PHYSICIAN-FOCUSED PAYMENT MODEL TECHNICAL ADVISORY COMMITTEE (PTAC)

PUBLIC MEETING

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

Monday, December 18, 2017
9:00 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
ELIZABETH MITCHELL, Vice Chair
LEN M. NICHOLS, PhD
KAVITA PATEL, MD, MSHS
BRUCE STEINWALD, MBA
GRACE TERRELL, MD, MMM

STAFF PRESENT:
Tim Dube, Office of the Assistant Secretary for Planning and Evaluation (ASPE)
Ann Page, Designated Federal Officer (DFO), ASPE
Sarah Selenich, ASPE
Mary Ellen Stahlman, ASPE

CONTRACTOR STAFF:
Adele Shartzer, PhD, Urban Institute

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Mercy Accountable Care Organization: Annual Wellness Visit Billing at Rural Health Clinics

PRT: Robert Berenson, MD (Lead);
Tim Ferris, MD; Len M. Nichols, PhD
Staff Lead: Tim Dube

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P R O C E E D I N G S

[9:04 a.m.]

* **Opening Remarks**

CHAIR BAILET: All right. Good morning. Good morning, everyone. We're going to go ahead and get started. We're the Physician-Focused Payment Technical Advisory Committee, or PTAC. Good morning. Welcome to -- welcome to our -- this is our third public session. We're pleased to have all you here. In addition to members that are in the room with us, there are some watching on the live stream. Also, there'll be some folks on the phone as well.

This meeting allows us to deliberate and vote on the physician-focused payment models submitted by members of the public. We'd like to thank all of you for your interest in today's meeting. In particular, we'd like to thank the stakeholders who have submitted models, especially those who are here today. Your hard work and dedication to payment reform is truly appreciated.

PTAC has been very active since our last public meeting in September. Since that meeting, we have submitted recommendations and comments on two physician-focused payment model proposals to the Secretary of Health and Human Services that were voted on at the September meeting.

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In addition, we've been very busy reviewing and evaluating physician-focused payment model proposals from the public. I'm pleased to report that interest in submitting PFPMs to PTAC continues since we first began accepting proposals for review on December 1st of 2016. We have received 20 full proposals and an additional 13 letters of intent to submit proposals.

These proposals represent a wide variety of specialties and practice sizes, and they propose a range of payment model types. For example, over a dozen different specialties and subspecialties are represented in the letters of intent that we've received. There is interest in physician-focused payment models by both small and large-group practices. Bundled payments and care management proposals comprise the majority of the proposals to-date, but we've also received proposals or letters of intent that relate to capitated payment and other payment models.

We are pleased that we have so much interest from clinical stakeholders in proposing physician-focused payment models, and we're fully engaged to ensure proposals are reviewed carefully and with the needs of both clinicians and patients in mind.

We are already looking ahead to the agenda for our next public meeting, which will be held here in the

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Great Hall of the Humphrey Building, March 26th and 27th. One simple reminder: To the extent that questions may arise as we consider your proposal, please reach out to staff through the PTAC.gov mailbox. The staff will work with me as Chair and with Elizabeth, the Vice Chair, to answer your questions.

We have established this process in the interest of consistency in responding to submitters and members of the public and appreciate everyone cooperating with us.

Today, we will be deliberating on four proposals and deliberate on three proposals tomorrow. To remind the audience, the order of activities for each proposal is as follows: First, PTAC members will make disclosures of potential conflicts of interest and announcements of any Committee members not voting on a particular proposal. Second, discussions of each proposal would begin with presentation from the Preliminary Review Team, or PRTs.

Following the PRT’s presentation and some initial questions from PTAC members, the Committee looks forward to hearing comments from the proposal submitters and the public. The Committee will then deliberate on the proposal.

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

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will vote electronically on whether the proposal meets each of the Secretary's 10 criteria.

Those of you who have read all the PRT reports ahead know that members of the Committee have used the term "not applicable" to refer to the elements of proposals that they believe the criteria are not applicable to.

We will discuss this more in the context of individual proposals, and we look forward to input from the public as this -- on this particular issue as we finalize our policy.

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

A few reminders as we begin discussions on the first proposal: The PRT reports are reports from three PTAC members to the full PTAC and do not represent the consensus or position of the PTAC. The PRT reports are not binding. The full PTAC may reach different conclusions from that contained in the PRT report.

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

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Secretary.

It is our job to provide the best possible recommendation to the Secretary, and I have every expectation that our discussions over the next few days will accomplish this goal.

I would like to take the opportunity to thank my colleagues, all of whom give countless hours to the careful and expert review of the proposals before them.

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

So, before we get started, I'd like to turn to my Vice Chair, Elizabeth Mitchell, for any comments she'd like to make.

VICE CHAIR MITCHELL: Thank you, Jeff.

And I would just like to add my thanks to the Committee members who have, as you have said, have really contributed countless hours to this process, and to the submitters for bringing such good ideas forward. I think we are achieving our aim, as set out in MACRA to create a transparent and open process for consideration of new ideas to expand the Medicare payment portfolio, and I just want to thank you all for your commitment.

CHAIR BAILET: Thank you, Elizabeth.

The first proposal we will discuss today was

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submitted by Renal Physicians Association, or RPA, and it's entitled "Incident ESRD" -- or end-stage renal disease -- "Clinical Episode Payment Model."

PTAC members, as we start the process, let's start by introducing ourselves and, at the same time, read your disclosure statements on this proposal.

Renal Physicians Association (RPA): Incident ESRD Clinical Episode Payment Model

* **Committee Member Disclosures**

DR. BAILET: So I'll start with myself. I'm Dr. Jeffrey Bailet. I am currently the Executive Vice President of Health Care Quality and Affordability with Blue Shield of California. On the first proposal, I have nothing to disclose.

We can go ahead and start with Tim.

DR. FERRIS: Tim Ferris. I'm the CEO (of the Mass General Physicians Organization, and I have nothing to disclose.

DR. TERRELL: Grace Terrell, CEO of Envision Genomics, and I have nothing to disclose.

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

I gave a presentation on alternative payment models to the Renal Physicians Association’s annual meeting in March of 2016, and I was compensated for my time and

travel. During that presentation, I described potential approaches to APMs for patients with chronic kidney disease. While there, I met with a group of RPA leaders to answer questions about APMs, and I provided comments on a very preliminary concept paper they had developed about bundled payments for chronic kidney disease. But I have had no further involvement with RPA or its members in the past 12 months, and I have not had any involvement in the preparation of the PFPM described in the proposal. The proposed payment model would have no special or distinct effect on me.

DR. CASALE: Paul Casale, cardiologist and Executive Director of New York Quality Care, the ACO of New York-Presbyterian, Weill Cornell, and Columbia. I have no disclosures.

MR. STEINWALD: I'm Bruce Steinwald. I have a little consulting practice here in Washington, D.C., and I'm doing some work on payment policy with the Brookings Institution. And I have nothing to disclose on this proposal.

VICE CHAIR MITCHELL: Elizabeth Mitchell, President and CEO of the Network for Regional Healthcare Improvement, and I have nothing to disclose.

DR. NICHOLS: Len Nichols. I direct the Center for Health Policy Research and Ethics at George Mason

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University, and I have nothing to disclose.

DR. PATEL: Kavita Patel, an internist at Johns Hopkins and Fellow at the Brookings Institution, and I have nothing to disclose.

DR. BERENSON: I'm Bob Berenson. I'm an Institute Fellow at the Urban Institute, and I have nothing to disclose.

DR. MEDOWS: Rhonda Medows, Executive Vice President, Population Health, Providence St. Joseph Health. I have nothing to disclose.

CHAIR BAILET: Could we go ahead and ask the staff to introduce themselves. Marry Ellen?

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

MS. PAGE: I'm Ann Page. I'm the Designated Federal Officer for the PTAC Committee, which is a committee governed by the provisions of the Federal Advisory Committee Act, FACA.

DR. SHARTZER: I'm Adele Shartzer. I'm a contractor. I work for the Urban Institute, and I'm helping staff this particular committee.

*** PRT Report to the Full PTAC**

CHAIR BAILET: Great. Thanks, everyone.

I'd like to now turn the microphone over to Dr. Paul Casale who led the Preliminary Review Team for the

first proposal. Paul?

DR. CASALE: Thanks, Jeff.

I'll look for the first slide.

[Pause.]

DR. CASALE: Thank you. So, yeah, the title of this proposal is "Incident ESRD Clinical Episode Payment Model," submitted by Renal Physicians Association, and I'll likely refer to it as the "RPA proposal" because it seems easier to say.

So, which way do I point this? Okay.

So, in my presentation, I'll briefly review the compositional role of the PRT, then give an overview of the proposal, summary of our PRT review, and then evaluation using the criteria, and finally key issues identified.

Jeff has already gone over this in terms of PRT. I'll just -- as a reminder, a PRT report is not binding on the PTAC, and PTAC may reach a different conclusion from that contained in the PRT report.

Where am I supposed to point this at?

CHAIR BAILET: Just testing you, Paul.

DR. CASALE: Okay.

CHAIR BAILET: Okay.

DR. CASALE: Yeah, yeah.

Okay. So model overview. The model focuses on optimal transition to dialysis. Some modalities, as an

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example, initiating dialysis with catheters, are associated with higher costs, higher rates of infection, and hospitalizations. Advanced preparation is required for less costly modalities.

So the eligible population for this proposal are patients with incident ESRD, who are enrolled in Medicare when they begin dialysis. The episode length is six months, beginning the first day of the month during which dialysis begins, unless it begins after the 16th of the month.

And the major components are a shared savings / loss based on total cost of care during the episode, and also it depends on performance on quality metrics. And then a second component is a transplant bonus of $3,000 if that occurs prior to beginning dialysis or $1,500 during the episode.

At the end of the presentation, there is a slide that provides much more detail around the specifics. I know everyone’s read the proposal, so I'm just leaving it at the back of the proposal for reference rather than going through the specific details around all of the payment. I'm sure we'll have discussion around that.

Okay. So summarizing the PRT criteria, you can see here, and then we'll walk through each one of these individually.

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So, Criterion 1 for Scope. The PRT conclusion was “proposal meets the criterion”. On the strengths, this APM is the only one that currently focuses on high-cost ESRD patients.

The Comprehensive ERCD Care, or CEC model, has limited participation of approximately 10 percent of nephrologists. So this model expands access to APMs to more nephrologists and their patients. And one of the ways it expands it is that this model does not include the requirement for minimum number of cases or patients or other geographic considerations that make participation in the CEC model difficult for many nephrologists.

One of the concerns we discussed in the PRT was the potential issue of random variation and spending for savings and loss calculations, particularly for small nephrology practices, given the fact that ESRD patients tend to be very high cost.

I went too fast. Okay.

Criterion 2 on Quality and Cost. The PRT conclusion was the proposal meets the criterion. The strengths that we identified was that the model addresses the high annual spending for incident ESRD patients, including potentially preventable hospitalizations related in part to suboptimal transition to dialysis, and the model makes shared savings payment contingent on a number of

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important quality measures.

The concerns, as outlined and discussed by PRT, the biggest opportunities for improvement need to occur prior to dialysis, but the episode begins at dialysis initiation. So the PRT is concerned about the ability of nephrologists to influence upstream care, given treatment patterns.

The minimum quality score for shared savings is 30, which is achievable merely by reporting performance. The PRT would like to see greater emphasis on patient experiences in the quality score threshold. And finally, the difficulty we identified in evaluating the impact of transplant bonus on quality and cost.

For Criterion 3, Payment Methodology, the PRT conclusion was that the proposal meets the criterion, except for the transplant bonus. So, the strength was at the model's design to direct higher payments to nephrologists who achieve better results for patients in the first six months of dialysis. Again, this is a time of particularly high cost and poor outcomes.

The concern is that the methodology does not include up-front payments to providers to support enhanced education and care management. The shared savings payments are based on risk-adjusted spending and regional benchmarks, but again, small numbers could impact the

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effectiveness of the risk adjustment.

Again, weighting of the quality measures, we feel should place more emphasis on patient experience.

And then the kidney transplant bonus is an area of major concern, as it is unlikely to change the net number of kidney transplants due to the organ supply constraints, and factors determining transplant are largely out of a nephrologist control. Encouraging transplant referral and education could more accurately reflect nephrologist actions.

For Criterion 4, Value over Volume, the PRT conclusion was that the proposal meets the criterion. The strength identified was the model provides incentives to reduce the total cost of care for incident dialysis patients in part by reducing the rate of hospitalizations and other avoidable complications of treatment.

The concern that by beginning the episode with the procedure, this model could create an incentive to start dialysis earlier in the disease process when patients are healthier and less likely to have complications.

For Criterion 5, Flexibility, the PRT conclusion, “proposal meets the criterion”. The strength that the -- we identified the model provides greater flexibility than fee-for-service Medicare or the CEC model in the types of activities physicians could undertake to deliver high-

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quality health care, and providers could then use the shared savings payments to support a range of activities to improve quality.

The concern that the model requires providers to make up-front investments that they hope to recoup during reconciliation, this could discourage practices, particularly small practices from making expensive but valuable investments.

the Ability to be Evaluated, the PRT conclusion, “proposal meets the criteria”. Under strengths, the PRT believed it is feasible to assess changes in spending and quality associated with model implementation. The goals of the model, the quality measures, and potential impact on health care costs are clear and can be evaluated.

The concerns, again, for assessment of quality outcomes, there may be challenges in reporting some of the quality measures through the EHR, particularly the patient experience measures, if a nephrologist does not participate in the RPA-sponsored Kidney Quality Improvement Registry.

Under Criterion 7, Integration and Care Coordination, PRT conclusion: “proposal does not meet the criteria”. The strengths identified: the model would indirectly encourage the nephrologist to establish better mechanisms for communication with other providers in the community regarding patients with CKD who are likely to

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need dialysis in the future, and the model would also implicitly encourage nephrologists to improve care coordination with the patient's other physicians. The concern, however, is that the proposal does not provide clarity about how providers would achieve better coordination, both prior to and during dialysis.

There's no indication as to whether or how nephrologists would involve other physicians in the APM Entity or share savings and losses with other providers.

Under Criterion 8, Patient Choice, PRT conclusion was that the proposal meets the criterion. The strengths identified was this proposal has the potential to expand the range of treatment options available to patients with incident ESRD by encouraging early education and preparation for the transition to dialysis.

The proposal also could encourage providers to identify patients unlikely to benefit from dialysis and educate patients about the alternative of conservative management of their CKD. The concern is that the model may incentivize providers to start dialysis earlier in the disease process when patients are healthier, and the transplant bonus may encourage patient choice by providing a pathway to overcome existing barriers, but the large size of bonus may influence the role of patient preferences.

Under Patient Safety, the PRT concluded “proposal

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meets the criterion". The strength identified was this proposal has a clear focus on avoiding hospitalizations, reducing infection rates, et cetera, for patients during the first six months of dialysis.

And for Criterion 10, Health Information Technology, PRT conclusion was "proposal meets the criterion". The strengths: All providers would be required to use CEHRT. Oh, yeah. Nephrologists and other participating providers would be encouraged to coordinate care prior to and during dialysis with the aid of health information technology.

The proposal notes that the RPA qualified clinical data registry would be available to model participants and would facilitate the collection of patient and disease data.

The concern was this proposal does not provide specific information about how to encourage use of health information technology specifically.

So, key issues identified by the PRT: The PRT supports the proposal's goal of improving the transition to dialysis for patients with incident ESRD. The PRT's major concerns are: One, the upstream activities. The model has potential to improve quality and reduce costs, but it relies on the assumption that the same nephrologists or nephrology practice is involved in the care of the patient

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for an extended time prior to and then after dialysis initiation.

In terms of upfront investments, the model's payment methodology requires upfront investments from providers for patient education, care management, and other services that could be returned to providers during reconciliation. However, small providers are particularly vulnerable to random variation that could put that investment at risk.

And the third concern relates to the transplant bonus. The PRT supports efforts to increase transplantation, but paying bonuses in this model is problematic and an unnecessary component of the model.

So, with that, I'll stop and ask my fellow PRT members if they have additional comments before opening it up. So, well, Harold and then Jeff.

MR. MILLER: I have none.

DR. CASALE: None? Okay.

* **Clarifying Questions from PTAC to PRT**

CHAIR BAILET: Thanks. I have no specific comments to make, Paul, but I think if there are clarifying questions, this would be a good time. Bob?

DR. BERENSON: Yeah, I just want to talk a little bit about the eligibility criteria here. As I understand it, it's people who are already on Medicare, not

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populations who will become eligible by virtue of having ESRD. Isn't that a relatively small percentage of a renal physician's dialysis population? And isn't it a pretty unique population? I guess -- so, one, do I have that correct, that it's a minority of dialysis patients? And I'll ask them, too, but did you explore that at all?

DR. CASALE: Yeah. It's our understanding that it's patients who are on Medicare who would be --

DR. BERENSON: So that's -- I mean, most people who -- my understanding is that -- and there's some data here which I don't understand -- is that most ESRD patients are below 65 and become eligible because they start dialysis. They are not already on Medicare. So we are dealing with a subpopulation of patients who are in a renal physician's practice here, and so, one, I think that exacerbates the problem of small numbers. But two is would we expect behavior change for just a relatively small percentage of a physician's practice, dialysis practice, is my question.

MR. MILLER: It's not as small as you're representing it to be, and I think we should ask them that. So anybody who would be -- have chronic kidney disease when they become eligible for Medicare and go on Medicare and who then progress to end-stage renal disease would be included in this.

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The population you're talking about would be people who were commercially insured or -- commercially insured who would then reach end-stage renal disease. And then there's a 20-month period when they don't become eligible for Medicare, anyway. So that's -- that population, the commercially insured becoming -- going on dialysis wouldn't be --

DR. BERENSON: Or the Medicaid insured or the uninsured.

MR. MILLER: Correct. But anybody who is -- goes on Medicare and has chronic kidney disease when they go on Medicare or develops it afterwards, presumably, and then progresses to end-stage renal disease would be included in this population, and that's -- I'm not sure that we ever tabulated that specifically. My recollection is that that's, I don't know, a third-to-a-half of the people. But we can ask them that.

DR. BERENSON: Okay. All right. Thanks.

CHAIR BAILET: Tim?

DR. FERRIS: So I have a question for the whole PRT that this proposal raises, but it's come up in other proposals, and the reason why I'm pointing it out is because we appear to be inconsistent in our recommendations about this, and so probably we're learning as we go.

But the concern raised on Criterion 3, the

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methodology, does not include upfront payments. We've actually stated the opposite concern in the past as well, which is if the payment is up front, then you -- and that's at risk, then you have a possibility for the practical problems associated with clawbacks and the associated practical problems. So both upfront payments and after-the-fact payments present challenges. We've stated it here as a concern, but I would say that I'm not also -- I'm not sure that we have come to some -- and I'm not sure, maybe the economists in the group can help us out here. But I don't know that there's a preferred way. It may be that both ways have positives and negatives and that the context might be important.

CHAIR BAILET: Right. Len, do you want to comment on that?

DR. NICHOLS: Well, just as the forenamed economist in the room, I would say both God and devil live in the details, and so it really does depend. You can do it smartly either way, and I would say our task is to decide, A, if what they proposed meets the standards we worry about; and, B, if there are modifications we would like to suggest, and I think that'll come out.

But to me, the big thing about the PRT's conclusion here was that they were afraid the investment upstream wouldn't take place without some kind of money

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because they'd have to do that on spec, in essence, and that's different. You could have a partial upfront and then an ex post. That would solve your nuance problem. Don't worry. There's a solution.

CHAIR BAILET: It'll work itself out. Paul.

DR. CASALE: I think in our PRT discussion, you know, one of the strengths of this -- because we were comparing it a bit to the CEC model, and one of the strengths was this would involve, you know, the smaller groups --

CHAIR BAILET: Right.

DR. CASALE: -- in areas where there is no CEC model available to them. And so I think part of our thinking around that was as you involve these smaller practices, potentially more rural, et cetera, the need for some upfront investment is going to be important.

MR. MILLER: Can I just add to Tim's point? Because I think that is a general issue going on. There's also a difference between whether the upfront payment is an incentive payment that's being given somehow then to be taken back if the practice doesn't achieve something, versus a payment that's designed to cover a cost. And I think on one of the other proposals, the issue was it's an incentive payment; it's not intended to cover a cost, and then it's being taken back if the practice doesn't achieve

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it. The issue here was the concern was if the practice needs to incur new costs and doesn't have any upfront way to pay for that and is dependent on getting a shared savings payment, which it doesn't know whether or when it will get, that that could be biased against very small practices that don't have those resources. So that was really -- that was the distinction.

CHAIR BAILET: Bruce.

MR. STEINWALD: It's my understanding that ESRD patients and Medicare beneficiaries are major consumers of Part B drugs, particularly Epogen for the relief of anemia related to kidney failure. And I didn't -- here's the standard disclaimer: I didn't see it in the materials I read, but the disclaimer is could have been there and I missed it, and that could apply to almost any of the proposals, so I'll just say -- so I won't repeat that disclaimer. But was there some discussion either in the proposal or your discussions with the proposer or amongst yourselves about how this model would affect the consumption of Part B drugs? And is that one of the targeted areas of potential savings under the model?

DR. CASALE: It’s interesting. I don't think we had that discussion in the PRT that I can recall, in particular whether it would be impacted.

MR. MILLER: The drugs you're referring to,

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Bruce, are bundled into the dialysis payment now. So if patients --

MR. STEINWALD: Not Epogen -- I don't think so -- or iron and some of the -- some of the drugs are, but others are not.

CHAIR BAILET: Well, the submitters are going to clarify that for us. I'm seeing a lot of heads nodding over there. So we'll get clarification on that point.

Kavita?

DR. PATEL: All right. I have a -- it's not really for -- actually, it is for the PRT, but it might be for staff, too. I'm just struggling. I'm kind of building off of Bob's analytic question, and in Table 1A on page -- I don't know what -- there's -- it looks like if I'm reading this correctly that there are a total of 51,240 patients who got the Medicare benefit and had some Medicare benefit that are kind of potentially in this denominator for this payment model. Am I -- and then of that, 31,000, so a little over half, got it because of age. And it looks like only 700 were in because of end-stage renal disease? So, I'm just trying to understand the, like, actual population of people, kind of just building on Bob's question of if this really is like people who are kind of imminently going to be on dialysis and would not have already had been on Medicare potentially or -- I'm just

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trying to ask what the denominator is.

And then the second question, somewhere in the conversation -- one of the criticisms that you pointed out, Paul, was this inability to kind of think about going up -- the coordination and going upstream. And in the back-and-forth with the clinical expert from Penn, they talked about that need. And then in response, RPA I thought provided a thoughtful kind of assessment of, yes, we agree but, unfortunately, by the time they come to us, it's so heterogeneous we can't really get to the upstream. I'm just curious if you all could put a little more color onto that potential to go more upstream into like the Stage 3 and 4 CKD, and I think you went into some of that.

DR. CASALE: Yeah, I'll take the second one first, so we can think through the numbers again. We had a lot of discussion around that, and with our expert from Penn and with the submitters, because I think it may -- you know, it depends a little if you're in an academic medical center versus in the community, I would say, a bit, where our -- the experience of our expert at Penn was, well, you know, they check in with me once a year, they're sort of managed -- you know, they have CKD that's advanced. They check in with me once a year, but they're really managed in their local community. And then they may then get started on dialysis. They may -- Penn may start their dialysis,

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but then ultimately they're going to be cared for locally because they're not going to be commuting back and forth for their dialysis. And so we did have concerns around that. So who's going to be responsible for that upfront education in terms of even for transplant evaluation and then, you know, preparation, putting the graft in, et cetera, and all of that?

And so I think there is a bit of difference, depending on the experience at the academic versus the community, although I think we recognize that one of the concerns is that a lot of these patients, you know, in the current system aren't really -- may not be seen any nephrologist until they start dialysis, and we talked about that. So they're trying to get upstream on that, and so that's going to require more care coordination, et cetera.

CHAIR BAILET: Yeah, and part of the -- a lot of the expense in the first six months is chewed up for people who go to dialysis because they have a catheter in place, so the infection rates, et cetera. Ideally, either they're going to get a transplant before they need dialysis, or they can get a shunt, which would be the ideal way, for peritoneal dialysis. And the challenge is that if it's a vascular shunt that needs to be placed, those have to mature, and there, you know, we talked with our expert and the nephrology submitters, and that takes months for that

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to mature. So it's a timing issue, and we also talked about, well, where's the marker? Because, again, we're trying -- ideally, the more care that can be delivered up front prior to dialysis instead of having people crash into dialysis, that's really going to get at the cost, the hospitalizations and some of the complications and mortality that they talked about. There's a significant mortality increase if you go into dialysis on a catheter.

The challenge is there's no specific marker. They talked about glomerular filtration rate and some of the other labs that get you into the different stages, but there was -- it's -- still there's not a consistent belief. There was some flexibility on interpreting when is the appropriate time. So there's a lot of moving parts, I guess is what I'm trying to say. We pressed hard on couldn't we just put a -- you know, if your glomerular filtration rate is X or your kidney function is Y, we're going to put a graft in at that time. That gives us 18 months of upstream, and then we can start to impact some of the complications.

The other point is that the statistics show that 28 percent of end-stage renal patients have not seen a nephrologist prior to starting dialysis, and another 43 percent see a nephrologist less than six months. So you're talking about 71 percent of the patients who end up on

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dialysis really had almost -- you know, had limited or no nephrology care, and that's where that upstream input would be necessary. So hopefully the submitters, when we get them up here, we can talk about that as well.

Elizabeth, you had a -- or Paul?

MALE PARTICIPANT: [Off microphone.]

DR. PATEL: [Off microphone.] Maybe somebody could clarify the numbers.

MR. MILLER: Sure. I wasn't sure exactly what your question was. Table 1A was our effort to try to determine how long people had been on Medicare who were -- people who were on Medicare when they started dialysis, the moment that they started dialysis, how long had they been on Medicare? And the answer is a long time, more than a year. It wasn't that they just suddenly became eligible for Medicare and then suddenly started on dialysis.

There are a lot of people who are on Medicare getting dialysis that didn't start dialysis on Medicare because they were still covered by a commercial insurance or whatever. In fact, it's one of the odd things about this structure, is that in a sense Medicare is getting them after somebody else has been responsible for start -- it's not the small -- a very small proportion, but if you look at all the people who are on ESRD, Medicare is, if you will, taking care of them after somebody else was

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responsible for paying for the start. So this is focused on the people that under Medicare, at least, there is the potential to be able to do something when they start.

You could potentially then extend this to other payers. You could say some commercial payer could have the exact same model because they would say we're paying for these patients for the first 20 months, and that's a time when based on all this data suggests that there is a very significant opportunity to be able to reduce costs, et cetera. So it would certainly be attractive to them also, but we're only doing Medicare right here.

So this particular area of disease has really fascinating margins between, you know, when commercial insurance, et cetera, and so also anybody here who would be -- who would be uninsured and who would be starting home dialysis would be starting under Medicare initially, but that's a fairly small population.

DR. SHARTZER: Kavita, if you flip back to Table C3, it shows the health insurance coverage status of incident ESRD patients, and it looks like 60, about 60 percent have Medicare when they're incident. Sorry. I know there are a lot of tables.

DR. CASALE: Okay. All right. Very good. Elizabeth?

VICE CHAIR MITCHELL: Thank you. My question is

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around the quality metrics, and this might be better for the submitters, but particularly around the patient centeredness and the PROMIS metric and the referral to transplant, were there any concerns about sort of collection of the information, particularly if it's across providers, and any thought about how -- what is an optimal outcome given the various scenarios for treatment? And, also, what interaction you might have had about having a threshold beyond just reporting to actual performance?

DR. CASALE: I think a lot of our discussion focused on the weighting of it, the concern that it wasn't -- there were a lot of measures, and the experience ones we felt should be weighted higher.

In terms of the collection, I think we identified the one around their -- around their registry and if you're not participating, particularly if you're trying to reach out to, you know, smaller groups and rural, et cetera, that may not -- may or may not be part of the registry.

I don't recall we had much -- you know, in terms of the outcome versus the reporting, I'm not sure we discussed that extensively. I think a lot of the emphasis was around the weighting of experience versus all the process measures. That would be important to weigh those higher in terms of qualifying for the shared savings.

CHAIR BAILET: Harold.

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MR. MILLER: I think the issue with this population, this model, is that patients who are on dialysis are known to have problems in terms of complications and hospitalizations, et cetera. And so, in a sense, the whole thrust of this is about reducing that and thereby improving it. So, in a sense, the quality improvement is really fundamentally focused around that idea, of helping patients during that initial period of dialysis to not have complications and end up in the hospital, to be able to get a fistula rather than a catheter, not have -- be subject to infections, et cetera.

So, in a sense, there's sort of -- this is really -- the payment model is fundamentally directed at a particular quality initiative. It is not saying we're going to somehow pay you more and we hope that you are doing it in the right way, or that you're spending less and we hope you're -- because if they're on dialysis, I mean, roughly about almost half of the cost of the -- during that period of time, is the dialysis itself, and most of the rest ends up being these avoidable hospitalizations.

So that's kind of why we thought it was important to make sure that the patient experience, et cetera, was being weighed appropriately, but it wasn't that somehow you were being rewarded for a mysterious quality improvement. That, fundamentally, if you're going to save money it's

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probably because you've achieved the quality improvement that this is about.

DR. CASALE: Although I would add, you know, in terms of the experience part, not, you know, certainly not going to the hospital and not being in the ER, that's all very good. But even our expert at Penn, you know, when they come in with their CKD, and he mentions dialysis, I mean, that's a big -- you know, that people don't want to hear that. And so the experience that people have around the conversations and the education and the -- as they move from CKD to dialysis, is important, and to be able to measure and understand what that experience is. And I think that's part of what you're, I think, trying to get at, in terms of how are patients -- and again, we highlighted that a little bit in terms of is there -- could there potentially be -- an unintended consequence of people moving to dialysis sooner than not, based on this model.

So I think the registry is helpful in terms of the reporting but not everyone necessarily will have access to that, potentially, and how would you measure it.

CHAIR BAILET: Grace?

DR. TERRELL: It's interesting to me that a lot of our conversation here is not around the "doesn't meet criteria" one that -- Criteria 7 -- about integration and

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care coordination. And so this is something that may be a comment now, it may be something that our presenters want to clarify. But I think it's a broader issue as it relates to how you all may have analyzed that.

And this has to do with some known facts about quality of care at this point in somebody's journey into end-stage renal disease, specifically one thing that I believe is well-known, you sort of alluded to it, Jeff, is vascular access and how that's performed in the community makes a great deal of difference. So if you've got a shunt placed by a vascular surgeon who does hundreds of these, then your outcome is better than somebody who does it occasionally.

So that, to me, looks like an opportunity to have talked in great detail about the care coordination and integration, but the response that they had back was, well, we wanted to make it so it would be relevant and sort of at the local level as it relates to there may be small rural communities or whatever where this -- you know, where innovation or care coordination would have a different tone or color than it would with somebody else.

So this is a big issue with respect to the U.S., and what constitutes a standard of care and what constitutes a standard of quality, as it relates to people coming to us, wanting to think and talk about care

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coordination and integration, because it's not equal everywhere in the U.S. But we do know that there are some very different outcomes that occur as the result of some communities having access to things.

I'm an internist at Wake Forest Baptist Health, and one of the debates that has happened there, and I believe been resolved, is they have many, many good vascular surgeons, they all like to do these shunts, they're going to have one guy do it, because he does the best and the access is -- you know, the outcomes are better.

That's a true, you know, quality outcome in a place that happens to have a lot of resources. That's not going to work so well in a rural area if there's one vascular surgeon within 200 miles or something. But yet the payment is supposed to be the same across the country.

So their response to this was actually not a bad one, which is we need to give it some flexibility across the country for rural communities, small communities as well as large ones, but that's kind of a big deal with respect to anybody's individual outcomes.

So I would like to hear how far the Committee actually pushed on this issue of integration and care coordination and then when the nephrologists have a chance to speak, I would really like to get their thought process

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in a little more detail about why they left it so vague. Because the PRT said "didn't meet criteria," but this is an issue that actually, I think, is a much bigger one, not only for this proposal but for many, and it just has to do with how are we going to evaluate things when we know that some types of behaviors and some situations are going to be better than others.

DR. CASALE: Yeah. I think we had a fair amount of discussion around this issue of care coordination and integration. We talked a bit about, you know, the vascular access, but I think it was even more around what I mentioned before, around patients with CKD who sort of have this every-six-months or yearly visit with a nephrologist somewhere, and then – but then they're sort of managed locally. And it's not until they then go on dialysis and then who is actually managing their care, and who is making the decisions about when they're going to put the graft in, et cetera, when there may be sort of the expert nephrologists who they have little contact with, and how are you going to specifically do that coordination with either the local internist, in particular?

But, you know, I think what you've said about vascular surgeons applies, to you know, many others, right, where certainly volume of procedures and outcomes certainly have a significant relationship. So I think -- and, Jeff,

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you want to add to that -- but I think we had a fair amount of discussion around the concerns around integration and care coordination.

CHAIR BAILET: I think the other point, Grace, was that in many instances patients with chronic kidney disease will see -- they'll travel a distance to see the nephrologist on these check-in appointments that Paul's alluding to. But when they get their dialysis, which is on a serial basis, they tend to get that closer to home. So that was another challenge.

So, in some centers and situations, the nephrologist that's treating them for the end-stage renal disease is also the nephrologist that was supporting them, but not always the case.

