dialysis  
18 session, so if you get it five days a week, Medicare pays  
19 more.

20 The cost is a separate issue. It appears that  
21 they don't think that they can do it at the Medicare  
22 payment rate per dialysis session.

23 One other thing I should -- worth highlighting

1 here is that the assumption is also that most or all of the  
2 patients who are in the nursing facility who need dialysis  
3 would qualify for a Medicare payment for more frequent  
4 dialysis. That's a MAC, Medicare administrative  
5 contractor, decision as to whether or not they are, and  
6 there is apparently some issues going on with that right  
7 now in terms of the MACs trying to change the rules, the  
8 MACs not approving as many patients as before, and so the  
9 belief from the applicant is that most of the patients  
10 would meet the criteria because they are sick patients and  
11 they're in a nursing home, et cetera, and so, therefore,  
12 more frequent -- they would qualify for more frequent  
13 dialysis. But it is currently dependent -- there's no  
14 proposed change to this. It's dependent on having the  
15 current rules for whether the patient is eligible for more  
16 frequent dialysis continued to persist in the future.

17 MR. STEINWALD: Thanks. I guess we can wait for  
18 the proposer to explain more about the relationship with  
19 the skilled nursing facilities and what their interest is  
20 in participating in the model.

21 CHAIR BAILET: Paul?

22 DR. CASALE: Just a question around that  
23 education bonus of \$500. Is that for patients who are

1 enrolled, or is it educating patients to get them enrolled?  
2 That was one. And, second, how did -- any insight on how  
3 they came up with \$500?

4 MR. MILLER: No.

5 DR. CASALE: No to the --

6 MR. MILLER: Well, to all of that. You should --  
7 you should ask them. I would say it is not -- it is not  
8 clear in the proposal. We did not try to pin this down, so  
9 you should ask them. My understanding or my impression is  
10 that it's a \$500 bonus to the nephrologist if the patient  
11 decides to use this service on the premise that the  
12 nephrologist has helped them understand the benefits of it.  
13 And the \$500 was intended in some fashion to make up for  
14 the loss of the education payment that the nephrologist  
15 gets if a patient is actually on home-home hemodialysis  
16 because they would ordinarily need to educate the patient  
17 about how to do that, and they would get paid for that. So  
18 the idea here is that you would get sort of the same thing,  
19 but whether or not anybody determined whether that was the  
20 right number or not, I'm not sure.

21 CHAIR BAILET: All right. So we're going to go  
22 ahead then and have our applicants come up, and if you have  
23 prepared remarks, that's -- we're going to restrict those

1 to ten minutes as best we can, and then obviously the  
2 Committee has a lot of questions.

3 MR. MILLER: You will not --

4 CHAIR BAILET: So if you could introduce  
5 yourselves, that would be great.

6 MR. MILLER: -- in any fashion if you disagree  
7 with things that I said in the spirit of clarification.

8 [Pause.]

9 CHAIR BAILET: All right. Very good. So Allen,  
10 Dr. Kaufman, do you want to -- okay. Very good.

11 One clarifying question. You have another member  
12 on the phone with you?

13 MR. ROTHENBERG: He is just listening, Dr. Nathan  
14 Levin.

15 CHAIR BAILET: Okay. Very good.

16 \* **Submitter's Statements, Questions and Answers,**  
17 **and Discussion with PTAC**

18 MR. ROTHENBERG: I would like to thank the  
19 Committee for considering our application. I think that  
20 the recent misunderstanding of our model, and I wanted to  
21 explain our model, first of all, by a short story, how I  
22 got into dialysis, that will explain this focus on  
23 dialysis.



1           So the story starts with a woman by the name of  
2 Margaret Schneck. She happened to be my mother-in-law.  
3 She was admitted to Mount Sinai Hospital in New York a few  
4 years ago when she was told her kidney failed and she had  
5 multiple issues that derived from the fact that she never  
6 took care of her kidneys.

7           She stayed in the hospital for two months, very  
8 expensive hospitalization, which typically happens to a  
9 crash dialysis patient. When she was released, she moved  
10 into my home, 62 years old, and she was assigned to a local  
11 dialysis clinic, run by one of the larger dialysis  
12 organizations. Her slot was 5:00 in the morning. She  
13 would wake up at 4, we would drive 40 minutes. She would  
14 be there for about four to five hours, we would pick her up  
15 around 10:00. She will come home and stay in bed until the  
16 next day. She would be completely wiped. And she was on  
17 multiple blood pressure medications, very frequently  
18 rehospitalized, and had many -- she suffered from  
19 depression because of it. She didn't see any reason to  
20 live.

21           When I found out about home dialysis I reached  
22 out to the dialysis facility and I asked them about it.  
23 Even though they advertised for it, they really tried to

1 persuade me away from it. When the found out that I'm  
2 persistent and I'm planning on going to a competition, they  
3 agreed to train me to be the caregiver for my mother-in-  
4 law.

5           Within about three to four weeks I was trained,  
6 and within a month of her being on that more frequently  
7 dialysis she was able to drop an additional 13 kilograms of  
8 water, which is about 26 pounds, that traditional dialysis  
9 was not able to remove. Her blood pressure medication went  
10 down from 4 to 0. She was able to travel. Her recovery  
11 time went down from almost a full day to about a half hour.  
12 Her life completely changed.

13           When she went back for a scheduled open heart  
14 surgery for a valve replacement, the doctor in the hospital  
15 asked her, "Who are you? Where do you come from? What did  
16 you do to yourself?" and she said, "I did home dialysis."  
17 And the doctor said, "I never heard about it." And to  
18 date, many doctors don't even know about this particular  
19 modality.

20           In the United States there are 500,000 dialysis  
21 patients, over 500,000. There are only about 1 to 2  
22 percent on home dialysis. What shocked me at that time is  
23 that in the state of New Jersey, where I live, out of

1 13,000 dialysis patients there are 94 on home dialysis, and  
2 it's not because they don't want it. It's because there  
3 are barriers to entry, and the barriers for this modality  
4 is, first, you need to find a really dedicated caregiver  
5 that's willing to commit to do it without taking off.

6           Second, doctors feel more comfortable when the  
7 patient comes to the dialysis clinic. They have nurses  
8 taking care of that patient and he doesn't have to be  
9 worried about getting phone calls, answering questions.  
10 Ninety-five percent of nephrologists that were surveyed  
11 around the country said if their family member would need  
12 dialysis they would recommend home dialysis, but that is  
13 not the case to their patients.

14           That's the time that I founded Dialyze Direct,  
15 with the mission to look at who are the patients that will  
16 benefit the most out of this particular modality. And the  
17 patients that benefit the most are the patients that  
18 actually cost to the system the most, and they are the  
19 patients that are the most frail and have specific needs  
20 that traditional dialysis does not address. Those are the  
21 patients that live in the nursing homes. Nobody likes to  
22 be in the nursing home and nobody likes to be on dialysis.

23           These patients are being shipped from the nursing

1 home to the dialysis clinic. They're long term or short  
2 term. And while in the dialysis clinic, if something goes  
3 a bit wrong or if something is a bit off, nobody takes  
4 responsibility. These patients are being shipped right to  
5 the acute care hospital.

6 A paper that was published recently, in the last  
7 few months, looked at state by state and incident dialysis  
8 patients, patients that started dialysis and they live in  
9 the nursing home. The average patient spent about 30 to 40  
10 nights in the hospital a year. That's a real cost to the  
11 system.

12 Dialyze Direct went and created a model of  
13 coordination of care in the nursing home, where our staff,  
14 our trained staff, licensed staff, are going into the  
15 nursing home and providing this care to these patients.  
16 These patients are now, we know, every change of  
17 medication. Instead of a paper that sometimes goes between  
18 the dialysis clinic and the nursing home, they meet face-  
19 to-face with the nurses to take care of these patients. We  
20 provide the care for these patients during dialysis, and  
21 what we see is that dialysis-related hospitalizations  
22 dropped so far by over 60 percent, that's significant,  
23 compared to the USRDS data as far as hospitalizations.

1           One more phenomenon that we see is that patients  
2 that are on Permcath around the country are very prone to  
3 infection. That's the access for the dialysis. Every  
4 preparation, specifically the ones in the nursing home, a  
5 very large majority of them are on Permcath because their  
6 veins are too weak. We see a dramatic, almost 100 percent  
7 reduction of infection rate with these patients. That  
8 drops hospitalizations as well.

9           So we resolved the issue of the barrier of  
10 patients having the ability to have the caregiver, because  
11 our caregivers are there. As far as having dialysis in the  
12 nursing home, we do not need hundreds of patients. We need  
13 about 10 percent of the patient population in the building.  
14 So if a building has 100 patients, 8 to 10 patients, that's  
15 what we have.

16           We are right now over 50 buildings. We keep  
17 growing rapidly. And I can tell you that most of our  
18 buildings, the census is 8 to 10 patients, and we have some  
19 waiting lists on them from the discharge planners from the  
20 hospital.

21           We do treat patients that are long term, and we  
22 do treat patients that are short term. I will tell you  
23 that the managed care on the Medicaid side, and state by

1 state, and the managed care on Medicare Advantage, they see  
2 the cost of these patients, they consider them to be a very  
3 high cost, and they are paying the amount that we said that  
4 we need just to break even, just over to break even. So it  
5 is the right thing for these patients, and they see how to  
6 save that money.

7           The only barrier that we didn't overcome with  
8 this model is the physician. A physician does not have an  
9 incentive to come to the nursing home, and the reason for  
10 it is the physician goes to the dialysis center, they have  
11 multiple patients at a time, they can see 20 to 30 patients  
12 at a time, depending on the amount of stations, and they  
13 just sweep by, and they did their visit.

14           So when we originally went and were recommended  
15 by somebody in CMS, based on the outcomes that they saw on  
16 CROWNWeb at the time, to meet with CMMI, CMMI noticed that  
17 the main barrier that we have is the physician, and that's  
18 why we were referred to the PTAC at the time.

19           Our model, we did not focus right now on  
20 increasing the payment to our treatment, but we focused on  
21 the main barrier for these physicians. When they do home  
22 dialysis, they do get this extra payment of \$500. We do  
23 not charge for training, which, in typical home dialysis

1 patients we would get paid separately for the training and  
2 the physician will get paid for the training. The  
3 physician doesn't train but he oversees the training. Over  
4 here, because it's our staff, we are not going to charge  
5 for the training.

6 But the overall savings to the system is the  
7 better coordination of care. Besides the actual  
8 medications that we see -- and trust me, there are a lot of  
9 -- nursing homes never send any information to the dialysis  
10 center and patients are coming to the dialysis center after  
11 they had a blood pressure medication and then when it drops  
12 a bit more, they are in dialysis, they end up in the  
13 hospital. We even provide IV therapy for the vancomycin,  
14 for example, that a patient would need. He would not need  
15 a separate IV therapy. They do it on site.

16 Our patients were able to do rehab on a daily  
17 basis as opposed to dialysis patients that cannot do it on  
18 a daily basis, because they are too tired. Our recovery  
19 time -- with this modality the recovery time is about 30 to  
20 60 minutes, and that's research-based. One of the less --  
21 Dr. Kaufman will speak about the modality and how big is  
22 the savings so far, and the outcomes that are known to very  
23 big studies that were done around the country with that.

1           I will tell you also that one of the research  
2 students that was published showed direct correlation from  
3 reduction of recovery time to hospitalizations, and the  
4 fact that we are reducing it from almost a full day to a  
5 half hour to an hour, that alone is a huge savings.

6           So these patients are coming from the lowest  
7 socioeconomic. Like you said, many of them are Medicaid  
8 patients. They are there on the long term. They don't  
9 have a chance with the regular treatment. They are being  
10 looked at as the outliers, and as a matter of fact, the  
11 system is almost incentivizing them to go to the hospital  
12 every 30 days because then they are not considered on the  
13 census of that particular dialysis clinic so they don't  
14 even affect the star rating, so considered transient.

15           We only focus on the real sick that cost the  
16 most. If regular dialysis patients are 1 percent of  
17 Medicare population -- they cost 7 percent of the budget --  
18 the 65 and older on dialysis are 20 percent, and as they  
19 get sicker and sicker, it gets much stiffer. So we are  
20 targeting the main reasons for hospitalizations, which the  
21 root cause for it is the fluid overload.

22           I think -- any questions? Our team is ready to  
23 answer.



1 CHAIR BAILET: Thank you. Len, Kavita, Tim, and  
2 Grace.

3 DR. NICHOLS: Thanks for starting with a story.  
4 That was very helpful.

5 I would like to ask about the model. You  
6 mentioned the target of the physician. But one of the  
7 things that's curious to me, as an economist, is where the  
8 savings sort of end up. And I guess the question really is  
9 why not build in a shared savings or some kind of shared  
10 risk for the hospitalization ED stuff into your larger  
11 system? That would seem to make it much more likely to be  
12 viable for you, you could share it with the SNF, whatever.