So, again, there -- one of the reasons that it "didn't meet" was it was underdeveloped relative to talking about the -- how this model is actually going to drive that integration. So it's not necessarily it wasn't there or isn't happening. It's just this model specifically didn't address it with the granular detail that we felt sufficient for it to meet the criteria. Does that -- is that a -- I'm just looking at my colleagues. Harold?

MR. MILLER: I would just add, for me this comes down to the issue we were talking about with Tim before, was -- is there -- Is the payment model designed in such a

way that it would actually support what you think people would want to do? We don't -- it's not necessarily that they have to be specified that, but there's actually lots of care coordination issues here. There's, “How do you reach out to the PCP, for people who are headed in this direction?” “How do you talk to the vascular surgeon?” “How do you deal with other specialists when the patient may have comorbidities that need to be managed to keep them out of the hospital, because it's a total cost?” So, they could be being hospitalized not just for complications of their dialysis but for, you know, access but for other kinds of conditions that they have.

So, the issue was, in theory, the nephrologist is going to have to be managing all those things, and it's just a shared savings model. So the question was, well, “Is that really going to enable all that to happen?” And we said -- it wasn't that we wanted to specify it, but we didn't see it articulated as to how one would imagine that working well and whether it would work well under this particular payment model.

CHAIR BAILET: Thank you, Harold. Bob, we're going to get to you and then we'll invite the proposers to come to the table.

DR. BERENSON: And this, again, I will be asking the docs, but I just wanted to know if the PRTs had any

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insight into this. The proposal had a lot of information about very high mortality rates early on. There was a discussion about both going upstream to predict and prepare for dialysis and also crashing into dialysis. I'm just wondering if there's two populations here, one that are going into the hospital and the ICU for some other reason and get acute renal failure, dialysis has started, and many of them don't survive.

So the technical question is, “does the episode start with outpatient dialysis for survivors of the hospital or for any dialysis?” So that's my concern, is that we may have two populations, and I'm just wondering who this payment model applies to, if you know what I'm asking.

DR. CASALE: Yeah, and Harold was just whispering to me. That reminded me that acute kidney injury, I believe, was excluded. So it would not apply to that scenario that you just suggested.

DR. BERENSON: Does it start with an outpatient dialysis or any dialysis? It doesn't -- it's not specified.

DR. CASALE: Yeah, I think it kind of --

CHAIR BAILET: It's -- I think it's inpatient or outpatient, but not acute.

MR. MILLER: No, I think it's outpatient. It's

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only -- it's outpatient. But the issue is they can't -- they're not starting it because of an acute injury that occurred in the hospital. They have to be starting -- they may have started in the hospital but, I mean, first dialysis, but it has to be because of chronic kidney disease, not because of something that happened during a hospitalization.

DR. BERENSON: So the question I will be about to ask is whether that high mortality rate and presumably, in the discussions you had with them, high cost in the first couple of months applies to that population that's not the acute kidney injury, and that's what I'm interested in.

CHAIR BAILET: Okay. Thank you, Bob.

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

CHAIR BAILET: So we're going to go ahead and invite the submitters to come on up. I think you've got to flip your tent table there, flip them over. We have 10 minutes, and then the Committee will engage in questions. Appreciate it. And thank you all for coming out. We appreciate that.

So if you could introduce yourselves and --

DR. GIULLIAN: Great. I'll start. My name is Jeff Giullian. I'm a nephrologist from Denver.

MS. SINGER: I'm Dale Singer. I'm RPA's

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Executive Director.

DR. KENNEY: I'm Robert Kenney. I'm a nephrologist from Baton Rouge, Louisiana.

DR. KETCHERSID: Terry Ketchersid, a nephrologist from Southern Virginia.

DR. SHAPIRO: Michael Shapiro, a nephrologist, San Diego area and President of the RPA.

CHAIR BAILET: Thank you.

DR. GIULLIAN: Thank you all very much for allowing us to come. As I mentioned, my name is Jeff Giullian. I'm a nephrologist from Denver, and certainly on behalf of my colleagues here we want to thank this Committee for inviting the Renal Physicians Association to discuss the physician-focused payment model for patients in the incident period of end-stage renal disease.

As you guys have already come to conclude, end-stage renal disease affects nearly half a million patients and accounts for seven percent of all Medicare spending, and each year over 120,000 new patients start dialysis, of which approximately 50 percent, by our estimate, are Medicare-eligible patients. And this account -- this time frame of incident dialysis accounts for a disproportionate share of those overall costs.

And since 1973, really, this group, the RPA, has represented nephrologists in the pursuit and delivery of

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quality renal health care and has been the leading advocacy organization for the renal community. And in this endeavor, the RPA represents the voice of practicing nephrologists in the United States, and we remain quite committed to public policy which supports patient-centered quality outcomes, clinical safety, and responsible resource utilization.

So, this morning we look forward to reviewing our clinical episode payment care model with you and answering the questions, many of which have already come up this morning, and we're looking forward to discussing those with you.

I want to start, though, by saying that throughout the design of this model, we have really maintained intentional focus on five key tenets, and I just want to share those with you so that we kind of level set.

The first key tenet is physician flexibility, which we just discussed, and we wanted to use that to better ensure care coordination, which I will go into in more detail, along with patient education and shared decision-making.

The second was to incentivize optimal transition to end-stage kidney disease and ultimately into the prevalent dialysis time period for distinct patient populations, and that includes, as we mentioned previously,

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those that had prior nephrology care and those that had limited or no prior nephrology care.

The third tenet was to reduce the very high spike in cost associated with the care of these populations.

The fourth was to increase patient-shared decision-making regarding options for renal replacement therapy, and very specifically for alternatives, including conservative medical management and renal transplant.

And the final tenet was to reduce and even eliminate unintended consequences that might undermine the clinical and cost-savings benefits of any new payment model.

So as we discuss this payment model, I want to kind of remind the members of this Committee of really the magnitude of this issue. Based on published data and in spite of clear medical benefits, nearly 80 percent of patients begin dialysis suboptimally, which might include initiation with a central venous catheter in place, without shared decision-making, and/or without the benefit of essential care coordination. And this places undue clinical and financial costs, both on the system and also on patients in those first few months of dialysis, and often leads to longer-term health-related issues.

And as noted by your committee's own analysis, the cost of dialysis in the first few months is quite

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expensive, and may even reach $90,000, with the direct nephrologist's billing account only for a very, very small amount of that total. Hospitalization rates, readmission rates during this time period tend to be very, very high, and that's related, in great extent to, as I mentioned, that suboptimal transition, inadequate patient-shared decision-making, and limited care coordination.

And so as we constructed this alternative payment model, we identified several opportunities within the current reimbursement environment which may contribute to the high costs and unsatisfactory clinical outcomes, which I just described. And some of these include non-dialysis options for patients whose quality and longevity of life might not well be -- might not be well served by receiving dialysis; enhancing alignment on reimbursement across the entire continuum of care, and enhanced payment structure aimed at reducing hospitalizations; provision of greater patient choice, and understanding of home dialysis options, which we think may mitigate some of those issues you discussed with regard to vascular access; waivers to allow mechanisms that will improve care coordination, patient transportation, and other obstacles across -- to improve health care access; and ultimately greater advocacy for, and access to, renal transplantation.

The RPA believes that a novel payment model,

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which includes costs for patients across this care continuum, will positively impact the patient experience, care coordination, clinical outcomes, and resource utilization during this time period, and ultimately that benefit will impact the prevalent dialysis time frame as well.

And so with these points in mind, the RPA based this proposal on a shared savings model, with requirements to achieve well-vetted, evidence-based clinical metrics and patient-centered outcomes. And these metrics, which we've begun talking about already this morning, were chosen to represent really tangible results to impact those clinical outcomes and reduce complications, decrease hospitalizations, and overall improve the quality of life that we provide to our patients.

So, in short, this CEP model will alter and refocus physician incentives to break down barriers that might exist for this vulnerable patient population, ultimately increasing care quality while reducing those expenditures.

So according to the findings of the PRT, as we've discussed this morning, the RPA has met or nearly met 9 out of the 10 Secretary's criteria for an alternative payment model, and so I want to discuss some of those quite quickly.

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Regarding the payment methodology criterion, the PRT has mentioned this morning, and with its notes back to us, that they had some concerns regarding payment of the preemptive and early renal transplant, and while the RPA remains committed to renal transplant as the gold-standard treatment for appropriate patients, we do understand the PRT's critique of this portion of our payment model, and as such we realize the need possibly to remove this reward payment for preemptive and early renal transplant.

And then moving on to the criterion number 7, integration and care coordination, we look forward to discussing more this morning several techniques that we've identified that would incentivize nephrologists to serve as the principal care coordinator for this very vulnerable patient population and allow the necessary flexibility to address local clinical variables. We fully anticipate that a model that aligns incentives to keep patients healthy, involve them in care choice, and keep them out of the hospital will appropriately incentivize this care coordination and integration, both somewhat upstream but also during these first six months of care during dialysis. And this is true for care coordination with other specialists and also with health care organizations.

So specifically, the RPA anticipates that practices will implement any number of process improvements

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to achieve greater care coordination. These might include items such as systematic referral of all appropriate CKD Stage 4 patients to kidney education, which is available throughout communities in the United States; formal coordination with vascular surgeons and interventionists ahead of time or in the early period during dialysis; expedited office visits for ill ESRD patients, so that they don't have to rely on the emergency room for care; and enhanced evaluation of post-hospitalization are all possible under this CEP model and do not require drastic infrastructure investments up front. We also look forward this morning to addressing all points raised by the PRT regarding the Secretary's criteria.

As we've noted in our previous comments to the PTAC, the RPA evaluated several potential clinical payment models before refining our current episode of care model, which begins upon completion of CMS Form 2728. So acute kidney injury patients, even AKI patients, acute kidney injury patients who receive outpatient dialysis, would not be included in this model because Form 2728 indicates the diagnosis of end-stage renal disease.

This model represents the RPA's effort to maximally impact cost, patient experience, shared decision-making, and high-quality clinical outcomes for nearly every subpopulation of patient transitioning onto dialysis, those

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with prior nephrology care, those with limited nephrology care, and those that we call crashers that had no prior nephrology care.

And additionally, while not explicitly directing the management of upstream CKD care and patient education, we strongly anticipate that this type of care model will positively impact both upstream and downstream care.

Regarding our proposal to initiate shared savings payment at a threshold of 30 quality points, the RPA believes that this was a starting point, which represents care that meets or exceeds current standards. We have proposed some metrics based upon well-vetted clinical outcomes and others based upon patient experience and functional status, which while evidence-based, remain to be fully normalized to this patient population, which ultimately is why we recommended a reporting metric for the first year so that we could ultimately normalize.

We also note that some of the clinical outcomes we believe will have patient experience benefits, such as the clinical outcome of home dialysis, which provides patients that otherwise wouldn't be offered this modality an opportunity to dialyze at home rather than dialyzing in a center. And we believe that this amalgamation of outcomes represents really the greatest opportunity to provide new ESRD patients better care, fewer hospitalizations, and

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superior quality of life.

And finally, the RPA wishes to recognize that there are other renal-focused alternative payment models that either have been proposed or are already in existence. There is likely not a single one-size-fits-all model for the heterogeneous states of early CKD, late CKD, incident end-stage renal disease, and prevalent end-stage renal disease, and this clinical episode payment model was designed to complement other efforts where appropriate but also stand alone by serving all practice sizes, geographies, and patient populations.

So, again, on behalf of my colleagues within the Renal Physicians Association, I wish to convey my gratitude for the opportunity to work with this Committee to refine this proposal. The RPA is highly committed to providing physicians the best possible opportunities to deliver world-class care and service to our kidney patients.

We are also committed to engaging with and equipping physicians with tools and resources needed to deliver optimal care that our patients and really our communities deserve.

Thank you all very much.

CHAIR BAILET: Questions for the submitters?

Tim.

DR. FERRIS: So, first of all, let me thank you

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all for an incredible amount of work that you put into this and for what is clearly an incredibly diligent effort to meet those five criteria, which I would say are sort of a model for how a physician association should approach the development of an alternative payment model.

My comment is not so much about the specifics of your proposal. It is more of an out-of-the-box, so this may be a little bit of a curveball.

But I'd like to hear you think out loud -- and you may have already considered this -- about the triggering event, and several -- if I were to summarize several comments from both the PRT and the members of the PTAC, that there is a lot of opportunity -- and I see this in my own patients and the patients we care for at Partners and Mass General -- just upstream of dialysis.

I don't want to get into a –- like, where there's more opportunity, because there's lots of opportunity on both sides of the dialysis divide. But I wondered, you know, in an ideal world if there was a trigger that was more upstream that you could use in a practical sense, would that be of use?

And then more specifically on that point -- because in my system, we do use a trigger more upstream to set in place a whole bunch of processes that we start, and it's GFR, as actually as Jeff said. So we know the GFR of

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every single patient we treat who's ever had, you know, a creatinine done.

But I live in a world where we have a system with an electronic medical record that [unintelligible] catches that on every nephrology patient and every primary care patient and every pulmonary, right? We have it for everyone treated in the system, and I thought -- you know, two triggers came to mind as potential options, and I wondered if you considered them.

The first is, you know, one of the, you know physicians like to complain about is ICD-10. But actually, ICD-10 does have specific codes for GFR that one could use if it was a billed event as a trigger. So ICD-10 is one potential option.

The other one, which is -- and I want to applaud you in your approach to the use of registries. I'm a big fan of the use of registries, but if every patient we treat is in a registry, then obviously a registry event, which is an auditable event, when a patient's GFR reaches a particular threshold, then one might want to then trigger all these interventions, care coordination, shared decision-making.

So an auditable registry event, where a GFR passed a certain threshold, or just an ICD-9 billed code struck me as two potential options for broadening the lens

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a little bit and including all that opportunity upstream.

Sorry for such a long question.

DR. GIULLIAN: No, it's a very valuable question, and I assure you we talked all about that because we would say the same thing. In an ideal world, starting a payment model at specifically, I think, a GFR of either 20 or maybe 25 would be optimal. Now, as you're well aware, the ICD-10, they don't make a distinction at 20. They make a distinction at 30 and at 15.

So when we first thought about ICD-10, we felt that 30 was really too early for something that was really going to focus on end-stage renal disease. Most patients still with chronic kidney disease Stage 4 and a glomerular filtration rate of 25 or 28 or 29 ultimately will never progress to dialysis.

The next step that’s formally recognized is a GFR of 15, and ultimately, that's really where patients in many cases are beginning dialysis or are right on the cusp and maybe too late for doing the formal education that's necessary for having a robust discussion about clinical options other than starting dialysis. And so that left us really with 20.

Where we fell on that, though, was a couple of things. As we've noted, about a third of patients would then never have been entered into this, and that makes what

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may be considered small numbers even smaller and really leaves out one of the most vulnerable patient populations where we can impact both care and cost.

But also 20, at that level of GFR, is actually highly variable with the current creatinine measures that we've got, and even as we look towards some newer biomeasures, it's still not perfect.

So somebody can have a GFR of 22, and we could add 40 milligrams of Lasix, and all of a sudden, they have a GFR of 19. Their kidney function hasn't really changed, but they've now become part of this model. And then you stop the Lasix because their edema is gone. Now their GFR is 22. So that left us with a little bit of a concern that maybe this wasn't the right approach, and it's not true just obviously for diuretics. It's true for ACE inhibitors and ARBs and certain antibiotics and those types of things.

And so when we looked at it, we really looked at CMS Form 2728 not as the beginning of a procedure, but rather the beginning of a diagnosis, a true time frame when you know there's no going back. That this is a point in time when a patient is uremic sufficiently and the physician does not believe that there’s any chance of reasonable renal recovery.

And so while, yes, in a perfect world, we would have a model that both works upstream and downstream and in

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the middle, we unfortunately couldn't figure out how to put that square peg into a round hole.

DR. KETCHERSID: Yeah. I would build on that, Tim, just to say that in my day job, we've recognized that outside of large vertically integrated health care systems, primary care providers don't frequently use the CKD ICD-10 codes. So the patients are coming in, and they are being seen for hypertension or diabetes. And, oh, by the way, the creatinine clearance or eGFRs, it's frequently ignored, so it creates another challenge. But we're with you in the ideal world.

CHAIR BAILET: So, we have Bob, Grace, and Bruce.

DR. BERENSON: [unintelligible] just a couple other questions. First, a general question, the mortality data, then, that you presented in various tables, and the $90,000, that excludes acute renal failure patients. So could you give me a sense of -- the mortality rates were remarkably high in the first two months. What do people actually die of? Could you give me a sense of that?

DR. GIULLIAN: So this is, again, a heterogeneous group, but one of the things that occurs often, although I don't have a specific number, is that patients that are really fundamentally not suitable for long-term dialysis have a terminal illness, end-stage liver disease, an oncology issue, terminal heart failure, oftentimes get

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started on dialysis as sort of a last-ditch effort.

There is now, I would say, relatively robust data that suggests that those patients do not do well on dialysis in terms of increased longevity of life or increased quality of life, and yet the default currently is, well, start them on dialysis.

We think that a model like this would further incentivize, albeit not directly, physicians to really have those coordination-type meetings with patients, with family, with the primary caregiver, and oftentimes with either palliative care or some team of physicians such as that. So that's part of the reason that mortality is so high.

The second reason mortality is high in this patient population is both cardiac events and infection events, and that goes along with starting dialysis non-optimally. When we place a dialysis catheter into a patient, it not only increases inflammation, which increases the likelihood of a cardiac event, but it's obviously a conduit for bacteria. The tip of that catheter sits right in the right atrium or right next to the right atrium, so when it gets infected, it's really the worst possible place to have an infection.

So we do believe that this type of model would positively affect mortality, both again by allowing for

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different options for those patients that might not benefit from dialysis and better options for those patients that will benefit from dialysis.

DR. BERENSON: So that's very interesting. Let me follow up, then. So the first population, you mentioned somebody -- those who come in with a severe, maybe life-ending disease started on dialysis, they would be in the program because a 2728 will be created for them?

DR. GIULLIAN: If they start dialysis, then, yes, they would be in the program.

And our assumption is that this is really an indirect incentive for physicians to have those meaningful and quality conversations with patients and families to say, you know, dialysis is an option, but it's not a good option for you. It's an option that ultimately is going to leave you no better off from a longevity standpoint and potentially worse off from a quality-of-life standpoint, thereby those patients never start dialysis if that's appropriate and part of their shared decision-making. That then benefits the APM as a whole because those high-utilizer patients ultimately don't start.

DR. BERENSON: And then the final question, for this population, for what you're proposing, which are people who are already on Medicare, what is the purpose of the 2728? It's not for eligibility into ESRD, or is it,

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even though they've already been on Medicare? So what's -- yeah, that's the question.

DR. GIULLIAN: Do you want to answer this, Terry? Or go ahead, Robert.

DR. KENNEY: The purpose of the Form 2728 is to notify CMS of enrollment in the ESRD program. It is required of all patients starting dialysis with end-stage renal disease, whether or not they have Medicaid or uninsured.

It also sets Medicare eligibility if other requirements are met as well.

DR. BERENSON: Does ESRD provide additional benefits beyond just Medicare? If somebody is already on Medicare, do they get anything additional by then being eligible for ESRD?

DR. KENNEY: No, they do not, but they become enrolled in all the programs and monitor the ESRD program.

DR. BERENSON: I see. Okay.

DR. SHAPIRO: And just to add, this is a physician's, the nephrologist's attestation that in their best judgment, this patient has reached end-stage renal disease sign. It's important and is taken very seriously.

CHAIR BAILET: Grace?

DR. TERRELL: I recently saw an end-stage renal patient of mine that I hadn't seen in seven years because

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she's been managed by a nephrologist who's done an exceptionally good job, but apparently, I guess she was under some sort of managed Medicare, thought that she needed a Medicare wellness visit, so they sent her back to me.

It speaks to an issue of who owns the patient and what I believe is a really essential issue with patients who have complex disease, particularly this population, in that I feel that this population needs to be owned by the nephrologists. They do a better job.

In my previous roles, we were working with the concept of a nephrology medical home for patients who have particular aspects of a chronic progressive illness that’s end-stage renal disease.

So when I was looking at this model of care, this payment model, I was trying to put it around a care model, which is an issue that we've talked about previously in other proposals here, and I would like to hear your thoughts on that because I believe that in the flexibility that you all put in the proposal, it may be there, but it wasn't explicitly talked about.

Who actually owns a patient for everything, whether it's a Medicare wellness visit or whatever, is really crucial, particularly when they're going through a transitional time like this.

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DR. GIULLIAN: Yeah, you're absolutely right. We had on this Committee a robust discussion around that.

The RPA actually put out a white paper two or three years ago that addressed this particular issue because there's some heterogeneity in the way different communities utilize the primary care physician in this.

I was fortunate in my community that my primary care physicians stayed very involved in the care of their ESRD patients, and in other places, when the patient became ESRD, the nephrologist became ultimately the primary giver, care coordinator.

So, in our white paper, we actually, I would say, coined a term, which we called the -- I'm going to find it here -- it's the "principal care provider," lowercase PCP, as compared to the Primary Care Physician or Primary Care Provider, uppercase PCP. And this designation in that white paper was very purposeful in sort of allowing nephrologists to understand kind of what their role is, again, based on the flexibility needed in their particular system or in their particular geography.

And so we agree that in most cases, I think the term Terry has used is “the nephrologist becomes the quarterback”. We're not always the best primary care physicians and oftentimes need the primary care physicians for true help in things that are a little bit outside of

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our wheelhouse, and yet when it comes to making sure that the patient goes and sees their cardiologist and that we have an understanding of what needs to happen volume status-wise or when the patient sees the endocrinologist and we have a better understanding of what needs to happen from a diabetes management standpoint, we are the ones that are sort of quarterbacking it. So lowercase pcp is the way we envision the role of the nephrologist within this model.

DR. KETCHERSID: Just to build on that though, Grace, it brings up a point that you raised earlier, and that’s -- it's really fundamentally one of the reasons why we were not overt about specific care coordination activities. It's to prevent that level of flexibility, and to some degree, it builds on exactly what Jeff described. We know that across the country in certain communities, not only are the primary care providers still involved, they fully intend to be involved. And we had no interest in disrupting that, and then in other circumstances, that's not the case.

The other impetus behind that was we were a little bit concerned that if we put overt mandated requirements that the first people to jump ship and not participate would be the small-practice nephrologist and those in rural communities. That was not because we missed that criteria. We were overt in that attention.

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CHAIR BAILET: Bruce?

MR. STEINWALD: Thank you.

You may have heard earlier I asked the PRT a question about the consumption of Part -- separately billable -- Part B drugs. I'd like to broaden my question for you a little bit.

You also said -- and I think it's widely believed -- that the current payment system discourages patients from selecting alternatives to in-center hemodialysis. So, could you say a little bit more about how you think your model would encourage those alternatives, to what extent they would encourage them, and then maybe build your response about Part B drugs into that answer?

DR. GIULLIAN: Yeah, absolutely.

I'm going to start with the second part of your question because it's now fresh on my mind.

The way dialysis providers, not physicians, but the large dialysis and small and medium dialysis organizations are paid is now what's called a "bundle." So they get a, in essence, a capitated rate per dialysis session, and that includes the vast majority of those medicines, those Part B medicines. Epo is in there. Iron is in there. Those types of things.

MR. STEINWALD: Just to clarify. So, they are in the bundle now? When did that happen?

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MALE PARTICIPANT: 2011

DR. GIULLIAN: 2011, if you didn't hear.

And so we don't necessarily believe that by changing anything within this model, there would be a differential impact. If anything, it would be a differential beneficial impact to shareholders in dialysis organizations, which, while great, is not what we mean to achieve by this at all. So that was the second part.

The first part of your question -- or maybe I have them backwards is -- is how is this really meaningfully going to have an impact on the choice of home dialysis. Home dialysis is considered one of the things that would be an optimal transition to dialysis. CMS has stated that they anticipate that between 20 and 25 percent of all patients would be eligible and should be on home dialysis, and yet in the United States, I think we're at 9.6 percent right now. So we've got a large gap to close.

The physician organizations -- I believe I speak for all of them -- would say that we're all on board with this, and finding ways to appropriately incentivize for home dialysis is meaningful.

So for crasher patients, for example, I would say the vast majority of patients right now start in-center dialysis with a dialysis catheter in place because it is the path of least resistance. It's easy, and

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interventional radiologists or interventional nephrologists or vascular surgeons can very quickly place a tunneled catheter in a patient on their third day of being in the hospital, and they can then go out to in-center.

The problem is, when that happens, they typically stay on in-center forever, so well past the first six months, well past the first year, inevitably, and maybe they get a fistula or maybe they keep that catheter for a prolonged period of time.

With this in place and home dialysis being one of the metrics that is a quality metric, we believe that there's actually an impetus now for even crasher patients to get emergency hemodialysis in the hospital but actually leave the hospital with a peritoneal dialysis catheter.

In the past 24 months, there's been significant, significant improvements by dialysis providers in providing what's called "urgent start peritoneal dialysis," and this would be an impetus for those patients to then leave the hospital with a peritoneal dialysis catheter and urgently start home PD.

There’s also now an impetus, I would say, not just for the upstream education for home modalities, but also for education once patients start dialysis on home modalities. And quite frankly, there's just no incentive for that at this point.

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DR. SHAPIRO: Well said.

CHAIR BAILET: Len?

DR. NICHOLS: So thanks. I appreciate Tim's really good question, and I appreciate your answer about this ideal triggering event. But I want to return to it just for a minute. Do you see a pathway whereby the discovery of an improvement on a trigger event could be part of a research program that went along with implementation of this model? Have you all thought about that?

DR. GIULLIAN: We have, and while I can't discuss specifics because we have a nondisclosure agreement, we've actually recently evaluated technology that would be better at determining actual glomerular filtration rate compared to estimated glomerular filtration rate. So I could personally envision, without making any promises on technology, that there could come a time in the future, maybe the near future, where we really have a gold standard where we know what somebody's kidney function truly is, not because they're on an ACE inhibitor, not because they're on a diuretic, but what their actually filter rate -- their actual filter rate is. And I would love to come back to this Committee at that point and say, "Woo-hoo, we've got it, let's move upstream."

DR. NICHOLS: Or perchance CMS.

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Go ahead, Terry.

DR. KETCHERSID: Yeah, Len, I'll add to that. A couple of us up here have enough gray hairs that, back when we were in training, there was this thing called "one over creatinine," right?

[Laughter.]

DR. KETCHERSID: And there was this idea that you could predict -- right? -- when things were going to start. And I -- I'm not trying to be a pessimist here. I welcome the idea of being able to get ahead of that and to be able to predict, because one of the challenges -- and we debated this as well, right? -- is let's say you did decide you were going to start with today's GFR trigger of 20. Then you could begin to wonder how many AV fistulas would be put in that would never be used, right? Because they have a GFR of 20 and I'm sure they're going to start --

DR. NICHOLS: Oh, yeah.

DR. KETCHERSID: -- in six months or 12 months. So it's a -- we really, really, really would like an ideal circumstance so that we could include the entire continuum of care.

DR. NICHOLS: We appreciate your restraint in reaching the simple solution. So, I was also intrigued at how your proposal allowed choice to different physician groups, sort of Track 1, Track 2, whatever. So what do you

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think about this idea that Tim elicited from me earlier about splitting the shared savings bonus into a kind of a PMPM, particularly for those small rural practices so they could have resources up front to do their investment in the upstream stuff? And then on the other end, you would lower their percentage of the savings or shared savings. Did you all think about that?

DR. SHAPIRO: I think we did look at what's the best model to capture the most patients, and one of the concerns -- and it's been -- I think it's been identified and discussed here already -- is that quite a large number, a third to 40 percent or so, of the patients are not engaged in the system in some way upstream. And so we reach them first or they reach us first when they're at that starting point at the 2728 Form of starting dialysis. And we thought that, well, given all the other things we talked about here with identification, use of the GFR, when to plug them into a payment model, we would capture everybody. The patients who are already being cared for with late-stage CKD who their physician thinks are likely to progress are going to -- those patients and those physicians will see the benefit if the patient reaches ESRD and enrolls in the model. But it also gives -- that six-month time frame gives the physicians an opportunity to be able to do something good on behalf of that patient with

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incentives to be able to do that, too, in a shared savings model where they wouldn't have had that patient if we moved upstream with a PMPM type of payment, exclusively, at least, anyway. How to best -- is there a way to be able to coordinate that?

DR. NICHOLS: Or blend it, that's all --

DR. SHAPIRO: Well, I guess just one more comment, and I'll let my colleagues opine here as well, that I think the resource requirements for a practice are fairly small to be able to provide education to the patient. Most nephrologists, if you ask them, "Do you run a CKD clinic? Are you running an education program?" they'll say, "Yes, of course we do." We've discussed that. But they can't always show the good results, and in today's health care economy for the practices, they need to show commercial insurers, they need to show perhaps ACOs in their environment, IPAs, why should we choose you to be our specialist? In that area, we have practices across town that do -- that look at their results. They're showing really good results. The impetus now in this triple-aim era is for the physicians to be able to say, "No, I had really good results; I get more patients with fistulas. I get -- "Well, what's the benefit to those nephrologists for expending or putting more money into their practice infrastructure? Well, one of them is to be the provider of

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choice and get some contract. Another here in this particular case would be, "You know what? If I do a really good job of this, when my patients do go on dialysis, they're going to be less costly and I'll get to share in that, in those savings as well."

DR. KETCHERSID: Len, I would add I don't recall overtly thinking about the split that you discussed, but I do think a couple of things did come up, one of which was would there be opportunity, much like the -- I hope it's okay to say "quality payment program" in this room. But that program offers to small practices. Is there an opportunity for us in some fashion to provide relief? Because we were concerned about small practices and rural practices.

But the last thing I'll mention is the experience that a number of us have had with the ESCO program, is the remarkable attraction that the Advanced APM bonus has for nephrologists that are participating in that program. And so with the opportunity to join this model and take the two-sided risk approach, certainly those benefits would extend. Now, granted, you're still weighting right? -- But that five percent bonus is fairly significant for a nephrologist. And even if this model were to come to fruition after the extinction of that bonus, the differential in the fee schedule increase that the A-APM

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provides is – that's --

DR. NICHOLS: That's a good point. Thank you very much.

Okay. So the last thing I'm impressed with is your geographic diversity here. We've got southern Virginia, we've got Baton Rouge, San Diego. Have you all thought about offering the option to lump small practices together in kind of a virtual group? I hope it's okay to say that in this room, too. So tell me about -- because that's -- obviously, diminishing the risk those guys will bear is a major concern.

DR. KETCHERSID: Yeah, absolutely. It's not overtly stated in the model, but we're hoping that the virtual group component of the MIPS program this year will gain some traction because the actuarial precision piece for the small practices we're certainly concerned about, and we think that by -- at a local region, probably, because we want the baselines to be local, assimilating those groups in a way that recognizes that if Michael's a small doc, I'm a small doc, and I'm asleep at the wheel but he's performing well, I don't take the whole ship down, if we could figure out how to solve that particular issue.

DR. GIULLIAN: And we actually did say that in the model. I can't find it right offhand, but it is three whole words, so it's not much. Don't blame you at all for

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overlooking it, but we did make that mention somewhere in here.

DR. SHAPIRO: And to differentiate it from the CEC model as well with the two contiguous CBSA (Core-based Statistical Area) limitation for that model.

CHAIR BAILET: Thank you. Kavita?

DR. PATEL: I have a brief question. You brought up a number of the kind of issues with the CEC model. If we were just to kind of speak openly, having -- if CMMI were to lift those constraints, would that model still kind of be a potential for more nephrologists to do what you're describing?

DR. KETCHERSID: Yes and no. So if the constraints were lifted, the challenge still exists to reach that kind of an actuarial credible number, and so you would need to at least invoke the virtual component.

The other challenge is, when we've looked inside our -- this is personally speaking -- our ESCO experience, of the beneficiaries that are assigned to the model, less than five percent are in their first 120 days of dialysis. So there's not a significant focus today because the bulk of those patients are prevalent dialysis patients.

DR. GIULLIAN: And I would add one other key difference, which is within the ESCO model, physicians must -- excuse me, patients must stay within a given dialysis

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provider that is the provider/owner of that ESCO APM. Our model is substantially different in that patients would have choice as to who their provider is and could go to a different provider, assuming that's what's better for them for any number of reasons and remain within the model.

CHAIR BAILET: Bob.

DR. BERENSON: Yeah, I want to get back to my question related to insurance status. If I understand the table that Adele pointed us to, it looks like about half of patients are already on Medicare that are in -- does that seem right to you? And that there's a substantial number who are on Medicaid. What happens -- does a Medicaid patient after the three and a half months or three-plus months to become eligible for ESRD, does ESRD Medicare become primary for those patients?

DR. GIULLIAN: I'm not sure I'm the perfect person to answer, so I'll open it up to the committee. But I do want to make sure that we explain there is a slight difference. So for patients that go on to in-center dialysis, they have a 90-day waiting period before they become eligible for Medicare. For patients that choose home dialysis, Medicare becomes available, assuming they don't have another insurance on Day One.

DR. BERENSON: Did you want to say something?

DR. KENNEY: If a patient has Medicare

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eligibility and say they had previously Medicaid, Medicare in almost all circumstances will be primary to the Medicaid.

DR. BERENSON: So that's what I was hoping you were going to say. I like the model, and it seems like it would affect 50 percent of the patient population on average. Is there any way to expand the model, probably not to commercial insurance, but, I mean, I'd like it so -- I mean, so my basic question is: I assume 50 percent of your practice is enough to change your behavior and that there would be some spillover or -- and is there any way to expand the model to other payers such as Medicaid?

DR. KENNEY: Not in its current proposed form, clearly. Now, whether or not -- because Medicaid is not just a federal program. It's a 50-state program. So I think that would be a little bit daunting right now.

We did try to include as many Medicare patients as we could. However, there are problems. For one thing, say a patient who is under 65 and is not disabled so, therefore, does not have Medicare, starts dialysis, whether it's home or in-center, they get Medicare eligibility, but there is a coordination period of 30 months at which point Medicare is secondary to whatever else they have. So how do we fit those people in this model?

So it just became the simplest thing to do was to

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have -- to include patients who have Medicare as their primary payer Day One of the enrollment.

DR. SHAPIRO: And regarding your question about expansion to other payers, that speaks to me very clearly, because I think that practices are looking for opportunities for a competitive differential advantage with -- especially in the commercial sector, where they have -- where they can become the provider of choice in that area. And this is a model where they'd say, you know what? Wow, this applies to my Medicare patients as well. If I need any infrastructure to be able to go into a commercial payer as well and say, look, look what we're doing, you know, we can do an APM type of model here and get paid a little bit differently, differentially. In our experience with that in my practice, we were able to reach commercial payers. They were quite interested in something like that.

DR. KETCHERSID: Bob, the only thing I'll add is we do anticipate a halo effect that you describe. To Robert's point, this was the simplest starting point, but we don't anticipate nephrologists treating different payer patients substantially different when they bill these things. We're seeing that in the ESCO program today.

DR. BERENSON: And the average renal physician treats the variety of patients? They don't sort themselves out?

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DR. GIULLIAN: I can speak for my own group when I was in practice. We were at about 50 percent Medicare patients in general, just all comers, CKD, et cetera. And so really there was a spillover effect. We didn't look at a patient and say, gosh, you're United Health, you're Blue Cross, you're Medicare. It was just whatever was sort of mandated was the standard of care for all patients, and so I anticipate a spillover effect for all patients.

CHAIR BAILET: All right. Thank you. Harold?

MR. MILLER: Two questions. Do you see the shared savings model and the transplant bonus as completely separable concepts? In other words, do you see that the nephrologists would be equally attracted to the shared savings model if the transplant bonus wasn't there, that they would be equivalently successful without it there? And, conversely, since you thought that the transplant bonus was a good idea, do you think that it would be a good idea if there was no shared savings model and simply have that? So talk about how you see them as -- are they two separable concepts or are they interlinked in some fashion?

DR. GIULLIAN: Yeah, let me back up just a little bit and say that, you know, the transplant bonus was completely novel and different than anything that's within the realm of fee-for-service or anything else. It was truly, I think, an opportunity for us to say a couple of

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things:

Number one, to say that transplant is the gold standard, both for quality of life but also for overall cost of care for patients.

Secondly, we wanted to make sure, as I mentioned in one of our tenets, that we were doing absolutely nothing that might be viewed as having unintended consequences. And so by somehow establishing a financial incentive for dialysis, which ultimately this APM does, we wanted to make sure that that in no way changed a physician's goal first and foremost of getting patients transplanted, either before they start dialysis or as soon as possible.

I don't know if this Committee knows, but patients can actually be listed for a renal transplant when that glomerular filtration rate hits 20. So, they actually can get on the list well ahead of time, and yet the vast majority of patients aren't referred to a transplant center in CKD Stage 4. The vast majority of patients aren't referred until they're well on to dialysis, and we still run into, unfortunately, discrepancies in which types of patients get referred.

So our primary goal in all of this was to make sure that we were advocating for the gold standard and to make sure that we weren't leading to any unintended consequences.

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That being said, we understood when we put this in there that this was completely novel, something that I don't think there is precedent for, for actually paying somebody a reward for something occurring, especially as it occurs a little bit outside of their control. As the nephrologists, we have control to refer the patient. We also have some control in terms of how much care coordination we do: Making sure that patients gets their cardiac evaluation, making sure that the primary care records make it over to the transplant center, and things like that. So there is some role of the general nephrologist, but it is also somewhat outside of our control.

So to answer your question, I do think they're separate. They weren't designed in tandem. In fact, the transplant bonus is the one part of this model that is upstream, in essence, that's outside of the ESRD time frame. And so while we certainly wanted to go down that road and are still interested in exploring options with this Committee, we do understand that they're different, and we do understand the PRT's concern with it.

MR. MILLER: Thanks. The second question is: Assuming that this model you proposed were actually approved and implemented, is there -- who else do you wish was also in a different payment model to help the

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nephrologist be successful in this? Primary care physicians? Transplant surgeons? Vascular surgeons? Hospitals? Cardiologists? Who else do you wish would be -- or, I mean, the other way to ask that question was: Who do you think might be rowing against you that you would like to have them changed?

DR. GIULLIAN: I don't know that anybody's rowing against us necessarily. I think the easy answer to your question is: All of the above. We are proponents of APMs, and so we're proponents of that being really the model of payment going forward as it works for other specialists.

We've also had conversations with other specialists in determining, hey, how can we think about, in the future as we get this under our belt, an APM that includes other specialists for things like placement of a vascular access or something like that?

I think what we have found, as we've discussed with other societies, is the bigger something gets and the more complex it gets, the harder it is to get off the ground. And that doesn't mean that these guys are simpletons -- I am -- but I think that the goal would be let's really prove that we can accomplish something, and let's take that and snowball that into more -- larger APMs that include hospitals, that include primary care physicians, that include vascular surgeons, et cetera. But

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right now we're really focused on what we can control, which is the treatment given by the nephrologist.

DR. KETCHERSID: Harold, if I might add to that -- and this is information that has kind of recently become available. It's out in the public domain, and I hate to keep relying on the CEC model. But it's interesting. If you look at the experience that the three large -- in CMS' eyes, large dialysis organizations have had in the first year of the CEC model, and you go out and you see who the participants are, there's one of those organizations that enlisted primary care providers and vascular surgeons as participants. There's another organization that partnered with a health care system. And then there's another organization that just worked with nephrologists. And the upshot was that the shared savings that was generated for Medicare was almost identical in all three.

And so I think the jury's still out. You know, we'd love to have everybody in the boat rowing in the same direction, but in terms of picking today, I think that's a heavy lift.

CHAIR BAILET: Elizabeth.

VICE CHAIR MITCHELL: Thank you. I wasn't going to ask anything, but you piqued my interest when you said so few patients are actually getting -- are having the conversations about transplants early enough. And this

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might be related to Harold's question, actually. Sort of who -- will this payment model address that problem? Will you get at some of the more upstream issues -- smoking cessation or any of the sort of population health interventions that could actually help patients earlier on? And if so, how?

DR. GIULLIAN: They're looking at me, so I'll take this.

Not specifically. So while all of that is important, some of that remains still outside of the domain of the nephrologist. For right or for wrong, some of the population health discussions that you just had -- smoking cessation, et cetera -- tends still to be on the side of the primary care physician, even into late CKD. And I may be speaking only on behalf of my own practice, but that's often what it was, because we in our clinic visits spent the majority of our time talking about cardiac risk factors other than smoking but specifically with regard to volume status, CHF stuff, things such as diabetes control and ultimately trying to prepare, when appropriate, the patient for dialysis.

So, I think that the issue for us is we wanted to make sure that there was nothing in this model that deterred a physician from referring out, for referring for renal transplant, et cetera, but we didn't build this model

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specifically to deal with the population health items that you just mentioned like smoking cessation.

I don't know if I answered your question clearly. So if you have further, I'll be more than happy to dig in deeper.

DR. SHAPIRO: But, again, I think the responsibility, the shared savings responsibility and opportunity in a two-sided model, I think encourages the physicians to attempt to manage or influence the outcome of the patients as early on as they have that opportunity and through their course of progression towards the SRD and to ESRD if, indeed, that's what happens, in which I think will have, as you were referring to it, the halo effect, the halo effect on the overall care of the patient.

We see that now again in commercial contracts when our incentive is to educate more, our incentive is to perhaps make sure that they optimally start preemptive transplant, home dialysis, et cetera. Those patient populations tend to -- or those practices tend to stimulate that type of conversation and education and reinforcement with those patients.

DR. GIULLIAN: And I should also mention that outside of the preemptive bonus or the bonus for preemptive transplant, one of the quality metrics remains referral to a renal transplant center.

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VICE CHAIR MITCHELL: That was actually my related question. Will any of these quality metrics actually get at this? So earlier education or engagement, I mean will that -- do you think that could be reflected in either the PROMIS score or the patient-centeredness score?

DR. GIULLIAN: Yeah, I do think so, potentially. So upstream education will impact a number of the quality scores -- quality metrics. So upstream education, we know has an impact on the choice of home dialysis, we know has an impact on both Day Zero catheter rates but also Day 90 catheter rates, and while maybe not directly impacting the PROMIS score specifically, we believe that by giving patients the shared decision-making, the modality choice, that ultimately that will have the downstream impact on patient centeredness.

DR. KENNEY: And if I may add to just what Michael was saying a second ago about the importance of addressing these things such as smoking cessation, remember population health metrics are still, for the most part, carried out one patient at a time. And anything we can do to improve comorbidities will translate into this reduced -- hopefully reduced mortality information this patient doesn't tell us in that early dialysis period, because as Jeff pointed out, the two biggest areas for cause of death, cardiovascular with all its attendant comorbidities and

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infections.

CHAIR BAILET: Thank you.

Paul, you may have the final word here.

DR. CASALE: I just wanted to add, my institution is the Rogosin Institute, which as you know is an ESCO, and the CEC is the smaller one as compared to -- and having seen their thinking and their work, there is clearly a halo effect, and that's on the prevalent. I mean, they are thinking upstream, but they've already seen that their transplant peritoneal dialysis rate has gone up. Their peritoneal dialysis rate has gone up. So it's sort of natural, though not implicit, and even in that model, which again is not on the incident, but on prevalent, that there's a lot of work being done to move upstream.

CHAIR BAILET: Yeah.

DR. CASALE: So I think there's a lot of opportunity.

CHAIR BAILET: Thank you, Paul.

So I'd like to thank our submitters for traveling here today and the valuable conversation that we just had.

We are now -- if I could -- we're going to move to the public’s comment portion, and then the next phase would be deliberation.

But I'd like to again thank the submitters, and if you guys could take your seats, we have one public

comment. And that is David White from the American Society of Nephrology. If you could come to the microphone. Is he here? Yes, he is. Awesome. Yes, please. Thank you.

* **Comments from the Public**

MR. WHITE: Hello.

Sorry. I have to change glasses.

Hi. My name is David White. I am a policy specialist at the American Society of Nephrology here in Washington. On behalf of ASN, I want to thank you for being here and for the work that you're doing on the PTAC, and we want to thank you for the opportunity to be able to speak about the Renal Physicians Association's incident ESRD clinical episode payment model, which we call the CEC.

ASN is a little like RPA. It's also comprised of nephrologists, and they are nephrologists, scientists, nurses, and other health professionals dedicated to treating and trying to improve the lives of people with kidney diseases.

ASN commends RPA for bringing forth this proposal. It is an extremely important proposal, and we believe that it should be recommended for testing to the Secretary. And we do so because we believe that it will encourage coordinated care.

There's a great deal that needs to be done in terms of improving coordinated care with ESRD populations,

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and there are many different approaches that need to be tested and to see what will work. And I think this is definitely a very promising one and could make a big difference in the lives and the costs for those beginning ESRD, beginning dialysis.

RPA and ASN both recognize the severity of the burden of ESRD on the American public and the entire Medicare system, which has become enormous. Patients with kidney failure among the sickest and most complex in the Medicare system and are resulting in a disproportionately high utilization of Medicare resources and also a very heavy toll on the quality of life for these people as well.

RPA-proposed CEC focuses on one of the most precarious periods for patients. That transition to dialysis and that first six-month period, it is a very important period to focus on and to test.

They also correctly highlight that the cost of the first six months of ESRD care are disproportionately higher than annualized cost, and that improvements in incident dialysis in the first six months could yield major improvements in patient care and reduction in cost.

In addition to cost, I have to always underline that this is an exceptionally risky period for these patients. You've seen the mortality rates, and it is something that if it were happening in some other form --

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so, for example, that number of car crashes a year or that number of other incidents -- there would be a major outcry in this country about trying to get a hold of this.

The proposed model builds a clear, straightforward care approach based on a well-defined episode that is ready for testing now. And it does that by streamlining ESRD patient care oversight by nephrologists. It does it by alleviating the need for new administrative infrastructures that's ready to go, in allowing flexibility for implementation by various practice sizes and geographic locations, which we've addressed a great deal this morning, and I would also say by undertaking innovative steps to increase patient access to transplantation, which is, as we've heard this morning, the gold standard.

ASN thanks members of the PTAC for this opportunity to comment on the RPA model and endorses the model for testing.

Thank you.

CHAIR BAILET: Thank you.

I'm going to -- we have a phone line. I want to make sure if there's someone on the phone that wants to make a public comment, now would be a good time.

UNIDENTIFIED SPEAKER: I don't want to comment. I'm just here on the phone is all.

* **Committee Deliberation**

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CHAIR BAILET: Alrighty. Nothing. Very good.

So, we are going to -- I'm asking my colleagues. We have the time for general deliberation, if there is additional discussion or move to deliberation and voting. So I look to my teammates here for any general comments. If not, we'll go to Criterion 1.

I'm feeling it.

All right. So we're going to make a transition here. So we're going to mark through criterion -- we have our electronic devices ready to go. Yes.

UNIDENTIFIED SPEAKER: [Speaking off microphone.]

* **Voting**

CHAIR BAILET: Yes. So I think that that is actually -- we need to revisit that.

UNIDENTIFIED SPEAKER: Can we do Criterion 3, maybe payment?

CHAIR BAILET: Okay. So the question is are we going -- we're voting on the proposal as it's written because the submitters made -- at least expressed a willingness to address the transplant challenge that was brought forward in the PRT report but also discussed here today. So perhaps we could get to that particular question when we get to the Criterion 3 under the payment model.

So why don't we go ahead and -- are we ready to go ahead and start with -- I don't see it up here. Are we

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ready to --

MS. STAHLMAN: Remember to watch and make sure that the light clicks on your voting technology and that you see that your vote's been cast.

CHAIR BAILET: All right. Just to level set here, as we walk through the criterions, 1 and 2 means it does not meet; 3 to 4 meets; and 5 to 6 meets and deserves priority consideration.

For Criterion 1, they either directly address an issue in payment policy that broadens and expands the CMS alternative payment model portfolio or includes alternative payment model entities whose opportunities to participate in APMs have been limited. And this is one of the high-priority criteria that the PTAC believes is important.

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

[Electronic voting.]

CHAIR BAILET: There you go. And, Ann, please?

MS. PAGE: Sure.

* **Criterion 1**

On Criterion 1, one member voted 6, meets and deserves priority consideration; three members voted 5, meets and deserves priority consideration; five members voted 4, meets; two members voted 3, meets; and zero members voted does not meet. They voted -- zero members voted 1 or 2 or not applicable. So according to the

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Committee's decision rules, we need six votes as a simple majority, and that roles down to meets, so the majority of Committee members voted that this meets Criterion 1.

CHAIR BAILET: Thank you, Ann.

And remind me. There’s going to be one more. It looks like there is one more vote than actual Committee members, and that's just for technical support; is that right?

MS. PAGE: That's right. In case we need another member.

CHAIR BAILET: Okay. All right. Very good.

All right. So, we're going to move on to Criterion 2, Quality and Cost, which is also a high-priority criterion, anticipated to improve health care quality at no additional cost, maintain quality while decreasing costs, or both improve health care quality and decrease cost.

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

[Electronic voting.]

CHAIR BAILET: Ann?

* **Criterion 2**

MS. PAGE: One member voted 6, meets and deserves priority consideration; two members voted 5, meets and deserves priority consideration; four members voted 4, meets; four members voted 3, meets; and zero members voted

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1 or 2 or not applicable. So the majority of members find that this proposal meets Criterion 2, Quality and Cost.

CHAIR BAILET: Thank you, Ann.

We'll move on to Criterion 3.

So I think before we vote, this is important that we revisit the question on what are we specifically voting on here today. The question really is: are we voting on the proposal as it's written, or are we incorporating information that was brought forward during the dialogue? And I would open it up to the Committee. I think we have different points of view, but I think it would be good to get clarity before we vote so we can be on the record.

So Tim and then Harold and then Len.

DR. FERRIS: I would move that we vote to -- let me see if I can word this correctly -- vote to not include the -- what am I trying to say here? -- the bonus in our deliberation at this point.

UNIDENTIFIED SPEAKER: [Speaking off microphone.]

CHAIR BAILET: So, no, I think what I heard Tim say is amend. Amend. Yeah. Remove it. Vote on it as if it's not incorporated in the proposal. Is that correct?

DR. FERRIS: Correct.

CHAIR BAILET: Okay.

DR. FERRIS: Based on what I heard from the -- I'm making that motion based on what I heard from the team

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that submitted the application.

CHAIR BAILET: So that -- okay. Thanks, Tim.

Harold.

MR. MILLER: I would second that.

I guess the way I would characterize it would be that we would anticipate making our recommendation that the transplant bonus should not be included, so jumping ahead to that, that that would be included as sort of a qualitative recommendation, and that we would vote now on the criterion with the assumption that that's what we will be saying. That's the way I would characterize it because we have to -- we have to say here what we're voting on. So I think the issue -- what Tim was suggesting is, that we would be saying what we're voting on is a modified model that has that out with the anticipation that we would be saying -- we recommend, if we decide to recommend it, that we recommend it without that in it. That's all.

I mean, so it's not that -- we're saying that that's what will be in our statement about the model, and that we're voting with the anticipation that that's coming.

Anyway, I'm seconding the motion.

CHAIR BAILET: All right. Very good.

So we have Len, Grace, and Bob at this point. Len?

DR. NICHOLS: I'm good.

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CHAIR BAILET: You're good?

Grace?

DR. TERRELL: The population that ends up on dialysis is one of the most vulnerable populations there is out there, and I'm a little concerned that if we don't have something about the transplant bonus in some way in our proposal that you're not going to see across the board, the thought put into how we would actually get that part of this important aspect of the entire proposal in there.

So just omitting it by taking it out -- I heard some things from the presenters that I thought was very important, which is there's a halo effect upstream. There is an impact in behaviors to have some motivation to do this, and there needs to be some thought in some way about not just us taking the original proposal, just because we can split this out and agree to one, not have something in there. So this could be an imperfect proposal in terms of that, but I do think that there needs to be some aspect of the transplant component that we address because I think that's actually pretty crucial.

CHAIR BAILET: So I'm going to just make a comment to your comment, Grace, because the PRT did have a discussion around modifying instead of the actual transplant, but modifying the education or the referral for a formal transplant. Am I getting that right, Paul? We

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had that discussion whereby it would still be bookmarked. It would still be part of the model, but it wouldn't specifically be the actual bonus for transplant. It was more the education, because I agree with you it's really important that that work gets done where it's appropriate. So I think that that's -- Harold -- I mean, Paul, you were leading the PRT.

DR. CASALE: Yeah. No, no. I agree with that. Our intent wasn't to ignore that part necessarily, but I think as the submitter said, it can -- it was a separate -- to Harold's question, how integrated is it into their model, and we had obviously sufficient -- we had a lot of concerns about paying a bonus for that in particular, and we already know the standard of care, which they have commented on is early transplant before dialysis. We know that that is optimal care, and we would expect that that would continue, regardless of any particular incentive around that in this model, and on top of that, the limitation of organ availability, which is really one of the critical issues.

CHAIR BAILET: Right.

So I've got Bob, Len, and then Harold.

DR. BERENSON: Yeah. I'm going to support, in this case, sort of removing the transplant part of the payment proposal from the original, because I don't see it

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as intrinsic or essential to the payment model. At the same time, I am worried about the potential or the precedent that people come and say, okay, we'll just take that out and we'll go forward.

So there's sort of a judgment -- I don't know any other way to say this -- a judgment call as to whether the proposal -- the proposed payment model is sort of basic to the proposal, in which case we shouldn't be negotiating it out at this meeting, or whether, as in this case, I would agree that that wasn't really core to this proposal.

And so I'm comfortable with, in this case, pulling it out, but I'm worried that we don't set this up so that each time we're sort of negotiating at this meeting, if that makes sense.

CHAIR BAILET: It does make sense, Bob, and I agree with you, and I think I'm seeing a lot of heads nod around the Committee. I think we all see that as a potential concern. But thank you for that, and we have Len next.

DR. NICHOLS: So I'm a little less worried about the negotiation because economists like negotiation, but I honestly believe, Bob, we're not quite required to reach the level of Solomon here. It's not that hard to see something that's truly integral and something that's truly modular, and we hope the line is always bright.

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But I want to come back to Grace and say I believe we can express our desire for the transplant option to be encouraged in the letter to the Secretary and still keep it out, because we don't have a payment model we're happy with about that. But Lord knows it needs to go on, and I think it could be facilitated, and I have some negotiable ideas. But I think it's something the Secretary should work out with professionals.

CHAIR BAILET: All right, Len, thank you. Harold.

MR. MILLER: Just quickly I would agree with Grace's point and Len's point. I think that we have, on a number of models, argued that we're recommending it but we think that the quality measures need to be tweaked in some fashion, and we're already saying that about this one.

There is a transplant referral measure that they already had included. They didn't boost its significance, I think, because they had this other -- they were anticipating this other component. But I think that that, to me, would be something that we would, if we recommended it, that we would say that we thought that needed to be strengthened as part of that.

CHAIR BAILET: So that's -- so, exactly. So thank you for everyone's input.

So I want to clarify, we are voting on Criteria 3

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as if the transplant bonus was not included, and I guess I just want to revisit the concern that we expressed here, which is this -- we want to avoid these, you know, last-minute modifications, and in some cases major modifications to the proposal at the time of deliberation. That's not our intent. But in this circumstance we are going to do that.

So that's the motion. It's been confirmed by the Committee. So at this point --

DR. CASALE: Sorry, Jeff, I was just going to answer that.

CHAIR BAILET: Yeah.

DR. CASALE: I mean, it is a bit last-minute, but on the other hand the PRT sort of thought about that --

CHAIR BAILET: Right.

DR. CASALE: -- and sort of separated it in the report. So there was -- so it's a little different than sort of just -- I mean, I know we're changing --

CHAIR BAILET: Right, and that's an --

DR. CASALE: -- but we did think through that.

CHAIR BAILET: -- that's an excellent -- yeah, that's an excellent point. Harold?

MR. MILLER: I just want to amend this. I think that we should be providing some further guidance to future applicants, that if they think that there are multiple

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types of changes in payment that would be helpful but are separable, that they should say that when they apply, so that we know that, so that we're not kind of making these judgments, to Bob's concern. Because I do think that there will be cases in which people come and identify multiple aspects of payment that need to be fixed, and rather than us getting two completely separate proposals that are disconnected, it would be better to look at them together but to know that -- whether or not the applicant thinks that they are integral or not.

CHAIR BAILET: Elizabeth and then Bob.

VICE CHAIR MITCHELL: Thank you. I am prepared to vote on the proposal as amended, minus the transplant payment, but I want to make sure that we get to Grace's point about identifying ways to incentivize early appropriate transplants. So can that be covered in the comments?

CHAIR BAILET: That was -- yeah, it can.

VICE CHAIR MITCHELL: Okay.

CHAIR BAILET: Again, I thought that was the intent.

DR. BERENSON: I'll pass.

CHAIR BAILET: All right. We are ready to vote. So payment methodology, pay the APM Entity with a payment methodology designed to achieve the goals of the PFPM

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criteria, addresses in detail through this methodology how Medicare and other payers, if applicable, pay APM Entities and how the payment methodology differs from current payment methodologies, and why the physician-focused payment model cannot be tested under current payment methodologies.

This is a high priority. We are ready to vote. Please vote.

[Electronic voting.]

CHAIR BAILET: Ann.

* **Criterion 3**

MS. PAGE: Zero members have voted 5 or 6, meets and deserves priority consideration; nine members voted 4, meets the criterion; and two members voted 3, meets the criterion; zero members voted 2 or 1 or not applicable. So the majority finds that this proposal meets Criterion 3, Payment Methodology.

CHAIR BAILET: Thank you, Ann. We're going to move on to Criterion 4, Volume over Value -- Value over Volume. I was -- now, wait, that was purposeful. I was just testing to see if my colleagues were awake. Very good, so Value over Volume. I think this is my last public meeting.

[Laughter.]

CHAIR BAILET: They're going to pull me off here.

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So provide incentives to practitioners to deliver high-quality health care. Boy, I'm going to have a hard time living that one down.

We are ready to vote, please.

[Electronic voting.]

CHAIR BAILET: Ann.

* **Criterion 4**

MS. PAGE: Zero members voted 6, meets and deserves priority consideration; three members voted 5, meets and deserves priority consideration; eight members voted 4, meets; and zero members voted 3 or 2 or 1 or not applicable. The majority of the Committee finds that this meets Criterion 4, Value over Volume.

CHAIR BAILET: Thank you, Ann. We're going to move to Criterion number 5, Flexibility. Provide the flexibility needed for practitioners to deliver high-quality health care.

Please vote.

[Electronic voting.]

CHAIR BAILET: Go ahead, Ann.

* **Criterion 5**

MS. PAGE: Zero members voted 6, meets and deserves priority consideration; two members voted 5, meets and deserves priority consideration; seven members voted 4, meets; two members 3, meets; and zero members voted 2 or 1

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or not applicable. The majority finds that this proposal meets Criterion 5, Flexibility.

CHAIR BAILET: Thank you, Ann. We're going to move to Criterion 6, Ability to Be Evaluated. Have evaluable goals for quality of care costs and any other goals of the PFPM.

Please vote.

[Electronic voting.]

CHAIR BAILET: Ann.

* **Criterion 6**

MS. PAGE: Zero members voted 5 or 6, meets and deserves priority consideration; nine members voted 4, meets; two members voted 3, meets; and zero members voted 2 or 1 or not applicable. And the majority finds that this proposal meets Criterion 6, Ability to Be Evaluated.

CHAIR BAILET: Thank you, Ann. We're going to move to number 7, Integration and Care Coordination. Encourage greater integration and care coordination among practitioners and across settings where multiple practitioners or settings are relevant to delivering care to populations treated under the PFPM.

Please vote.

[Electronic voting.]

CHAIR BAILET: Ann.

* **Criterion 7**

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MS. PAGE: Zero members voted 6, meets and deserves priority consideration; one member voted 5, meets and deserves priority consideration; two members voted 4, meets; seven members voted 3, meets; one member voted 2, does not meet; and zero members voted 1, does not meet; and zero members voted asterisk, not applicable. The majority finds that this proposal meets Criterion 7.

CHAIR BAILET: Thank you, Ann. We're moving to 8, Patient Choice, which encourages greater attention to the health of the population served while also supporting the unique needs and preferences of individual patients.

Please vote.

[Electronic voting.]

CHAIR BAILET: Ann.

* **Criterion 8**

MS. PAGE: Zero members voted 6, meets and deserves priority consideration; one member voted 5, meets and deserves priority consideration; eight members voted 4, meets; two members voted 3, meets; and zero members voted 2 or 1 or not applicable. The majority finds that this proposal meets Criterion 8, Patient Choice.

CHAIR BAILET: Thank you, Ann. We're moving to Criterion 9, Patient Safety. Aim to maintain or improve standards of patient safety.

Please vote.

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[Electronic voting.]

CHAIR BAILET: Ann.

* **Criterion 9**

MS. PAGE: One member voted 6, meets and deserves priority consideration; one member voted 5, meets and deserves priority consideration; five members voted 4, meets; four members voted 3, meets; and zero members voted 2 or 1 or not applicable. The majority finds that this proposal meets Criterion 9.

CHAIR BAILET: Thank you, Ann. And number 10, Health Information Technology. Encourages the use of health information technology to inform care.

Please vote.

[Electronic voting.]

* **Criterion 10**

MS. PAGE: Zero members voted 5 or 6, meets and deserves priority consideration; three members voted 4, meets; eight members voted 3, meets; and zero members voted 2 or 1 or not applicable. The majority finds that this proposal meets Criterion 10.

CHAIR BAILET: Thank you, Ann. Are we going to summarize? I believe all of the criterion were met.

MS. PAGE: Yes. The Committee found that this proposal meets all 10 of the Secretary's criteria.

CHAIR BAILET: Okay. Thank you. We are now

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going to have the overall vote on the recommendation to the Secretary, and I want to remind the Committee members, as we go through this part of the process, if there are specific points of view relative to recommendations, elements that we want to include in this Secretary's report, and want them on the record, we need to make sure that as we go around -- we will, before we're finished, we will go around and make sure those points are emphasized. And the Committee has an opportunity to weigh in as well.

So -- all right. So we're going to do an electronic vote first, and then we go around and speak to it individually on how we voted. So, we're going to switch over here. Matt, the Magician.

MS. PAGE: And for the attendees, a summary on this overall recommendation to the Secretary, a two-thirds majority vote rather than a simple majority vote determines the Committee's recommendation.

CHAIR BAILET: So, we have a small modification, but I'll just start with -- so, number 1, not recommend the proposed payment to the Secretary; number 2 is recommend the proposed payment model to the Secretary for limited-scale testing; number 3 is recommend the proposed payment model to the Secretary for implementation; and 4 is recommend implementation to the Secretary with high priority.

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We have an asterisk, which is another category, which we will probably discuss in greater detail as other proposals come forward, which means that certain -- it wasn't the point in this particular proposal, but there may be criteria, which are not applicable. That was not an issue but we will revisit it, but that's why that's up there. I just didn't want to confuse folks as we go through the process.

So we're going to go ahead and vote electronically first.

[Electronic voting.]

CHAIR BAILET: Ann.

* **Final Vote**

MS. PAGE: Zero members voted not applicable; zero members voted 1, do not recommend; one member voted 2, recommend for limited-scale testing; seven members voted 3, recommend; and three members voted 4, recommend for implementation as a high priority. The two-thirds majority of members find that this recommendation should -- that this proposal should be recommended to the Secretary for implementation.

* **Instructions on Report to the Secretary**

CHAIR BAILET: Thank you, Ann. Thank you.

We'll start -- we'll just go around individually, and again, this is the time, if there are specific comments

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we want to include in the report, we can go ahead and discuss those as well. So starting with Tim.

DR. FERRIS: Okay. We'll get the oddball out of the way first. So I'm very much for this proposal. I think it's terrific and would be good for the public. I think there were sufficient questions in my mind about the implications of all the concerns. I highlighted eight of all the concerns that were listed, that, to me, make it a great proposal for limited-scale testing, so they have an opportunity to work out these things before it goes to full scale. But I'm for this proposal.

I would say, in order to get it on the record, as I think our submitters did struggle with the tension between ideal and real, and one of the things that I found about this proposal that I think we should, as a PTAC, think about, is the one-size-fits-all. So they actually made quite a few compromises to make sure that everyone was in. I'm not sure that's the best thing for the American public or the U.S. population as a whole.

Something like this could be done very differently and done way more upstream in an integrated delivery system. And I just wonder why every time we have a payment model it's sort of -- we design a payment model for the lowest common denominator, which is sort of an independent rural practitioner. And we, I think, should

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think about maybe encouraging people to have two different payment models, one in the context of an integrated delivery system and one in the context of that independent rural practitioner, because I actually think that would accelerate progress in the improvement of delivery of care.

So I just wanted to make that point about this particular proposal, but I actually think it applies to quite a few of the proposals, because all these proposers have thought through the process about the biggest tent possible for the inclusion of their payment policy, and that's an absolutely laudable goal. There is no criticism of that goal. But I just wonder if we're not -- in that process -- selling the potential for alternative payment models to make a difference for a large swath of the population more quickly and more advantageously. Thanks.

CHAIR BAILET: Thank you, Tim. Grace.

DR. TERRELL: I really like this proposal a lot, and I felt that the two things that I articulated earlier are things that need to be addressed in the comments. One is with respect to the aspects of early transplant and basically putting something in place that will encourage that, as part of a payment model, it was alluded to that -- that could be done through quality metrics. Maybe. If that's not case, but we actually need to tie it to some sort of payment system, then I would like, in whatever

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testing is done, if this does go to testing, that to be explored with this group to think through that.

The other thing that I hope will be in the report, in the oral testimony today I heard that there are certain things that can be done in any practice, all over the country, with respect to care coordination and integration, and there were several things mentioned. One was education. There were several others. I would like those specific things articulated, that came out of the oral testimony that did not come across in the written thing, and so therefore the critique back from the PRT was that it didn't meet the criteria. Because we voted that it did, and I think a lot of that was because we heard that there were things that were across the board.

Finally, to get to Tim's point, because I think it was a little of what I was talking about earlier in my initial comments, which is there's a range of possible ways of providing renal care, depending on the setting across the country. It would be also worthwhile for them to be thinking about -- for us to be thinking about, for the Secretary to be thinking about – “How does that relate to quality parameters such that we move the entire country forward, irrespective of where they are?” Should quality benchmarks be the same across the country, or is this a place in space where we could actually be thinking through,

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you know, gradations of that?

CHAIR BAILET: Thank you, Grace. Harold.

MR. MILLER: I voted for this as a recommend for testing with priority consideration. I said that because -- the priority part, for two reasons. One is I'm troubled by having payment models from CMMI that are as narrowly focused as the current CEC model is, to suggest that patients can only get the kind of better care that is possible through something like that if they happen to be in an area that is large and has large numbers of patients and large dialysis organizations, or whatever.