13 MR. ROTHENBERG: I think it's a very good  
14 question, and the answer to it is as follows. We treat  
15 these patients, some of them for a short time, some of them  
16 for a longer time. We are not responsible for the full  
17 care for these patients. There are other providers and  
18 other stakeholders to take care of these patients.

19 What we measure is the dialysis-related  
20 hospitalizations. As an example, a patient could have many  
21 other issues, but the things that are related to dialysis  
22 that typically take X amount percentage of his  
23 hospitalizations, which is very high in the dialysis

1 patients, those are the ones that we see huge successes and  
2 we can monitor that, and provide those types of outcomes.

3 But as far as overall care for these patients, we  
4 are not responsible for it. It's very different than, for  
5 example, an ACO or a primary care that's really in charge  
6 of the whole care for these patients. We only take care of  
7 the dialysis part. We help to manage the other chronic  
8 diseases, because when you take that particular part of the  
9 care, if you address that part of the care, ultimately the  
10 human body handles better other diseases as well that  
11 derive from the complications.

12 DR. NICHOLS: Yeah. All I was getting at was  
13 that I think the appeal of the model to CMS -- forget us --  
14 the appeal of the model to CMS will be maybe there's a  
15 shared coordination arrangement with the other providers,  
16 in the ecosystem of these patients. You identified, focus  
17 on managing the dialysis portion of it, but the savings  
18 right now would seem to me to be redounding to either the  
19 MA plan, the MCO if it's Medicaid, or the SNF or somebody,  
20 or the hospital.

21 And so, fundamentally, it would seem there's a  
22 much more elaborate model that one could develop here, that  
23 would take advantage of what you're doing.

1           MR. ROTHENBERG: I just want to add two things  
2 that I realized that I missed. First, in the past year,  
3 CMS went and took action about this modality in the nursing  
4 home. On the nursing home side, they went and published a  
5 state operating manual that demanded the nursing home to  
6 educate patients about the possibility of having it onsite,  
7 and if a patient elects to have it, then nursing home has  
8 to provide documentation that either they help to move them  
9 to a facility that has it or they provide it onsite. On  
10 the dialysis side, they went and published, this month,  
11 guidance to provide home dialysis in the nursing home.  
12 This is where CMS sees a huge benefit for these patients.

13           The next thing that I will tell you, the idea  
14 over here of us providing this model, it's not for Dialyze  
15 Direct. We truly believe, and what we see so far and how  
16 the industry goes, and how this directly helps these  
17 patients, we hope that every single provider, dialysis  
18 provider around the country -- we cannot handle the whole  
19 country -- will take from that, and we are not even looking  
20 to do that -- will take that and do it everywhere else.  
21 It's simple to learn and to adopt and to do, if we show  
22 that we overcome those particular barriers.

23           So this is the opportunity to really make it more

1 available. There are 75,000 dialysis patients in the SNF  
2 right now, according to CMS. We believe it's more because  
3 the short-terms are not really calculated in that. So it's  
4 about 10 to 15 percent of the dialysis population in total.  
5 And there are 7,000 nursing homes that will take care of  
6 these patients. We see, right now, in the Midwest, for  
7 example, you would have -- I mean, Dialyze Direct  
8 purchased, yesterday, a company in Illinois that has 400  
9 patients just in Chicago alone in the nursing homes. So it  
10 is there. The issue is what are the incentives of these  
11 physicians?

12 CHAIR BAILET: Kavita.

13 DR. PATEL: You sort of answered it. I was  
14 trying to understand kind of the denominator. Can you tell  
15 me a little bit more about -- you mentioned the, kind of,  
16 I'll say, staffing ratios of what assistance might be  
17 required. What would that entail if you actually tried to  
18 do this, because at least in the nursing homes I've worked  
19 in and have worked with, they wouldn't be able to  
20 necessarily meet some of those thresholds, even if there  
21 was a very attractive kind of alternative payment model.

22 So do you think this is going to be limited to  
23 skilled nursing facilities of a certain size, or do you

1 have a sense of what that might be in terms of market  
2 uptick for this?

3 MR. ROTHENBERG: Sure. So first of all, the  
4 nursing home that we feel is the right nursing home to  
5 start with are not the ones that are 40 or 50 beds, unless  
6 there are specifically vent units, that they have a  
7 specialty. The nursing homes that we have, most of them,  
8 the average nursing home size, which they are about 100  
9 beds and up. I can tell you that we have, to date, over  
10 200 facilities that have already signed up with us, waiting  
11 for us to go in there. There is a huge push and need from  
12 the nursing home asking for this particular service.

13 What Dialyze Direct offers them, it is our staff,  
14 not the nursing home staff. We spend one caregiver to two  
15 or three patients, depends on if you have four patients or  
16 six patients. Until this month we only did four patients  
17 in a room at the same time in the den setting. CMS took  
18 away that restriction and now we are doing six or eight,  
19 depends if it's a very large nursing home. When a patient  
20 has need as far as a vent patient, a patient that has  
21 isolation needs, a patient that has an injury and cannot be  
22 moved, that will be on the bedside. It will be one to one.

23 DR. PATEL: Do you mind -- this is just a follow-

1 up. This is more of a comment. It feels like -- and I'll  
2 speak just for myself, but you are identifying almost all  
3 the flaws, especially with your mother-in-law's story, in  
4 doing what I think is the right thing for patients, that  
5 are somewhat regulatory, somewhat just this arcane nature,  
6 the way we pay for medicine, and then, quite frankly, it  
7 sounds like the business model for a nephrologist, whether  
8 that's an employed nephrologist or an independent solo  
9 nephrologist, really is not viable in a patient-centered  
10 world. The way you describe it's kind of forcing this  
11 function.

12           And the struggle that I have is that it's hard to  
13 think about this as a payment model. It feels, to me, like  
14 this more needs to be a conversation with, frankly, the  
15 very people who were here earlier today, the Secretary, the  
16 head of CMS, and the head of CMMI, to say, "Come on. This  
17 is ridiculous. We have some tangible barriers that could  
18 be overcome with some of the changes and the fee schedule,  
19 relaxation of some of these regulations," and, quite  
20 frankly, the way we pay for Medicare benefits in the  
21 nursing home setting. And my only kind of statement is  
22 that I think that might go a lot further than creating a  
23 model where I think there are some significant gaps.

1 CHAIR BAILET: Tim.

2 DR. FERRIS: So I'm going to pick up where Kavita  
3 left off and approach it a little bit more from a  
4 conceptual level.

5 My summary would be that you have identified,  
6 through your personal encounter and then through figuring  
7 out what the ecosystem is around home dialysis, a better  
8 model of care, a model that because it exists now -- and  
9 I'm talking about the care model first. I'll get to the  
10 financial model. But the care model, it is clearly,  
11 unequivocally a better care model.

12 It exists now, which means that the possibility -  
13 - there may be barriers, but as Kavita was saying, there  
14 are barriers in everything we do in health care. Nothing  
15 is ideal. And it seems to me that you are -- you said  
16 yourself you are rapidly growing, which means, actually,  
17 whatever barriers that exist, you are finding ways to  
18 overcome those barriers, in fact. And there is an  
19 information gap, but that information gap is present with  
20 any new technology.

21 And so it seems to me that the incentive that's  
22 being sought here is the incentive of how do we disseminate  
23 a proven, better model of care, and what are the finances

1 associated with that dissemination and more rapid adoption,  
2 so that more people can take advantage of that?

3 I would say traditionally, in economic terms --  
4 and I recognize physicians practicing economics is probably  
5 a bad idea -- that, in general, it's a fairly simple  
6 solution and that generally doesn't involve necessarily  
7 alternative payment mechanisms. It involves just paying  
8 what is necessary to get the job done, to incent people to  
9 get the work done. So I'm thinking about new codes. I'm  
10 thinking about properly valuing codes. But I don't  
11 necessarily move to the place of a new payment model when I  
12 think about I want something that's relatively new, maybe  
13 not so new, but clearly better, and I want that more widely  
14 adopted.

15 So it's sort of just a frame in which I think  
16 about dissemination of technology, adoption of technology,  
17 and maybe you could respond to that.

18 MR. ROTHENBERG: Sure. Two things I would like  
19 to say. We believe that the success of this model and the  
20 success of the outcomes that will really save cost, really  
21 relies on the continuity of care. And the person that  
22 knows the patients the best is the person that has history  
23 with the patient. Right now, many of the physicians that



1 see these patients don't want to continue to see the  
2 patient while he is in the nursing home, because they don't  
3 have the incentives.

4           If we want to save money, to the government and  
5 the payer, is by encouraging this continuity of care, and  
6 it will not happen unless there is a payment model that  
7 will target that. Ultimately, yes, we feel that we are  
8 saving a lot of money to Medicare for the acute care stay,  
9 tremendously, and the transportation, when the  
10 transportation is warranted. But we targeted what we feel  
11 is the biggest barrier to really have the best outcomes for  
12 these patients. When you bring in a physician from the  
13 outside, yes, we manage to circumvent and go around this  
14 barrier, but that's not really the right, the best way in  
15 order to get the best outcomes. You're bringing in  
16 somebody new that never cared for this patient, starting  
17 from zero, and that's the reason why we are pushing for  
18 that.

19           CHAIR BAILET: Grace.

20           DR. TERRELL: So my background is I'm a general  
21 internist. I trained at Wake Forest, which has done a lot  
22 of work in the past, as a major center for end-stage renal  
23 disease, and a lot of work on peritoneal dialysis, and was

1 a medical director of a nursing home, where I couldn't  
2 stand to get an end-stage renal disease patient in because  
3 I just would end up hating the nephrologist I was dealing  
4 with. And then also I was over a Medicare shared savings  
5 program where we were able to get our benchmark and our  
6 savings much around bringing our cost down from whatever  
7 the benchmark was, \$70,000 for end-stage renal, to about  
8 \$50,000, by putting in some basic things, not this, that  
9 were about medical home and whole-person care.

10 So, number one, I love you guys, applaud you for  
11 what you're doing, but I have a few concerns based on my  
12 experience, that I just want to sort of flesh out with you.  
13 First of all, are you just talking about vascular dialysis.

14 MR. ROTHENBERG: Hemodialysis.

15 DR. TERRELL: Yeah. You're not doing any  
16 peritoneal dialysis at all, because there's a lot of that  
17 done at the homes. So just a series of little interrelated  
18 questions.

19 Second is, a lot of the work in the past on  
20 peritoneal dialysis has been because it could be done  
21 easily at home, and I think the rationale for what you're  
22 talking about here is that it is a nursing home. This  
23 these people's home, but we know that they're more complex.

1 They can't be at home. They need skilled care. So as it  
2 relates to that, how much thought have you put into what a  
3 non-nursing home home is like in terms of the resources,  
4 many of which, as you articulated well, are not adequate  
5 for this population, and what is actually needed and needed  
6 from a measurement standpoint in terms of resource. Has  
7 Medicare done that for you?

8           And then I guess my final concern, or at least  
9 I'd like you to talk about it, we talked about this being a  
10 better model of care, but I really almost winced when you  
11 said "but we're not going to take total care, because these  
12 patients are complex and others are involved."

13           I would like for you to comment on this within  
14 the context of my understanding of a really good model,  
15 which is about a specialty medical home where you do take  
16 total care, because I think that the people that I've seen  
17 in nephrology who have done it best basically take these  
18 patients and they become the primary provider. It has  
19 always seemed to me that the problem is that they don't  
20 like to do that in the nursing home, because it's awful.  
21 But as a medical director, my concern was that if they  
22 weren't doing that, the rest of the people on call were  
23 going to kill the patient, because they weren't used to

1 thinking about them being an end-stage renal patient when  
2 it came to that call in the middle of the night as it  
3 related to potassium or whatever.

4           So partly this is, I want you to think about what  
5 you all have relative to other alternatives within your  
6 specialty, and just explain to me why you got to this as  
7 opposed to some of that, because I know that work has been  
8 done.

9           MR. ROTHENBERG: So I will divide my answer  
10 between me and Alice Hellebrand. Alice Hellebrand is our  
11 Chief Nursing Officer. She is also the President of  
12 American Nephrology Nurse Association, and she will address  
13 the second part.

14           The first part, PD. Patients in the nursing home  
15 are cared for, but since the access for PD is close to the  
16 groin and there are issues with diapers and other things,  
17 as far as infection it is an issue for these particular  
18 patients, and that's the reason why we do not offer PD.  
19 There is one program in the country that does it, has a  
20 very small model. Rogosin Institute somewhere in New York  
21 has a small model that worked in one particular nursing  
22 home, but anybody else that tried that part really was not  
23 that successful.

1 DR. TERRELL: It's more of an outcomes issue.

2 MR. ROTHENBERG: Right. It's more of an outcomes  
3 issue.

4 I would like Alice to explain about your answer  
5 as far as the nursing home. I would tell you that in the  
6 nursing homes that we operate, it's not only that we just  
7 take care of dialysis and go. Besides the fact that our  
8 dietician goes and sees every single supplement the patient  
9 gets and they know that no new supplements are being given  
10 unless it runs by us as well. We know about any change of  
11 medication that we said. But also, we are there. So when  
12 they want to admit a patient, we first look at it, is it  
13 because maybe they just drank too much? Maybe we have to  
14 dialyze them instead of the afternoon, in the morning?