So I think that it's important that whenever there's clear opportunities in the early results from that model suggests that there are significant savings and quality improvement possible. So I think it's important that other similarly situated patients have the opportunity to benefit from that.

I also didn't -- I didn't think that limited-scale testing was appropriate because what we have used that for otherwise was to be able to refine parameters, et cetera. I don't think that that is as important here as I think what we will learn from this is really the issue of how does this work and work differently in different places. And the only way to figure that out is to be able to do it broadly.

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And I think the other reason, from my perspective, for the high priority, is that CMS ought to be able to move forward quickly on this, because there has been so much thinking already done with respect to this on the CEC model.

I would respectfully disagree with Tim about the notion that we're getting lots of things that are designed for the lowest common denominator. I think that general impression in the country is that most everything that CMS has done has been for big organizations and big integrated delivery systems, and that, in fact, the PTAC was specifically established to try to help encourage small providers to come in. And I think that's what we're seeing and I would commend the RPA for actually trying to do something like that.

That being said, though, back to the earlier point about separable payment model proposals, et cetera, I don't think we should, in any fashion, implicitly be encouraging applicants to come in with one-size-fits-all models where they don't think a one-size-fits-all model is necessary or desirable. And if they think that there are two different ways one could structure a payment model that could work differently, depending on differently resourced or structured entities, that they should be free to bring those to us. It would actually be, I think, helpful to us

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in some fashion to say, here's how this can be done in a rural area and here's how it could be done in a larger system, and then potentially have both of those proposals.

So that's the explanation for the vote.

The one thing I would like to see reflected in the report -- other than what we've talked about already, which is not the transplant bonus and having modifications to the quality measures -- is I think that this -- I am troubled about shared savings models, and I'm troubled about that particularly with this one for small practices. And I think I would really strongly encourage that when something like this is put in place, that it be monitored and modified so that it, in fact, works the way as expected to, and that if practices are suddenly being penalized financially or rewarded in some unusual windfall way because of random variation in the population, that there be rapid modifications to the model to be able to adjust the way the shared savings calculation is done. And there may need to be exclusions of certain kinds of cases, or there may need to be different kinds of risk corridors built into it, or whatever it is, which will probably only be known once the model gets implemented. But I really am troubled by the notion that we would -- that this would be put into place, and put into place for five years or something like that, and evaluated without any

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modifications to it if along the way problems were developing and that people were being forced to drop out because of that.

So the thing I would like to see recommended in the report is that this be modified as necessary along the way to ensure that it is -- practices can, in fact, successfully participate and achieve what they had hoped to be able to achieve from it.

CHAIR BAILET: So I guess I want to -- this is an opportunity for the Committee to speak to Harold's point to make sure we get this -- if we have -- so I agree with you, Harold, but I guess the point you're making about the ability to modify as experience builds, I think that's a point that would be applicable to, frankly, any alternative payment model, not specifically this one.

MR. MILLER: Well, potentially. But my point is this is a model that has shared savings on a big amount of money for potentially very small practices. And so I would say the same thing for other models like that, but that's specifically the reason why I'm saying it here.

CHAIR BAILET: I understand, okay.

MR. MILLER: I think that -- and it has already been coming up with respect to the Oncology Care Model, is that practices that are in that are saying, "We are highly subject to random variation in costs that are not

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accurately captured by the risk adjustment methodology," et cetera. And I think rather than saying, "Sorry, you've got to just continue with that and take it or leave it," that there needs to be a modification.

CHAIR BAILET: Thanks for clarifying, Harold. That was a -- So, Grace, you have a point you want to make?

DR. TERRELL: Two things. I was instructed that I didn't say what my actual vote was, which was -- I voted highest priority.

But the second one is with respect to Harold's comments, PTAC was specifically about small rural practices, there's nothing in the criteria from which we're voting on, nothing in the law that I see that says that. And it may be that it can be inferred or otherwise. But as I'm doing evaluation, I need to be thinking about it across the spectrum of where care is. If it happens to be better for an integrated system or it happens to be better for a small or rural practice, then that's something that we need to understand and think about with respect to our recommendations. But I do not believe my mission is to just be thinking about this within the context of a particular type of practice.

So the concept that many of those submitters are thinking about things across the board, as this particular group did, is to my mind not about the lowest common

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denominator. It's about the flexibility that's part of the criterion from which we're supposed to evaluate.

CHAIR BAILET: Thank you, Grace. Paul?

DR. CASALE: Yeah, I voted to approve to go forward, and just a couple comments and not to repeat what's already been said, which several I agree with.

A couple of points. One is although -- so, sorry, I just want to take a step back. I do think that a lot of experience has been built on the CEC program, so I think in terms of, you know, limited testing versus just full expansion, and I think in our discussions that the PRT had with CMMI, it was clear that there was -- the ability to expand that model was limited, and so this I think clearly expands it significantly. And although only three words, they said, related to virtual in their proposal, I do think the idea of, just as in the CEC, where they're allowing the smaller ESCOs to combine their efforts and be at risk with each other, I think it would be important that we point that out, because we do have concerns around the small -- we've discussed this -- concerns around the small practices and random variation, and these are high-cost patients, so I do think that that is an important point to emphasize in our recommendation.

And I do think on the transplant, which has already been mentioned, we can incorporate that into the

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quality measures.

CHAIR BAILET: Thank you, Paul. Bruce?

MR. STEINWALD: I voted as Paul did. I didn't see in the proposal and the discussion the same level of concerns that led us in other proposals to recommend for limited-scale testing.

In addition to that, the information that could be learned from broader scale, which includes both small practices and integrated delivery systems, might be -- might be very informative on going forward to improve the model maybe in different ways in different settings. I do think that the discussion should include, when we talk about potential improvements to care that might be associated with this model, that should include giving patients meaningful choice for the alternatives to in-center dialysis when those choices are clinically appropriate, and that the evaluation, of course, should identify whether those choices are actualized as the model goes forward.

CHAIR BAILET: Thank you, Bruce.

So I voted for implementation as well, and, clearly, the content, the elements of this model address some of the critical -- the critical elements that I think this Committee really was existed to analyze, which are high-impact, high-cost models that can really improve

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quality for patients in a broad sense on significant -- where not only significant dollar spend but also significant diseases. We've talked about these patients are incredibly -- can be incredibly sick, and the institution of dialysis can be a life-altering up to and including mortality. So I think that this is an important model. I think there's enough information that was already garnered from the ESCO experience where this could move to implementation and doesn't require small-scale testing.

I know that the sweet spot for these patients is to get as upstream as possible. I think the country is falling down right now on the care that's delivered. I think there's tremendous opportunity. Ten percent of the nephrologists today are participating in the CEC, so this really broadens the exposure and, I think more importantly, the focus on this particular population. And I'm confident that as more nephrologists can get in and participate, that they will -- we will discover ways to get more upstream, and this will become more visible, and I think it will have a greater impact. So I like the model. I'm fully supportive. Thank you.

Elizabeth?

VICE CHAIR MITCHELL: Thank you. I also voted for implementation. And not to repeat what's been said, but I would want in the comments to have it reflected that

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we are -- we recommend exploring incentives and coordination to move this as upstream as possible, so to avoid dialysis.

I think there may also be -- it might be worthwhile to look at multi-payer models given the populations that we're talking about. So could this be a good candidate for a multi-payer program?

And then, finally, I am actually concerned by just the requirement for reporting on quality metrics. I don't think that's adequate. I think there should be a performance threshold. I understood that it was just a sort of starting point, but I would like to look at requiring some sort of performance threshold as soon as possible.

CHAIR BAILET: Len?

DR. NICHOLS: So I voted to recommend with high priority because I see this population as incredibly vulnerable, and I applaud the applicants for trying to forestall unpleasant trajectories. I think that's really important.

To the general point I think we've spent a lot of time discussing, I personally view our general -- which is sort of for the record, I view our unease with this concept of one size fits all or maybe I'd like to say it our embrace of many sizes fit America. I view that as a

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strength, and I would suggest we express our awareness of the tension between what integrated practices can do versus what smaller and often rural practices can do in terms of compared to what feasible alternative. Yes, Tim, I agree with you completely, a higher standard for integration would be ideal, but this model, if it had some kind of upfront payment versus risk share options or virtual group type tools, maybe some proper encouragement of transplants, et cetera, could create a delta everywhere, and that delta could be in quality and cost of patient care across the country. And I fear without that flexibility in the model, these rural patients are going to continue on their current paths, which we all agree are not ideal if we set the standards for participation too high and too fast.

I think we should think about when we recommend to the Secretary a concept of a dynamic evolution of standards of care, not so much a static ideal that may be achievable now only by a subset, if we think that improvement is possible everywhere, as I think it is in this model's case.

CHAIR BAILET: Thank you, Len. Kavita.

DR. PATEL: I also voted to approve this model, and just a couple of comments for the Secretary's note.

Number one, to highlight something that the submitters said about the lack of even appropriate

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diagnoses from the primary care settings, so even though this APM is obviously very specifically focused on nephrology, the Secretary has a great bit of latitude to also think about what could we be doing to better identify, even through proper coding, the kind of the patients that really should be in the upstream.

And then the second point to the Secretary, I'll just emphasize, because I think where Tim was going -- and he is describing the lowest common denominator -- is actually the approach that most of us have to take in developing alternative payment models. And I think the Secretary should think carefully about how, if they expand or open up the CEC model, how CEC -- and the submitters did a nice job of highlighting this in some of their responses -- how a CEC participant would interact with this model and potentially interact with a larger ACO model, et cetera, et cetera.

So I'll just say that highlighting for the Secretary that multi-model overlap is potentially a good thing, but it is complicated and makes these layers of payment difficult for an applicant to understand.

CHAIR BAILET: Bob?

DR. BERENSON: I supported this, but not at high priority. It's a good model. I would only emphasize one point. As my questioning sort of led me to this, I'm

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concerned that the high costs associated with patients who have other primary conditions who just need dialysis near the end of life will dominate the spending analysis and the potential for shared savings, having very little to do with what we're hoping to have, which is more attention to upstream preparation for dialysis and is a function with small numbers, as Harold emphasizes, of involvement with those patients. And I'm happy -- I wouldn't want to eliminate them from the calculations at all, but I would have narrow trim points. I find it unlikely that the renal physician is going to be a decisive factor in telling the oncologist or the cardiologist or the family that no -- because of your need for dialysis, we're going to want to sort of terminate your -- in other words, I think you can have an influence, but I don't think it's a decisive one. I would want them to be involved with that, but I think the statistical shared savings approach should be emphasizing the cases that are not those. And I won't -- does that make sense? You're looking at me quizzically, Jeff.

CHAIR BAILET: I'm just trying to follow, but go ahead.

MR. MILLER: Well, can I just --

DR. BERENSON: Does anybody know what I'm saying?

MR. MILLER: Yes, I endorse --

DR. BERENSON: Oh, okay.

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MR. MILLER: I mean, his point is that the shared savings could be coming from the subset of patients who you just, if you could do it, convinced not to get end-of-life treatment or whatever, not trying to reduce complications from infections, et cetera. And I think that --

DR. BERENSON: That's my point.

MR. MILLER: And so that, I agree with him wholeheartedly, that's part of the -- it needs to be monitored carefully, and if, in fact, it looks like whatever, somebody's either being penalized or rewarded or diverted into a different direction than was anticipated, that then it be modified, because you could -- you could modify the shared savings model to say we're going to give different weight to different patients in different kinds of circumstances, et cetera. That would make it more complicated, which we always get pushback, because you don't want to make the models complicated. But, on the other hand, if they end up incenting the wrong things, I think that that's a problem.

DR. BERENSON: Harold said what I was trying to say. I think if we had the data on the median spending for these patients, it would be very different than the average spending for these patients, and we want to really be moving the median for those patients who actually have chronic renal disease and not those who have other primary

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diseases who just happen to have dialysis.

CHAIR BAILET: Right. So I guess for the Secretary's report, then, I'd like to make this a specific point, that we are calling this out relative to inclusiveness. So we're -- this model could best be served if we actually exclude or make an adjustment for this population in the calculation.

MR. MILLER: My proposal would be that -- I was talking about longer term, but maybe there should be some examination of whether some modifications to the shared savings methodology should be made to try to anticipate some issues like that so that it doesn't end up directing in -- but I think that's the question, is whether a sort of a standard just total cost of care no matter what methodology is appropriate when you think that there may be two completely different populations involved.

CHAIR BAILET: All right. Rhonda?

DR. MEDOWS: So I voted number 3. I thought this proposal was very well done. It addressed a complex and vulnerable population that doesn't always get the attention that it needs. I think that it addresses both Medicare and the dual-eligibles as well as they rise through the ranks.

I believe that the questions that I had that I came into the room with were actually addressed in both your opening statement and in your comments later on. My

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two questions were focused on the importance of patient engagement in shared, informed decision-making, which you addressed very well for me. Thank you very much.

In addition, my other question was about patient care coordination with primary care, particularly family physicians as well as internists, and that was also addressed in your comments. I think that was what I needed to hear from you, and I appreciate that. Thank you.

CHAIR BAILET: Thank you, Rhonda.

And I'd turn to Ann. Ann, do you have what you need?

MS. PAGE: I'll turn to Adele [off microphone].

CHAIR BAILET: Adele.

DR. SHARTZER: Sure. I think so. I will just run through a couple of the major points, but I just want to note that we'll comb through the transcript and all of the detailed notes that we took to make sure that we do include everything that you said. But in terms of discussion, it sounds like obviously the transplant component will be a big element of our conversation. And then sort of this debate about one size fits all and the appropriate --

MR. MILLER: Well, can we just be clear what we're -- not a big part. We're saying we don't think it should be included. And, I think everybody has agreed to

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that.

DR. SHARTZER: Right, but that will -- we'll have to be clear about our decision, your decision, and why, and some of the concerns about precedent that I think you mentioned.

And I think sort of -- Grace, you mentioned the gradations and adaptability to different areas. I think that will definitely be included.

And an emphasis on trying to get the quality measures right, modifying proposals over time if evidence shows that -- that practices are being adversely impacted. The emphasis on patient choice, so -- and some of the, you know, the benefits of focusing on this vulnerable population. So is there anything else big picture --

DR. NICHOLS: The one size fits all you started to mention [off microphone].

DR. SHARTZER: Okay. So there was some discussion about whether a one-size-fits-all model is what is best for the country, and we will just kind of try to touch on some of the points that were raised. We'll look through the transcript to try to get the exact verbiage. I don't want to mischaracterize it.

DR. FERRIS: Since I raised it, it was really not -- I didn't raise it to be a comment about this proposal specifically, so it probably was a mistake to raise it in

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the context of deliberation of a specific proposal. But it is from my perspective a pattern, and it's a big country, a lot of different ways of delivering care. The idea that any one payment model is going to be useful across the country for any number of reasons is, to me on its face, simpleminded. And so, but that's not a -- I didn't -- I thought I introduced my comment crediting the group who submitted this proposal with doing a great job, and that they were struggling, I think was the word I used, with all the compromises that one is forced to make when trying to be inclusive of everyone.

CHAIR BAILET: So, Harold and then Bruce. Harold?

MR. MILLER: I actually think we should keep that point, to be honest with you. I guess the way I would make it, though, is I want to be clear, I think what we're saying is the shared -- there's modifications on quality, but the shared savings methodology may need to be modified, both initially and early on after early evaluation of what's happening, and it may need to be differentiated. I guess I would make an amendment sort of along the lines of -- in response to Tim's point. It may need -- There may need to be differentiation in those modifications for different size practices in different places, because in a sense you'd say if, in fact, this is a big nephrology

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practice but not -- a big integrated group and not big enough to be in the ESCO model but big, you would have less concern about the fact that you had total cost of care for all reasons for patients being admitted than if you had the single nephrologist in the rural area who was really getting hurt by the fact that some of those patients were being dealt with by physicians that he had no relationship with.

So, anyway, I do think that rather than saying there has to be one model and that it can -- if it's going to be changed, it has to be changed for everybody, that it could be -- I think we should suggest that, in fact, we think that there could be diversity. But that would be my proposal if you -- you're welcome to agree or disagree with that.

DR. FERRIS: Harold, I'd like to nominate you as the person who rearticulates what we're saying so --

[Laughter.]

DR. FERRIS: So that it makes sense, and then --

CHAIR BAILET: All right, very good. Bruce, bring us home.

MR. STEINWALD: Adele, I don't know if you intended this, but I think the discussion of patient choice, particularly the choice of dialysis modality, could be part of the discussion of upstreaming, because -- and

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it's really, I think, part of that same issue.

DR. FERRIS: That was how I intended it [off microphone].

MR. STEINWALD: Oh.

DR. FERRIS: That was how I intended it, is the ability to move upstream, as my comments and their response was -- my question to them was about that issue. That is the issue, which I think the delivery, the care delivery system is less or more, well able to deal with, depending on how integrated you are. And I would just love to see us move more, but I do want to emphasize I don't want the perfect to be the enemy of the good here. I think this is good. I'm just thinking: What could be better?

MR. STEINWALD: Yeah. I was just trying to be helpful to Adele. But it's nice that you agree with me. Thanks.

MR. MILLER: Can I just say -- because I think just to be clear on Tim's point, because I agree with Tim's point. I think what we're saying, to make sure I understand, is we're not saying we think this model should be modified to upstream, but that we think that we should not sort of stop at this point and say all we're ever going to do is fix dialysis forward, but that there should be some supplemental effort to look at other things. At least that's what I would want.

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CHAIR BAILET: Alrighty. I think we have completed our analysis and our deliberation. Again, I want to compliment the submitters on this model, and I look forward to what's possible as this goes now downstream for consideration by the Secretary.

[Laughter.]

CHAIR BAILET: Now, let's not -- well, upstairs. There we go. It's going to go upstairs.

So what we're going to do is we're going to take a break until 1 o'clock, which is a half-hour earlier than the original schedule, but we're trying to move along. And, again, thank everybody for their attention and participation, and we'll be back at 1 o'clock. Thank you.

[Whereupon, at 11:55 a.m., the meeting was recessed, to reconvene at 1:00 p.m. this same day.]

AFTERNOON SESSION

[1:04 p.m.]

CHAIR BAILET: We're going to go ahead and reconvene the PTAC.

So welcome back. The next proposal that we're looking at is the New York City Department of Health and Mental Hygiene, a multiple-provider, bundled episode-of-care payment model for treatment of chronic hepatitis C, using care coordination by employed physicians in hospital

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outpatient clinics.

The review team is comprised of Rob -- Dr. Berenson, Robert Berenson; Jeff Bailet; and Grace Terrell.

Before we officially launch into the review process, what I would like to do is have everyone go around the room on the Committee and introduce themselves, and at the same time, if there's a disclosure, could you please read your conflict-of-interest disclosure.

New York City Department of Health and Mental Hygiene (NYC DOHMH): Multi-Provider Bundled Episode-of-Care Payment Model for Treatment of Chronic Hepatitis C Virus (HCV) Using Care Coordination by Employed Physicians in Hospital Outpatient Clinics

* **Committee Member Disclosures**

DR. BAILET: And I will start. I am Dr. Jeffrey Bailet, the Executive Vice President of Health Care Quality with Blue Shield of California, and I have nothing to disclose on this particular proposal.

Tim.

DR. FERRIS: Tim Ferris, CEO of Mass General Physicians Organization. Nothing to disclose.

DR. TERRELL: Grace Terrell, practicing general internist, part of the Wake Forest Baptist Health System and CEO of Envision Genomics. No disclosures.

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MR. MILLER: Harold Miller, CEO of the Center for Healthcare Quality and Payment Reform. I have no disclosures.

DR. CASALE: Paul Casale, Executive Director of New York Quality Care, the ACO for New York-Presbyterian, Columbia, Weill Cornell.

I noticed in the proposal, they mentioned Weill Cornell was sort of part of it. So I do have a faculty appointment and see patients at Weill Cornell Medicine, and as I mentioned, I direct their ACO.

MR. STEINWALD: I'm Bruce Steinwald. I have a little consulting practice here in D.C., and I have nothing to disclose.

CHAIR BAILET: Elizabeth?

VICE CHAIR MITCHELL: Elizabeth Mitchell, CEO of Network for Regional Healthcare Improvement, nothing to disclose.

DR. NICHOLS: Len Nichols. I direct the Center for Health Policy Research and Ethics at George Mason University, and I have nothing to disclose.

DR. BERENSON: I'm Bob Berenson. I'm a Fellow at the Urban Institute, and I have nothing to disclose.

DR. MEDOWS: Rhonda Medows, Executive Vice President, Population Health, Providence St. Joseph Health. I have nothing to disclose.

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MR. STEINWALD: And I'm Mary Ellen Stahlman. I'm the ASPE lead on PTAC.

CHAIR BAILET: Sarah?

MS. SELENICH: I'm Sarah Selenich, and I am an analyst at ASPE, and I supported this PRT.

MS. PAGE: And I'm Ann Page, and I'm the Designated Federal Official for this Federal Advisory Committee Act Committee, PTAC.

CHAIR BAILET: Thank you, everybody, and I just want to go on record and compliment the staff that worked tirelessly to support our efforts. The information comes in fast and furious, and these guys really go above and beyond to support us. And we're all very appreciative, so thank you for that.

So I'm going to turn it over to Dr. Berenson to lead the discussion and summarize the proposal review team's report.

Bob?

*** PRT Report to the Full PTAC**

DR. BERENSON: Okay. So that's the title, the Multi-Payer – *"Multi-Provider, Bundled Episode-of-Care Payment for the Treatment of Chronic Hepatitis C, Using Care Coordination by Employed Physicians in Hospital Outpatient Departments."* It's a proposal that comes from the New York City Department of Health and Human Services.

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This is the typical presentation overview that we will go through. I won't go through this one in detail, just to say that we did take advantage of obtaining additional information from a hepatologist. We had good phone conversations with the proposers. I want to thank them for their participation. You represent various institutions and had a coordination issue of your own.

I think we got the information that we wanted, so thank you very much, and just to reemphasize, the PRT report is not binding on the PTAC, as you know. PTAC may reach different conclusions from those contained in the PRT report.

All right. So there's a lot of information on this slide. The proposal is based on the HCIA Round 2 Demonstration Project, Project INSPIRE. The proposal focuses on integrated care coordination of patients, particularly higher need patients, especially dual eligible patients with behavioral health and substance abuse disorders, with HCV to ready them, to initiate, and adhere to life-saving pharmacology.

The intervention is that patients would undergo a comprehensive psychosocial evaluation to identify barriers to care and medical evaluation to determine the complexity of their liver disease. The care team would then assist patients in overcoming barriers through various means, such

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as referrals for psychosocial issues or other comorbid conditions, direct counseling services, helping patients navigate appointments, importantly assistance with obtaining prior authorization for costly pharmacotherapy, which is an issue for sure in New York. Primary care physicians would take on a greater role in managing patients with HCV. They will be trained by hepatologists and other gastroenterologists through tele-mentoring, although our view was that there was less emphasis on the tele-mentoring in the proposal compared to the INSPIRE model. We will be discussing that, I believe, with the proposers.

Nonclinical care coordinators would also play a key role, and we would observe that nonclinical staff cannot be billed using the chronic care management codes, and that becomes an issue as well.

The next one -- we're still talking about the overview. The payment, which is core to the proposal obviously, is that the expected participants are employed physicians in the hospital outpatient clinics who treat HCV. The APM Entity would receive a bundled episode payment and actually specified at $760 for each eligible patient that agrees to participate.

The episode is comprised of three phases: Pretreatment assessment involving care coordination; the

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treatment period; and the report of a sustained virological response at 12 weeks postpartum, which is abbreviated as SVR12, sustained virological response. The episode is not expected to exceed 10 months, and often is 9 months.

The APM Entity would be eligible for bonus payments and at risk of paying penalties based on its risk adjustment SVR rate. The proportion of participating patients who complete a full course of antiviral treatment and have undetectable HCV, ribonucleic acid 12 weeks after treatment cessation, so a very concrete performance measure that is the basis for determining bonus payments.

The APM Entity's SVR rate would be compared to the benchmark set by CMS. An APM Entity with an SVR rate at or below the benchmark would receive a bonus payment. An APM Entity with a rate below the benchmark would be required to pay back a penalty.

The bonus payments for each patient who achieves SVR target would be calculated by applying a CMS-determined shared savings rate or rates through the product of the following formula, and you've all seen a lot of detail on this formula. But the key thing is the expected annual cost avoided from treating HCV times the life year estimates of the life years gained with the successful treatment. Whoops.

CHAIR BAILET: Bob, I don't mean to interrupt,

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but I just, I'm just processing one word that you said when you said 12 weeks "postpartum." Was I the only person that heard that?

DR. BERENSON: Did I say 12 weeks postpartum?

CHAIR BAILET: Yes, you did, Doctor.

[Laughter.]

DR. NICHOLS: We all knew what you meant, so it's okay.

DR. BERENSON: What did I mean?

CHAIR BAILET: But I just want the record -- for the people on the phone who might have been listening in, I just want to make sure --

DR. BERENSON: What did I mean?

CHAIR BAILET: Post-treatment. Post-treatment.

DR. BERENSON: Oh, post-treatment. Oh, my goodness. That's interesting. I'll have to think about that one.

DR. NICHOLS: Don't think too hard.

DR. BERENSON: So, as you can see, we're going to go through each one of these. We found the proposal deficient on a number of the criteria. We'll go over those in more detail now.

Whoops. I keep pressing the wrong button.

All right. The key issues identified by the PRT. One is that care coordination of these higher-need patients

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with HCV is important, has the potential to improve quality and reduce costs.

The efficacy of pharmacotherapy for HCV enables payment to be tied to a meaningful outcome measure. However, the PRT is not convinced that a new payment model is necessary to support the care model. The PRT believes the proposal could be accommodated within current payment methods if you take away the shared savings component, and we will be talking about that. But that the care coordination support could be accommodated within current payment methods.

The PRT has specific concerns regarding the payment methodology, including the shared risk arrangement, and associated with that, the attribution methodology and the lack of sufficient risk adjustment.

Shared savings are based on expected annual costs from continued HCV infection avoided and the number of life years gained with the SVR, with SVR, meaning no more virus. Our view was that the approach is untested, unprecedented in Medicare, and imprecise. To the extent that it has merit, it should first be tested in a manner that is specifically designed to study the feasibility of such an approach and how to incorporate this methodology within an APM.

The shared savings rate or rates have not yet

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been determined, but rewarding facilities for practicing high standards of care with potentially huge bonus is based on savings that are not in fact attributable in large part to these high standards of care is problematic. Such a precedent would likely lead other parties, including drug manufacturers and providers, to advance similar claims to a share of these savings.

Very specifically here, the major advance to produce a cure is medication, and so we think there's a mismatch between what's largely responsible for the savings and giving the bonus to the physicians who do a better job in managing patients.

Physician-determined attribution and a lack of adequate risk adjustment could lead to patient selection imbalances that could undermine accurate evaluation. Beneficiaries with HCV frequently have substantial comorbidities, including behavioral and mental health conditions, but there does not seem to be continuity between care coordination for purposes of accomplishing HCV treatment and what should be ongoing care coordination for HCV patients with comorbidities.

So now going through each criterion, scope is the first one. HCV is a high-impact condition, affecting nearly a quarter of a million beneficiaries in 2016. Many of these beneficiaries have substantial comorbidities, and

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this patient is high cost. So that's a positive.

There are issues in payment policy regarding HCV, particularly due to the high cost of pharmacotherapy. However, the PRT believes that care coordination can be accommodated under current payment methodologies. I'll be getting back to that one. While the proposal could in theory be generalizable, it seemed very much designed for employed physicians and hospital outpatient clinics, not all physicians providing care for patients with HCV, and seems rather specific to the large integrated health systems in New York City and to circumstances somewhat specific to the New York practice environment.

On the criterion -- so we said this does not meet the criterion, unanimously.

The next one is quality and cost, where we said it does meet the criterion. Coordinating care for higher-need patients with HCV in a careful and concentrated way and providing health education, appointment navigation, and connection to supports and services seems likely to increase the proportion of patients who achieve SVR. Activities that increase the number of patients who are treated and cured would reduce costs associated with complications. Higher cure rates would reduce disease transmission and subsequent costs.

Medicare beneficiaries with HCV frequently have

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substantial comorbidities, including behavioral and mental health conditions, and are high cost. Focusing on this patient population seems likely to reduce certain costs, such as those associated with avoidable emergency department visits for comorbid conditions.

The final HCIA evaluation would help the PRT better understand the model's potential impact on quality and cost, and our understanding is those results will be forthcoming soon but are not yet available. Interim findings have been available.

The next is the payment methodology, and here's where we spend the most time and say it does not meet the criterion. On the one hand, the proposal directly ties payment to a meaningful outcome measure and uses a straightforward episode-based approach for providing care coordination funding.

However, we think that billing the current complex chronic care management codes would seem to provide payment in line with the proposed episode payment. The PRT recognizes that there are some restrictions on how the current codes can be used, suggesting that fixes to the predominant fee schedule-based payment model are worthy of consideration.

And here, we were negligent in not including a bullet that makes clear that the current payment for the

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chronic care management codes actually exceed by a few hundred dollars, what they have been requesting, what they are requesting at the episode-based payment. In their proposal, they actually have provided some information about suggesting that it comes short by about $400, but they've included only the professional component of the fee and not the facility fee. Our calculations are that using the relevant 99487 code produces revenues that exceed what they're requesting under this proposal.

Patient eligibility and attribution are unclear, and there does not seem to be any risk adjustment to the episode payment. Physician-determined attribution and a lack of adequate risk adjustment could lead to imbalances in selection.

Now, this again is sort of a state-of-the-art shared savings model, and our view is that shared savings based on annual -- on expected annual cost from continued HCV infection avoided and the number of life years gained is untested, unprecedented in Medicare, and imprecise. To the extent that it has merit, as I said in the summary, this isn't the place to test it.

The shared savings rate or rates have not yet been determined, but rewarding facilities for practicing high standards of care with potentially a huge bonus is based on savings that are due to many factors, including

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the success of the pharmacology to care coordination under the auspices of physicians doesn't seem to us an appropriate method for determining shared savings and again is maybe a bridge too far.

Value over volume does meet criterion. We are concerned about the potential for avoiding patients who are more complex and high cost. That's what we were alluding to with the risk adjustment issue.

CHAIR BAILET: Bob, you need to advance the slide.

DR. BERENSON: Oh, I forgot. I'm moving my slides but not your slides. There we go.

On flexibility, we said it meets criterion. The care team appears to have broad flexibility in meeting the unique needs of each patient. Delivery model supports tele-mentoring of PCPs to enable them to take on a greater role in managing patients with HCV.

The ability to be evaluated, we said it does not meet criterion, largely because the shared savings are based on expected annual cost from continued HCV infection avoided and the number of life years gained. Given the relative newness of the use of HCV drugs, the initial modeling may prove to be inaccurate, and the inaccuracy could result in -- we really wouldn't know what the impact is for many years.

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Integration and care coordination. The proposal does focus on integrated care coordination of patients, particularly higher need patients with HCV. The proposal supports tele-mentoring. The submitter notes that an advantage of implementing the model in hospital-based clinics is the ability for care coordinators to make referrals to other diagnostic and treatment services within the same facility. These facilities are also likely to have integrated EHR systems.

But our major concern is that beneficiaries with HCV frequently -- more than frequently, it turns out that something like national numbers -- and they confirmed this is also their situation -- most of these patients are Medicare-eligible by virtue of having disabilities. That's the original reason. They are frequently dual eligible. They have serious mental health and other conditions, and we did not see that the proposal addressed how care coordination occurs across outpatient department settings with other providers.

The proposal seemed to focus on care coordination for managing the treatment of HCV but very little attention to the overall, and what we think should be ongoing care coordination using existing payment codes that Medicare makes available in the fee schedule.

Patient choice meets criterion. There was not

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much of an issue so I'll skip over that. Patient safety clearly is a positive from the model. It targets a population with high rates of mental and behavioral health issues, coordinating care for these patients and helping them overcome issues that may interfere with their readiness to initiate and adhere to pharmacology could improve patient safety.

Health information technology. Most of this care is within health systems. It's not an interoperability outside. Doesn't appear to be a major issue. We thought this met criterion.

And that is the summary of our review.

* **Clarifying Questions from PTAC to PRT**

CHAIR BAILET: Thank you, Bob. We're going to open it up to the Committee to ask the PRT questions or clarifying questions before we have the submitters come to the table.

I just want to remind everyone that we, as a Committee, have not discussed this proposal until right now, and while the PRT has had a very exhaustive analysis and talked amongst themselves and talked with the submitter and an outside expert and looked at the literature, et cetera, we, as a Committee, have not indulged in the analysis. And so this is really live, and I just wanted to make that point, because I think there's been some

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speculation that perhaps the Committee has been meeting off-camera and deliberating, and I want to make sure that that has not, will not happen. We have a very good DFO who keeps us on task for that.

So I would like to now open it up to Committee members for clarifying questions of the PRT. Bruce.

DR. BERENSON: I should have asked my fellow reviewers if they have any comments they would want to make. Grace and Jeffrey?

DR. TERRELL: I've just got a quick comment, and you talked about it in ways, as you were talking about the problem with the payment methodology. I've been thinking a lot, over the last few days, about the fact that it's an incredibly good thing that this proposal came to us, because it means that there's a new technology, in this case a drug out there, that's going to make a great deal of difference in the lives of a lot of people, if they take the drug, and therefore don't get cirrhosis or transplant or other things that are related to having chronic hepatitis C.