15 So there is definitely more coordination of care  
16 on that part, but Alice, maybe you could speak more.

17 MS. HELLEBRAND: As a nurse I'd like to point  
18 out, you know, the challenges with a nephrologist, and, you  
19 know, having some conflicts there. But I also want to say  
20 that when we first came into this, and coming from  
21 dialysis, you know, the majority of the skilled nursing  
22 home staff or owners of the skilled nursing home did not  
23 want to accept dialysis patients, and we found that they

1 were ending their life in not the best situation in an  
2 acute care hospital, because no one would take them because  
3 of the understanding of their special needs and high  
4 comorbidities.

5           Because we're in the skilled nursing home and  
6 we're collaborating with the staff that's onsite, and we're  
7 providing the education and the understanding of how to  
8 care for these patients when we are not providing that  
9 direct dialysis, they are more accepting from those  
10 patients. And not only, as Josh said, that we are bringing  
11 in our dieticians but we are also bringing in our social  
12 workers, and our social workers are actually talking to the  
13 patients and helping them to adjust to two totally horrible  
14 situations that these patients are in. No one grows up and  
15 says, "I want to live in a skilled nursing home," and I  
16 have never, in my over 30 years of being in dialysis, have  
17 ever had someone say, "I want to be a dialysis patient."  
18 And I will preface that by also saying that I don't know  
19 many nephrologists who say, "I'm going to medical school  
20 and I want to go into a skilled nursing home," which is  
21 really one of our barriers to success in this, and that's  
22 why we are proposing this model.

23           So our collaboration is improving the day-to-day

1 lives of these patients. I can't say that they're going to  
2 live longer. You know, we like to think that even dialysis  
3 cures the flu. It does not. I want to put that out there.  
4 But what we're trying to do what we have accomplished is  
5 giving these patients a better life and a better  
6 understanding within the medical community.

7 DR. TERRELL: So within the context of your  
8 concern about not considering taking on the total cost of  
9 care, I think most specialties don't need to take on the  
10 total cost of care. I just wonder if within the context of  
11 actually owning, if you will, an end-stage renal disease  
12 patient, if this is actually a specialty that could and  
13 should, because of the potential that's out there, and why  
14 you basically, specifically said you didn't want to do  
15 that.

16 MR. ROTHENBERG: So because we are in a different  
17 facility that has different -- they have interests that  
18 some aligned with us, but they have their own staff and  
19 their own interests. And they're really responsible for  
20 that care.

21 We are contributing as much as possible for this  
22 care, but there is a conflict over here that we could not  
23 take complete care for these patients because they are the

1 ones responsible primarily for everything.

2 But what we did put inside is that although we  
3 are not responsible, there are things that they have to  
4 report to us before they change. Like you said, the  
5 middle-of-the-night call and changing, nobody is  
6 prescribing any new medication until they show up in the  
7 morning. If it is that life-saving, they should be in the  
8 hospital.

9 And we see that that type of corroboration helps,  
10 but they still want to be in charge of that part. We will  
11 not have customers as far as nursing homes if we would say  
12 we want to take charge of this whole -- of the whole care  
13 of these patients.

14 CHAIR BAILET: Bob.

15 DR. BERENSON: I probably missed this, but I'm  
16 trying to do some quick studying on the internet about CPT  
17 codes and things like that. Now, now.

18 So did you say that the nephrologist who you want  
19 to incentivize to go to the nursing home would actually be  
20 doing the training?

21 MR. ROTHENBERG: No.

22 DR. BERENSON: No, all right.

23 MR. ROTHENBERG: It would not be the training.



1 It's just instead of the training, where they would get --

2 DR. BERENSON: Right.

3 MR. ROTHENBERG: And right now, they're being  
4 incentivized to oversee the training. They never train.

5 DR. BERENSON: Right.

6 MR. ROTHENBERG: But to oversee the training for  
7 home dialysis, in the clinic, they would go home-home by  
8 \$500. We're trying to -- we can --

9 DR. BERENSON: So there is a CPT code for the  
10 physician --

11 MR. ROTHENBERG: Yes, yes.

12 DR. BERENSON: -- to oversee the training?

13 MR. ROTHENBERG: Yes, correct.

14 DR. BERENSON: And then there's a separate  
15 payment for the clinic --

16 MR. ROTHENBERG: Correct.

17 DR. BERENSON: -- that does the training. Is  
18 that right?

19 MR. ROTHENBERG: Correct, correct.

20 DR. BERENSON: So wouldn't there be an  
21 opportunity to just extend, create a new code for training  
22 in the nursing home, not just at home, for overseeing  
23 training in the nursing home?

1 MR. ROTHENBERG: But there's no training. You're  
2 eliminating the training. It's our staff.

3 DR. BERENSON: Because it's not in the home?

4 MR. ROTHENBERG: Because it's staff-assisted,  
5 it's our staff. Our staff are trained. They're not  
6 training for this particular patient.

7 DR. HELLEBRAND: Right. We're not using the  
8 person who's developing -- providing the care is not the  
9 husband, wife, friend, whatever.

10 DR. BERENSON: I see. So I got it.

11 DR. HELLEBRAND: It is dialysis --

12 DR. BERENSON: So there is no training necessary.

13 DR. HELLEBRAND: It is dialysis professionals.

14 DR. BERENSON: So then you can't justify  
15 overseeing the training.

16 MR. ROTHENBERG: Right. There is money available  
17 should that patient -- would have been -- gone home, but we  
18 are bringing out staff to provide it. So that's why we're  
19 trying to say there's --

20 DR. HELLEBRAND: There's code.

21 MR. ROTHENBERG: Correct.

22 DR. BERENSON: All right. So that's helpful to  
23 understand that barrier.

1           The second one I have is, as you described the  
2 economics of all of this, that nephrologists are more than  
3 happy to see 20 patients in a center, getting \$237 per  
4 month or something that I just quickly looked at --

5           MR. ROTHENBERG: \$280.

6           DR. BERENSON: And that's supposedly based on  
7 resources and actual costs, which is practice expenses and  
8 work, which sounds like it's exorbitant for what they're  
9 doing, and that the practice expenses and work would go up  
10 if you're seeing only a few patients in a nursing home, so  
11 that, again, another HCPCS code or CPT code that pay at a  
12 higher level for seeing a patient in a nursing home would  
13 be a potential solution. Is that not something that --

14           MR. ROTHENBERG: I think that will be way too  
15 complicated, as with all the -- with all the codes they  
16 right now have to deal with as far as -- you see a patient  
17 when they go to a center. They expect -- in order for them  
18 to get the full monthly capture rate, they have to see the  
19 patient four times a month. So they come once a week, and  
20 they see all the patients per shift.

21           And for a home patient, they see them once a  
22 month. So those codes are there. To start to have now a  
23 separate code to something that it is home dialysis, but

1 it's not really home dialysis that has to be -- it's a  
2 different model because right now, it's just bundled up.

3 DR. BERENSON: No. It would have to be  
4 designated as --

5 MR. ROTHENBERG: And we were told --

6 DR. BERENSON: But you are in a whole new payment  
7 model. That strikes me as pretty complex also as opposed  
8 to --

9 MR. ROTHENBERG: Well, we think --

10 DR. BERENSON: -- there's a CPT code for -- how  
11 many times does a nephrologist have to go to the nursing  
12 home to supervise the dialysis?

13 MR. ROTHENBERG: At least once a month.

14 DR. NICHOLS: So, Josh, you just started to say  
15 we were told it was too complicated to add a new code.

16 MR. ROTHENBERG: Correct. And where we were  
17 directed, when we're directed to PTAC from CMMI, it was  
18 because of that, and --

19 DR. BERENSON: Did you ever go to CM? I mean,  
20 did you ever go to the people in charge of the fee  
21 schedule?

22 MR. ROTHENBERG: We were --

23 DR. BERENSON: Who are they? Who are these

1 people who told you?

2 MR. ROTHENBERG: It was a whole committee of  
3 CMMI, and then it was like six, seven people around there  
4 in the room. And they said, "This is great, and if you  
5 tell us this is your problem right now and we see why it  
6 is, go to PTAC" --

7 DR. BERENSON: So you started at CMMI?

8 MR. ROTHENBERG: Yes.

9 DR. BERENSON: Okay.

10 MR. ROTHENBERG: That's what it is. We started  
11 at CMMI, and they said go to PTAC to see if you can get  
12 this --

13 DR. BERENSON: Okay. Now I'm getting it. Now  
14 I'm getting it.

15 [Laughter.]

16 DR. HELLEBRAND: Your world is as complicated as  
17 ours.

18 DR. BERENSON: You know, there's 9,000 codes in  
19 the Medicare Fee Schedule. There's 9,000. They're not all  
20 active at all times, but there's -- there's actually 9,500  
21 that I just had to work through to do 2.0.

22 The point is the nephrologist doesn't need to  
23 know 9,000 codes. If a nephrologist has a specialty in

1 going to the SNF to do dialysis, they'll learn what the  
2 three codes are or whatever it is, the Rutkin value, the  
3 extra work that's associated with the fact that you do not  
4 have any economies of scale because there's fewer patients,  
5 and this doesn't strike me as a payment model. This  
6 strikes me as the need for some targeted coding to solve a  
7 problem, is I guess my initial thinking on this.

8 I'm done.

9 CHAIR BAILET: Thank you, Bob.

10 Harold.

11 MR. MILLER: So I'd like to reorient just a  
12 little bit here because I think we -- all the questioning  
13 so far has been primarily about is it good to be doing what  
14 Dialyze Direct is doing, and I think what they're doing  
15 makes perfect sense. And once the PRT sort of struggled  
16 through that, we thought, sure, it basically makes sense.

17 The question is about whether it's always the  
18 best thing, but in general, the best thing. And then  
19 people sort of leaped over and sort of just accepted the  
20 assumption that the nephrologist needed an incentive, and  
21 then Bob started talking about trying to create codes.

22 So I'd like to sort of focus, though, on that  
23 part in the middle because, I mean, that to me is what this

1 is all about. The question is, Does the nephrologist need  
2 something different, and what is that something different  
3 that they need? And that's the thing -- that's all we are  
4 talking about here. We're not in the position of saying is  
5 Dialyze Direct a good program. You're not asking for  
6 different payment for the dialysis. We have nothing to do  
7 with that.

8 All you're proposing here is a model to pay the  
9 nephrologists differently, and what you've proposed -- I'm  
10 surprised you would say creating a code is complicated when  
11 you're talking about trying to calculate 90 percent of the  
12 savings on transportation when the transportation isn't  
13 even covered.

14 But I'd like you to sort of articulate more  
15 clearly. What exactly do you think the barrier is for the  
16 nephrologist? Why do you think this proposal that you have  
17 made for the change directly solves that? Because I'm not  
18 convinced that it does. What other options you considered,  
19 and why you rejected them in favor of this one, and why you  
20 think that this actually works when we didn't think that it  
21 would work.

22 So I'd like to just focus very specifically on  
23 that. Let's assume -- don't tell me about why Dialyze

1 Direct is a good thing. I accept that. What I want to  
2 understand is if the nephrologist is the barrier, which  
3 apparently it hasn't been too much so far, but if the  
4 nephrologist is the barrier, what exactly is the -- what's  
5 your analysis of the causes of the barrier? Because there  
6 is currently concern about nephrologists not wanting to do  
7 home dialysis, and I don't think that would be solved by  
8 what you're proposing.

9           It's because -- back to Bob's issue is -- they  
10 get paid less for a home dialysis patient than they do for  
11 a center dialysis patient, a slightly smaller amount. They  
12 would be -- it's a disadvantage for them today to see the  
13 patients in their office. It would be even more  
14 challenging for them to have to go to nursing homes to be  
15 able to do that.

16           Is that the barrier, and what do you think your  
17 thing does to solve that? What did you consider  
18 alternatives, and why do you think it actually works? That  
19 to me is the nub of what we have to decide today.

20           MR. ROTHENBERG: Let me give it a true.

21           We believe that the barrier is to have the  
22 patient continue with the same nephrologist that they have  
23 until now. The nephrologist doesn't have -- every



1 nephrologist is asking, "What is in there for me? Why  
2 would I want to go to the nursing home if I can have them  
3 come to my center, to the center I'm associated with?"

4 MR. MILLER: So can you just stop there for a  
5 second? So what is the nephrologists doing in those  
6 circumstances? Are they saying to the patient, "No, no,  
7 no. You don't want to do this"? What is the thing that's  
8 happening that you're trying to overcome?

9 MR. ROTHENBERG: Okay. Two things happen.  
10 Either they say go find a nephrologist that will take care  
11 of this patient, or they will try to persuade the patient  
12 to just continue, come to the center. And then it's  
13 patient choice. We just tell the patient the facts. It's  
14 his choice to decide if that's what he wants, but if the  
15 patient wants, he would have to give up his nephrologist,  
16 which is we feel detrimental to the success. When I speak  
17 for the success, I speak about outcomes and about  
18 ultimately saving the cost, the overall coast.

19 When we will go to nephrologists and say there's  
20 a different payment for this and you would get paid, these  
21 incentives over here, that you will get paid per patient in  
22 addition to your monthly capture rate that you get  
23 regardless, that will make -- we believe will make the

1 nephrologist -- when we see evidence to say, "Okay. Now I  
2 understand that I do have incentives over here."

3 MR. MILLER: Can you explain to me why you  
4 believe that what -- you would do that? Have you talked to  
5 nephrologists --

6 MR. ROTHENBERG: Yes.

7 MR. MILLER: -- and they said, "You give us \$500,  
8 man, and we'll send all of our patients your way"?

9 MR. ROTHENBERG: It was "Put us on your payroll.  
10 Give us something for coming in there and doing it, and if  
11 there's incentives, we will do that." Yes.

12 MR. MILLER: Wait, wait, wait. Pause here. "Put  
13 us on your payroll," that's not a \$500 one-time bonus?

14 MR. ROTHENBERG: Well, they have few patients.  
15 The point is, the idea is that what is in for me. I need  
16 to see an incentive to come in there.

17 MR. MILLER: But what I'm saying to understand,  
18 really specifically, is you've proposed a one-time \$500  
19 bonus for something the nephrologist is going to have to do  
20 on potentially a long-term basis, not for the short-term  
21 patients. For the short-term patients, I can kind of  
22 understand it, potentially, but for a long-term patient,  
23 one time, \$500, you're telling me is enough to convince a

1 nephrologist. Or have you promised them some very large  
2 amount from this 90 percent of things that doesn't exist,  
3 and do they believe that there is some continuing payment  
4 coming from that?

5 MR. ROTHENBERG: Okay. We did not speak to them  
6 about the transportation part.

7 As far as the \$500, yes, because they're looking  
8 at it that this model can grow more, and there's more  
9 patients that's coming. And it's just additional money  
10 that they can get. This is basically what that -- that's  
11 the feedback that we got. The idea is to say, "Listen,  
12 there is incentives for a nephrologist to have" -- or for  
13 home dialysis. Obviously, somebody thought that that \$500  
14 is worth it.

15 The reason why they do not offer it is not  
16 because of the \$500. The reason why they do not offer it  
17 is because they feel that they feel more comfortable with  
18 the nurses taking care of the patients. Plus, they feel  
19 that when the patient is home, they have to be more  
20 available to answer the phone calls as opposed to when the  
21 nurses are there, they're taking care. We took care of  
22 that part.

23 But the incentives of the \$500 does not exist

1 there. So we wanted to show that you're still going to get  
2 that part, and you can grow your practice with that as  
3 well.

4 Allen?

5 DR. KAUFMAN: Let me just answer. I just would  
6 like to make one other point.

7 You know, the majority of patients, maybe 60  
8 percent, are short-term transient patients, coming and  
9 going for some kind of rehabilitation situation. They  
10 might average about a month and a half or 6 weeks or  
11 something like that, that they say in there.

12 So if you look at the model, the education model,  
13 the extra \$500 model -- so let's just say a patient becomes  
14 a home dialysis patient for a two-month period of time, and  
15 then they're gone. Remember that, though, this is the  
16 majority of patients coming and going.

17 So a physician will have a Medicare monthly  
18 capitation rate of about \$250 a month. It could be \$260.  
19 I think it is in New York. So it's \$250 a month. He gets  
20 that twice. Well, you've now effectively doubled his  
21 capitation fee at least for the short-term patients.

22 MR. MILLER: Could you tell me about the long-  
23 term patients, though, please?

1 DR. KAUFMAN: Well, but here's -- let me just say  
2 about it. So here's -- this is where it becomes efficiency  
3 of scale a bit. If I'm a physician and I'm coming into the  
4 nursing facility and I'm seeing the short-term patients  
5 because I'm incentivized to do it, for me, it means nothing  
6 if I see another two patients that are living there day in  
7 and day out, you know, forever.

8 So once you get a physician to come into a  
9 facility, then it becomes efficiencies of -- once I'm  
10 making a trip to that facility, because I get certain  
11 benefits, it's nothing to me to go and see the patients  
12 that are living there, and by ratio, in general, is going -  
13 - it's about 60 percent for the short-term and about 40  
14 percent for the long-term patients.

15 So I think that's -- you look at the overall  
16 picture. Overall, it's a net plus for the physician.

17 MR. MILLER: Let me just ask one follow-up  
18 question, and then I'll shut up.

19 So Medicare, thanks to the Chronic Care Act, is  
20 going to be doing telehealth, telemedicine visits for  
21 nephrologists now.

22 DR. KAUFMAN: Right.

23 MR. MILLER: Do you think that that's going to

1 solve the problem, and will you be able to do that, such  
2 that you don't need to incentivize them anymore because  
3 they'll be able to see the patient at least every two  
4 months in the two-month window by telemedicine, by some  
5 kind -- because you would have the capability, I would  
6 assume, to set something like that up for the more easily  
7 to do that. Do you think that that's going to make a  
8 difference?

9 DR. KAUFMAN: Well, let me answer that. First of  
10 all, every technology that's developed or utilized, we're  
11 going to try to utilize and try to get the most out of it.  
12 You know, we're going to try to figure out how it works.

13 However, on the one hand, we're talking about the  
14 -- a minimal requirement to see a patient, and on the other  
15 hand, you have to act like a doctor. And you have to see  
16 patients as often as you have to see them. That's a  
17 separate thing. I know we're talking about the economics  
18 and the fiscal thing, and you have to see home patients  
19 once a month. But it may not be appropriate to see a  
20 skilled nursing facility patient once a month. You may  
21 decide to come twice a month or three times a month,  
22 whatever the thing demands.

23 We absolutely will use telehealth if it's a tool

1 that will help in any way, but I just don't see it as  
2 actively as solving this problem because these are the --  
3 you know, telehealth in a home-based --

4 MR. MILLER: Well, just to be clear, the reason  
5 why I'm asking is because -- you're not quite addressing --  
6 I mean, I understand the issue now if how this could be  
7 very lucrative for the nephrologist for the short-term  
8 patients. I'm trying to go with the long-term patients,  
9 where I think there's a lot of potential value here. But a  
10 one-time \$500 thing ain't going to do that, from my  
11 perspective.

12 So it seems to me like you're saying, all of a  
13 sudden, now I have to -- even the nephrologist has to have  
14 lots of short-term SNF patients to make this work.

15 But if in fact they can do now a larger number of  
16 those visits by telemedicine, then the penalty of them  
17 having to see the patient every month goes down, which  
18 would make it a little bit better for them to do the long-  
19 term care patient. So I just wondered if you'd been  
20 thinking about that.

21 DR. KAUFMAN: Yep. Yes, we have, and we are  
22 going to utilize every tool available.

23 MR. ROTHENBERG: As soon as that's available.

1           I would also say that it's estimated the dialysis  
2 population to grow in the next 10 years by over 30 percent.  
3 Most of them are the elderly population because we live  
4 longer as well, and there's a big flow of baby boomers that  
5 have diabetes and other diseases that will cause  
6 deterioration of the kidney and ultimately ESRD.

7           There is not enough doctors and enough nurses and  
8 enough slots to treat for those patients. This is  
9 something that the more it's incentivized, will free more  
10 slots in the community, and it will help to care for these  
11 patients as well.

12           DR. KAUFMAN: Just one last point. The fastest-  
13 growing demographic within the dialysis world is the  
14 elderly patients. That's the most rapid-growing  
15 demographic in the world, and it's just going to have its  
16 impact in the next decade or so. It will be really clear  
17 what happens.

18           DR. HELLEBRAND: And, unfortunately, that is the  
19 population that receives the least amount of medical care  
20 and certainly the oversight from the nephrologist. So any  
21 incentivizing that we can do to get the nephrologist in  
22 there to help us to care for these patients is a benefit on  
23 any level, whether we approve this model or not. But there



1 is that barrier to access of having the nephrologist  
2 engaged and seeing a platform why the home patient, who's  
3 home, who is very well, healthy, probably does not need  
4 that much oversight. They receive this payment. It does  
5 not take a lot of their resources to care for this patient  
6 because they usually walk, talk. They're healthy in all,  
7 but yet there's no incentive for the patient that is  
8 utilizing more of the resources, more of their time that's  
9 residing in the skilled nursing home. And that's how we  
10 came up with this model.

11 CHAIR BAILET: So we have Paul, then Tim, and  
12 then I have a comment. So go ahead, Paul.

13 DR. CASALE: Great.

14 So I was just going to push a little bit more on  
15 this total cost of care, which I know you've been asked a  
16 couple of times. As you probably know, the renal  
17 physicians came with their model, and we asked them  
18 specifically because they did want to accept total cost of  
19 care responsibility. And they said that when patients go  
20 on dialysis, the nephrologist -- and you can speak to this  
21 -- often becomes, not that they take over the primary care,  
22 but they become their principal physician.

23 And so I understand this dynamic around the

1 medical director of the nursing home and all of that, but  
2 it would seem to me much more attractive as a physician-  
3 focused payment model if in this actually incorporated  
4 total cost of care into the model as opposed to this sort  
5 of transactional one that you're proposing.

6 MR. ROTHENBERG: I agree. However, like I said  
7 before, we have customers -- we would not have customers as  
8 far as nursing homes if we will dictate to them that that's  
9 what they want. They would not accept that because the  
10 dynamics of the nursing home. We're talking about the  
11 nursing home part.

12 DR. CASALE: Yeah. Again, I don't know all the  
13 dynamics, but I'm just saying from a --

14 MR. ROTHENBERG: I understand.

15 DR. CASALE: You've repeatedly said that it's  
16 hard to get the nephrologists sort of engaged. They need  
17 an incentive. Well, in a total cost of care model, I think  
18 there would be a lot of incentive, given the fact that --  
19 just all the reasons why you say your program reduces  
20 hospitalizations. The ER visit does much better care of  
21 patients. That would be reflected financially in a total  
22 cost of care model.

23 MR. ROTHENBERG: Right.

1 DR. FERRIS: The question I have is very specific  
2 and just reflects my ignorance about this, and I'm trying  
3 to understand some of the financial dynamic.

4 So Dialyze Direct provides dialysis services; is  
5 that correct?

6 MR. ROTHENBERG: Mm-hmm. Correct.

7 DR. FERRIS: So is there a regulatory barrier for  
8 Dialyze Direct to just pay the incentive to the  
9 nephrologist?

10 MR. ROTHENBERG: Yes.

11 DR. KAUFMAN: Do you want to answer that?

12 We'll let our regulatory guy answer.

13 MR. PAULL: Yeah, there is.

14 Essentially, what you're describing would  
15 implicate significant risks with the anti-kickback statute  
16 primarily for the reason that included in the physician's  
17 monthly rate already is his services that he's supposed to  
18 provide care for that patient, and he's already being  
19 reimbursed for it through those codes.

20 In the situation where then we were paying the  
21 physician something on top of it, it would be -- that would  
22 say extremely likely that the OIG would view that as being  
23 remuneration in exchange for patient referrals from the

1 physician.

2 DR. FERRIS: So --

3 MR. PAULL: If we switched to that model, I would  
4 quit my job that day.

5 DR. FERRIS: Yeah. So just to follow up on this,  
6 because we've been brainstorming a little bit here, so  
7 apologies to you guys for our brainstorming, but it seems  
8 to me that the OIG problem -- and again, my ignorance, so  
9 please help me here -- would go away if they didn't bill  
10 the alternative.

11 I'm not sure I -- like couldn't a waiver under  
12 specific circumstances also be a solution? So there are  
13 ways to go after a waiver situation which will allow under  
14 the condition of dialysis being delivered in a nursing home  
15 that you get a safe harbor for a payment that incents the -  
16 - because it's clearly in CMS's interest because CMS wins  
17 big for that waiver, right? They get the benefits, all the  
18 benefits that you have talked about, and the cost is not  
19 borne by them. The cost is borne by you, and you did state  
20 earlier that you just bought a company, a new company,  
21 which suggests to me that you're not in the red.

22 So I'm just going after solutions here, but it  
23 seems to me that an incentive for a safe harbor provision

1 that said in the case where the nephrologist needs to go to  
2 make a visit to a SNF, that that's a safe harbor from the  
3 anti-kickback statute, which I will just say there are lots  
4 of exceptions and exemptions from anti-kickback statutes  
5 under very specific conditions. So it would not set a  
6 precedent to suggest that one be applied here.

7 MR. PAULL: So I won't speak in terms of the  
8 financial viability of that type of arrangement. I'll  
9 leave that for Josh.

10 But what I could say is that you're right that  
11 there are certain situations that the OIG has provided safe  
12 harbors for certain arrangements.