The thing that is worrisome for me is the concept of the technology and tying that to life years saved, which I think has got some real strong ethical things that have to--to the point that we made in the PRT--have to be thought through at a much broader, larger level than this

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one thing. You can imagine that a surgeon who does an appendectomy on somebody with a technology called a scalpel has saved many life years, and you can imagine that a general internist who is checking feet compliantly and therefore somebody doesn't have an amputation is saving much to the system.

So part of the real issue with respect to this, I think the reason it came up, is because it came up because it's a new technology and we know that if we can figure out how to coordinate this across a group of patients that it is a great thing for them. But I absolutely believe that the way that it was articulated with respect to the payment system is something that is a large, broad, ethical issue that needs to not be sort of determined by this particular PRT.

CHAIR BAILET: Thank you, Grace, and I would just -- I would echo your comments and just add that this is a very challenging population for the compendium of additional medical maladies -- illnesses, and also the behavioral health component with this population. And so I applaud the proposers and the submitters for bringing this forward. I think it's a unique circumstance in that there's actually a cure, and that not only helps the individual patients, it also limits the exposure and the risk of downstream infections.

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So again, I think it has tremendous merit on that alone. What I do struggle with, as a PRT Committee member, is the payment methodology. Again, this life savings has a lot of challenges associated with it, some of which we're going to discuss in more detail as we deliberate. I think that's the only other comment I would make at this point.

Bruce.

MR. STEINWALD: Thank you. Once again, if the answer to my question is in the materials and I missed it, please forgive me.

Are the chronic care management codes already being used to bill for services to hep C patients?

DR. BERENSON: Are they being used by these particular facilities, or are they being the old -- in general?

MR. STEINWALD: In general.

DR. BERENSON: Yes.

MR. STEINWALD: They are. Okay.

DR. BERENSON: And, in fact, I would quote from the proposal, which is now a number of months old, "With recent expansion of the Medicare monthly chronic care management codes, key supportive services such as health promotion and medication adherence support that are critical for patients to achieve self-sufficiency and treatment completion are now reimbursable to providers and

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can foster creation and adoption of a payment model to support integrated care leading to a cure of HCV."

So it seemed to us that the proposal itself was saying that the chronic care management codes, with this issue of non-clinical staff, I think there's an answer to that one, which we can get into. It seemed like they were saying we already have the ability, under the Medicare fee schedule, to support this delivery model. And so in discussions I think we should sort of probe a little more as to why they need a new payment model. Our view was largely for the shared savings component, which we have problems with.

CHAIR BAILET: Harold.

MR. MILLER: I am going to -- most of my questions I'm going to direct to the applicant, but the one thing I wanted to ask Bob and colleagues for, if I read this correctly -- and maybe I'm just completely misperceiving this -- it's not a shared savings model. They are -- the way I understood the way this is written is that it is -- there is an outcome and they get a bonus or a penalty based on whether they achieve the outcome, and they're trying to calculate the magnitude of the bonus or penalty based on an estimate of some amount of savings. The actual amount that they get is not related, in terms of how much they actually save. It's simply an estimate.

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And I think, if I read it correctly, that they could have come in and simply said it's a $200 bonus if we make it and it's a $200 penalty if we didn't, but they tried to sort of relate it to something. Which, in a sense, if you'd say, well, we have the whole MIPS system, which makes up the number four percent, nine percent, you know, like so what's that based on? But here they tried to, in fact, say that the bonus or penalty was related to something. Whether it's related to the right thing or not is a different question that we'll come back to.

But am I misperceiving that? It's not actually -- it was not intended to be based on actual savings. It's simply a calculation of a bonus or penalty amount.

DR. BERENSON: I think that is correct, and so it's not really shared savings. It is they get a portion of estimated savings over what could be a lifetime of illness or burden.

MR. MILLER: But it doesn't change based on what anything actually happens. There could be no savings and they would get the bonus and they're --

DR. BERENSON: No, but I would say, in defense, that the SVR measure is a good surrogate measure for successful treatment and predictability of what spending would be, but to go out many years I think is problematic.

But to your other point, if this were a simple,

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like pay-for-performance model, that they would get a bonus if they hit the target, with some penalties if they don't, that would have been a different thing to consider. But they felt very strongly that this was the payment model they wanted to go forward with.

MR. MILLER: Okay. I'll ask them more questions about that whenever they come up.

CHAIR BAILET: Any other comments from the Committee members before we invite the submitters?

[No response.]

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

CHAIR BAILET: Okay. We'd like to invite you folks up to the table, and flip over your table tent nametags there and introduce yourselves. And you guys have 10 minutes and then we'll open it up for questions. Thank you.

And just to be clear, there's you guys here, in person, and there are about four or five folks on the phone as well. So we want to make sure everybody has an opportunity to participate. Thank you.

DR. WINTERS: Hi. On behalf of all the partners associated with Project INSPIRE, we'd like to thank the PTAC members for reviewing our payment model and the PRT for providing their preliminary findings.

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My name is Dr. Ann Winters and I'm the Principal Investigator on INSPIRE and the Medical Director of the Viral Hepatitis Program at the New York City Department of Health. Joining me today from the Health Department is Marie Bresnahan, program director, and Dr. Kyle Fluegge, health economist. From Weill Cornell Medical College, Dr. Bruce Schackman and Dr. Czarina Behrends, and, most recently from Montefiore Health System, now transplanted to South Carolina, Dr. Alain Litwin.

Our colleagues joining by phone are, from Montefiore, Dr. Shuchin Shukla, primary care provider; and Mr. Paul Meissner, program administrator. From Mount Sinai Medical Center, Dr. Ponni Perumalswami, liver disease specialist; and Dr. Jeff Weiss, behavioral health specialist. And from our payer partners, Lauren Benyola from VSNY Health, and Rashi Kumar, from Healthfirst.

INSPIRE stands for *Innovate and Network to Stop Hepatitis C and Prevent complications by Integrating care, Responding to needs, and Engaging patients and providers*. It was based on the Ryan White HIV Care Coordination Program, which is a proven model of integrated medical and behavioral health service for people with HIV/AIDS. INSPIRE is an approach to the treatment of patients chronically infected with the hepatitis C virus that includes comprehensive care coordination services to

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support patients through treatment and educational or mentoring sessions for clinicians learning to treat patients with hepatitis C.

This collaborative effort was funded for three years by the Centers for Medicare & Medicaid Innovation, as a Health Care Innovation Award designed to develop new payment and service delivery models. It was a time-limited intervention that officially ended on August 31, 2017. It is our goal to share clinical and payment innovation with physicians and payers more broadly to create a sustainable path forward, ultimately leading to the elimination of hepatitis C.

Given the population health burden of this disease and the availability of new therapies used to cure it, we felt it imperative to move this work forward in hopes of creating a national model to support care for hepatitis C.

We also feel it is important to highlight the timeline of our evaluation activities. In our final written communication with the PRT on December 8th, we provided preliminary results of the analyses supporting our proposal. We regret that we were not able to provide this information sooner. However, we are happy to engage with the PRT and the full PTAC to discuss these findings to help the Committee more fully understand the nuances of our

proposal.

We also want to emphasize that although the results are new, they don't change our original payment model in any significant way. They only provide empirical support for the model as it was originally proposed. Given the time limitation of our Health Care Innovation Award and the urgency of hepatitis C as a public health crisis, we wanted to take this opportunity to present to you all today.

Now I will turn the floor over to my colleague, Dr. Alain Litwin, who will discuss hepatitis C and the Project INSPIRE intervention in more detail.

DR. LITWIN: Great. Thanks so much, Ann. I'm Dr. Alain Litwin. I worked until recently at Montefiore Medical Center, and as was pointed out previously, have now moved down to the Vice Chair of Department of Medicine at University of South Carolina School of Medicine and Greenville Health System and Clemson University. I was one of the lead clinical partners, along with Mount Sinai Medical Center, on Project INSPIRE and I want to take a few minutes today to describe a bit more about Project INSPIRE and to highlight and clarify some key aspects of our proposal.

Deaths associated with hepatitis C in the United States have reached an all-time high of 19,659 in 2014.

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That is the most deadly infectious disease in America today. This number exceeds those attributable to 60 other reportable infectious diseases, including HIV and tuberculosis. An estimated 3.5 million Americans are living with chronic hepatitis C, which is the leading cause of liver failure and hepatocellular carcinoma, and accounts for approximately 40 percent of liver transplants in the United States. Liver cancer is one of the fastest-growing cancers in the U.S., and 50 percent of cases are related to hepatitis C infection.

Approximately 75 percent of persons with chronic hepatitis C infection were born from 1945 to 1964, the baby boomer cohort, and this aging population is more likely to have other chronic illnesses that could be complicated by hepatitis C infection. An estimated 40 percent of persons living with hepatitis C have comorbidities, including behavioral health problems, substance use disorders, and chronic conditions such as HIV, diabetes, and kidney disease. Persons with a history of injection drug use who tend to have numerous comorbidities are at the greatest risk for hepatitis C infection.

Both the World Health Organization and the National Academies of Science, Engineering, and Medicine agree that aggressive treatment of hepatitis C is necessary to eliminate the disease as a public health problem by

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2030. Guidelines from the Infectious Disease Society of America and the American Association for the Study of Liver Diseases recommend treatment for nearly all individuals affected with hepatitis C, given the highly effective treatments currently available and the large burden of hepatitis C in the United States, especially among the baby boomers, a sizeable portion of the Medicare population. We feel strongly that now is the time to move forward on this proposal.

In addition, the treatments are so effective. We've heard that. But if we don't match the care delivery systems to these treatments we're really not going to meet those goals. And, you know, our patients are dying over the next, you know, five years. Many have cirrhosis. Half of our patient population has cirrhosis. And so it's really -- we know, with the current models of care, there's no Ryan White system for -- you know, as there is for the HIV population. The majority of patients have a history of injection drug use and there's no health care system. It's a fragmented health care system, and I'll talk a little bit more about how the care coordinators are helping, you know, across these comorbidities.

Historically, treatment for hepatitis C has been limited specialists, which has resulted in long wait times, low rates of cure for patients, since they're not getting

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seen. One of INSPIRE's main strategies is to increase provider capacity for hepatitis C treatment by training primary care providers, addiction medicine, and infectious disease physicians to manage patients, and to allow patients to remain connected to the outpatient clinic where they are likely already comfortable receiving care.

The INSPIRE model is led by a liver disease specialist, usually a hepatologist. This specialist meets regularly with primary care, addiction medicine, infectious disease, and other physicians via in-person meetings, webinars, or teleconferences during which they learn how to treat hepatitis C and connect to a liver disease expert to support and mentor them. In addition to providing this mentorship, a specialist remains available to accept timely referrals for patients with advanced liver disease.

You know, one of my patients we treated with triple therapy and then developed liver cancer, but because we were screening appropriately we were able to get the patient to see a colleague, Dr. Jonathan Schwartz, in a timely manner, you know, undergo chemoembolization and radiofrequency ablation, and then when it was needed for a liver transplant, able to get a transplant for the patient. It's not just about handing over to the specialist, but the primary care and specialist can work together, hand in hand, because there are a lot of issues of fear, of

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mistrust. And even at the time when the transplant was available, you know, the patient had some barriers with transportation, needed to take the subway, and, you know, we were able to, you know, hold that liver so that he could, you know, get that, you know, transplant, and he is doing very well today. So I just wanted to -- it's really about, with the screening, you want to be able to work hand in hand so we can optimize our screening protocols.

In New York City, in addition to providing some mentorship, the specialist remains available to accept timely referrals, as I mentioned. The call for specialist support of primary care physicians and other non-specialists has been a recurring theme for the U.S. health care system for years. Our care delivery model directly addresses this largely unmet need.

In New York City, this model was implemented at 23 participating primary care, infectious disease, and drug treatment clinics affiliated with Mount Sinai Medical Center and Montefiore Medical Center. Even in a dense urban environment such as New York, providers with limited time cannot easily travel across town to consult with and learn from a specialist. All of our tele-mentoring sessions were conducted using readily available, inexpensive teleconferencing, webinar, and screen-sharing technology. And we feel confident this model can easily be

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replicated in other settings, including the urban, suburban, and rural settings, just as Project ECHO proved.

Let me provide a bit more detail about how the intervention works. The tele-mentoring services were designed based on the Project ECHO program, which sought to improve access to care for rural, underserved hepatitis C patients in New Mexico. As in Project ECHO, the webinars included presentations by hepatitis C specialists, hepatologists, infectious disease specialists, and behavioral health providers, as well as others working with chronically infected patients. Primary care and other physicians were able to present cases for discussion during the webinars and receive real-time feedback on care and treatment options from the other clinicians, including liver disease and behavioral health specialists.

In our surveys with clinicians who participated in tele-mentoring, they reported an increased confidence in their ability to identify and treat patients with hepatitis C, and along with gains in knowledge they spoke about the sense of community that developed with their INSPIRE colleagues as a result of the tele-mentoring sessions and ongoing transfer beyond the sessions. They reported the satisfaction of being able to receive real-time feedback on how to treat some of their more complicated patients as compared to traditional consultation. And after a few

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months, most of the clinicians involved felt ready to mentor other physicians interested in treating hepatitis C and began serving as an expert within their clinic for hepatitis C-related questions from other staff.

In this model, the other significant benefit to the physicians was working alongside the care coordinators who provided health promotion and coaching, and the promotion is along multiple domains. It's around mental health, around substance use and alcohol use, diet and exercise, alcohol- and substance-use counseling, medication adherence support, appointment reminders, referrals to medical and social services.

You know, with respect to the point of kind of care coordination across these other comorbidities, 80 percent of our patients who are currently injecting were seen by substance abuse treatment, and 40 percent of who were former injectors were also in care, so that was really crucial in taking care of this population.

The liver education related to hepatitis C reinfection risk as well as guidance on future liver health, including the ongoing need for liver cancer screening after cure for patients with advanced fibrosis and cirrhosis. And, again, 51 percent of our patients had advanced fibrosis and cirrhosis, and we were able to demonstrate we could take care of these patients in a

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collaborative manner.

A coordinator's guide to their patients to effectively navigate the health care system by keeping them connected to the outpatient clinic and out of the hospital and emergency room, in particular because of focus on those comorbidities.

In addition, a key role of the care coordinator is to support the clinical team and patient navigating the health insurance system, the hepatitis C medications and prior authorization requirements that require significant time and attention on the initial paperwork and subsequent appeals that, in some cases, are required. Having a supportive role of the care coordinator to handle these issues allows the clinical providers to focus on optimal care delivery.

Just some brief comments on our proposed payment model but I think important. Overall, the proposed INSPIRE advanced alternative payment model is designed to support a more efficient and effective approach to hepatitis C care and treatment by allowing physicians and liver disease specialists to work at the highest level of their training, thereby ensuring overall care is streamlined for the sickest patients. The bundled payment will support tele-mentoring and care coordination of people with complex needs. There are critical elements that are inextricably

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linked in getting eligible patients access to treatment, you know, motivating them to want treatment, which, in fact, many do not; supporting them through therapy and achieving cure.

The PRT did ask us to consider existing payment methodologies, but we found that a reimbursement approach using the Physician Fee Schedule and the Outpatient Prospective Payment System would not fully support the INSPIRE bundle of services as providers would lose an average of $98 per patient. Our bundle includes tele-mentoring to provide the team-based training necessary to expand hepatitis C treatment into primary care settings and the care coordination services. We feel a one-time bundled payment is necessary to cover the cost of these two critical elements.

With respect to the risk component of the payment model, we recognize the PRT's concern with our shared savings definition, which is based on future medical cost savings associated with this curative treatment. However, this approach project . . .projects benefits in a manner consistent with value-based payment methodology and represents a particularly innovative path beyond traditional fee-for-service reimbursement in Medicare. Furthermore, these savings calculations reflect the recent advances in hepatitis C pharmacotherapy options, which

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consistently achieve cure rates of 95 percent, and also slow progression of disease and liver complications by more than 80 percent, with some patients experiencing regression of liver cirrhosis after therapy.

In our proposal, the estimate of future cost savings is based only on the presence of cirrhosis and age. These data are easily extractable from a claim form, thereby enhancing our model's transparency. The savings are calculated using only medical costs for hepatitis C-related disease avoided due to cure and do not attribute any economic value to the life years gained and are not estimates of lifetime savings.

Furthermore, to ensure that savings estimates are conservative, they have also been revised downward to account for the fact that additional years of life saved do, in fact, result in additional medical care costs to Medicare for other diseases. The revised estimates in the savings table from our original proposal may be further revised downward to reflect a more modest assessment of a total savings potential to Medicare.

We want to emphasize that although the amounts seem large for the type of intervention we have conducted, the bonus and payback rates set by CMS can impart a very reasonable average bonus and payback structure, and we have demonstrated this in our payment model simulation results

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sent to the PRT on December 8th. In this way, the proposed payment model is very flexible in its design.

So I want to thank everyone for the opportunity to clarify important information about our proposed payment model supporting and expanding treatment of hepatitis C in primary care and other settings, and we look forward to the questions you might have. Thank you.

CHAIR BAILET: Thank you.

So, we now open it up to the Committee for questions. Harold, it looks like you're first up.

MR. MILLER: Thanks. So, first of all, commendations to you for the work that you've been doing on an important problem and for trying to think through a way to support it. As I read through all the material, and I guess it sort of struck me, as I was reading through it, that there seemed to be -- I'm just going to sort of tell you my impression, then you correct me where I'm wrong -- that there's really two things going on here. One is you're trying to get people to take and complete the course of medication to be able to successfully do that. And, second, you're trying to help manage their overall care to keep them from showing up in the emergency department, hospitals, et cetera. And those are two very different things, which have some -- a little bit of overlap in the sense that what you're calling care coordination involves

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contacting the patients; some of which is take your meds, finish the course; some of which is, you know, see your PCP or don't go to the ED or whatever. So there's kind of like the same person is doing some of those things, but they're two really very different things, which you've sort of lumped together in a way that I think kind of is a little bit confusing and problematic.

The first part I think is an innovative concept. You're basically, it seems to me -- it sounds like you're creating an outcome-based payment that says if you actually achieve not just process measure, did they actually take their meds, but if they actually achieved SVR, then there's a bonus or a penalty, so it's an outcome-based payment, which we have almost nothing like that in Medicare, and my impression again, which I appreciate your reaction to, as I said earlier, is that it's simply a bonus or a penalty based on whether you did it or didn't and you've tried to figure out the amount of that based on this rationale, but fundamentally that's determined in advance. There's an amount that you calculated, this is the bonus, this is the penalty.

Then, the second part -- and I'll just try to lay out my understanding of this, and you can tell me where I'm wrong. So then the second part is you're -- oh, and part of that is that there's a mentoring process for the PCPs or

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FQHCs or whoever it is that you're doing -- that also needs to be paid for in some fashion. It sounded to me like a lot of that mentoring is coming from the specialist, a little bit maybe from the care coordinator, but I wasn't quite clear on that.

And then the second piece is there's care coordination to try to keep people out of the ED, et cetera, but it seems oddly focused just during this period of time when they're taking their medications; whereas, it didn't sound to me as though the risk associated with going to the ED, et cetera, was somehow uniquely associated with that period of time. And the notion that somehow we're going to pay for this care coordination during that particular window of time -- not before, not after, but only during that window of time -- seemed odd -- odd to me.

And so in some sense it seems to me that -- and I'll have some further questions, but there may be value in trying to pay to get people to take their medication because today nobody gets rewarded if they actually successfully do that, right? So there might be some value to doing that. And there might be some value to trying to do care coordination with this population if they're highly at risk.

So the question is, after all that is, am I, in fact, correct that there's like those two pieces and you

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kind of sort of mushed them together into this model? Or have I missed the boat?

DR. LITWIN: Sure, I can start. So many of our patients, 65 percent of our patients, have a history of injection drug use, and so with that comes a lot of comorbidities and so forth. And the actual period of engagement is -- and correct me if I'm wrong -- about 10 months, so it's really the pre-treatment period which may last up to 24 weeks. Treatment actually now, you're correct, is quite short. It could be even as short as 8 to 12 weeks; and post-treatment, where people are at risk of reinfection. So it's really a moment, kind of a long period of time in which we can engage patients who otherwise have not been able to be engaged. And so in many ways, the hepatitis C becomes kind of the vehicle and the foundation for being able to -- people, you know, although some need to be motivated, others are already motivated and just need that access to care because they're being denied it by other providers because of certain behaviors, and then now can engage in other areas, in other comorbidities, whether it's their addiction or mental health. And there's been, you know, literature out there to show that there's kind of upward spiral, transformation, because people are used to -- unfortunately, in the United States, many states restrict people that are actively using drugs to even get

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the hepatitis C treatment. But by allowing them to have that treatment, which is what the guidelines say, then you can work on other areas. So I think --

MR. MILLER: But am I correct, I'm just asking, are there two goals? One is get people to finish their meds and get SVR --

DR. LITWIN: Yes.

MR. MILLER: -- and the other is to try to manage them to keep them out of the ED, out of the hospital, et cetera?

DR. LITWIN: Yeah. I think there's more than that, though. I think the overall goal is to improve the health of --

MR. MILLER: Okay, at least two goals.

DR. LITWIN: Yes. Those two goals are correct.

MR. MILLER: At least two goals, okay.

DR. LITWIN: Absolutely.

MR. MILLER: So let me just focus on the first one for a second. I have a couple questions about that. So you didn't mention at all -- I didn't find it -- any statement about what the start and not complete rate was for people. Is that high in this population or not?

DR. LITWIN: Sure.

DR. WINTERS: Start and not complete for patients who enrolled in our intervention or in general patients

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with hepatitis C --

MR. MILLER: Who take -- who start the medication but don't finish all the dosage.

DR. WINTERS: So we --

MR. MILLER: Or does everybody who starts it automatically get to the end, almost always?

DR. WINTERS: So definitely everyone who starts does not get to the end.

MR. MILLER: What percentage would you guess that would be?

DR. WINTERS: So it's difficult to look at that over a large population because we don't have all of the claims data from all payers to look at everyone who's ever been started on treatment. But we can say that -- looking at New York City, we can say that our care cascade shows that we estimate 146,500 patients living with chronic hepatitis C and using a combination of surveys, where we think about 60 percent of patients know their status, going from there we think only about 17 percent of those patients have completed treatment, and that's as of 2016. We've had good, direct-acting antiviral therapy available since 2014. So even though we have these excellent drugs available, we know that patients are not getting treated, and there are a lot of barriers involved to that.

So while I agree with Dr. Berenson that this

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medication is really magic, that's not all it is.

MR. MILLER: But my question, I just want to be precise about my question. How many people start but do not finish therapy? Just your guess. Is it 10 percent, 50 percent?

DR. WINTERS: Actually, we have some of our payer colleagues on the line, and I'm wondering if one of our colleagues from Healthfirst might be able to answer that. Sort of into the air.

MS. KUMAR: Yes, hi. This is Rashi. Can you hear me?

DR. WINTERS: Yes.

MR. MILLER: Yes.

MS. KUMAR: Okay, good. So I'm actually seeing if I can look up the data right now, but from my recollection, it was really only a handful of patients who started the therapy and didn't complete.

DR. WINTERS: Rashi, are you talking about patients on INSPIRE or patients in general?

MS. KUMAR: I'm talking about INSPIRE patients who were in Medicaid.

MS. BRESNAHAN: And then can you tell about the Medicare study that you also looked at, Rashi?

MS. KUMAR: Sure. So we're based in New York, and a lot of our members are in the Bronx, and we looked at

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one delivery system in the Bronx, and there it's Medicare beneficiaries who were infected with hep C, and we actually saw that only about a third of them had actually accessed in recent years a beneficial drug therapy for that -- for that condition. And we also noticed that a lot of them that were on the treatment -- not a lot, but a decent proportion, maybe 10, 15 percent, it looked like they either didn't complete treatment or had interrupted their otherwise inefficient treatment.

MR. MILLER: Okay. I was just wondering because if simply getting them to start is the key thing, that's different than saying that they started and stopped, because you presumably have wasted a very expensive medication. And I didn't see that mentioned in terms of what you were achieving, is that that might be involved with that.

DR. LITWIN: I would say 10 to 20 percent, I mean, different -- you know, from our experiences because of intersection with the criminal justice system because of drug use, you know, going on binges and maybe being out of care, lost to follow-up, mental health conditions, being hospitalized across different sectors. Many patients will get into one institution or another or go away to rehab.

MR. MILLER: Okay.

DR. LITWIN: So it does happen. It's not 50

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percent, but it's a significant problem.

MR. MILLER: Okay. Just two more questions. The second one, I didn't quite understand how -- you didn't seem to be stratifying the patients in any fashion or stratifying the payment. There was sort of a payment for everybody, as opposed to saying, boy, this subset of patients are going to really need intensive support, these aren't; and these patients are going to be much less likely to complete or whatever, or need much more care coordination. I didn't quite see that, and I wasn't sure why.

DR. FLUEGGE: Hello. I'm Kyle. We've -- So we've done some additional work on that. You didn't read it in the proposal because it wasn't fully outlined.

MR. MILLER: Why don't you pull the microphone a little closer to you?

DR. FLUEGGE: Sorry. So we have -- Is this better?

MR. MILLER: Mm-hmm.

DR. FLUEGGE: Okay. So we have kind of thought about this issue further in terms of how we would try to get away from solely having a physician attribution system for payment -- or for patients, and we've come up with having two bundles essentially. So we have the Bundle 1, which comprises sort of the care trajectory for more

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complex patients, so these would be dual-eligible patients, patients with substance abuse disorder with a prior treatment failure for hepatitis C, and other really complex conditions. And then we have a second bundle that is for less complex patients, so those who would not fit into that category.

So we did a cost analysis that would adjust the episode of care payment that we originally derived and included an adjustment for that. In terms of, you know, carrying the two-bundle approach forward, we would recommend having a different -- potentially a different SVR benchmark for the patients enrolled in Bundle 1 versus Bundle 2, and then also having some modification with the shared savings payback amounts based on the type of bundle we're talking about.

MR. MILLER: When I was reading the evaluation, the evaluator's report, the second-year report on the HCIA award, it described you as working on a three-phase payment model, and you didn't propose that, and I'm curious as to why. You didn't propose that to us, but it sounded when I read the report as though that's what you had been working on.

DR. FLUEGGE: You're correct. That is accurate. But we had designed it in terms of three phases, like you mentioned, but for the third phase, it was mostly just

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focused on SVR where there wouldn't be a tremendous amount of interaction between the patient and the provider, and so that portion of the -- we just weren't confident that that portion of the bundle would be covered by something like complex chronic care management codes. So that's why we wanted to create a bundle that includes the entire episode from enrollment to SVR documentation.

MR. MILLER: Yeah, but then you were kind of going through all kinds of machinations to figure out how you were going to give it back if you didn't complete. That's why I was wondering why you -- because your original model sounded like it would be a more natural -- as the person reached each stage of what you were trying to get them to, you would get another payment associated with that, which seemed to me it was better matched -- because to me, payment should be matched to what you're trying to do rather than us trying to “let's see if we can figure out how to make the chronic care management code fit this thing that we're trying to do”. But your episode payment didn't quite fit it either because it presumed that people were going to do everything whenever they weren't, and then you had to figure out how to give it back or to adjust your methodology. So it just seemed to me that that was better aligned with the way you were actually treating patients and spending dollars.

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I'll stop there. Thank you.

CHAIR BAILET: Thank you, Harold. Len?

DR. NICHOLS: Thank you. So I was intrigued -- first of all, cool. Second, I was intrigued with the costs that you left out, and in particular, I guess what struck me was, if I read the sentence right, the payment model will not cover labs, imaging. I get that. Medication, which is surprising, and I'll come back. Mental health and psychiatric services, and then some cancer I can't pronounce.

So, what I'm really curious about is two parts: One, the mental health; and the second then are the medication, because if I understand, if you will, the logic of the expected future savings, a lot of that has to do with the services that will not be delivered because the person gets medication and gets cured. But you've taken the cost of the medication out and yet Gilead priced it to capture that value you're trying to claim. So there's kind of a potential double counting here. So --

DR. SCHACKMAN: So, the market is acting very quickly in terms of the pricing of the medications right now, so the prices have come down substantially due to competition and new introduction of new treatments. The list price has dropped from, I think it was $90,000 originally, was the original and directed price, to

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something around $26,000 now. And we felt that the market dynamics are such that the market is, in fact, sort of speaking in terms of what is going to happen in terms of that valuation. And so it would be very hard to predict what those prices would be -- cost would be going forward, and to introduce Part D considerations into this payment model would add too much complexity.

DR. NICHOLS: I totally get the complexity and I love the way the market's actually working. That's a good thing. We're happy about that. In [unintelligible] school, right? But the point is, yes, those prices have come down. They should come down more. But the larger point is those prices were set originally and are still to some degree fighting over the potential savings to the patient, which your model is trying to claim. That's what I'm getting. Why not have that cost be part of the calculation that then offsets some of the gain that has been -- because you wouldn't get the gain without the medication. That's the question.

DR. FLUEGGE: So I think one of the ideas we had to include that was to adjust the bonus payment table by the amount -- essentially the non-adherence that generated missed, you know, medication. So, yeah, that's one avenue that we're considering, but, again, it adds complexity that we didn't necessarily want to --

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DR. NICHOLS: Okay, okay. And so, obviously, you settled on this really novel notion of expected future gains, which in principle I'm attracted to, but I guess maybe you could go through some rationale. Why did you reject a more traditional shared savings calculation so that we could understand why you chose what you did as opposed to --

DR. FLUEGGE: Yeah, sure. So --

DR. NICHOLS: -- what we're used to.

DR. FLUEGGE: Right. Well, so we're focused in this intervention on a cure, which a lot of APMs that have been proposed to you previously, really that's not something that you see a lot of, and so we wanted to recognize that and incorporate it into our payment model. We wanted to align a payment model with our national elimination goals. We wanted to give physicians the opportunity to see that there is a potentially great bonus to be had by identifying and following up with patients with the use of tele-mentoring, with the use of care coordination, and so we really feel like that gives the appropriate incentive to actually attain that.

CHAIR BAILET: So we have Bob, Grace, and then Paul.

DR. BERENSON: Yeah. I want to try to pin down this issue of the applicability of the chronic care

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coordination codes because I just have this feeling that you've come up with shortfalls by not including the facility fee that, my guess -- and this is purely a guess -- is being kept by central administration at Montefiore and Mount Sinai and isn't flowing to the clinics, but the payments are being made. For every $53 that you did acknowledge in your proposal for the 99487 code, complex chronic care management, $72 is being paid to your institutions. Those payments together make up significantly more than the $760 you're requesting, would support the $98 shortfall for tele-mentoring, and so my -- so I have two questions.

One, is my logic right or wrong? And two, are your institutions actually actively using the complex chronic care management codes today? So rather than estimating shortfalls based on just what's printed in the Federal Register, you're actually having experience by using it. As Harold said and as our PRT report said, these patients need complex chronic care management before, during, and after their treatment for hepatitis C, and I haven't gotten any sense -- and we've asked -- that that's actually happening. So if somebody would try to handle those two issues.

DR. FLUEGGE: So I can try to address your first question. I think somebody on the call, on the phone, can

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probably address whether they're being used or not.

So we actually -- we took the PRT's advice and tried to cost this out based on our internal analysis to see whether the combination of codes within the physician fee schedule and the outpatient prospective payment system could actually support the intervention as we've designed it.

And what we've found was that in the initial phase -- so this is the pretreatment phase, when care coordination is at its most intensive effort -- the use of monthly chronic care management codes is not sufficient to support that effort, but then if you factor in that all patients actually enter into Phase 2, that is to say, they are treatment eligible, then hospitals and providers would be able to recoup the entire cost of the intervention.

But the problem with that is not all patients start treatment, and so as we've outlined in our final written response to the PRT was there's about $100 loss per patient, and so we don't feel like that is -- we feel that is enough of a deterrent that using the complex chronic care management codes wouldn't be --

DR. BERENSON: But the complex chronic care management code could be used for patients who don't enter treatment, so okay.

DR. LITWIN: Paul Meissner, are you on the call

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there?

MR. MEISSNER: Yes, I am. Hi. Good afternoon.

I'll just say this from the Montefiore perspective. We have not billed for this, and because the code takes the place of all levels of services and it can only be assigned to Medicare patients, and so this has always created an issue for us. And so it has not really -- we really only get a Level 2 billing or a Level 4 billing, and so one level of billing is what we would be allowed to do.

And it is done in the outpatient ambulatory facilities, and in our state in New York, we are Article 28 clinics only. And so that is only a part of the Montefiore enterprise. I mean, those are the parts that serve as our Medicaid-serving facilities.

DR. BERENSON: But surely you're not asking for a payment model from Medicare to pay for Medicaid patients, are you?

MR. MEISSNER: No. No, no.

DR. BERENSON: Is that what you're doing?

MR. MEISSNER: No. No, no, no.

DR. BERENSON: But many of these patients are Medicare duals, and I don't understand why you couldn't get the CCM (Chronic Care Management) payments for that significant population. In any case -- go ahead.

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MS. BRESNAHAN: We understand that most facilities aren't using the CCM codes at their. . . . that they're difficult to implement and not easy to use.

DR. BERENSON: Well, that's what I was suspecting.

And my supposition or at least view that in fact a facility fee is going somewhere but not -- so you're not using it, so it's not going anywhere, so never mind.

CHAIR BAILET: Grace.

DR. TERRELL: So one of the things that you commented on was actually tying this to real outcomes and having physicians benefit from that. I want to really pin you down on that a little bit because I really think this is a big, big issue.

So the cost of services is what we're actually talking about right now, and there may be semantics. It may be PRT got it wrong; PRT got it right; you're not using the code that you could have, would have, should have, whatever. But there's a cost to this service that you all can measure and then figure out whether you're getting paid adequately for it also. Okay. That should be a baseline thing.