13 I can't speak in terms of the OIG's process and  
14 how complicated that might be in terms of creating one of  
15 those for this very specific type of situation. I would  
16 say that it could be also possible that the OIG would be  
17 hesitant to create a safe harbor in the situation because  
18 the very dynamic would potentially invite abuse, where you  
19 do have a provider that is directly funneling payments to,  
20 I guess, the purest definition of what a referral source is  
21 in the eyes of the OIG.

22 That being said, I don't work for the OIG, but I  
23 guess being a regulatory attorney and my experience with

1 the AKS and federal agencies and everything with that, I  
2 would see that there could be some hesitation there.

3 MR. ROTHENBERG: And as far as our model, as far  
4 as for us to bear the cost as is we are bearing the cost  
5 and we are creating all the savings for CMS and for the  
6 thing, I know there's not enough money out there to also  
7 pay the nephrologists as well on a per-patient basis.

8 CHAIR BAILET: Rhonda.

9 DR. MEDOWS: I'm just a little slow. It took me  
10 a while to finally -- now I get it. Okay. So you need an  
11 incentive payment to get a nephrologist to partner with you  
12 to take care of patients.

13 MR. ROTHENBERG: And continue the care.

14 DR. MEDOWS: Right. In the nursing home.

15 MR. ROTHENBERG: Correct.

16 DR. MEDOWS: But you're talking to the PTAC,  
17 which is pretty much under a direction to find a way to  
18 either improve quality while keeping the cost flat or  
19 reducing the cost while keeping the quality maintained.  
20 Those are our two driving principles coming forward.

21 So a straightforward incentive to get the  
22 nephrologist to participate without any ties to it, not  
23 going to pass muster. It's almost like you need to have

1 some kind of a quality outcome ties to that \$500 or  
2 whatever it is, and it could be something that they were  
3 going to be doing, anyway, right? Their performance. But  
4 it's almost like there has to be something tied to it. It  
5 can't just be a flat \$500 for you to participate. Do you -  
6 -

7 MR. ROTHENBERG: I understand what you're saying.

8 DR. MEDOWS: Yeah.

9 And then when you were talking about the short-  
10 term incentives, why somebody would want to do it, totally  
11 got it. It took me forever. Finally got it. Thank you.  
12 Thank you. Thank you.

13 Longer term, I'm understanding that the benefit  
14 to the nephrologist would not only be the \$500, but it  
15 would also be that your service would be of such level, of  
16 subpar, that actually you would be managing quite a bit for  
17 the patient care as opposed to when you provide similar  
18 care to somebody are home, right?

19 MR. ROTHENBERG: Correct.

20 DR. MEDOWS: The nephrologist gets called less  
21 frequently because they have not only your service, but  
22 they have a nursing home staff around them as well.

23 MR. ROTHENBERG: Correct.

1 DR. MEDOWS: So you're trying to find something  
2 to get them in the door.

3 MR. ROTHENBERG: Correct. And with saving them  
4 money.

5 DR. MEDOWS: But it's got to be tied. So the  
6 only problem is we got to tie it to something. It can't  
7 just be a straight-up incentive.

8 MR. ROTHENBERG: I understand what you're saying.

9 DR. MEDOWS: It has to be tied to something, and  
10 I think that's part of what's missing in the way that the  
11 proposal is going. We are taking what you have said and  
12 what you have presented and what the nephrologist has  
13 presented in terms of overall it's better for patients to  
14 have hemodialysis more frequently and to have it at a  
15 setting where they don't have to get into an ambulance and  
16 go out and be exposed to cooties, which is a technical term  
17 for diseases all over the place, that kind of thing, but  
18 that's technical --

19 CHAIR BAILET: Rhonda, is that right up there  
20 with bug juice?

21 DR. MEDOWS: Yes, it is.

22 CHAIR BAILET: Okay, very good.

23 DR. MEDOWS: Right. So I'm admitting that --



1 MR. MILLER: There's going to be a quality  
2 measure for no cooties coming up in MIPS.

3 DR. MEDOWS: Right. But there's got to be  
4 something. You understand that incentive has to be tied to  
5 something more definitively, and is there a way to look at  
6 the model that you're proposing to tie it to something?  
7 Because we can't just say give them \$500 so they'll  
8 participate because we think this is a better way to  
9 provide care. It has to be give them \$500 -- it's better  
10 model of care, and this is what they're going to achieve.  
11 It has to be -- do you understand what I'm saying? There  
12 has to be a quality outcome at least tied to it. Does that  
13 make sense?

14 That's my humble opinion, and they may disagree.

15 DR. KAUFMAN: I just want to say one thing and  
16 just in the world that we live in right now. I totally get  
17 the quality outcome discussion that we're having.

18 There is one problem. The problem is that as of  
19 today, there are no -- nobody has quality outcomes for  
20 skilled nursing facility dialysis patients in America. We  
21 are working on that, and it's a whole nother discussion,  
22 which we will come out with later on.

23 But the problem is that all of the great work

1 that the RPA does, that they have their quality outcomes,  
2 that they have their algorithms, that they know how to do -  
3 - they know how to measure a doctor's performance,  
4 potentially, is all based upon end-stage renal disease, the  
5 general population.

6           The nursing home population is completely  
7 different from the -- it's the 15 percent of the dialysis  
8 population that is the sickest, the most comorbidity.

9           If I can have a skilled nursing facility patient  
10 that I'm taking care of for a year and they have two  
11 hospitalizations, is that great? Is that terrible? It's  
12 terrible if it's a home dialysis patient that's in his  
13 private home. That's awful. It may be great for a skilled  
14 nursing facility patient who otherwise would be four or  
15 five times in a hospital during the year. So the problem  
16 is to even start with that quality outcome business, you  
17 have to make quality outcomes.

18           By the way, within our model, using Medicare  
19 billing as guidelines for hospitalizations, we do plan to  
20 have -- we looked at the power -- to reach a -- we did a  
21 power analysis of how many patients do we need to see to  
22 have a 85 or 90 percent chance of finding a meaningful  
23 difference between more frequent dialysis patients and

1 patients who are on conventional dialysis paired for the  
2 nursing him. So we have a model, as we explained within  
3 our model. It will choose about a 5-to-1 ratio of our  
4 basic group, which will be it needs about 300 patients.  
5 We'll have about 1,500 paired patients using Medicare  
6 billing to track hospitalizations of the two paired groups.

7           And this will actually be one of the first ways  
8 to judge outcomes. So the problem is this is the problem,  
9 but we are where we are. And we're in the current date of  
10 time, and we're like doing the best we can with the tools  
11 that we have. But I can't make up tools that we don't have  
12 so far, which we will have, but not today. But not today.  
13 Not today. We can't.

14           CHAIR BAILET: Thank you, Ron.

15           And I'd like to -- because I was on the PRT. I  
16 applaud the work that you're doing. You're taking care of  
17 some of the most vulnerable of the vulnerable amongst the  
18 end-stage renal patients, and that's notable.

19           I just go back to the work that we're trying to  
20 do here relative to evaluating a proposal and making a  
21 recommendation to the Secretary about an alternative  
22 payment model, a physician-focused alternative payment  
23 model.

1           I understand the clinical benefits of more  
2 frequent dialysis. It wasn't lost on me. I've seen  
3 dialysis patients struggle with recovery. It pretty much  
4 saps them, and they're offline for quite a while. And the  
5 fact that they're able to go through this process with not  
6 only better, stable vitals, but a better state of mind.  
7 And they can actually live their life more completely  
8 instead of having these cycles of essentially brown-outs,  
9 if you will, are great.

10           But if I look at it through the lens of a model,  
11 the model that you have proposed, the backbone of the model  
12 is savings generated by transportation, and I think as we  
13 have explored this multiple times and we've had discussions  
14 today, but we've also had multiple discussions -- Dr.  
15 Kaufman, we chatted with you a bit as well -- that really  
16 isn't -- when the smoke clears out of the room, that's  
17 really not the Willie Sutton. That's not where the money  
18 is.

19           The money could be where you're pointing out,  
20 hey, these folks don't end up in the hospital. That's not  
21 a small amount of savings if that can be validated. The  
22 challenge is it's not embedded in your model, and we don't  
23 have the statistical information to prove it out. So for

1 us to make a recommendation on the model based on the  
2 savings, I think that's a soft spot in my own mind. I'll  
3 speak for myself.

4 Tim, you wanted to make a comment there?

5 DR. FERRIS: Just --

6 CHAIR BAILET: Because I'm not done, but --

7 DR. FERRIS: No, no.

8 CHAIR BAILET: No, no. Please go ahead. No.  
9 Please, Tim.

10 DR. FERRIS: [Speaking off microphone.]

11 CHAIR BAILET: All right. So I have a -- I'm  
12 challenged. I'm challenged there. We're talking about  
13 providing some kind of incentive payment to the clinician  
14 to get them into the home because they don't want to go to  
15 the skilled nursing facility when they can go to a dialysis  
16 center and they can see 15, 20 patients, and they're now  
17 going to have to go travel to a different place with  
18 different resources, right? It's not going to be a  
19 resource-rich environment, and they're going to see a  
20 smaller number of patients.

21 So, financially, it's going to be more  
22 challenging for them. Clinically, it could be more  
23 challenging because they don't have all of the depth of the

1 support, but the model as it's constructed, as it's  
2 proposed, what I'm struggling with is I don't know what I'm  
3 recommending. I don't know what I'm recommending, and I  
4 think what you're hearing from the Committee members is  
5 we're probing, and I don't have anything to hold onto yet,  
6 and that's a challenge I have and maybe I'm -- we can vote.  
7 You know, we can go through the criteria. We can vote and  
8 we can come up with a recommendation. But I struggle with  
9 I don't know what we're recommending. So I'll leave it at  
10 that and let Tim jump in there.

11 DR. FERRIS: I think along those lines, what I  
12 heard was there is a very real problem that they are trying  
13 to address, and maybe in the spirit of the comments we  
14 heard this morning, from the Secretary, the Administrator,  
15 and the Director of CMMI, that it sounds like they were  
16 referred to us. Without predicting what we're going to do,  
17 we may be saying we're not the right place for this.

18 I think it would be unfortunate if the result was  
19 the ping pong ball. A better outcome here would be if  
20 there was actually some dialogue between us and the right,  
21 as Bob was pointing out, the right group to think about  
22 this problem.

23 And I'm going to be optimistic here, but it is

1 possible that through the articulation or the endorsement  
2 of the problem, and the endorsement of a solution, maybe  
3 not solution as proposed but identifying the problem as a  
4 real problem, we might help the American public by  
5 elevating this discussion to the right place within CMS.  
6 I'm understanding that may be an optimistic --

7           CHAIR BAILET: And Tim, where I'm going, where  
8 I'm going to land is we've been here once before. My  
9 concern is if this Committee goes through and completes our  
10 process, and we vote, and it comes down where we're not  
11 going to recommend this model -- and I'm not suggesting  
12 that that's where we're going to end up, but I'm just --  
13 worst case, it creates a deeper hole. And what I want to  
14 create is optionality for you.

15           And so what Tim is suggesting is perhaps -- I'm  
16 throwing this out -- we could pause the process. You could  
17 withdraw your proposal, which allows us not to have to vote  
18 on it. We then can take advantage of the relationships  
19 that we have and see if we can solve this issue directly in  
20 a way that does not require creation of an alternative  
21 payment model, and all of the, what we have been told, the  
22 18-month pipeline for building it out and implementing it  
23 and getting it out. So I'm just throwing that out there as

1 a question.

2 MS. SELENICH: [Off microphone.]

3 CHAIR BAILET: A statutory change issue. What is  
4 this?

5 MS. SELENICH: [Off microphone.]

6 CHAIR BAILET: Oh. Well, my point is they have  
7 the opportunity at this point to withdraw their proposal.  
8 Is that correct?

9 MS. SELENICH: [Nods in affirmative.]

10 CHAIR BAILET: Okay. So I just want to make  
11 sure. See, this is my team that keeps me between the fence  
12 line here, so I just --

13 MR. ROTHENBERG: We thought, originally, that we  
14 fit more to the CMMI, overall, for the whole model. We  
15 were surprised they sent us to PTAC, and that's what I said  
16 originally.

17 CHAIR BAILET: Yeah.

18 MR. ROTHENBERG: I could be now that there is new  
19 direction. It is, but somebody has to tell --

20 CHAIR BAILET: Right, and again, I'm not washing  
21 out -- I'm not trying to wash out all of the good work that  
22 we've done --

23 MR. ROTHENBERG: No, I understand.



1           CHAIR BAILET:  -- and I'm not throwing in the  
2 towel, you know.  I'm just making a suggestion and I'll  
3 stop there.  Len?

4           DR. NICHOLS:  Well, I first want to ask Sarah, if  
5 they were to withdraw, could we still write a letter?  I  
6 get the statutory charge issue, but it seems to me write a  
7 letter, because, if I remember correctly, one of the three  
8 Adam mentioned this morning was the live ESRD proposal that  
9 came before, that we recommended.  And I would just say, in  
10 the spirit of, there's a panoply of options.  This is a  
11 specific population that is not being addressed, in  
12 general, for which you could imagine Plan 7(B), my favorite  
13 little thing.  I'm just saying it seems to me we have  
14 standing, if you will, to comment, because the proposal  
15 came before us.  We have another lawyer that is consulting.

16           CHAIR BAILET:  In a caucus.  A caucus here.  
17 Please, bear with us.

18           MR. ROTHENBERG:  As long as we don't have a  
19 protest in the back of the room.

20           CHAIR BAILET:  Please.  Go ahead, Len.

21           DR. NICHOLS:  I'll offer, and maybe ask -- here's  
22 what I think happened, for what it's worth.  CMMI heard  
23 nephrology needs a payment.  CMMI didn't want to do the

1 code business, or didn't direct you to the code people, for  
2 whatever reason. You, God bless you, went home, came back  
3 with a payment for the doc and a shared savings thing,  
4 because that's what you think you've got to do to get it  
5 past us, and here you're trapped with a shared savings  
6 thing that's not really the focus of the whole thing.

7 So I submit they did their job --

8 CHAIR BAILET: Oh.

9 DR. NICHOLS: -- and they were given --

10 CHAIR BAILET: Yeah.

11 DR. NICHOLS: -- well-intentioned, not good  
12 advice, and the solution here is to use our ability to  
13 comment on the nature of the population you're addressing  
14 to get the conversation at a higher level, at the right  
15 level of HHS.

16 MR. ROTHENBERG: And then we can really discuss  
17 the whole model --

18 DR. NICHOLS: Bingo.

19 MR. ROTHENBERG: -- not just the physicians.

20 DR. NICHOLS: Exactly. Right. But for the first  
21 time --

22 MR. ROTHENBERG: That's why we were like, why do  
23 have to go to the physician, but that's what they told us

1 to do.

2 DR. NICHOLS: Trust me. Welcome to my world.

3 CHAIR BAILET: So, Len --

4 DR. NICHOLS: Well, I was going to ask the  
5 question is, can we do this?

6 CHAIR BAILET: Well, so they're working on that,  
7 but Paul and Harold, if you want to go ahead.

8 DR. CASALE: Yeah. I was just going to, because  
9 I think, Len, I was thinking exactly the same. From the  
10 comments that were made this morning, and clearly CKD was  
11 called out, that it is one of the things they're working  
12 on, and we know that they've alluded to bringing in RPA for  
13 their discussion. So it seems like it's an opportunity  
14 where that is going on, and wouldn't it make sense, as you  
15 said, if we can provide a letter to elevate this into that  
16 discussion, because, as you just said, they're not going to  
17 do 10 different models, certainly, and it would be an  
18 opportunity to bring this into that conversation.

19 CHAIR BAILET: Harold.

20 MR. MILLER: So I'm having a bit of trouble. I'm  
21 happy to go along with it but I'm having a bit of trouble  
22 understanding what the great problem is with evaluating  
23 this. I don't think -- I think it has, as we said in the

1 PRT report, some positive things that we could say about it  
2 and then say that it's not a good payment methodology and  
3 it's not an alternative payment model, and then write a  
4 letter to say that.

5 I mean, I think the fact that we would recommend  
6 that it's not an alternative payment model does not mean  
7 that we're recommending that nothing should be done. We  
8 can say this is not an alternative payment model but we  
9 think something should be done.

10 Now we could skip over all the voting and  
11 everything, I guess, if we wanted to, or do it quickly by -  
12 - we could use the non-applicable route, which we've used  
13 before. I'm not a big fan of the non-applicable route,  
14 because, I mean, I think that the issue is the criteria are  
15 applicable. I just think that it's going to fail, at least  
16 from my perspective, a bunch of the criteria. But I think  
17 it gets us to writing the letter to say what needs to be  
18 done. And I just don't see a problem with us saying no,  
19 we're not recommending this as an alternative payment model  
20 but we are saying that we think that there is an  
21 opportunity here that needs to be addressed.

22 CMS could create -- I mean, you haven't talked  
23 about how you would operationalize this bonus anyway, but

1 it would be probably be a code that somebody would build.  
2 So, mean, you know, it would just be some code. So they  
3 could create a code if they thought that it was a desirable  
4 thing to do. It would not be unheard of to say, you know,  
5 nephrologists are allowed to bill \$500 for a \$500 payment  
6 whenever a patient goes to this thing, but it would get to  
7 the point that Rhonda was raising, would be that there  
8 would be some definition of what this thing is that  
9 everybody views as desirable, that you want to reward the  
10 nephrologist for.

11           And the problem is right now we don't -- I'm  
12 troubled that we don't have that, and I think if I were CMS  
13 and I would be looking at this I would be saying I would be  
14 a whole lot more interested in doing this for long-term  
15 nursing facility patients, and I would be interested in  
16 doing this maybe differently for the short-term facility  
17 patients. So I'm not getting lots of churn with people  
18 trying to get more \$500 payments just by getting more  
19 people into a SNF. So I think a lot of work has to be done  
20 along those lines.

21           I think, as Rhonda pointed out, it's not -- I  
22 think, to me, that fundamentally it's not a physician-  
23 focused payment model. This is basically something that

1 some other entity is going to be doing and it wants to  
2 throw \$500 at the nephrologist so that they don't stand in  
3 the way. That, to me, is not a physician-focused payment  
4 model. That's a physician buy-off model, or something like  
5 that. But it's not a physician-focused payment model. So  
6 I think we could say good problem, needs a solution, not  
7 this, and becoming, after a careful, detailed review.  
8 That's my thought.

9 CHAIR BAILET: Yeah, we do have guidance. So we  
10 can't write a letter offline. We have to deliberate, come  
11 to our conclusions, and we have to create a --

12 DR. NICHOLS: Then I follow Harold's suggestion.

13 CHAIR BAILET: So the process is --

14 DR. NICHOLS: The best outcome is to vote.

15 CHAIR BAILET: -- we go through, we follow our  
16 process --

17 DR. NICHOLS: -- write a letter, try to get the  
18 conversation we talked about.

19 CHAIR BAILET: Yeah. Okay. So that means we're  
20 at the point now where we'd like you guys to -- again,  
21 thank you for coming and presenting. We're not done yet  
22 but we're going to see if there are some folks on the phone  
23 who want to comment. We could have questions amongst

1 ourselves, and then we're going to go ahead and vote on the  
2 criteria, and then we're going to vote on the  
3 recommendation. Okay.

4 MR. ROTHENBERG: And we concur with the previous  
5 doctor that you guys are doing a great job.

6 CHAIR BAILET: Oh, thank you. Yeah, if it was  
7 easy everybody would be doing it. Kavita.

8 DR. PATEL: Just so I can understand, I, at  
9 least, kind of side with like -- I'm concerned. Are we  
10 still going to offer them a chance to withdraw the  
11 application, knowing we cannot write a letter. I  
12 understand that. What, are we going to talk to anybody  
13 about?

14 CHAIR BAILET: Well, look --

15 DR. PATEL: I feel like we're delaying it maybe a  
16 little bit, but not that much.

17 CHAIR BAILET: So, Kavita, if they withdraw that  
18 does not preclude them -- us facilitating them going to  
19 speak to someone.

20 DR. PATEL: Correct.

21 CHAIR BAILET: It doesn't preclude any of us  
22 going to speak to --

23 DR. PATEL: Correct.

1 CHAIR BAILET: -- leadership. But we're not  
2 going to write a letter to the Secretary --

3 DR. PATEL: Okay.

4 CHAIR BAILET: -- unless we do it here and go  
5 through our process.

6 DR. PATEL: So can I just, for transparency sake,  
7 just restate that if we were to not vote, for whatever  
8 reason, because someone withdrew, a rock landed on your  
9 head, I don't know, all of the things that could happen in  
10 the next five minutes, all we would be doing is potentially  
11 delaying something, if submitters were to take some of this  
12 feedback and think about what we've said and reflect on it,  
13 and potentially resubmit it later.

14 CHAIR BAILET: That's an option. They have that  
15 option as well.

16 DR. PATEL: That would be one. The second option  
17 would be to go ahead and to deliberate for the purpose of,  
18 not knowing how everybody individually is going to vote,  
19 but I would still be pressed to keep my vote with some of  
20 the caveats that I made as comments to our submitters, and  
21 that could potentially create a perception of, at least in  
22 my case, that I didn't think was sufficient. So that seems  
23 like the other potential here. So I'm just trying to weigh



1 the pros and cons of both of those decisions.

2 CHAIR BAILET: Okay. So Harold and then Len.

3 MR. MILLER: The law says that we are to make  
4 recommendations to the Secretary, comments and  
5 recommendations to the Secretary on proposals that we got.  
6 The laws says nothing about the categories. We invented  
7 the bloody categories that we vote on, and we can invent a  
8 different category if we want. We invented a different  
9 category called non-applicable a while back. If we want to  
10 invent a different category here -- we can go through  
11 evaluating based on the criteria and then we can say we're  
12 voting to send a letter to the Secretary saying, you know -  
13 - and Sarah can tell me if I'm wrong, but we're making  
14 comments and recommendations to the Secretary.

15 I think the thing that people are concerned about  
16 is they don't want a statement that we voted to say not  
17 recommend. We don't have to vote not recommend. We can  
18 vote to send a letter of comments to the Secretary saying  
19 that we think it's a problem and it needs to have an  
20 action, and I think that's a perfectly legitimate thing to  
21 do, and then we're following the process. It's just that  
22 we've invented yet another category.

23 I think we have to go and we have to rethink all

1 the categories anyway, because nobody understands what  
2 limited scale testing is or why we're doing it, and nobody  
3 understands what any of the other things are. So we've got  
4 to do that, so we might as well just start here and create  
5 yet another one. Okay.

6 CHAIR BAILET: Harold, I'm actually going to  
7 double down on your comment, because it's been recommended  
8 one of the categories we could -- I'm going to throw out a  
9 straw model here -- would be we recommend for further  
10 evaluation, or further development. So, Len, you had --  
11 Grace, go ahead and then Len.

12 DR. TERRELL: Just a quick comment. I am  
13 inferring, perhaps not correctly but I suspect I am, that  
14 we think, at least from our conversation, that they have  
15 correctly identified a real problem, okay, but we are not  
16 necessarily thinking that we're going to think that this is  
17 the solution. Okay. So the problem we have is that we're  
18 trying to figure out, within the context of what you're  
19 talking about, how to say that to the Secretary, which is,  
20 "Yep, they nailed it. There's a problem. Nope, maybe we  
21 don't necessarily think this is a physician-focused payment  
22 model." Okay.

23 So the category may be, yep, they nailed it.

1 There's a problem. You need to go fix this, dude. And,  
2 you know, whether it needs to be in CMMI or whether it  
3 needs to be a code recommendation as it relates to, you  
4 know, sort of the typical way that CMS would deal with it,  
5 I don't see that that's something that we can't comment on,  
6 so long as we basically say we recognize that they have  
7 correctly, appropriately identified a significant problem  
8 that needs to be fixed. We think that these are some of  
9 the ways that we suggest. You think about it. What's  
10 wrong with that category?

11 CHAIR BAILET: I think we have the latitude to  
12 create categories, as Harold has said --

13 DR. TERRELL: Okay.

14 CHAIR BAILET: -- and if that's the will of the  
15 Committee, if that's where we think we want to land, I'd  
16 like to arrive at the landing zone before we go through --

17 DR. TERRELL: Right.

18 CHAIR BAILET: -- the voting process. Sarah?  
19 Yeah, please.

20 MS. SELENICH: So you can create new categories.  
21 As you know, the ones that you've set up, you've set up. I  
22 would add that in the past you have allowed public comment  
23 -- I know you're going to have that tomorrow -- on your

1 practices and procedures. And in an earlier meeting you  
2 all discussed remaining consistent with your current sort  
3 of processes. So I just wanted to mention that.

4 MR. MILLER: Well, we consistently said before we  
5 had a consistent, non-applicable recommendation, did we  
6 not?

7 CHAIR BAILET: Exactly. We did.

8 MR. MILLER: So we could, and I think we actually  
9 did that without public comment.

10 CHAIR BAILET: And we could -- but a non-  
11 applicable --

12 MR. MILLER: I was saying if we wanted to be --  
13 do something that we had done before, we did non-  
14 applicable. But I'm saying we did non-applicable on the  
15 spot without having public comment, and then we later on  
16 institutionalized, Ann, am I -- do I remember correctly?  
17 It was done at the meeting and then we later on agreed to  
18 adopt it into our formal voting options, but we scrambled  
19 that day to add that to the list of things to do, if I'm  
20 remembering correctly.