The thing that bothers me a lot is the idea that the cost of services that happens to have an awesome outcome ought to necessarily always be correlated with an

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awesome payment if the cost recovered.

As I mentioned earlier, examples like appendectomy, let's go -- I'm a general internist, so there's a lot of things I do that probably have a big outcome that maybe could be measured, like a vaccine or something, for which the cost is in the Medicare fee schedule covered. But it's not this big, big amount of shared savings on top of that, that's related to outcome.

At the level of when you all were thinking about this, which I think's a radical idea -- it may not be a bad idea, but it's radical -- Did you think about the implications of that? I'm talking about at a deep ethical level with respect to trying to value what you're doing, which has enormous value, in something that's not tied to the actual cost of providing it, because it's a big deal.

DR. FLUEGGE: Yes. So, we did consider that. I did consider that, but I really want to stress a point that I think might have been overlooked in the PRT review process, and that is there was -- I get the sense that there was a hyper-focus on the amounts in the bonus payment table, that these are huge savings that will be distributed, and in reality, so we -- I included it in our final written communication, an actual simulation of this payment model in terms of what would potentially be the outcomes, whether it's a bonus or a payback. And the

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simulation for just using the Medicare beneficiaries and accumulating all this data on their liver disease stage and their age and the top performing clinics and INSPIRE generate -- they met the benchmark, as we defined it here. And they received about a $340 bonus per patient for those high-performing facilities. It depends on what you set the savings rate at or the payback rate at, but these are not intended to be tens of thousands of dollars in potential bonuses.

DR. TERRELL: But there's nothing particularly in your methodology that would prevent it from being tens of thousands of dollars; for example, if 100 percent of the savings over a lifetime. So it could be 1/1,000,000th of what that number would be or it could be 100 percent of it, right?

DR. FLUEGGE: Well, in theory, it could be 100 percent, but we would advise adding a cap to that --

DR. TERRELL: Okay.

DR. FLUEGGE: -- so that there isn't -- you know, you can only go up to a certain level before -- I mean, there's opportunity to grow and earn a higher bonus, but then once you reached a certain cap, you can't go any higher than that.

DR. TERRELL: Yeah. But the general principle is in there, okay, that there would be an outcome payment

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that's based on a total savings to the Medicare medical system over time that's related to the outcome as opposed to the cost of providing the service.

DR. FLUEGGE: Yes.

DR. TERRELL: Okay.

DR. LITWIN: I just wanted to say that hepatitis C, again, is a public health crisis in that 20,000 deaths per year, more deaths in 2007 for HIV, and the current system and current paying models have not adequately addressed. And so that's why we're -- this radical, innovative model is necessary because, you know, we've been working -- I've been working in this space for 17 years, and patients are not getting cared for. Only 10 to 20 percent of people are getting care, and meanwhile, my patients' average age -- 50, 55, 60 -- they're dying of liver cancer. They're dying of -- they're not getting transplants because they don't have the social support. There's not enough organs out there. They're using drugs or drinking alcohol.

And so I do think, just to separate a little bit, I think there's a window. If we don't get this right in the next 5 to 10 years, you know, our fellow Americans, they're going to be dead. And these other conditions you bring up, I'm not certain that there's the same barriers that were seen, you know, with appendectomy, for instance.

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DR. TERRELL: Okay. Let's talk about Pap smears for a minute. Okay. If women didn't get Pap smears, there would be a lot of people out there with cervical cancer that are not there now. We've done tremendous things as a result of this public health, private screening, preventative care since 1940s, when it was first in place. When that first came out, should those physicians have gotten outcomes payments because it hadn't yet crossed the system?

I mean, the issue is that you're talking about, a current crisis with a new cure, it's not embedded itself yet into the medical system with a solution that you all have that's making a big impact. So this is a big deal, but these are big questions with respect to how it ought to be -- how it ought to be thought through above and beyond hepatitis C because what if we -- what about the next thing that comes out and the next and the next? That's what I'm getting at.

You're saying it's a crisis now, so we ought to do this, but there will be new crises. And one day, maybe this will be routine care. So can you address that from that point of view?

DR. LITWIN: Sure.

I'm just going to say one thing and starting over, but I do think it potentially could be a model for

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other important problems, whether it's on the prevention side or treatment side, that are not being addressed adequately, and thousands, tens of thousands of lives are at stake.

But I'm going to turn it over to --

DR. WINTERS: Yeah. I just was thinking about what you were saying, sort of the ethical side of having this SVR as the outcome and paying based on that, and I think Kyle has clarified that there can definitely be a limit on that, so that people are not making this 100 percent of the possible bonus.

But I think, you know, I sort of like flipped it a little bit to think about, “Why do we even need this when we have had curative therapy?” In the testimony from your expert, Dr. Goldberg, he noted that gastroenterologists do not want to treat these patients, and they don't treat these patients because there's a lot that comes with treating the patients that they can't take on, that the care coordinators in our model are taking on. And so I think, you know, we are just trying to think of an innovative way to get people interested in these patients and to take something that's easily measurable with electronic health records and to set a hospital facility-level mark, and that can be adjusted down.

So if you have a clinic that serves 100 percent

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in active injection drug users, you know you're not going to get an SVR of 80 percent, so this can be adjusted in the model.

But I think the ethical question for us is, you know, we don't want to pay providers hundreds or thousands of dollars to do this. We just want them to do it, so we're trying to figure out how to motivate them.

DR. TERRELL: And a regular pay for performance couldn't do that, performance not based on years lives saved, medical treatment, just standard of care?

DR. FLUEGGE: Well, I think how we devised the model was with a -- very much a population health objective, and we wanted to base potential bonuses on that as opposed to individual outcomes.

But I just want to add one other thing. You mentioned about the outcomes-based payment, and I really don't know of another payment model where testing that approach would be appropriate because, like I said earlier, we are focused on a cure, and there aren't -- there simply aren't that many, at least now, hardly at all -- I don't know of any -- that focus on that as the outcome.

And so if you were looking at our payment model for a potential limited-scale implementation, I think it really speaks to that kind of experimental approach to see whether this outcomes-based reimbursement would actually

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work and what kind of quality outcomes it can deliver.

DR. WINTERS: Just one more comment, is that I think the precedent is already set with the pricing of the medication, so -- I mean, we aren't the first to sort of think about this and kind of what costs are averted, and ours is a much smaller consideration.

CHAIR BAILET: Thank you.

Paul.

DR. CASALE: So I'm married to a hepatologist, so that can be very dangerous because I have a little bit of knowledge but maybe not enough to understand what I'm talking about.

But you mentioned about supporting the tele-monitoring of PCPs. So it's my understanding that at least there's this movement. As you said, the gastroenterologist, the average gastroenterologist may not be interested or is not interested in treating, but there's been this sort of movement to train the nurse practitioners in particular, internal medicine, as you've mentioned.

So I guess I'm looking for some comments. Isn't there already a movement to -- whether it's not necessarily tele-monitoring, but develop team members, nurse practitioners, specialists in particular to help do all of the things that you are describing to do in this model in terms of improving treatment rates, helping to coordinate,

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get the authorization for the right medicine, all the things that are difficult to do but need to be done?

DR. LITWIN: That's a great question.

The fundamental problem is that the majority of the patients who were affected, infected with this virus and by this disease in the community were not even yet engaged in care, and so to move patients from Point A to Point B out of their kind of place or their neighborhood and their patient-centered home where they get their care, whether it's a drug treatment center or an HIV clinic, ID (infectious disease) clinic, or an FQHC, that's where the patients are comfortable. And when we've looked at referring people to capable people, whether they're nurse practitioners or hepatologists to another place, where they might not have wrap-around services, the cascade of care is just dismal.

So I do think it's a piece of it, and that's part of it, but that's not going to get us to where -- that's been happening for some time, and that won't get us to where we need to go.

Dr. Perumalswami or Dr. Weiss, do you have any comments on this question?

DR. PERUMALSWAMI: Alain, this is Ponni Perumalswami from Mount Sinai.

I would completely agree with you. I think

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definitely figuring out ways to engage these patients, where they reside is a really important part. One of the strengths really of the tele-educational piece to this model, where we could really work with primary care physicians in the community, where these patients are located, to engage them and really get them optimized before we start them on treatments or health promotion and then coordinate their care and get them initiated and through treatment to cure.

MS. BRESNAHAN: And I just wanted to add that with this model, we were really looking at cost savings, and we found that care coordinators are less expensive than other health professionals, and they're often -- we recruited them from the communities. Many of them are bilingual. They speak Spanish. They know the neighborhoods, and we found it so effective in helping these patients. And yet really their cost is minimal in terms of -- than other people. The other health care team can work to the level of their license rather than doing the kind of health promotion and other work that the care coordinators have done in our work.

DR. LITWIN: I just want to point out that Dr. Perumalswami is a transplant hepatologist at Mount Sinai.

DR. CASALE: Great. That's helpful.

And just one other, Jeff, if you don't mind.

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Thinking not just in New York or in a big urban center, but thinking of hep C nationally -- and as you mentioned, it's the baby boomer population, and again, a little bit of knowledge may not be a good thing. But there's a lot of baby boomers who may have done a little bit of IV (intravenous) drugs back in the '60s, and they've gone on and they don't realize that they have hep C. And you're trying to get to them too, right? So they don't have necessarily the complex -- you know, the mental health, the ongoing IV addiction, et cetera, and this would be for that group as well, presumably.

And so in the whole sphere of hep C treatment for U.S., what percentage makes up the very complicated sort of metropolitan New York versus this other group? Which is they don't know they have hep C. We're trying to get them in. They are identified. They get treated, and off they go because they don't have all of that. So I'm trying to understand that issue.

DR. LITWIN: I think, you know, it's certainly a mixed bag here. I think setting up a system like this, and a model, will incentivize institutions to incorporate, you know, a cohort screening within the EMR (electronic medical record), and, you know, things that we've done at Montefiore and Mount Sinai, so that we can pick up those people that are otherwise, you know -- before they get

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cirrhosis, and unfortunately we see these patients all the time. Our model also accounts for the two different bundles. I don't know if you went into that, Kyle, yet?

DR. FLUEGGE: Yes.

DR. LITWIN: Go ahead.

DR. FLUEGGE: So yes, the two-bundle definition is intended to address that issue, and I can't quite speak to the proportion, in terms that you're requesting, but, yeah, the bundle two, the less-complex patient, is intended to be at a reduced cost, and, like I say, have potentially higher quality metrics associated with it, you know, less risk adjustment because, like you say, you know, these patients did drugs one year in their life and, you know, have been straight -- on the straight and narrow since.

So, yeah, the two-bundle approach is how I --

DR. LITWIN: And increasingly across America, you know, clearly there are pieces that are undiagnosed and that would be a great outcomes that they get diagnosed and into care, and won't need the level of services. But many of the people that don't have those comorbidities, who, you know, maybe had in the distant were cured, and so now we're trying to work with the 80 percent of patients who do have comorbidities who will really need these models of care. And it is the majority in urban centers, but beyond that,

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you know, suburban and rural areas as well.

DR. FLUEGGE: There is that significant under-diagnosis problem with hepatitis C. So I don't think -- I think even if we gave you any kind of initial idea, we could be wrong.

DR. PERUMALSWAMI: This is Ponni Perumalswami, hepatologist from Mount Sinai. You know, data from the National Academy of Medicine and Centers for Disease Control and Prevention still estimates that, you know, 50 percent of people have not yet been successfully diagnosed and transitioned into care. So I do think that what we've certainly seen at centers such as ours, where we do see a number of patients with hepatitis C, a large majority of the patients who we are now having to engage do have a lot of active comorbidities, psychosocial issues, and really, you know, from a clinical standpoint, can benefit from really having care coordination models integrated into their care, so that they can be referred to other social services, make sure that they make their other appointments in order for them to prioritize hepatitis C care, evaluation, and management. So I do think that's an important piece to this.

DR. WINTERS: I'd just like to add one more thing, just, again, in regard to Dr. Goldberg's comments. So I think that patients who appear at a private

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hepatologist, at a medical center like University of Pennsylvania, or who, themselves are now getting transplants -- so those are the populations that he was referring to -- those patients, you know, who are presenting themselves for care and are making it to the appointments, I think we feel like a lot of those patients in New York have been treated. So the very private hepatologists are not seeing the same volume that they saw a couple of years ago.

On the other hand, patients who are in substance-use programs, or in opioid replacement therapy, patients who are not yet diagnosed but have known substance-use issues, and homeless and other communities, I think these are the patients that we want to treat where they are or where they're comfortable being, and not just for themselves but to prevent transmission. I think that's a really major, an important piece of all of this.

So I think patients who have been easy to treat, many of those patients have been treated.

DR. LITWIN: And we really need this model now to address -- you know, in some of our Sinai clinics and Montefiore clinics we've treated many of our patients, but just across the country, in FQHCs and substance use treatment programs there's, you know, hundreds and thousands of patients that are sitting around, progressing

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to cirrhosis, and it's -- you know, we need to incentivize and motivate our providers through an innovative model, is our belief.

CHAIR BAILET: Thank you. Tim?

DR. FERRIS: So I'm going to ask you a question that's based on the notion of if you were in our shoes. So clinical model, outstanding. Absolutely critical public health problem, and you've got a clinical model that addresses that, and I haven't heard anything here that disputes how fantastic your clinical model is. Most of the discussion is about the payment model.

And I want to ask you, so the CCM codes are difficult to implement. We've implemented them and it took us years after they were first rolled out. If -- and say the CCM code were simplified and you could bill it -- and, by the way, just to clarify a comment that was made by someone on the phone earlier. You definitely can bill for services in addition to the CCM code. That is the intent of the CCM code. It's care coordination services on top of the usual services.

So if such a code existed and it was usable, and it fully reimbursed the costs -- and this is where the put yourself in our shoes -- if that existed and that was applicable to heart failure, COPD (chronic obstructive pulmonary disease), all the other things that both require

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significant adherence issues -- daily Lasix, volume status up and down, same set of issues -- and the care coordination issues, but was based on more of a cost-plus model, which is more of a standard way to think about here's your costs and then there's some incentive that's on top of it, to make sure that people are excited about doing it, right. Now, I'm not going to represent that the CCM code necessarily does that, but it is existing, and they actually have changed the rule. They've simplified the rules related to its use and clarified some things over time, which is the standard way policies work in the world.

If such a code did meet these needs, would it might be your first choice for a national policy related to how to address this issue?

DR. FLUEGGE: I can speak to that. No, is my short answer, and the reason is because our model is not specifically a care coordination-only model. And I think we're at fault, to some degree, because in our original proposal we didn't emphasize this enough. But there is a significant tele-mentoring component that is very instructive for how we expand access to care. And beyond that, I've heard -- I've watched you guys online before -- and I've heard this mentioned before, that, how can we --

MR. MILLER: So, what did you think?

[Laughter.]

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DR. FLUEGGE: I have to admit it, though. It was enthralling to watch.

[Laughter.]

DR. FLUEGGE: Oh, bravo. Fantastic. But you all have mentioned that it would be ideal to sort of have these various payment models and accumulate the best attributes of some of those.

So, what the tele-mentoring component provides in our model is not only a way to train primary care physicians for treatment of hepatitis C but it is bigger than that. It could include PCP training and mentoring for other complex chronic conditions that currently are not being reimbursed within CMS, according to the Social Services Act.

So we really think that, you know, unfortunately we didn't emphasize it enough in our original proposal, but we really think that's on par with the value that care coordination offers. So I would say, again, no.

CHAIR BAILET: Harold.

MR. MILLER: So, Tim and I are thinking along similar lines. So if the CMS administrator were to show up on your doorstep tomorrow and say, "We really like what you're doing. We'd like to offer you a $700 per payment, patient payment, that you can use for tele-mentoring and for care coordination, and we'll give you a $200 bonus if

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you successfully hit SVR status for the patient, and we'll give you another $200 bonus if you keep their rate of ED and hospitalization below an average level," would that support your program?

DR. FLUEGGE: I don't think so. It's not -- I mean, this was --

MR. MILLER: It sure sounds like it's paying for the cost. It's giving you the incentive to be able to get people to complete treatment. It's giving you the incentive to manage their care effectively.

DR. FLUEGGE: But it's not transparent, and here's why. You're throwing numbers out there as if, you know --

MR. MILLER: You can change the numbers.

DR. FLUEGGE: Right. But we wanted to create a payment model that was based on actual claims and clinical data that would suggest the value of an SVR. And, you know, the $200, well, what --

MR. MILLER: I understand what you want. I'm just asking you a separate question.

DR. FLUEGGE: Right.

MR. MILLER: If somebody came to you with that model tomorrow and said, "Here it is," would it support your program, which I understand the funding has ended for. If somebody came and said, "We'll give you $700 per

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patient, and we'll give you a bonus for success, and we'll give you a bonus for reducing ED visits," would it support the continuation of the good work that you're doing?

DR. FLUEGGE: I would think it probably would.

DR. WINTERS: Is somebody coming to offer us that plan?

MR. MILLER: We are hoping that someone will come and offer someone something, based on what we do here, but we need to figure out what it is that we're doing first.

CHAIR BAILET: All right.

DR. WINTERS: I would just also add that, you know --

MR. MILLER: We'll bring you, at most, one $700.

DR. WINTERS: -- just to be able to answer a question like that is really challenging. I mean, I think you can tell that Kyle has spent a lot of time thinking through and doing a lot of analytical work, so it's a little bit challenging to be able to say “yes” or “no” to a theoretical question like that.

MR. MILLER: I understand that. So just one quick follow-up. I mean, you said that the costs that you needed to support were roughly $700 per patient, or so on, right? The rest of it was, quote/unquote, "an incentive." So I'm simply asking, you are doing good work, you need to be able to cover that cost. We can debate about whether

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the chronic care management code does or doesn't do it, and whatever. I'm just saying that if, in fact, that's what it costs -- because at least from my perspective, I understand what you're trying to do and I think there's some merit in thinking about how you price an incentive, based on something.

But, fundamentally, what we're trying to deal with is if there is good care to be delivered that cannot be supported under the current payment system, what is the nature of the payment that needs to be able to be done to do that? And if we get into really complex incentive models and payment amounts that are unnecessarily complicated, that your whole thing falls apart because you didn't achieve some ideal that you wanted when we could give -- because somebody might say, "It's worth $700, right? We agree and we're going to give you an incentive to make sure that you achieve the outcome. Be done with it." And if that would work, then --

DR. WINTERS: I think when we started thinking about that, that wasn't something that we had available to us. So I think that we're trying to think creatively about it.

CHAIR BAILET: Bob?

DR. BERENSON: Yeah. Just a couple of points. One is, to just pick up on Kyle's point, the -- we -- about

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a year ago I did a disclosure here that I was doing work with Project ECHO, and I was actually disappointed that this proposal really didn't emphasize tele-mentoring. And we didn't explore it, and tele-mentoring might be a very good payment model that we would -- I mean, a delivery model that we would want to support.

The presentation -- I mean, the proposal basically -- even the title of it is "Using Care Coordination." It wasn't part -- it was mentioned. It was sort of a given that we do tele-mentoring, and we need care coordination support. So that's point number one, and if, in fact -- so I think that would be a different proposal, actually, if it was emphasizing tele-mentoring.

And then the second. I've got a real problem with the fact that the administrations, apparently, of these two institutions have found the complex chronic care code too difficult to work with. It got a lot simpler in 2017. A place like Partners is able to do it.

[Laughter.]

DR. BERENSON: These are patients who not only need care coordination for their hepatitis C treatment, but as the PRT emphasized, they should have ongoing care coordination because they have -- by far the leading cause of hospitalization in patients with hepatitis C is psychosis, and you can go down the list of non-liver-

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related conditions that these patients have. Sixty-seven percent of them are on Medicare for disabilities, not because they aged in, and yet these two institutions somehow can't bill for the code and can't otherwise support, so that you're going to lose $98. I just find the whole thing --

So I don't think you're asking for a new payment model. I think your savings thing is a new payment model, which a lot of us have expressed some concerns about. But care coordination is not a new payment model. In Medicare it may be too complicated, it maybe should be simplified. You're just looking for some cash flow, and that's my concern. I think that's the issue here, is that -- now tele-mentoring would be new, but just figuring out how to send a check for care coordination strikes me as not innovative.

CHAIR BAILET: Thank you, Bob. Elizabeth.

VICE CHAIR MITCHELL: Thank you. I also want to compliment you on what is obviously excellent and important work.

I guess I would just note that I think a significant portion of our conversation is talking about elements of the proposal that aren't actually in the proposal, that they could have, or should have, or would have been, or Harold’s going to go to your institution and

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write you a check? I don't know. But I think that there's clearly merit here. The fact that we're actually talking about a cure at all is remarkable. But I guess I would just suggest that we needed to keep this to the actual proposal in front of us, and I think that we might need to move to public comment.

*** Comments from the Public**

CHAIR BAILET: Your timing is impeccable, Elizabeth, because I see no other placards up, and that's the next move.

We have two people on the phone. Yeah, so maybe before we start we're going to ask you guys to return to your seats. That would be great. And thank you, again. Thank you for coming, and we appreciate all the dialog.

So we have two people on the phone, and as they're taking their seats, the first person is Annette Gaudino, Treatment Action Group, and we're going to go ahead and, please, you have three minutes to make your comments. Thank you.

UNIDENTIFIED SPEAKER: Three minutes.

CHAIR BAILET: I said three.

UNIDENTIFIED SPEAKER: I thought you said 30.

CHAIR BAILET: No, no. I said three. I said three. Some might have heard 30.

Please, go ahead. Thank you.

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MS. GAUDINO: Good afternoon, everyone. Thank you for providing me the opportunity to make a public comment. I apologize for the background noise. I had to sneak away to participate. I will also submit comments in writing.

I'd like to just speak in strong support of the payment model and the work that's being done by the New York -- sorry, by New York City DOHMH. I truly believe that care coordination is the evidence-based intervention that we need in order to scale up hepatitis C treatment and to start to move towards elimination of hepatitis C as a public health threat, which the WHO (World Health Organization) has set as a target, and which we think is feasible in the United States and in New York State.

I believe that the piece that the payment model is trying to address, the care coordination, which has been discussed, is something that the other health care paraprofessional can do is that kind of one-on-one interaction with patients that not only can help them deal with their other health needs but them engaged in care, to know that there is cliff, two cliffs in the care cascade. First is diagnosis. Second is getting people started on treatment, and with all the barriers that exist for treatment, but particularly with patients who are dependent on the public health care system for their care.

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I really appreciate the comment that was made about a significant number of patients who haven't aged into Medicare but are actually -- have a disability diagnosis, and that is how they are getting their care through the Medicare system. These are patients that have a lot of needs, and a care coordination model can meet those needs. I think it's a really creative way to price into the health care system care coordination and that kind of extra support.

I appreciate the comments that have been made in terms of, you know, the details of that payment model and how you balance the cost and sustainability of that care versus just a pure incentive. Smarter minds than mine can speak to those details, but I think the overall direction and approach that has been taken in New York City and New York State has been one that we really want to build on and want to encourage.

So, again, I just want to wrap up and say I strongly support, and Treatment Action Group strongly supports this payment model and we really hope that CMS will take a good look at this payment model and consider supporting it, not just for hepatitis C but for other chronic conditions, particularly with marginalized patients and patients that struggle with psycho-social issues. Thank you very much.

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CHAIR BAILET: Thank you. The next person on the phone is Edwin Corbin-Gutierrez from the National Alliance of State and Territorial AIDS Directors.

MR. CORBIN-GUTIERREZ: Hi. Can you hear me?

CHAIR BAILET: Sure, we can.

MR. CORBIN-GUTIERREZ: Thank you. I would like to start by thanking the Physician-Focused Payment Model Technical Advisory Committee for the opportunity to share comments on Project INSPIRE, led by the New York City Department of Health and Mental Hygiene.

NASTAD is the association that represents public health officials who administer HIV and hepatitis health care, prevention, education, and supportive service programs in state, local, and territorial health departments. NASTAD works closely with health departments across the country to build sustainable financing mechanisms to provide access to hepatitis C prevention and care and its related support services. And hepatitis and health systems integration programs at NASTAD collaborate to increase the coordination across public health programs, to leverage existing infrastructure and expertise, to improve health outcomes, identify strategies to maximize public and private insurance coverage options, and identify promising practices to engage health care systems and payment delivery and evaluation mechanisms that will

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support health outcomes for individuals living with hepatitis C.

As has been mentioned, more Americans now die as a result of hepatitis C infection than from 60 other infectious diseases reported to the CDC (Centers for Disease Control and Prevention) combined, and we also know that in over just five years, the number of new hepatitis C infections reported to CDC has nearly tripled, reaching a 15-year high.

Yet despite the looming public health crisis that this epidemic poses, there is much more that we can do as a nation to ensure that we are deploying the most effective models for care, to ensure that vulnerable populations living with hepatitis C have access to a cure.

And given the prevalence of hepatitis C and the rising mortality stemming from the epidemic, particularly among baby boomers who make up a significant portion of the Medicare population, Medicare payment models must ensure that patients are linked to care, retained in care, and adherent to treatment. Models that provide financial incentives for care coordination activities are critical to ensuring that the most vulnerable populations infected by the epidemic have the support they need to achieve a sustained virologic response to treatment.

From our experience with HIV care through the

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Ryan White HIV/AIDS program, we understand how important comprehensive care coordination and service integration models are to supporting individuals living with HIV to achieve viral suppression.

NASTAD applauds and unequivocally supports Project INSPIRE's integrated model of primary care, addiction medicine, and infectious disease providers, and believes that this model has great promise for Medicare and other health care payers. By incentivizing an interdisciplinary approach to hepatitis C prevention and treatment, including through an innovative care coordination plan, we believe that this model will also support hepatitis C elimination plans across the country.

Furthermore, Project INSPIRE's effort to screen for comorbidities and its strategies to leverage the public health surveillance program is a great example of how public health and health care providers can work in close collaboration to reduce costs and improve individual and population-level health outcomes.

To conclude our comment, I want to reiterate how critical Project INSPIRE's model of care coordination is for vulnerable Medicare beneficiaries infected by hepatitis C to successfully navigate a complex health care system to complete their treatment, and NASTAD urges the Committee to expand coverage for these essential services through the

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Medicare program.

Thank you.

CHAIR BAILET: Thank you.

Any other comments? Folks on the phone? Folks in the room?

[No response.]

* **Committee Deliberation**

CHAIR BAILET: Okay. So, as a Committee, are we ready to move forward with deliberations? Yes.

All right. So let's go ahead and start with Criterion 1 and just note that Dr. Kavita Patel is not participating in this vote, so there will be 10, not 11 folks voting.

Matt the Magnificent.

[Pause.]

* **Voting**

CHAIR BAILET: There we go. I'm feeling it.

[Electronic voting.]

CHAIR BAILET: Alrighty. So just to reiterate, on the voting, 1 to 2, Numbers 1 and 2 do not meet; 3, 4 meets; 5 and 6 meets and deserves priority consideration. You also see an asterisk, which indicates not applicable. That is another element, which we haven't discussed. We touched on it a little bit this morning, but will become more relevant as we get into the proposals later in the

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day. But it is there, and it is available.

So, we are going to go ahead and start voting on Criterion 1, which is Scope, which we see as a high priority that directly address an issue in payment policy that broadens and expands the CMS APM portfolio or includes APM Entities whose opportunities to participate in APMs have been limited. So, we're ready to vote on scope.

Here we go. Ann?

MS. PAGE: Zero Committee members have voted 5 or 6, meets and deserves priority consideration. Zero members have voted 4, meets; five members voted 3, meets; five members voted does not meet. According to the rules of the Committee, we need a simple majority of six members, six votes to determine a category, so that will roll down to does not meet, unless you want a revote.

CHAIR BAILET: I believe this is an opportunity for us as a Committee to discuss it and then revote for sharing points of view, and I see that Harold is activated. Harold?

[Laughter.]

MR. MILLER: Activated. So what's the value of that?

So I voted 3. The reason I -- I think we've all struggled -- I certainly have -- with trying to rate the criteria separately, and I -- part of the reason why I

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asked the questions I asked earlier were that I think there are at least two or three different pieces to this model. Not clear to me that care coordination per se does anything to expand the CMS APM portfolio for all the reasons described earlier, but something that's designed to be able to get people to take their hepatitis C medication, particularly amongst a high-risk population does seem to me to do that, something that enables hepatologists to participate, something that enables PCPs to treat patients with HCV, et cetera, all seems to me to be -- to broaden the portfolio.

So whether one likes the payment model or not, it does seem to me that if, in fact, there was the right payment model that this would, in fact, expand the portfolio. That's why I voted the way I voted.

CHAIR BAILET: Len?

DR. NICHOLS: So rather than line up and explain why we voted for, I want to hear why somebody voted no and then have 45 seconds to rebut.

I can't imagine, this is a population of great need. They're not being addressed at the moment in New York City. Jesus, how hard is this?

CHAIR BAILET: Well, so, Bob?

DR. BERENSON: Yeah. I would say that I would give that credit under Criterion 2, Quality and Cost.

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Here, the scope goes to whether this is a new payment model that deserves high priority, and I guess some of us don't think there's -- in what we've reviewed or liked, this potentially is a -- I mean, clearly, the lines aren't clear because payment model might be where that negative shows up, but I don't think the scope -- so I would put what you said and what Harold said in Number 2 is why, so we can quibble.

CHAIR BAILET: I'm looking to Ann for clarification.

DR. MEDOWS: I move that we re-vote.

CHAIR BAILET: Yes. We will re-vote, but I want to make sure, before we get another outcome, where this is going to go.

So help me understand because this is the first time we've had a split like this.

MS. PAGE: Right.

So the decision rules say -- so we tend to roll down, starting at the highest meets -- and deserves priority consideration, meets, and then the third rule is if the majority of votes are 1 or 2 or if the majority of votes is 1 or greater but not 3 or 4 or 5 or 6, the proposal does not meet the criterion, so that's what our decision rules say.

But, of course, our decision rules allow for what

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you all are just talking about. If there's a split, if there's a significant disagreement, the Committee has the option to talk about it and revote.

CHAIR BAILET: And I'm hearing, then, that we're going to revote. One more time with feeling.

[Electronic voting.]

CHAIR BAILET: One more.

Well, that cleared it up.

[Laughter.]

CHAIR BAILET: Ann?

* **Criterion 1**

MS. PAGE: Zero Committee members voted 5 or 6, meets and deserves priority consideration. Zero members voted 4. Six members voted 3, meets. Three members voted 2, does not meet. One member voted 1, does not meet; and zero Committee members voted not applicable.

A simple majority is six, and so six members have voted that it meets this Criterion 1. That is the Committee's decision.

CHAIR BAILET: Okay. We're going to go on to Criterion 2, Quality and Cost, which is a high-priority item anticipated to improve health care quality at no additional cost, maintain quality while decreasing cost, or both improving quality and decreasing cost.

Go ahead and vote, please.

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[Electronic voting.]

* **Criterion 2**

MS. PAGE: Zero Committee members voted 5 or 6, meets and deserves priority consideration. Two members voted 4, meets. Seven members voted 3, meets. One member voted 2, does not meet; and zero members voted 1 or not applicable.

The majority finds that this proposal meets Criterion 2.

CHAIR BAILET: Thank you, Ann.

Moving on to Criterion 3, Payment Methodology. Pay the APM Entities with the payment methodology designed to achieve the goals of the PFPM criteria addresses in detail through this methodology. Medicare and other payers, if applicable, pay APM Entities and how the payment methodology differs from current payment methodologies and why the physician-focused payment model cannot be tested under current payment methodologies.

A high-priority item, please vote.

[Electronic voting.]

* **Criterion 3**

MS. PAGE: Zero members voted 5 or 6, meets and deserves priority consideration. Zero members voted 4, meets. One member voted 3, meets. Five members voted 2, does not meet. Four members voted 1, does not meet; and

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zero members voted not applicable.

The majority of Committee members have determined that this proposal does not meet Criterion 3, Payment Methodology.

CHAIR BAILET: Thank you, Ann.

We're going to go on to Criterion 4, Value over Volume. Provide incentives to practitioners to deliver high-quality health care.

Please vote.

[Electronic voting.]

CHAIR BAILET: Ann?

* **Criterion 4**

MS. PAGE: Zero Committee members voted 6, meets and deserves priority consideration. One member voted 5, meets and deserves priority consideration. Three members voted 4, meets. Six members voted 3, meets; and zero members voted 1 or 2, does not meet. And zero members voted zero, not applicable.

The majority has determined that this proposal meets Criterion 4.

CHAIR BAILET: Thank you, Ann.

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

Go ahead and vote.

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[Electronic voting.]

* **Criterion 5**

MS. PAGE: Zero members voted 5 or 6, meets and deserves priority consideration. Six members voted 4, meets. Three members voted 3, meets. One member voted 2, does not meet. Zero members voted 1, does not meet; and zero members voted not applicable.

The majority finds that the proposal meets Criterion 5.

CHAIR BAILET: Thank you, Ann.

Criterion Number 6 is Ability to Be Evaluated. Have the evaluable goals for quality-of-care cost and any other goals of the PFPM.

Please vote.

[Electronic voting.]

* **Criterion 6**

MS. PAGE: Zero members voted 5 or 6, meets and deserves priority consideration. One member voted 4, meets. Three members voted 3, meets. Five members voted 2, does not meet; and one member voted 1, does not meet. And zero members voted not applicable.

The majority determined that this proposal does not meet Criterion 6.

CHAIR BAILET: Thank you, Ann.

Criterion Number 7, Integration and Care

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Coordination. Encourages greater integration and care coordination among practitioners and across settings where multiple practitioners or settings are relevant to delivering care to the population treated under the PFPM.

[Electronic voting.]

* **Criterion 7**

MS. PAGE: Zero members voted 6, meets and deserves priority consideration. One member voted 5, meets and deserves priority consideration. Zero members voted 4, meets. Seven members voted 3, meets. One member voted 2, does not meet. One member voted 1, does not meet; and zero voted not applicable.

The majority finds that this proposal meets Criterion 7.

CHAIR BAILET: Thank you, Ann.

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

Please vote.

[Electronic voting.]

* **Criterion 8**

MS. PAGE: Zero members voted 5 or 6, meets and deserves priority consideration. Four members voted 4, meets. Six members voted 3, meets; and zero members voted

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1 or 2, does not meet. Zero members voted not applicable.

The majority finds that the proposal meets Criterion 8.

CHAIR BAILET: Thank you, Ann.

Criterion 9, Patient Safety. Aim to have maintained or improve standards of patient safety.

Please vote.

[Electronic voting.]

* **Criterion 9**

MS. PAGE: Zero members voted 5 or 6, meets and deserves priority consideration. Three members voted 4, meets. Six members have voted 3, meets. One member voted 2, does not meet. Zero members voted 1, does not meet. Zero members voted not applicable.

The majority finds that the proposal meets Criterion 9.

CHAIR BAILET: Thank you, Ann.

And the last, Health Information Technology, encourages the use of HIT (health information technology) to inform care. Please vote.

[Electronic voting.]

* **Criterion 10**

MS. PAGE: Zero members voted 5 or 6, meets and deserves priority consideration. One member voted 4, meets. Nine members voted 3, meets; and zero members voted

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1 or 2 or not applicable.

The majority finds the proposal meets Criterion 10.

CHAIR BAILET: Thank you, Ann.

Do you want to summarize on all 10 real quick? Thank you.

MS. PAGE: The Committee found that the proposal met 8 of the Secretary's 10 criteria. The two criteria that the proposal did not meet is the payment methodology and the ability to be evaluated.

CHAIR BAILET: Thank you, Ann.

I look to my colleagues before we vote on the final recommendation, if there are any other additional comments based on the voting. Are we ready to go ahead and move into the --

[No response.]

CHAIR BAILET: Very good. So the way this will work, we will vote initially electronically, and then we'll go around the room individually and talk about our vote. And included in those comments specifically, we're going to record comments that we would like to be incorporated into the letter to the Secretary, and we're going to make sure that we take the appropriate time to bookmark those so that there's no confusion after the fact, because we can only deliberate in public, so --

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MS. PAGE: And a reminder to those in attendance that on this recommendation, the Committee's decision is based on a two-thirds majority rather than a simple majority, so we will need seven votes in favor of a particular recommendation.

CHAIR BAILET: All right. So 1, we will not recommend it to the Secretary; 2, recommend for small limited-scale testing; 3, recommend to the Secretary for implementation; 4, recommend the payment to the Secretary for implementation with high priority.

And I'd like to clarify the differences between 2 and 3. While the wording -- 2 is if it's pretty much untested or there are elements that are untested, where a small -- smaller limited implementation would allow learnings to be able to sharpen the proposal to a larger-scale testing or larger-scale implementation. That was the middle ground. Three, although you don't see the word "testing" in 3, that doesn't mean that in the implementation process, there wouldn't be a testing. It's just the limited-scale testing that we wanted to call out specifically in 2.

So, we are ready to vote, please.

[Electronic voting.]

* **Final Vote**

MS. PAGE: Zero members voted 4, recommend the

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proposed payment model to the Secretary for implementation as a high priority. Zero members voted 3, recommend to the Secretary for implementation. One member voted 2, recommend the proposed payment model for limited-scale testing; and nine members voted 1, do not recommend proposed payment model to the Secretary.

Those nine members constitute more than a two-thirds majority, and so that is the recommendation of the PTAC to the Secretary.

* **Instructions on Report to the Secretary**

CHAIR BAILET: Thank you, Ann.

I'd like to start with Rhonda. If we could then speak to our individual votes. Thank you.

DR. MEDOWS: So I'm the sole 2 vote, recommending -- What am I trying to say?

CHAIR BAILET: Limited-scale testing.

DR. MEDOWS: Yes, that's what I wanted to say. Because I am most interested in naturally seeing put to test the measures that are based on life years gained with SVR and seeing a different way of taking a look at this population.

CHAIR BAILET: Bob?

DR. BERENSON: Yeah, just a couple of points. One is that this is one of a number of proposals we've seen where the burden of trying to use the Medicare chronic care

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coordination codes has come up. I think our comments should reflect the -- I mean that fact and the need to see if -- there have been improvements already, and some institutions like we've heard are now moving to use those codes. But it seems to me that we've had an inordinate number of proposals to use for new payment models when solutions may be found with changing the rules. So I think we'd want to emphasize that and that that was one of the -- I hope there's agreement, one of the primary reasons we did not recommend this.

And then the second thing I would say is it would be great if we had proposals, more than one, on tele-mentoring as a potential innovation that deserves its own consideration as a payment model, and I am just wondering if we are allowed today and whether we would be allowed with some prospective changes in our authority to actually send our solicitations for we would like to see proposals on such and such a topic.

Are we allowed to do that rather than be passive recipients of proposals that come in over the transom, to send out a request for proposals on Topic A or B?

MS. PAGE: We would need to check with counsel on that.

DR. BERENSON: You're shaking your head, Mary-Ellen.

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MS. STAHLMAN: I suspect not because PTAC, it's not in your statutory charge to send out. An RFI (request for information) or an RFP (request for proposal) would be a government function.

DR. BERENSON: Yeah, yeah.

MS. STAHLMAN: So I'm guessing not, but we will definitely follow up with general counsel and confirm back with you all.

But I will say that there are other opportunities for you to -- in your -- the material that you put on the website, submitter's instructions or other documents, or speaking engagements that you have as private and in your own careers, that would allow you to encourage models, not --

DR. BERENSON: Well, okay. I get that.

So I just -- I would like our report to the Secretary to reflect the fact that in fact this was presented as a care coordination proposal, was emphasizing care coordination, and that we were interested more than we had an opportunity to delve into the potential of broad application of tele-mentoring as an innovation that needs support, something like that.

CHAIR BAILET: Len.

DR. NICHOLS: So I voted to not recommend, but I do so with a heavy heart because this population should be

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addressed. I'd like those people involved when it gets addressed, and what really breaks my heart is that they've been doing it with this HCIA funding, and that's about to die, and we're not going to be able to continue it in time. So that's bad.

I would also say the main reason I voted no was because I'm really worried about the principle of basing a payment on projected savings that can be attributed to a number of different activities. In this case, the real savings is from the medication. I get that they wouldn't get the medication without your intervention. That's why I want you to be funded. But we can't base payment based upon prospective value because then we're back to what's the value of penicillin. It's pretty high. So we got to be really careful about that. But it seems to me in about an hour we could come up with a better way to work this out, and Harold's already put together a possibility. It just seems to me that I would say to the Secretary this principle is important for us to establish, that we shouldn't base things on future value of life saved, but this population and these people need to be connected to a payment model that will work. And I would be thrilled to lay down some principles to make that happen, and I think we should encourage the Secretary and the Department to work out another alternative and have them come back with a

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different proposal. That's what I would like to say.

CHAIR BAILET: Elizabeth?

VICE CHAIR MITCHELL: I'm on the same team. I'm really supportive of the care model, concerned about the payment model. Maine tried to fund a state health program once with projections of avoided spending. Didn't work. And I think that there are possible solutions that hopefully will be found and would just recommend, I guess, expedited attention to how do you fund a program with this high clinical value.

CHAIR BAILET: I echo my colleagues' comments, and the interesting -- This has a lot of merit. You have a circumstance where the consequences of not treating these patients is dire. On the flip side, treating them actually leads to a cure, which is it's not every day in medicine that we have those, both of those ends of the spectrum in front of us, and so, clearly, to me that speaks to the merit to move forward.

I, too, struggled with the payment part of the model, and I want to make sure that we include that that's an opportunity for the Secretary to potentially find an avenue to recognize the work and the effort that this model embodies. But given the model as it's constructed and proposed today, I voted not to recommend it.

MR. STEINWALD: I don't have much new to add. I

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agree with Bob we need to emphasize the use of the care coordination codes. It seems like this is a population that ought to benefit from the availability of those codes, and if not, we should certainly find a way to fix them.

Second, I also agree with Len and others that to base a payment on projected future savings is, I think, fraught with difficulty, and the things that happened in Maine could happen here as well.

I would also agree with emphasizing that it's a population of great need, and with a potential cure for many of those who are not receiving the appropriate drug, there ought to be some suggestion in our language of our report that the Secretary might seek other ways of finding out how to diagnose and treat those patients.

CHAIR BAILET: Paul?

DR. CASALE: Yeah, I also said do not recommend, but also like Len, you know, a bit of a heavy heart for a lot of reasons. One is I'm old enough to remember when there was no name to this virus. It was non-A, non-B. And then they identified the virus, and then they used to treat it with interferon, which was, you know, very difficult treatment. And to have this cure in 6, 8, 10, 12 weeks is unbelievable. And again, being married to a hepatologist, I hear -- you know, I sort of relate and understand. So, they are doing tremendous work.

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In terms of ongoing -- they may potentially be able to continue with trying the complex care management codes, you know, in the interim, you know, once the grant expires to see as an interim potentially. I had the same issues around tying the shared savings to life years gained.

And then, finally, to the tele-mentoring, I think that should be an important part of our discussion with this Secretary, and I think it really highlights the critical issue of access to specialty care, which was brought up, you know, amongst many fields. And so I think we should use this opportunity to really emphasize that, and tele-mentoring is a way to really approach that.

CHAIR BAILET: Thank you, Paul. Harold?

MR. MILLER: I voted to not recommend. I would recommend that in our report we explicitly encourage the applicant to come back with a revised proposal. I would further recommend that we suggest to them that if they do come back, that they describe a payment model in three components, however they wish, but -- because I think we heard there is a component of the model, which is designed to get people to take and complete their treatment. There is a component of the model, which is the tele-mentoring thing, which has been discussed, which is how to reach out to a broader range of primary care physicians for that

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process, and there is a care coordination process for patients, and they may or may not choose to propose all three, I don't know. But it just seems to me that if -- my recommendation would be if it comes back, it would be helpful to see those things clearly articulated in those buckets, because I found it very difficult to understand kind of the mushed-together concept.

I would endorse and maybe put a fine point on it, I do think that we need to say something in our report to the Secretary about the continuing concerns that we have heard here and that I have heard in other settings about the care coordination codes, that they are either too narrowly defined or too complicated to administer, et cetera, which is, from everything I have heard, diminishing their ability to achieve whatever it was that they were supposed to achieve. And I understand the desire to try to define codes narrowly, but it seems to me that it's not working terribly well. And I think we in some fashion, whether it's in the report or in a separate communication, we should be asking applicants who want to do care coordination to come in and clearly describe what they can and can't do with those care coordination codes.

I am troubled by us suggesting that somehow whatever someone wants to do could be squeezed into existing codes when it can't. But I'm also troubled by

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applicants coming in and saying, "No, we just don't bother with those things. We want to have a different model for it." And I do think that if someone attaches an outcome to that, that is, in fact, different. If somebody has a care coordination model that is accountable for outcomes, that's different than what's in the fee schedule because there's no accountability for outcomes there.

The third thing is I would like to have in the report -- my colleagues may not agree with this, but I would like to have in the report -- and if it's not in the report, then I want to be on the record that I think it is -- I am disappointed that the Center for Medicare & Medicaid Innovation has funded many, many projects with the Health Care Innovation Awards, which seem to have had good results, and they're coming out to us with payment models. We are getting no indication from CMMI as to whether they think the payment model -- the project should be continued. It appears that they are simply being allowed to disappear, which the history of health care reform is littered with these projects that were funded with one-time grants and had wonderful results and then just disappeared. And the notion that that is happening again and that they were supposed to be -- it was an integral part of those programs to develop a payment model. And the fact that people are coming to us with payment models that are problematic

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suggests that whatever was being done in those projects was not being done well. And I think that those HCIA awards need to have much closer coordination between us and CMMI, and there needs to be a clearer statement from CMMI as to whether or not they think those projects should continue, because we're being stuck in this weird limbo of trying to decide what needs to be done to support a project. But I think we need to make a statement in there about the fact that it is problematic that those projects are ending and coming to us with no clear indication from CMMI as to whether they have intentions with respect to them, whether they think they should be continued or not, because we may be getting more of them, and as everybody said, with a heavy heart, it's unfortunate to be looking at a project that's clearly ending its funding and maybe at a big institution that can continue it for a while, but if it's smaller institutions, it wouldn't be able to do it, and that's a real problem to put on the burden of us to look at something and say, well, it's not a good payment model, but, gee, it'd be really sad if we're the ones that are saying, no, you can't continue simply because you don't have, you know, the exactly right payment model. So that's what I would like to have in the report.

CHAIR BAILET: And, Harold, since you focused on that, I think -- are there other points of view relative to

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what Harold said? Because we want that to go specifically in the letter to the Secretary. Any other additions? Like I said -- Len, you've got a comment?

DR. NICHOLS: I'm with Harold a hundred percent, and I think putting it in the Secretary's letter is the place to put it. I would put it also in the class of things like tele-mentoring that are things we should try to encourage on a proactive basis. There must be other HCIAs that are in different forms of death throes here. Let's find out what they are and try to save some of them.

MR. MILLER: This is at least the third. I can't remember for sure. I think we have at least three that I remember right now.

CHAIR BAILET: Paul.

DR. CASALE: Yeah, no, I'm just -- I would also support that, and anticipating what Harold said, we would likely continue to see more as these grants sunset.

CHAIR BAILET: Elizabeth?

VICE CHAIR MITCHELL: I would pile on, absolutely agree, and I think that that lack of clarity from CMMI is actually creating stress and anxiety for those who are trying to sustain a really important program. And I think they really deserve some sort of clarity about how to maintain the gains they've achieved.

CHAIR BAILET: And I think to sharpen the

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message, I guess, because of what I'm hearing, I guess I would ask the Committee, should this be -- should this be portrayed as a unanimous perspective that the entire Committee feels that this -- Grace?

DR. TERRELL: No [off microphone].

CHAIR BAILET: Okay. Very good. No.

DR. TERRELL: And maybe this is a little bit of a different issue, but a lot of what I was hearing today was about timing. You know, this may have been a little bit early because they didn't have the results --

CHAIR BAILET: Right.

DR. TERRELL: -- completely done. So I don't know, the Committee may be right that there's all these projects that are -- have great outcomes for which they're dying because there's not a process to go forward. So they're saying, well, go to PTAC or whatever, and we don't have the information. But before we put a unanimous, you know, seal of approval on those comments, I think there needs to be some qualification about is there a process that could take into account something's winding down, but the results of that tend to be a little bit later versus what I'm hearing is almost the desperation that some of these people have in getting something in place that's ongoing.

So before we just sort of make the assumption

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that the process needs something else, we need the understanding if there was a mistake based on their urgency that was related to this coming to us too early, if that makes sense to you, relative to the outcomes and data that would -- you know, because some of the information we didn't get 'til after we had issued the PRT report, for example.

CHAIR BAILET: Paul and then Harold.

DR. CASALE: No, I understand -- I recognize that point, Grace, but I think part of the reality is they've had this funding, they built the infrastructure, and now they don't have the funding, but it's important work they'd like to continue. So, even if the results have this -- now lag, they're looking for a way to continue that work. So I think that's the concern. We don't clearly have an understanding from CMMI, you know, if they're going to provide any -- what they're thinking.

CHAIR BAILET: Well, and to be fair, the results aren't entirely -- they're not complete yet. The data's not complete. Harold?

MR. MILLER: So that is not unique to this project. I mean, the whole structure is -- they're all done now, and we're going to wait for another year to find the evaluation. And so do you say to people, "Gee, sorry, you know, figure out how to continue your program for a

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while until we get the evaluation results"? I think preliminary evaluation results should say, okay, we need to continue this until the final evaluation results are in.

I think the problem is we're being stuck in the middle of any project like that is going to come to us for continuation funding before there is definitive evaluation information available, and that's the problem that I'm trying to describe, is I think that it's a problem that people are coming to us for a payment model with no indication of whether or not it should be sustained from CMMI, whether they have a payment model in mind, whether they have been already thinking about doing the payment model, because if you read the evaluation report, they've been working on a payment model, and all of a sudden it comes to us, and we get no signal whatsoever. That's the issue, is I think that -- it is not -- if it were unique to this project, it would be different. But it is common to that program.

CHAIR BAILET: Okay. And, Grace, when you're done with your comment, then we can finish up as well.

DR. TERRELL: He's got [off microphone].

CHAIR BAILET: Oh, my goodness.

[Laughter.]

CHAIR BAILET: I got left-sided neglect here. Sorry, guys. Go ahead, Grace.

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DR. TERRELL: Unless there is an implicit policy change where they're wanting our analysis before they go forward with something, and if that's the case, CMMI needs to tell us that, which is a little bit of a different and a nuanced -- not that folks were spontaneously just coming to us out of desperation, but if they're being told, well, go to PTAC now, or if they're feeling that, it would be nice for some clarification from CMMI if that's the case, because if we're part of a process, then we need to do it in a much more coordinated way, and that I agree with everybody on. But if this is just sort of random spontaneous, "What do we do next? Well, let's go to the PTAC 'cause, you know, we don't know what to do," then that's something different. So some clarification on that particular aspect from CMMI I think would be useful.

CHAIR BAILET: Thank you, Grace.

Rhonda, and then work our way towards Len.

DR. MEDOWS: [Unintelligible], I just wanted to make sure that it's in the record, whether we agree about the wording around CMMI or not, that the concern is not only that the programs are not funded but there's the risk of care disruption. That's what I heard from the presentation today, and that actually causes me great concern. I know that it's not in the purview of this Committee to make decisions based on trying to preserve

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care, but you cannot listen to this and not understand that something has to be done, particularly when we know that we have a cure.

CHAIR BAILET: Right. Thank you, Rhonda. Bob?

DR. BERENSON: Yeah, well, I wanted to pick that up and repeat what I was implying earlier, is that I find it remarkable that two not-for-profit institutions with requirements for doing community benefits, given results of a successful demonstration which saves lives, aren't willing to carry this program for a year or two until either the CCM codes are modified or a new payment model is developed, that it's all on Medicare's payment to make this whole. We're talking about chump change. And yet apparently these terrific people are being asked to beg us to have some interim payment because those institutions somehow aren't able to continue funding. I just find -- I wanted to have that in the record because I find that unconscionable.

CHAIR BAILET: Len.

DR. NICHOLS: So I think what we got Grace to agree to is asking CMMI for an inventory of HCIA projects that are still extant and for whom there could be some -- and then the question about what is the plan for working in the payment models that were part of the proposal. I would observe every project has an evaluation that's going to be

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formal and finished a year later, but all projects that are multiyear -- and this was at least three years -- surely have interim results that you can use to judge the reasonableness of continuing.

I agree with Bob, in a perfect world, but we don't live in a perfect world, and the do-gooders get cut off when stuff stops flowing. That's what happens, even in those big institutions. So I think the urgency is real.

DR. TERRELL: You got me to agree with that, with the caveat that they make -- they make it explicit, whether they see -- what they see our role in --

DR. NICHOLS: No, Grace. Grace, they don't get to tell us what our role is. They get to tell us what they're doing, and then we talk about how to navigate the role.

CHAIR BAILET: All right. So thank you, guys, for that.

Grace, we need you to go on record relative to your vote, and Tim as well, so please.

DR. TERRELL: Yes, so I voted against this for the payment model aspects. I think most of the reasoning has already been well articulated by the others. There is a couple of things that I heard that I think need some comment on perhaps, and one of it had to do with the concept of covering the cost of care versus I think it was

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Kyle who said motivating physicians to do the right thing. And that is a bit of a theme that I think that we will either have had or will be getting from various payment models with respect to care that in some cases evidence-based, in some cases just a new model of care.

But we've got to understand our role in that. The statute was about the physician-focused payment model and to come up with new, innovative ways to think about how physicians may be paid. We as a Committee, the way our vote went, did not like this particular option that was out there. But that issue is a pretty inherent and important one. I actually think when it's easy for physicians, they do do the right thing. Nobody's ever had to pay me to, you know, give a vaccine so long as my cost of care and the administration is covered and it's easy for me to do.

So the issue, as it was talked about with respect to the difficulty of the chronic care codes, is relevant to what makes it easy for physicians to do the right things for patients. And if we can, as we're deliberating on various things, come up with an approach to that, I think we'll be doing a service not only to this, but it's going to help us with other models that come up.

The second point that Dr. Litwin referred to was related to this as a public health problem, and it is. And one of the things that we have not talked about explicitly

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is if this is a public health problem because we've got a cure out there, there's a portion of the population that's not getting it because of a public health policy issue or because private or in this case government payment isn't covering those services, then that may need to be thought about outside of this particular Committee as it relates to policy in terms of how public health is prioritized and how, if anything, the way physicians are paid ought to be part of the way we think about public health policy. We haven't talked about that, but that may be something that's important for us to think about.

CHAIR BAILET: Thank you, Grace. Thank you for that. Tim.

DR. FERRIS: So my vote is not a surprise. But I voted similarly. It was because of the payment model. I want to associate myself particularly closely with Grace's last comments. I think they were right on point. Our presenters, who are doing amazing work, referred multiple times to the Ryan White Act. I would say the Ryan White funding is highly, highly successful, and does not use any projected savings as the basis for the model. And so, as just one example of the framing of the incentive, both the cost and then what you need to do to incent, and it really is around the infrastructure necessary to make it easy and the right thing to do.

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I do -- and also, so two more points. One is Kyle, who I have to say it was so cool and creative what he did, that I'm feeling a little bit as if I'm being, in my sort of response to his model, I'm being overly conservative, because I want to just acknowledge, that was a really cool idea, to do that.

I will say, though, that he referred to it -- he said, you know, someone else has done it. Private industry did this when they were pricing Sovaldi, right. We're not talking about private industry here. We're talking about U.S. taxpayer dollars and the mechanism by which we calculate incentives for U.S. taxpayer dollars. I think that's a really different thing and a different set of criteria that one would use to look at the basis, the principle around the basis for payments.

I'm sorry. Two more things. One is this separation of the screening from the care coordination really is a separate issue. Screening should be universal. There should be either pay-for-performance or mandated rules around hepatitis C screening for the at-risk population. We've required it in our health system for several years. And so the screening piece of this really -- I see as a different mechanism for implementation and incentives than the others.

And then I just want to be clear, because -- so

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that we're not all on record as being in agreement. So Harold said that there are three different components or phases. I wouldn't recommend coming back with this broken into three parts. I prefer more of a lumper than a splitter. The three different activities that they talked about are all part of what one needs to do to take care of these patients, and we actually fund the ECHO model underneath our care coordination activities because it's -- it's sort of part of it. So I'm not sure I would necessarily say to anyone, you know, break this down into the three components, because then the next one comes and it's eight components, or whatever. I would say they've identified adherence, mentorship, and care coordination as critical pieces of this. I completely agree those are critical pieces. I wouldn't necessarily come back with funding for each of those separately. I'm not sure that is the most productive way forward.

Thanks.

CHAIR BAILET: Thank you, Tim. Len, your placard is up. Did you have a -- you were just testing me?

DR. NICHOLS: I'm nodding.

CHAIR BAILET: Very good. All right. So again I want to extend appreciation to our proposer/submitters for coming, participating, the folks on the phone who have been here for the whole ride, and everybody's attention and

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engagement as we work through the model.

Any other last points? Sarah, because this is the report to the Secretary. You guys --

MS. SELENICH: Sorry.

CHAIR BAILET: It's okay. No, I got it. I got it. Go ahead, Sarah.

MS. SELENICH: So you all were very clear on the key points that you wanted to make in the report, so I don't think I need to rehash them. But one area I would like you to talk a little bit more about was on the care coordination criteria. This is where the full PTAC diverged from the PRT. And so if you could just provide additional comments.

MR. MILLER: I don't understand.

DR. BERENSON: Yeah, if I could just summarize. The PRT failed it on care coordination because the care coordination for hepatitis C didn't seem in any way related to care coordination for these patients ongoing. I mean, you actually made this one before and after the nine-month period. So the vote was not to have a problem with that, and that's what you're asking about.

DR. NICHOLS: I think I learned things from the presentation I didn't get from the proposal and the PRT report, and so I was persuaded, they knew what they were doing.

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MR. MILLER: I would say this is maybe, yeah, one more example of don't let the perfect be the enemy of the good, is that it seemed to me that there ought to be more care coordination than just during that period, but it sounded like what was being done was helpful. It wasn't clear exactly what all was being done there but it was clear that the care coordinator was critical to that. And so it seemed to me that it sort of met the threshold to say there is clearly something good enough going on there that's desirable. Maybe there could be more, maybe there could be more, but it was enough of that, so at least that's the way I looked at it.

MS. SELENICH: Great. Thanks. One other --

DR. TERRELL: One more aspect of it is, both of the proposals that we have seen today have one thing in common with respect to care coordination, which is they are talking about it around the critical point in time with respect to a disease and the potential overall outcome. And I think when I was hearing the conversation today about this one, it became more apparent in that, that's something that perhaps we were thinking about it a different way at the level of the PRT, which was, well, what about the universe and beyond?

But one thing that I'm learning today from -- is that there have been strategies around particular points in

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time for which certain types of coordinating activities may have an impact, and that is something that if you can get a care model and a payment model right around those two components, that are time-limited, that will be something that I think that we should explore in detail as we go forward.

CHAIR BAILET: Thank you, Grace, and --

DR. CASALE: Sorry. Just kind of --

CHAIR BAILET: Paul.

DR. CASALE: -- just one other comment, and again, I think this goes back to the tele-mentoring part of it, because, you know, when I asked about the -- you know, the NPs treating and such, you know, the remark was a lot of their patients don't want to leave their clinic to go somewhere else, which I get. But by using the tele-monitoring, now you can coordinate not just their hep C care but, you know, their cardiology care and their heart failure, et cetera, because now it's sort of coordinated in sort of their home base.

CHAIR BAILET: Thank you. So we've completed our process. I see Ann, Dr. Winters, up at the microphone, and I can't read your mind so I don't know what you're going to say. But, yeah, just -- but -- so -- all right.

DR. WINTERS: Sorry. I know this is probably not the right procedure but we're taking advantage of having

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all of you here. First of all, we just want to thank you so much for thinking so carefully about this, but also we did want to clarify, for the record, that our clinical partners, Mount Sinai and Montefiore, have been extremely supportive, and though they haven't been able to make use of the CCM, the codes, they are continuing to support the program through 340B pricing, but this is not a permanent solution.

CHAIR BAILET: Thank you for that clarification. I think it lifts a little of the heaviness. But you're right, it's not a sustainable model going forward, so thank you for that, Dr. Winters.

So we are going to take a 10-minute break and be back for the remaining two models, to deliberate on. Thank you, guys. Appreciate it.

[Recess.]

CHAIR BAILET: All right. We're going to go ahead and reconvene. So the next proposal is Dr. Yang, Medicare 3-year Value-Based Payment Plan, abbreviated Medicare 3VBPP. Bruce Steinwald is the lead, and I'm going to turn it over to Bruce to walk through the proposal review team's recommendations.

MR. STEINWALD: Thank you very much.

CHAIR BAILET: Oh, I'm sorry. We have to do introductions and disclosures, Bruce, but go ahead. You've

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got the microphone.

Zhou Yang, PhD, MPH: Medicare 3-Year Value-Based Payment Plan (Medicare 3VBPP)

* **Committee Member Disclosures**

MR. STEINWALD: I'm Bruce Steinwald. I have a health economics consulting practice in Washington, D.C., and I have nothing to disclose on this proposal.

DR. CASALE: Paul Casale. Nothing to disclose.

MR. MILLER: Harold Miller, CEO of the Center for Healthcare Quality and Payment Reform. Nothing to disclose.

DR. TERRELL: Grace Terrell, internist at Wake Forest Baptist Health and CEO of Envision Genomics. Nothing to disclose.

DR. FERRIS: Tim Ferris, primary care doctor at Mass. General and CEO of the Mass. General Physicians Organization. Nothing to disclose.

CHAIR BAILET: Jeff Bailet, Executive Vice President of Health Care Quality and Affordability with Blue Shield of California. Nothing to disclose.

DR. MEDOWS: Rhonda Medows, EVP (Executive Vice President), Population Health, Providence St. Joseph Health.

DR. BERENSON: Bob Berenson, Institute Fellow, Urban Institute. Nothing to disclose.

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DR. NICHOLS: Len Nichols, Director of Center of Health Policy Research and Ethics, George Mason University, and I have nothing to disclose.

VICE CHAIR MITCHELL: Elizabeth Mitchell, CEO, Network for Regional Healthcare Improvement. Nothing to disclose.

CHAIR BAILET: Bruce.

* **PRT Report to the Full PTAC**

MR. STEINWALD: Okay. I'm going to give an overview of this proposal, and I invite my fellow members of the Preliminary Review Team -- Bob Berenson and Elizabeth Mitchell -- to jump in whenever you feel like jumping. Okay?

And I'm not going to go over the PRT composition and role -- no, I'll do it. I'm not going to go over that because we've done that enough. I am going to slowly go over the composition of the proposal, however. I'm not going to read the slide, but I'm going to take my time so that you can read what the elements of this proposal are.

This is a proposal that essentially is for restructuring Medicare in significant ways, at least on a demonstration basis, for three years. Enrollment would be open to beneficiaries 85 years or younger. You can read the rest of that yourself. Each 3VBPP participant would be given a Medicare spending account to cover services over

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those 3 years. Each participant would be given options for plan selection, and you can see what the nature of those are: an HMO plan, a PPO, a high-deductible -- thank you, Harold -- PPO plan, and a low-premium fee-for-service plan.

Covered services would include all traditional A and B services. It could include prescription drugs and other services. You can read the rest of that.

There would be an option to waive some premiums and deductibles for plans to encourage patients to select their plans; a financial reward for wellness care; reduced Medicare contributions to premiums and reimbursement after the initial account balance is exhausted if -- for high-user beneficiaries; catastrophic coverage over the three years if expending exceeds certain amounts during a demonstration period. If there --

MS. PAGE: Click.

MR. STEINWALD: Oh, yeah, I didn't do it. Why don't you do it?

So if there's a plan balance, in other words, if the spending account isn't exhausted after three years, what's left in the balance could be used to purchase Medicare coverage in subsequent years.

There are opt-out provisions. Beneficiaries don't have to opt in, and they can opt out at any time. And then there's a financial reward for postponing Medicare

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initiation until after age 65. And I hope you had enough time to read all of those elements. Let's go on.

This is the first of what we have provisionally termed within PTAC as an "atypical proposal," and you will see that the PRT rated each of the elements of the Secretary's criteria, each of the criteria as not applicable. The reason for that is that the proposal is extensive in its expansion of -- or in its creation of a new set of benefits and participation rules for Medicare. But what it doesn't have is a physician-focused payment model. In fact, the proposal pretty much leaves payment up to the plans and the beneficiary's selection of the plan, and payment of the physicians within those plans would be up to the plans. In other words, there's nothing in the proposal that specifies exactly how payment would be altered of the physicians. And because of that, we didn't see a way that we could evaluate the proposal against all of the Secretary's criteria individually.

A rationale for that is covered in the PRT report under Item 3, Criterion 3, Payment Methodology. But the same reasoning applies to each of the criteria. And we came up with the term "not applicable" in large part because we wanted to be -- we wanted a neutral term to express our conclusion that this is not a proposal that we think should fall within the purview of PTAC. And so

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that's our rationale for the use of the term "not applicable."

The other important thing that we concluded is there is -- the PRT strongly believes that there should be no suggestion implied by us or inferred by anyone else that there's something about the proposal that we don't like qualitatively. It may have merits, and there may be other venues where a proposal of this nature could be evaluated. We just don't think it should be within PTAC. But just to emphasize that our conclusions on this, which would -- and specifically the use of the term "not applicable" is not meant to imply any qualitative judgment about the merits of the proposal, only that we don't think it's appropriate for PTAC to be reviewing it and recommending to the Secretary either adopt it or don't adopt it. We think we should just rate it as “not applicable” and go from there.

Bob and Elizabeth, would you like to add anything?

DR. BERENSON: Yeah, I would just -- in the proposal summary, there's 11 points of what this proposal does and about eight of them are really restructuring the Medicare program. The first two are a core where people get a spending account to then choose between whether they go into traditional Medicare, into what would be an updated sort of Medicare Advantage program, and other alternatives.

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This is a much broader notion than a physician-focused payment model, is I guess what we concluded. And I would reemphasize what Bruce said, is it may have terrific merit. We don't know. We're not the right group of people to be considering this proposal.

It is conceivable that CMMI would want to do a demonstration of this, but this is not our strength. This is not why we were empowered by the Congress to be -- to assist in reviewing physician-focused payment models. This is not a physician-focused payment model. It is a much broader restructuring of how the Medicare benefits work. It does have some elements that relate to physician payment, but pretty marginal.

VICE CHAIR MITCHELL: The only thing I would add, I think, again, to underscore we're not weighing in on the merits of the proposal, just that it is beyond our authority or scope or purview. I think there would likely be several statutory changes required to implement this. So I think it, again, just doesn't fit the physician-focused payment model.

* **Clarifying Questions from PTAC to PRT**

CHAIR BAILET: Thank you. Thank you, Bruce.