21 CHAIR BAILET: Len and then Grace.

22 DR. NICHOLS: So, you know, we've had now a  
23 physician play economist and I'm going to be an economist

1 playing a lawyer, for fun. Okay? If I remember sort of  
2 some of the legal decisions I've been forced to read in my  
3 life, there is this concept of something without prejudice,  
4 and it has to do with, in a sense, passing the decision  
5 down the chain, but not indicating which way you would have  
6 ruled if you'd been forced to rule. And sometimes it's  
7 remanded with that, so that kind of thing.

8           So the notion here that's in all our heads, is  
9 how do we use the one lever we have, which is a letter to  
10 the Secretary, to ensure the highest likelihood this  
11 conversation takes place, that we all believe should take  
12 place, and it seems to me it's perfect valid, and, indeed,  
13 desirable, in our letter to say these people were sent to  
14 us by CMMI and the model they came up with was designed to  
15 solve the problem they have, in some sense, already solved,  
16 but along the way of solving it they discovered the  
17 barrier, which the physician-focused model would help  
18 overcome.

19           Now, I think it is a physician-focused model. I  
20 don't think it's a physician-focused model we would design  
21 nor recommend wholeheartedly. But it is enough of a  
22 physician-focused model to engender the letter. I just  
23 feel like we've already recommended 10 models that got

1 either rejected or delayed and transmogrified, so rejecting  
2 it doesn't feel smart. Saying it's not applicable is  
3 disingenuous. And so I like the idea of saying this  
4 conversation should continue without prejudice, and lay out  
5 the fact of how we think that conversation should take  
6 place, and leave it to the Secretary, who is the only  
7 creature we can actually advise, leave it to the Secretary  
8 to figure out how to engender that conversation.

9 DR. NICHOLS: Grace.

10 DR. TERRELL: I think the problem is the category  
11 of non-applicable is something that if we had just a  
12 different word. Because if you think about what the non-  
13 applicability has to do with it, it had to do specifically  
14 with the issue of is it a physician-focused payment model.

15 But I would say that there is a potential other  
16 distinction between ones that get here, and one of them is  
17 there may be some things that are just not applicable  
18 because they're not applicable. They're not physician-  
19 focused payment models. They're just something else that  
20 landed in our lap, okay?

21 And then there's another thing that's out there,  
22 which is, okay, maybe it's in our purview, but we just  
23 think that there is a problem that is stronger than says

1 that it's not recommended. It's about there is a problem  
2 out there that is absolutely important that they  
3 identified.

4           And a lot of these things that we've actually  
5 rejected are not recommended. In many respects I has that  
6 characteristic. Right? I mean, I can't think of a single  
7 person who has come to us. They've all been thoughtful in  
8 many different but their own ways, to basically say, "I see  
9 a problem. You know, Congress said that there was a place  
10 that I could bring the problem, and it would be deliberated  
11 on." And then, unfortunately, the way we've got it  
12 categorized now is either non-applicable or don't  
13 recommend, but there's been no focus on the fact that there  
14 are some really important problems that we still need to  
15 make sure that somebody is thinking about.

16           So is there another word?

17           CHAIR BAILET: Yeah.

18           DR. TERRELL: Is there another word that could be  
19 used that would essentially allow us to do that in a way  
20 that it's still within our purview --

21           CHAIR BAILET: Okay.

22           DR. TERRELL: -- because it's applicable to the  
23 fact that they are finding problems.

1           CHAIR BAILET: I think we could untie the Gordian  
2 Knot here by actually recommending for other attention, or  
3 for further development. So we're recommending it, but  
4 we're recommending it for other attention, because we are  
5 required to evaluate the model against the 10 Secretary's  
6 criteria. We haven't gone through that process, but we  
7 have to do that. And so I think we should do that, and  
8 then let's get to the output. But I don't think, until we  
9 do that, I think that's the next step. That's my  
10 recommendation, if the Committee would indulge me.

11           DR. NICHOLS: So your suggestion is other  
12 attention --

13           CHAIR BAILET: Right, other attention --

14           DR. NICHOLS: -- or further development.

15           CHAIR BAILET: -- or further development. I  
16 mean, I'm going to leave it to the -- I mean, we can hash  
17 that out. I've got Rhonda and Harold. Rhonda?

18           DR. MEDOWS: Can I just make a motion that we  
19 write a letter to the Secretary, somebody second it, we all  
20 vote, and then we send the letter?

21           CHAIR BAILET: You mean without going through the  
22 criteria? I think we have -- I thought we --

23           MS. PAGE: Whatever that letter says we have to



1 deliberate in public.

2 CHAIR BAILET: -- we have to deliberate. We have  
3 to evaluate it against the --

4 MS. PAGE: In public.

5 CHAIR BAILET: -- in public.

6 MS. PAGE: Whatever that letter says we have to  
7 deliberate in public.

8 CHAIR BAILET: Right.

9 UNIDENTIFIED SPEAKER: [Off microphone.]

10 DR. NICHOLS: Well, I'm -- I understand we would  
11 deliberate in public. I'm clear on what everybody is  
12 saying. I mean, the law says we are supposed to evaluate  
13 against a criteria, so I think the safest thing is for us  
14 to evaluate against the criteria. I like Jeff's  
15 suggestion. I would just take out the word "other." I  
16 mean, it merits attention.

17 CHAIR BAILET: Yeah.

18 MR. MILLER: And we can explain what kind of  
19 attention we think it merits. I think the issue is we  
20 don't necessarily believe that the best thing is, at least  
21 as a first line of defense, is that they should go back and  
22 try to create the kind of model that would fit into the  
23 category that we ordinarily do. I mean, what we're saying

1 is they ought to go to CM and see whether they think that  
2 there's something different that could be done, to the fee  
3 schedule or whatever else, and then after all of that's  
4 done, if it turns out that there's something better, bring  
5 it back here. But the point is they shouldn't continue to  
6 cycle with us until those other things.

7           So I'd just say -- we're saying to the Secretary  
8 it deserves attention, you know. And then if somebody  
9 sends them back to us, it will have been hopefully with  
10 some information as to why nothing else worked.

11           DR. MEDOWS: Mr. Chairman, can I call the  
12 question, please?

13           CHAIR BAILET: Please.

14           DR. MEDOWS: Let's vote.

15   \*       **Voting**

16           CHAIR BAILET: I'm right with you, Rhonda. I'd  
17 like to go through the criteria. Let's go. Clickers in  
18 hand. Our expert, the man behind it is going to go ahead  
19 and get this thing teed up. We're going to vote on the  
20 first criteria, and we all know what that is. Scope, aim  
21 to either directly address an issue and payment policy that  
22 broadens and expands the CMS and APM portfolio or includes  
23 APM entities whose opportunities to participate in APMs

1 have been limited.

2 Please vote.

3 [Electronic Voting.]

4 \* **Criterion 1**

5 CHAIR BAILET: Can I just make -- are you  
6 required to read all the zeroes? You are. Very good.  
7 Okay.

8 MS. SELENICH: We read them for the transcription  
9 and also for the folks on the phone.

10 CHAIR BAILET: Got it.

11 MS. SELENICH: There's also a lag for  
12 livestreaming.

13 CHAIR BAILET: Thank you.

14 MS. SELENICH: So zero members voted 5 or 6 for  
15 meets and deserves priority consideration. Zero members  
16 voted 4, meets; three members voted 3, meets; four members  
17 voted 2, does not meet; three members voted 1, does not  
18 meet; and zero members voted not applicable. We rolled  
19 down, and in this case the majority is 6. A simple  
20 majority is 6, so the finding of the Committee is that the  
21 proposal does not meet Criterion 1, Scope.

22 CHAIR BAILET: Thank you.

23 Criterion 2 is quality and cost. Anticipated to

1 improve health care quality at no additional cost, maintain  
2 health care quality while decreasing cost, or both, improve  
3 health care quality and decrease cost. High priority.

4 Please vote.

5 [Electronic Voting.]

6 \* **Criterion 2**

7 MS. SELENICH: Zero members vote 5 or 6, meets  
8 and deserves priority consideration; zero members vote 4,  
9 meets; two members vote 3, meets; four members vote 2, does  
10 not meet; three members vote 1, does not meet; and one  
11 member votes not applicable. The finding of the Committee  
12 is that the proposal does not meet Criterion 2.

13 CHAIR BAILET: Criterion 3, payment methodology.  
14 Pay the APM entities with a payment methodology designed to  
15 achieve the goals of the PFPM criteria. Addresses in  
16 detail through this methodology how Medicare and other  
17 payers, if applicable, pay APM entities, how the payment  
18 methodology differs from current payment methodologies, and  
19 why the physician-focused payment model cannot be tested  
20 under current payment methodologies.

21 Please vote.

22 [Electronic Voting.]

23 \* **Criterion 3**

1 MS. SELENICH: Zero members vote 5 or 6, meets  
2 and deserves priority consideration; zero members vote 3 or  
3 4, meets; one member votes 2, does not meet; seven members  
4 vote 1, does not meet; and two members vote not applicable.  
5 Therefore, the finding of the Committee is that the  
6 proposal does not meet Criterion 3, payment methodology.

7 CHAIR BAILET: Thank you. Value over volume.  
8 Provide incentives to practitioners to deliver high-quality  
9 health care.

10 Please vote.

11 [Electronic Voting.]

12 \* **Criterion 4**

13 MS. SELENICH: Zero members vote 5 or 6, meets  
14 and deserves priority consideration; two members vote 4,  
15 meets; six members vote 3, meets; one member votes 2, does  
16 not meet; one member votes 1, does not meet. Therefore,  
17 the finding of the Committee is that the proposal meets  
18 Criterion 4.

19 CHAIR BAILET: Thank you. Flexibility. Provide  
20 flexibility needed for practitioners to deliver high-  
21 quality health care.

22 [Electronic Voting.]

23 \* **Criterion 5**

1 MS. SELENICH: Zero members vote 5 or 6, meets  
2 and deserves priority consideration; zero members vote 4,  
3 meets; six members vote 3, meets; four members vote 2, does  
4 not meet; zero members vote 1, does not meet; zero members  
5 vote not applicable. Therefore, the finding of the  
6 Committee is that the proposal meets Criterion 5,  
7 flexibility.

8 CHAIR BAILET: Thank you. Ability to be  
9 evaluated is the sixth criterion. Have evaluable goals for  
10 quality of care, cost, and any other goals of the PFPM.

11 [Electronic Voting.]

12 \* **Criterion 6**

13 MS. SELENICH: Zero members vote 5 or 6, meets  
14 and deserves priority consideration; zero members vote 4,  
15 meets; four members vote 3, meets; four members vote 2,  
16 does not meet; one member votes 1, does not meet; and one  
17 member votes not applicable. Therefore, the finding of the  
18 Committee is that the proposal does not meet Criterion 6,  
19 ability to be evaluated.

20 CHAIR BAILET: Thank you, Sarah. Criterion 7 is  
21 integration and care coordination. Encourage greater  
22 integration and care coordination among practitioners and  
23 across settings where multiple practitioners or settings

1 are relevant to delivering care to populations treated  
2 under PFPM.

3 Please vote.

4 [Electronic Voting.]

5 \* **Criterion 7**

6 MS. SELENICH: Zero members vote 5 or 6, meets  
7 and deserves priority consideration. Zero members vote 4,  
8 meets. Five members vote 3, meets. Two members vote 2,  
9 does not meet. Three members vote 1, does not meet. Zero  
10 members vote not applicable.

11 Therefore, the finding of the Committee is the  
12 proposal does not meet Criterion 7.

13 CHAIR BAILET: Thank you.

14 Patient choice. Encourage greater attention to  
15 the health of the population served while also supporting  
16 the unique needs and preferences of individual patients.

17 Please vote.

18 \* **Criterion 8**

19 [Electronic Voting.]

20 MS. SELENICH: One member votes 6, meets and  
21 deserves priority consideration. One member votes 5, meets  
22 and deserves priority consideration. Two members vote 4,  
23 meets. Six members vote 3, meets. Zero members vote 1 or

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

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

4 CHAIR BAILET: Patient safety. Aim to maintain  
5 or improve standards of patient safety.

6 [Electronic Voting.]

7 \* **Criterion 9**

8 MS. SELENICH: One member votes 6, meets and  
9 deserves priority consideration. One member votes 5, meets  
10 and deserves priority consideration. One member votes 4,  
11 meets. Four members votes 3, meets. Two members vote 2,  
12 meets; and one member votes 1, does not meet.

13 CHAIR BAILET: We want --

14 MS. SELENICH: Oh, two members vote 2, does not  
15 meet; and then one member votes 1, does not meet. Zero  
16 members vote not applicable.

17 So the finding of the Committee, although you may  
18 want to discuss this further, is that the proposal meets  
19 Criterion 9, patient safety.

20 CHAIR BAILET: Do we want to discuss it, or do we  
21 want to move on?

22 [No response.]

23 CHAIR BAILET: I think we're going to move on to



1 Criterion 10, which is health information technology.  
2 Encourage use of health information technology to inform  
3 care.

4 [Electronic Voting.]

5 **\* Criterion 10**

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

11 Therefore, the finding of the Committee is the  
12 proposal does not meet Criterion 10, health information  
13 technology.

14 CHAIR BAILET: Thank you, Sarah.

15 So we are ready to make the recommendation and  
16 vote. So we're going to go ahead and do that now.

17 We need to spend one minute on renumbering these  
18 puppies here.

19 So could we add five, then? Could we add just a  
20 fifth? That would be the easiest to just --

21 DR. CASALE: [Speaking off microphone.]

22 MS. SELENICH: Yeah. I was going to say, I don't  
23 think we can --

1 DR. CASALE: [Speaking off microphone.]

2 MS. SELENICH: Right. So if it's fine with the  
3 Committee, if we can use --

4 DR. CASALE: I was suggesting that since there's  
5 consensus that not applicable is not applicable, just  
6 substitute the merit's attention for the not applicable.  
7 Then people want to vote on the others.

8 MR. MILLER: I would move that we consider for  
9 the voting process, when we vote the zero button, that we  
10 are voting as though we are voting the statement being  
11 merits, consider whatever. What's the phrase?

12 CHAIR BAILET: Recommend for -- well, I had  
13 recommend for other attention, and you said --

14 MR. MILLER: Recommend attention.

15 CHAIR BAILET: Recommended --

16 MR. MILLER: So I would move that we -- that we  
17 are for the purpose of this vote striking the words "not  
18 applicable" and substituting the words --

19 CHAIR BAILET: "Recommend for attention"?

20 MR. MILLER: "Recommend for attention."

21 DR. MEDOWS: Second.

22 CHAIR BAILET: All right.

23 DR. NICHOLS: [Speaking off microphone.]

1 CHAIR BAILET: There is no star.

2 MS. SELENICH: It's zero on your voting pads.

3 CHAIR BAILET: All right. So --

4 MR. MILLER: We have to take a vote, Jeff.

5 CHAIR BAILET: We are going to take a vote.

6 You know, Harold, I'd be lost without you.

7 [Laughter.]

8 MS. SELENICH: Just a quick clarifying question.

9 So, currently, the way this is set up, you need a two-  
10 thirds vote, and we've been rolling down the categories.

11 If you all do not reach a two-thirds vote --

12 MR. MILLER: No, no, no. We have to vote on the  
13 motion.

14 MS. SELENICH: Oh, yeah.

15 MR. MILLER: We don't need two-thirds.

16 CHAIR BAILET: We are going to vote on the  
17 motion. We have a second. All in favor?

18 [Chorus of ayes.]

19 CHAIR BAILET: Any opposed?

20 [No response.]

21 CHAIR BAILET: Motion carries.

22 Please continue, Sarah.

23 MS. SELENICH: So part of that process is are we

1 going to roll down to this recommend for attention vote.

2 MR. MILLER: I would suggest we see what the  
3 votes are, and then we should decide how we will interpret  
4 that.

5 CHAIR BAILET: Yeah. I guess we'll cross that  
6 bridge. All right. Here we go.

7 MR. MILLER: I would suggest we can make a motion  
8 that we suspend our normal rules for rolling down for the  
9 purpose of this vote.

10 CHAIR BAILET: Let's go. I don't think we need  
11 to.

12 So are we ready to go? All right. Hit it.

13 [Electronic Voting.]

14 \* **Final Vote**

15 MS. SELENICH: So zero members vote 4, recommend  
16 proposed payment model for implementation as a high  
17 priority. Zero members votes 3, recommend proposed payment  
18 model for implementation. Zero members vote 2, recommend  
19 proposed payment model for limited scale testing. One  
20 member votes do not recommend proposed payment model, and  
21 nine members vote recommend for attention.

22 Therefore, the finding of the Committee is to  
23 recommend the model for attention.

1 MR. STEINWALD: I'm sorry. I remembered "further  
2 development" or something. "Attention" --

3 CHAIR BAILET: Yeah. So it's "for attention."  
4 Yeah. Because I think -- so do you want to -- should we --

5 MR. MILLER: Can I just suggest too that -- and  
6 maybe everybody agrees -- the phrase should be "recommends  
7 the proposal for attention," not "the model for attention"?

8 CHAIR BAILET: Yeah.

9 MS. SELENICH: So "recommends the proposal for  
10 attention."

11 CHAIR BAILET: Yeah. Do we have a motion -- a  
12 second for that?

13 DR. MEDOWS: Second.

14 CHAIR BAILET: All in favor?

15 [Chorus of ayes.]

16 CHAIR BAILET: All right. So we've got the new  
17 language, Sarah?

18 MS. SELENICH: Yes.

19 CHAIR BAILET: Very good. So that's what we just  
20 voted on.

21 Bruce, do you want a revote because --

22 MR. STEINWALD: Yes.

23 CHAIR BAILET: Yes, I think we should revote.

1 Please. Could we revote? We're going to revote because  
2 Bruce didn't -- he needs to -- he wants his vote to reflect  
3 what he believes, so he took a nap, so let's --

4 Okay, very good. One more time with feeling.  
5 We're going to go ahead and vote. Please.

6 The language, Sarah, please? Read the language  
7 back.

8 MS. SELENICH: The language for what we're  
9 substituting the not applicable category for is "recommend  
10 the proposal for attention."

11 CHAIR BAILET: Okay. Let it rip. There we go.  
12 All right. Because I think it's important for the vote to  
13 reflect the collective consciousness of the group, and it's  
14 unanimous.

15 [Electronic Voting.]

16 \* **Final Vote**

17 MS. SELENICH: So zero -- I'll do it quickly.  
18 Zero members vote 4 -- recommendation categories 1, 2, 3,  
19 and 4, and 10 -- everyone voted for recommend the proposal  
20 for attention.

21 \* **Instructions on Report to the Secretary**

22 CHAIR BAILET: So we have spent a lot of time  
23 getting here. The next step is -- since we all -- you all

1 voted 10, so we don't have to declare personally.

2 Sally, you have been writing feverishly. It  
3 would be nice for you to share what we already have said,  
4 and then we can fill in any gaps that we think we want to  
5 make sure get incorporated in the letter. Does that work,  
6 Sally?

7 DR. STEARNS: Sounds good.

8 All right. So the discussion of this model  
9 showed substantial enthusiasm for the underlying care model  
10 of facilitating more frequent dialysis in nursing home  
11 settings, particularly the care model that enables nursing  
12 home participants to avoid risks and costs of transport and  
13 to potentially achieve better health outcomes.

14 The discussion identified the barrier of a  
15 nephrologist willingness to follow patients into the  
16 nursing home, despite the value of enabling many patients  
17 to continue to receive care from the same nephrologist with  
18 the benefits of MFD.

19 Okay. And it was also noted that MFD in nursing  
20 home has benefits in terms of improvement health outcomes,  
21 including the possibility of reduced hospitalization.

22 In terms of concerns on the model, the main  
23 concern was that the model is not a true physician-focused

1 payment model because it involves a payment to nephrologist  
2 -- or simply because it involves a payment to nephrologist.  
3 The proposed shared savings pertain -- as laid out in the  
4 proposal pertain only to transportation, and the savings  
5 may be particularly questionable for some groups such as  
6 short-stay SNF patients.

7           So the proposal did not have -- or did not  
8 involve broader potential for shared savings by including  
9 other components of care or attention to total cost of care  
10 that might be affected.

11           So, in summary, the PTAC feels that the problem  
12 merits attention. It is not clear, however, that the  
13 submitters should try to develop a physician-focused  
14 payment model. Instead, it would be desirable to  
15 facilitate attention by HHS leadership through further  
16 discussion

17           DR. MEDOWS: Is this the addendum?

18           CHAIR BAILET: Yeah. This is -- right. This is  
19 the time when we can pile on. So Len and then Rhonda.

20           DR. NICHOLS: So, Sally, I'm not sure I -- well,  
21 I would not support saying that this is not a physician-  
22 focused payment model.

23           I think we should say this is not an ideal



1 physician-focused payment model for the problem that it was  
2 designed.

3 I also think we should acknowledge in the letter  
4 that they came to us because they were sent to us by CMMI,  
5 and that given everything we talked about, which I'm sure  
6 the transcript will flesh out, but also, I want to go back  
7 to -- I think it was Josh who talked about the new  
8 requirements, regulations in the nursing home industry to  
9 provide these inside services. That says CMS is already  
10 moving, and therefore, we're just trying to get this  
11 chassis attached to that conversation. And, therefore, I  
12 think it is a physician-focused payment model, and I  
13 wouldn't want to say it's not because I'm just afraid that  
14 will lead to it being discarded right away.

15 CHAIR BAILET: Rhonda.

16 DR. MEDOWS: Can we include some language around  
17 the quality piece, an acknowledge that while there is data  
18 that substantiates the improvements in dialysis patients  
19 outside of the nursing home, but there does not exist yet  
20 the baseline data for SNF patients on home dialysis? That  
21 is to be explored.

22 CHAIR BAILET: Grace.

23 DR. TERRELL: I agree with Rhonda with respect to

1 the quality aspects needed to be fleshed out in general, as  
2 was articulated well by the applicants.

3 I am somewhat skeptical, however, that peritoneal  
4 dialysis is always a -- should be excluded in a model of  
5 care that involves somebody in a nursing home, and so some  
6 of the things that I think needs to be thought about  
7 broadly with respect to quality may be more than just what  
8 a dialysis company itself might know. There may be  
9 evidence that greatly supports that. I just don't know.  
10 So I think there needs to be a broad conversation about  
11 quality.

12 With respect to the fact that we need to say that  
13 this is a problem that they accurately identified, I think  
14 that there should be some specific language with respect to  
15 how we think this attention by the Secretary should be  
16 thought through, whether a code, a simple code, and  
17 therefore going straight to CMS would be the way to go  
18 versus a waiver, which was talked about by the applicants  
19 as the way to go. So if we put language in there that sort  
20 of follows them, think about these things, please, that  
21 would be useful.

22 Finally, they continue to make the point that a  
23 nursing home would not want them to take care of the total

1 cost of care. You mentioned the total cost of care, Sally,  
2 and it's because the entity that brought this forward, I  
3 think, is very specific in what it's doing, which is  
4 providing dialysis for nursing homes.

5           However, that just is because of the way nursing  
6 homes are paid versus what you all were paid for now. We  
7 need to make sure as we're talking and articulating about  
8 what we think could be done better as they are thinking  
9 through what this problem is, is to make sure that it's not  
10 only about facility fees versus procedure fees versus total  
11 cost of care fees versus physician-focused payment fees,  
12 but that the problem itself needs to be thought about  
13 comprehensively as the way all these types of things  
14 currently dysfunctionally interrelate with one another.

15           And they actually identified a new problem for  
16 me, which is because they are a dialysis company, the total  
17 cost of care is a barrier for them to even provide. So  
18 that ought to be thought through as well by CMS.

19           CHAIR BAILET: Harold.

20           MR. MILLER: I think it's important to say that  
21 we think there are two different populations here that need  
22 to be examined separately -- the long-term nursing  
23 population and the short-term SNF patient. And that if

1 examination of those two populations leads back to one  
2 model or one approach that works for them, fine, but I  
3 think that the needs of the populations, the payment  
4 methods that exist today for each of them, et cetera, are  
5 all so different that they just have to be looked at  
6 separately. And I think to me that was one of the  
7 weaknesses of this proposal, was it just sort of blended  
8 them all together and didn't make that distinction.

9           So I think that when this greater attention  
10 occurs, it's important that they be looked at separately,  
11 and I raise that particularly because I think it may be  
12 different people may be looking at that, at CMS, and need  
13 to be thinking about those different pieces.

14           And, again, if it comes back to one approach,  
15 fine, but I think that the people who know each of those  
16 separate components and what's associated with them should  
17 look at them separately and decide what makes sense to do.

18           CHAIR BAILET: Thank you.

19           Rhonda -- oh, very good. See, I'm surprised I  
20 caught that.

21           This has been a long day.

22           [Laughter.]

23           CHAIR BAILET: So I want to thank first the

1 applicants. You guys have put a lot of work into  
2 preparing. I remember, if you people who were looking at  
3 the transcript, Dr. Kaufman, you know, that conversation  
4 that we've had, I mean, you guys have really leaned in. We  
5 appreciate your patience with us, as we have refined our  
6 process. And we're here to support the clinical community  
7 and make recommendations to the Secretary, and I think we  
8 landed in a great spot. And I want to compliment my  
9 colleagues around the table here for sticking with it  
10 because it was high level of engagement that led us to the  
11 solution, and I think we actually did a nice job, if I  
12 would say so myself.

13 Thank you, and I guess, do I have a motion to  
14 adjourn?

15 DR. FERRIS: Motion.

16 DR. MEDOWS: Please.

17 CHAIR BAILET: Second?

18 DR. MEDOWS: Second.

19 CHAIR BAILET: All in favor.

20 [Chorus of ayes.]

21 CHAIR BAILET: Meeting is adjourned.

22 [Whereupon, at 6:11 p.m., the meeting was  
23 recessed, to reconvene Friday, September 7, 2018.]