Any other questions from the Committee for the PRT? Tim?

DR. FERRIS: So this is just a comment and a

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question for the PRT about our process, because this is the first time that I think we've come to this – the PRT has come to this conclusion. But I expect it won't be the last time, and we're sort of making case law here about what is and -- what we think is and is not applicable. But others could disagree. We don't have -- and we are interpreting regulations that were written, and I just wonder if the PRT in choosing this process had concerns about how this might -- how this process -- again, I'm not speaking about the proposal at all -- how this process might be, A, you know, problematic for us going forward, and, two, is there any way -- and maybe this is directed at our staff and DFO. Is there any way to clarify if our process -- or maybe you already did this -- if this is a good -- does anyone else think this is a good -- I mean, maybe we should put it out for public comment. I'm just -- I'm just thinking about setting -- setting -- what injury might we be causing by choosing this process, and it may be none. And is there any other way to get feedback about whether or not this is the best way to handle when we are faced with this situation now and in the future?

MS. STAHLMAN: So you are putting it out for public comment as soon as it can go live. We sent out a draft document last week. We're going to post it on the website hopefully this week under the public comment tab to

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get comments from the public on what this process --

MR. STEINWALD: Also, we do think we followed due process, and your expression of "building case law" I think is a good one. You will see that every criterion is evaluated. They're all evaluated the same way, but we think we gave the proposal a fair review, especially, you know, some considerable discussion about whether we thought we should be evaluating it.

We also decided that it was premature to try to develop a policy for that a priori that would cover every proposal, and even though there are at least two or three atypical proposals, they're all different. And so it -- the struggle that we may face as a Committee is to figure out if we can develop policies or guidelines that identify uniquely the proposals that we should be reviewing and the proposals that we don't think we should.

CHAIR BAILET: Grace?

DR. TERRELL: With respect to what those may be, it appears to me that the issue with this particular proposal is that it's a benefits design proposal change, which is not within the scope of how you pay physicians or qualified providers. So as we're building what the points in case law would be as to what distinguishes something, I think that, you know, there may be different reasons related to different proposals, but I think you all did a

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good job at, in your first statement, making explicit that this was not about physician -- payment to physicians but about a benefits design for Medicare beneficiaries. So perhaps that would be one criterion if we're going to be creating things over time for which there may be others on a list.

CHAIR BAILET: Len?

DR. NICHOLS: So all this talk about case law has gotten me excited thinking about bright lines, you know. I'm not married to a lawyer, but I dated one once, so I'm even more dangerous than you. But I would say, look, we're looking for bright lines, and I would ask the question of the PRT: If the proposal had included a specific physician payment model that was unique and, you know, APM-like, et cetera, then what? Then you would need to evaluate that piece of it, but there would still be these issues related to the benefit design and the bigger picture.

So it seems to me we've got -- you got to have a payment model that actually affects the way physicians are paid and yada, yada. You cannot ask for statutory changes in the benefit design, it seems to me. And maybe it's worth trying to articulate those in the rationale for why this one was not considered in the purview. I'm just asking that question.

MR. STEINWALD: Well, it's a good question. If

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it proposed a benefit design redesign but within that there was a physician-focused payment model, we might -- I don't know what we would have done. You know, it could have been a dilemma.

DR. NICHOLS: It would be more than this [off microphone].

MR. STEINWALD: Yeah, it would be more than this. But it's a good question, and it's probably one of the reasons why we need to look at different proposals that are atypical and see if we can come up with some standard policy.

DR. BERENSON: And my comment would be we did have a discussion, which I think Tim would resonate to, which is that we didn't want to have a proposal that had to describe how an intermediary organization was going to pay its individual constituent members, but -- so we don't want to go that far. So paying -- how it pays an intermediary organization might satisfy, but I would have a problem with a proposal that had fundamental changing of benefits. This is a defined contribution proposal. And the fact that there's a -- that the payment model, I don't know that it could be pulled out from the broader structure that's envisioned. I mean, in this proposal, again, I don't have any opinion about the merits of it. It seemed to be integral; the payment model and the incentives that would

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be placed through the health savings account would change behavior.

I would want us at some point in the relatively near future to be able to try to head these off so we wouldn't have that problem and basically take the position that payment models should not include fundamental restructuring of Medicare, fundamental changes in the benefit design, et cetera, et cetera. And I don't have that language today.

CHAIR BAILET: Do you have a specific comment? Go ahead, Len.

DR. NICHOLS: Yeah. So, Bob, I'm not sure we want to get in the business of precluding people proposing, let's just say, an MSA-based model or a health savings account-based model with -- if it was also coupled with a fundamental change in the way physicians are paid. So, you know, if you look at the RFI from CMMI, this administration is looking for different creative ways to use those kind of accounts. I don't think we should rule them out. I think as long as the core of the proposal brought before us has to do with the payment itself, and then it's up to Medicare, CMS, to decide if they're willing to grant a waiver.

I totally agree we're not about evaluating the large scope of the benefit package changes that were

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contemplated in this particular proposal. But I don't think we want to say don't bring us a --

DR. BERENSON: No, I think I would say that, so we have a disagreement. I don't think we are constituted to have the expertise to be reviewing some of those, and to the broader restructuring of Medicare, I don't think we should be getting into that territory. So I think we disagree.

DR. NICHOLS: No, no, no. I'm talking about if it was fee-for-service Medicare and we had a savings account component --

DR. BERENSON: Within traditional Medicare?

DR. NICHOLS: Within fee-for-service Medicare, that's what I'm talking about.

DR. BERENSON: Okay. All right. We agree on that.

CHAIR BAILET: Harold.

MR. MILLER: So I think this is along the same lines. I guess I would be cautious about using the term "benefit design" too -- loosely or broadly, because I think there's a difference between saying specific value-based benefit design elements that may accompany a payment model that -- for example, it's a problem that patients have to pay cost sharing on their care coordination fees, et cetera. And CMMI is, in fact, testing some of those kinds of changes.

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I don't know what the right terminology is to use here, which is big benefit design change versus little benefit design change. But I would be cautious that somehow we're not -- I would not want us to be saying that no one can bring us a suggestion for a change in benefit structure that would complement a payment model. I think the issue is sort of if there's a payment model and then there's benefits that would go along with it, then that might be something that we would be able to recommend. That's different than saying big benefit change and, oh, by the way, that might lead to some payment changes. That's kind of, it would seem to me, what we're trying to preclude.

The other thing I would say, to Mary Ellen's point, is I think all we're asking for public comment on, though, at the moment is the notion that we would have a "not applicable" category as opposed to I guess I would suggest that maybe we want to simply ask for some public comment about whatever comes out of the discussions that we have about the case law, the rationale for the things that we said were not applicable, to see whether anybody has comments about those things for the future. But I'm not sure -- I'm not sure if I were asking for public comment on it, having us have a "not applicable" category -- I'm a member of the public. I'm going to be saying, "Well, how

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are they going to use that?" You know, and if we don't actually ask for input on how we're going to use it, I'm not sure how people will say good idea or bad idea. So we may need to think about whether there's some follow-up questions that we ask after we get through today and tomorrow on that, just to get feedback on that, because these proposals came in and they were out for public comment, but our reaction to them is not really -- I mean, I guess people could have sent in comments on the PRT reports, but I think, you know, the notion that there is some precedent here is -- you know, might not be obvious to people.

CHAIR BAILET: Thank you, Harold. We'll follow up on that. Bob?

DR. BERENSON: Yeah. So I agree with Harold on the benefit design terminology. That's why I've been tending to call this "fundamental restructuring," and yet I'm not sure that exactly works. I'm just wondering whether we can do -- that we're not going to come up with the right terminology, so we might come up with some examples. A value-based insurance design as part of a new payment model would be something that would be inbounds. A defined Medicare converted into a defined contribution program would be out of bounds. In other words, we -- it will take a while to get this right, but I am with you in

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terms of I don't think benefit design works.

CHAIR BAILET: Okay. Grace.

DR. TERRELL: Well, to get a little David Hume-ian on you, it really depends on what's a priori, right, with respect to an algorithm of what logically follows what, and if in this particular case, if it's a Medicare beneficiary, benefits design that is fundamentally a benefits design for which a physician-focused payment model is subservient to that within the context of the beneficiary design, that's one thing.

If it's a payment model with respect to how a physician is paid for which there is something underneath it -- so I really think it's the logic of what follows what. So I'm not sure it's so much about the terminology per se, but if in this particular case it was about a fundamental redesign of the -- of how Medicare beneficiaries interact with their entitlement, right? And so within that context, I think that would be the way to think through the language.

MR. STEINWALD: Yeah, that's helpful.

You prompted a thought. It wasn't that Hume -- David Hume, the British philosopher of three centuries ago.

DR. TERRELL: Right.

MR. STEINWALD: You're a well-read person. I'll say that.

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But what's my point?

[Laughter.]

DR. TERRELL: Well, Kant, depending if you want to get into Immanuel Kant --

MR. MILLER: Wait until she starts talking about the Jeremiah. Then you might be in trouble.

MR. STEINWALD: All right. All right. All right.

So you made this point about the payment model being subservient to the benefit redesign as an element that may help us decide whether this is something we should be reviewing or not. I can’t talk anymore.

CHAIR BAILET: Are you okay, Bruce? I'm losing you, man. I'm going to have to trach you. I'm going to trach you in a minute!

[Laughter.]

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

CHAIR BAILET: All right. So at this point, I'd like to have Dr. Yang come on up and address the Committee.

Hi. Thank you for coming. We really appreciate it, and you have 10 minutes. And then after that, the Committee will ask questions.

Thank you.

DR. YANG: I will use less than 10 minutes.

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So, first of all, I want to thank you for, in particular, the preliminary review committee for reviewing this proposal because different from the previous ones. They have a legion of people. It's just me. So I really appreciate this kind of attention.

But the Medicare three-year value-based payment plan is a highly innovative alternative payment model. I respectively request the Committee give the proposal a thorough evaluation for demonstration. So I respectfully disagree with this is a wrong fundamental with some of your, you know, comments -- status, as a fundamental overhaul of the Medicare program. And I myself, size 2 right here, don't have that power.

So this model is a small-scale demonstration instead of a broad overhaul of the entire Medicare system. It targets a small group of physician and Medicare beneficiaries based on a voluntary participation under close supervision of Centers for Medicare & Medicaid Services.

Therefore, Medicare 3VBPP fits well within the advanced alternative payment model, the advanced APM category as defined by the regulation of "Medicare Access and CHIP Reauthorization Act of 2015, quote/unquote," MACRA, for eligible physicians or patient groups.

It is also well within the administrative power

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of the Secretary of Health and Human Services, as regulated by MACRA, and the Patient Protection and Affordable Care Act.

The purpose of this proposal is to test an innovative payment model that incentivizes physicians and patients to engage in better communication and cooperation on preventive care and chronic disease management and to better align the financial incentives of the patients and physicians. Therefore, it is necessary to launch a demonstration of such financing model that gives the patients more choices that Medicare Advantage, of the Medicare Advantage capitation model for a further evidence-based discussion about Medicare Reaffirm.

My response to the four points raised by the PRT as talked by Bruce are below. First, this model is, indeed, an innovative advanced alternative payment model to target a small group of clinicians and patients for a pilot and demonstration. Its purpose is to test here -- and I'm saying it again. It's to test. You can say the jurisdiction is at CMMI, but I want to hear what you guys are thinking. You're running -- you're CEOs and whatever, and you're running the organization, but I want to hear what you are thinking because I have never run any organization. I'm just a health economist, but I'm doing my best, okay?

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So it's an innovative model, and then you evaluate the results in the field. Its participation is voluntary, and I said it before, and I'll say it many, many times. And I'm going to say it again. It's voluntary. If tested successful, it will lead to further discussion about more general policy modification. So going beyond this Committee in this room, ultimately I think all the people in this room want to make Medicare better and more efficient and more financially sustainable.

So besides guaranteed benefit of their services currently covered by Medicare A/B and D, there are added elements in the package of Medicare benefits available to the beneficiaries in Medicare 3VBPP. These changes are for more choices, better value services, and more patients' empowerment. The proposed changes, such as fully covered preventive services and wellness care and financial reward for participation and wellness care, will enhance the benefit and value of the services provided by traditional Medicare.

And third, the combination of expanded threshold in catastrophic coverage provides the financial protection to guarantee that the proposed copayment and coinsurance will be lower than the traditional Medicare fee-for-service on average. Therefore, if tested successful, the proposed payment model will not only strengthen the status of

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Medicare as the cornerstone of social insurance for the seniors, but also, more importantly, provide stronger and more sustainable financial protection for the seniors by liberating them from the unpredictable out-of-pocket expenditures on supplemental insurances.

And finally, I strongly disagree with Bruce. So, you think I made a strong point of the Medicare eligibility age. I would argue that there is no change, no change of Medicare eligibility rules. The proposed voluntary postponement of Medicare initiation can only be triggered by the beneficiaries instead of the physicians or the federal government or, you know, CMS or whatever.

The choice of initiation age after 65 gives the incentives for the seniors who have other sources of the insurance to tap into Medicare on their own pace. If tested effective, such mechanism will inspire more discussion about more responsible and financially savvy retirement planning policy.

And last, I welcome constructive ideas regarding the technical element of this proposal from the Committee members, and based on the discussion I learned before -- I never thought about this, you know, the terminology of beneficiary design or benefit design. I still believe this is a payment model, and I disagree with the payment -- the definition of payment model as a cult. I heard cult a lot,

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like this is how we pay the physicians and you fall into this cult and we define this and this is how we pay the physicians. I think the physician payment model is just how you pay the physicians, how this money flows from the federal government to the physicians through the transaction of services.

So my argument is this feels within the alternative payment model, and again, this is not a fundamental operate of the entire Medicare system. I don't have that power, and nobody does in this room; in particular, me.

So I think, you know, based on whatever, the law, the MACRA or PPACA or whatever new laws will come through the pipeline, I think there must be some route that such idea could be given a chance of a demonstration in the field and see if it will work for the benefit of the Medicare patients.

Thank you.

CHAIR BAILET: Thank you, Dr. Yang.

So questions from the Committee, starting with Harold, Bruce, and then Grace.

MR. MILLER: Two questions. First of all, could you say a word about what led you to develop this and whether you have some physician groups that you've talked to that want to implement this if it were approved?

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DR. YANG: How did I develop this idea? Because I started thinking about this during the grand -- the great bargaining. Is it 2012 when the federal government was talking about an overhaul of the tax system, while uplifting of the entitlement program? I was thinking about a financial system ability and the value-based payment at the same time. But I don't want to use the word "defined contribution" because this is not a defined contribution program, indeed. You can call it defined contribution, but I don't think this proposal or this idea deserves that hat.

For the physician groups, I talked to a bunch of private practitioners within my community. I never talked to any CEOs, but I talked to real practicing physicians like oncologists, my family physician, my kids' pediatricians, and policy experts and health economists. They welcome this idea because, basically, this is ordinary people's reaction. They would like to -- the physicians' response is like the medical care decision and the payment and the transaction should eventually be between the patients and the physicians. It's not -- it shouldn't be through the federal government.

And again, I don't want to go into the political discussion like Congress because this is technical, but like some of my family physicians, they started to reject Medicare patients. Like I go to see my doctor in the North

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Atlanta family practice, and since maybe two years ago, they refused to see Medicare payments -- Medicare patients anymore, but I had -- because I am still working, I have private insurance, and they like to see me. But my family physician told me that, "We don't want to see Medicare patients anymore because it's not worth it."

So I started thinking about something that will align -- here, I like to use the word "align" -- the benefits and the expectations and the value, whatever you call it, of the patients and the physicians and the federal government together because if we want to achieve more sustainable Medicare benefit, Medicare system, whatever, everybody has to give up something.

MR. MILLER: So a second question is in the proposal, you had -- there were several ways the beneficiaries could use the money, and the fourth one, which seemed to be the one that was closest to an actual physician payment model, you described as a low-premium fee-for-service plan with negotiated rate of reimbursement between the providers and the patients.

Could you say a little bit more about that? I mean, are you envisioning direct contracting between patients and providers? Are you imagining that they would have to actually pay sort of a whole capitation-type premium to a group of providers, or they would simply

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contract directly for individual services that they might contract with somebody for primary care and then contract with somebody else for management of a hip problem or whatever? What exactly are you envisioning happening there?

DR. YANG: I think that's a very good question.

So I am envisioning because I -- you probably -- you know, I mentioned somewhere in the -- later, you know, later in the proposal. I think the most ideal situation for this kind of contracting is through a more comprehensive physician group, like they have both general, like some physician groups with multi-specialty, with both general practitioners and specialists, so that patients can obtain comprehensive service within the physician system. But their transaction fee, like how the physicians are getting paid, will be based on the contract between the patients and the physician.

MR. MILLER: Yeah. Well, so technically, today, I mean, a physician group could organize a Medicare Advantage plan and have the patient sign up for that, and then the physicians could pay themselves. However, they wanted to through the Medicare Advantage plan. So I wasn't quite sure what you were seeing as different here and whether it was really the notion of direct contracting for an individual patient with individual physicians or whether

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you're simply seeing this as a version of a provider-sponsored Medicare Advantage plan.

DR. YANG: I would not use the word "Medicare Advantage" because the Medicare Advantage is capitation, but this one is a low premium. It's like, based on the premium, is like lock in the patients with the physician group, but the rest of the payment will be fee-for-service.

And, you know, the cost control is through the patient self-control of the Medicare are capped instead of the Medicare, the Medicare MA (Medicare Advantage) capitation, which is imposed by the federal government.

And on top of that, the Medicare MA, I think is well-known knowledge. It's common sense. Medicare MA doesn't save money because on average, the Medicare MA capitation rate is higher than the average fee-for-service reimbursement, and the fee-for-service expenditures at PMPY (per member per year) level, I think before it's 1.06, and the patient per -- you know, the PPACA reduced the rate to 1.3?

MR. MILLER: So let me just ask one final question. So you had a statement in here that says, "However, there is no annual limitation on Medicare contribution." What did that mean?

DR. YANG: Oh, yeah. Because this is -- what's the difference between the Medicare MA and the model I am

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proposing, because imposing an annual limitation, saying -- that is defined contribution. When you're saying this is the amount, the Medicare will contribute to you within a year, and there is an annual limitation on how much you can use Medicare money. That is defined contribution.

But what I am proposing is not defined contribution. It's this is your money, and this is still your benefit, but we're going to pay the service provided by you through physicians in a different way and give you more power to control the benefit, the whatever, the benefit money you're entitled to.

MR. MILLER: Okay. Thank you.

CHAIR BAILET: Grace.

DR. TERRELL: This is just a question, and I don't know if you read all the public comments on this particular proposal. But there was a specific, fairly lengthy one from the --

DR. YANG: BIO (Biotechnology Innovation Organization).

DR. TERRELL: -- Biotechnology Innovation Organization that came out pretty strongly about concerns that the way that this is structured would lead to potential lack of access or judgments on the part of the patient that would allow them to really have access to innovations, biotechnology, as the field progresses.

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So I just wondered if you had specific thoughts on their concerns about that, that you would like to share with the Committee.

DR. YANG: I think this proposal will not only -- not only will not -- you know, this proposal -- first of all, I don't think this proposal will limit patient choices at all because, first of all, this is voluntary participation, and second of all, this will enhance the patient choices because in one of the elements I suggest to combine, the Medicare Part B services with Part A and Part D together, and that way, I will get rid of the Medicare donut hole for Medicare Part D, because to give the patients more choices and higher budget from the federal government to protect, you know, for the -- to reimburse prescription drugs.

And through the mechanism, the patients not only have a higher budget from the federal government, but also have more choices both in the inpatient settings and from the outpatient settings as they're through Medicare Part D. So the B program and D program will be more mingled together and give the patients more flexibility and choices.

So I respectfully disagree with points from BIO.

DR. MEDOWS: Dr. Yang?

DR. YANG: Yeah.

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DR. MEDOWS: Would you help me, please? I want to make sure I'm understanding this. The Medicare account would be front-loaded with three years' worth of Medicare payments based on risk-adjusted?

DR. YANG: Yeah.

DR. MEDOWS: And then the patient would have to manage that account, pick from the choices, but manage it over that three-year period?

DR. YANG: Yeah.

DR. MEDOWS: If they don't manage it correctly and they run out of funds or something catastrophic happens, how will they get their care paid for? I mean, are they pretty much kind of out of it at that point?

DR. YANG: No. The cap is not. The cap is not to -- if you read it through the lines, above cap, they not fall into the cliff. It's just the copayment, and the copayment is means-tested. So the copayment is means-tested.

So for the lowest-income people, even if they go over the cap -- probably before they don't pay anything, but now probably they pay two percent. But the higher-income people will pay a higher percent, maybe 10 percent, 15 percent, or up to 30 percent.

And then I also explained -- and based on field experience with Medicare Part A, a lot of the enrollees and

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a large percentage of the Medicare MA enrollees are low-income populations; in particular, like Latinos or African American community, because the capitation system get rid of the out-of-pocket payment. And it's highly popular among the low-income population.

And technically, for implementation, here's my recommendation. I think the same as Medicare Part D. For the low-income people, there should be. I'm saying if this is going large scale, okay -- so I don't want to lose track. Like first of all, I'm talking about demonstration, and then suddenly, we're talking about large implementation. And that's the reason I recommended demonstration is, for example, we can test this within a small community, like low income or, for example, minority communities, like to see how people react to this plan, because it's not very easy to manage the same as Medicare Part B.

So for Medicare Part D, there are a lot of supplemental measures. Like there is additional government support for people who fall into Medicare -- fall into the -- and there's a community-outreaching activities to help people, to help the low-income or low-informed or low-educated people facing a lot of problems with access to pick the plan that really helps them with social workers or NGOs (non-governmental organization) and those kind of

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things.

But I appreciate it. That's a very good questions.

CHAIR BAILET: All right. So, Bob, final comments? Yeah, please.

DR. BERENSON: I mean, I think there's some revisionist stuff going on here. I appreciate the proposal but -- let me just read to you from your proposal and you explain to me why this is not defined contribution. "Each participant is given the choices to spend their Medicare account to enroll in one of the plans below: a capitated HMO plan, that the Medicare account contributes to the capitation, a PPO plan, that the Medicare account contributes to the premium; a high-deductible PPO plan," et cetera, and then, finally, "low-premium fee for service model." Why isn't that a defined contribution? What happens -- don't -- yeah, that's the question. Why isn't that a defined contribution?

DR. YANG: So first off, can you define what is a defined contribution?

DR. BERENSON: It's given a fixed amount of money to go purchase health insurance, rather than the current Medicare program, which is a defined benefit program, where you're guaranteed benefits no matter how much you spend. It's a contribution to go purchase health insurance.

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DR. YANG: Well, I disagree with you, because, first of all, my program -- the proposal I have proposed, is to give the Medicare beneficiaries to -- the choices to enroll into a Medicare program -- the carrier to contract with the Medicare benefit carriers who can do a better job of prevention and care coordination.

And second of all, I come back here again. There is no definite amount of money defined in this proposal, and saying I'm going giving you $10,000, where I'm only giving you $13,000. There is no set element. There is a quote/unquote "financial cliff" that requires copayment, but there is no limitation, either at annual base or lifetime base, that's saying this is a definite defined, precise -- precisely defined amount of money that the government will come to give to you.

And on top of that, based on my proposal, all the beneficiaries, all the voluntary Medicare beneficiaries have access to all the traditional Medicare benefits that have been offered through Medicare Part A, Part B, and Part D, and they are getting better value off the federal investment.

DR. BERENSON: You're giving them money to find a better choice, right, so that's defined contribution.

In any case, there's no point in arguing.

* **Comments from the Public**

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CHAIR BAILET: So, Dr. Yang, thank you for submitting your proposal and the discussion today. And while you are taking your seat, I understand, actually, you may have to leave for another meeting. But I want to make sure that if there's someone on the phone or in the audience that has a comment, as Dr. Yang steps away, this would be a good time for anybody to make a comment at this point.

[No response.]

CHAIR BAILET: It looks like there aren't any. Okay. Thank you.

DR. YANG: Thank you. Thank you very much, and you have my email. If you want to talk to me, just, you know -- thank you.

CHAIR BAILET: Good. Alrighty.

*** Committee Deliberation**

CHAIR BAILET: So we now move forward with deliberation and voting. I'm sensing that we are ready to -- Len.

DR. NICHOLS: So, Mr. Chairman, I got this little voting toy and I don't see asterisk on here. Is that like the question mark?

MS. STAHLMAN: Press zero.

MS. PAGE: Yeah, if you want to vote not applicable you hit zero.

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*** Voting**

CHAIR BAILET: Okay. So why don't we set up the voting parameters here. We're going to start with Criterion 1, and let me just review the scores here. Number 1 and 2, do not meet; 3 and 4, meets; 5 and 6, meets and deserves priority consideration; and then for you, Len, the asterisk means it's not applicable, and because there's not an asterisk key on this, we are going to actually -- we have designated the 0 to reference the asterisk. Alrighty, then? All right.

So we're going to go with Criterion 1, Scope, which is a high priority item for the Committee, aimed to either directly address an issue in payment policy that broadens and expands the CMS portfolio, APM portfolio, or including APM Entities whose opportunities to participate in APMs have been limited.

So let's go ahead vote on this first criteria, please.

[Electronic voting.]

CHAIR BAILET: Ann.

*** Criterion 1**

MS. PAGE: Zero Committee members voted 5 or 6, meets and deserves priority consideration; zero Committee members voted 3 or 4, meets the criterion; zero members voted 2, does not meet; one member voted 1, does not meet,

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and nine members voted not applicable. So the majority has determined that Criterion 1 is not applicable to this proposal.

CHAIR BAILET: Thank you, Ann. We're going to go with the second criterion, which is Quality and Cost, also high priority. Anticipated to improve health care quality at no additional cost, maintain quality while decreasing cost, or both, improve quality and decrease cost.

High priority item. Let's vote, please.

[Electronic voting.]

CHAIR BAILET: Ann.

* **Criterion 2**

MS. PAGE: Zero Committee members voted 5 or 6, meets and deserves priority consideration; zero members voted 3 or 4, meets; zero members voted 2, does not meet; three members voted 1, does not meet, and seven members voted not applicable. So the Committee has determined that Criterion 2 is not applicable to this proposal.

CHAIR BAILET: Thank you, Ann. Criterion number 3, which is Payment Methodology, a high priority. Pay the APM Entities with a payment methodology designed to achieve the goals of the PFPM criteria, addresses in detail through this methodology how Medicare and other payers, if applicable, pay APM Entities and how the payment methodology differs from current payment methodologies, and

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finally, and why the physician-focused payment model cannot be tested under current payment methodologies.

A high priority item. Let's go ahead and vote, please.

[Electronic voting.]

CHAIR BAILET: Ann.

* **Criterion 3**

MS. PAGE: Zero committee members voted 5 or 6, meets and deserves priority consideration; zero members voted 3 or 4, meets; zero members voted 2, does not meet; three members voted 1, does not meet, and seven members voted not applicable. The Committee has determined that Criterion 3 is not applicable to this proposal.

CHAIR BAILET: Thank you, Ann. Criterion 4, Value over Volume. Provides incentives to practitioners to deliver high quality health care.

Vote, please.

[Electronic voting.]

CHAIR BAILET: Ann.

* **Criterion 4**

MS. PAGE: Zero Committee members voted 5 or 6, meets and deserves priority consideration; zero members voted 3 or 4, meets; zero members voted 2, does not meet; three members voted 1, does not meet, and seven members voted not applicable. The Committee has determined that

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Criterion 4 is not applicable to this proposal.

CHAIR BAILET: Thank you, Ann. Criterion 5, which is Flexibility. Provide the flexibility needed for practitioners to deliver high quality health care.

Please vote.

[Electronic voting.]

* **Criterion 5**

CHAIR BAILET: Ann.

MS. PAGE: Zero members voted 5 or 6, meets and deserves priority consideration; zero members voted 3 or 4, meets; zero members voted 2, does not meet; one member voted 1, does not meet, and nine members voted not applicable. The Committee has determined that Criterion 5 is not applicable to this proposal.

CHAIR BAILET: Thank you, Ann. Criterion number 6, Ability to Be Evaluated. Have the evaluable goals of quality of care cost and other goals of the PFPM.

Please vote.

[Electronic voting.]

CHAIR BAILET: Ann.

* **Criterion 6**

MS. PAGE: Zero members voted 5 or 6, meets and deserves priority consideration; zero members voted 3 or 4, meets; zero members voted 2, does not meet; two members voted 1, does not meet, and eight members voted not

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applicable. The Committee has determined that Criterion 6 is not applicable to this proposal.

CHAIR BAILET: Thank you, Ann. Criterion 7 is Integration and Care Coordination. Encourage greater integration and care coordination among practitioners and across settings where multiple practitioners or settings are relevant to delivering care to populations treated under the PFPM.

Please vote.

[Electronic voting.]

CHAIR BAILET: Ann.

* **Criterion 7**

MS. PAGE: Zero members voted 5 or 6, meets and deserves priority consideration; zero members voted 3 or 4, meets; zero members voted 2, does not meet; three members voted 1, does not meet, and seven members voted not applicable. The majority has determined that Criterion 7 is not applicable to this proposal.

CHAIR BAILET: Thank you, Ann. Criterion number 8, Patient Choice. Encourage greater attention to the health of the population served while also supporting the unique needs and preferences of individual patients.

Please vote.

[Electronic voting.]

* **Criterion 8**

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MS. PAGE: Zero members voted 5 or 6, meets and deserves priority consideration; zero members voted 3 or 4, meets; two members voted 2, does not meet; zero members voted 1, does not meet, and eight members voted not applicable. The majority has determined that Criterion 8 is not applicable to this proposal.

CHAIR BAILET: All right. Thank you, Ann. Nine is Patient Safety. To maintain and improve standards of patient safety.

Please vote.

[Electronic voting.]

* **Criterion 9**

MS. PAGE: Zero members voted 5 or 6, meets and deserves priority consideration; zero members voted 3 or 4, meets; zero members voted 2, does not meet; three members voted 1, does not meet, and seven members voted not applicable. The majority has determined that Criterion 9 is not applicable to this proposal.

CHAIR BAILET: Thank you, Ann, and the last Criterion is number 10, which is Health Information Technology. Encourage the use of health information technology to inform care.

[Electronic voting.]

* **Criterion 10**

MS. PAGE: Zero members voted 5 or 6, meets and

deserves priority consideration; zero members voted 3 or 4, meets; zero members voted 2, does not meet; three members voted 1, does not meet, and seven members voted not applicable. The PTAC has determined that Criterion 10 is not applicable to this proposal.

CHAIR BAILET: Thank you, Ann. Ann, if you could just give us a quick summary. Thank you.

MS. PAGE: The Committee determined on all 10 of the criterion did not apply to this proposal.

CHAIR BAILET: All right. Thank you, Ann.

We are now actually going to vote for the recommendation to the Secretary. We are going to start voting electronically and then move to an individual report out. Again, the four numbers here are 1 is do not recommend to the Secretary; 2 is recommend payment model to the Secretary for limited-scale testing; number 3 is recommend the proposed payment model to the Secretary for implementation; and then 4 is recommend proposed model to the Secretary for implementation as a high priority item. And then the asterisk is not applicable.

So please vote.

DR. BERENSON: And could I just --

CHAIR BAILET: Yes, please, Bob.

DR. BERENSON: So not applicable with this overall recommendation would be that we would tell the

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Secretary that we did not evaluate this proposal because it was not --

CHAIR BAILET: Well, I would just -- again, I think we did evaluate the proposal and that we found --

DR. BERENSON: No, we didn't.

CHAIR BAILET: Well, and we found it wasn't --

DR. BERENSON: We found that we are not recommending the proposed payment model, but we also did not do -- we did not make a judgment on the merits of the proposal.

CHAIR BAILET: No, we did not.

DR. BERENSON: So which way do we go, in terms of --

DR. NICHOLS: Asterisk is very different than 1.

MR. STEINWALD: We will, I hope, highlight -- well, we haven't voted yet, but looking ahead, that we have -- we rendered no judgment about the merits of the proposal. It's not applicable because it's not a physician-focused payment model, and our language needs to capture both of those elements so that there is no ambiguity.

VICE CHAIR MITCHELL: And I just --

DR. BERENSON: So how are you going to vote?

MR. STEINWALD: I am going to vote not applicable.

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DR. BERENSON: Okay.

VICE CHAIR MITCHELL: So I intend to vote do not recommend, because even though I don't think the criteria applied, what I did read I thought was ill-advised. So I would not have recommended it.

MR. MILLER: I am also going to vote do not recommend, because of that. The applicant thinks it's a payment model. I don't think that it is defined well enough to describe a payment model, and I think we should not recommend it.

DR. TERRELL: Ditto.

CHAIR BAILET: Len.

DR. NICHOLS: I'm stunned. It seems to -- I thought we were precluded from evaluating it in a serious way, precisely because we determined it was not applicable. I'm happy to tell him it's a bad idea, but I don't think we want to -- I thought the whole point of the neutral language was to avoid judgment about the nature of this kind of proposal -- forget the specifics -- this kind of proposal. And, therefore, I see a real distinction between asterisk and 1, and I thought we had all been headed toward asterisk.

MR. STEINWALD: I agree.

CHAIR BAILET: Bob.

DR. BERENSON: Except for, I mean, on all of

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those votes we had one or two people who wanted to positively turn it down. They gave it 1s or 2s, and a whole bunch of us gave it asterisks. So I think we want to maintain that same distinction. There are some people who are confident about turning it down. Some of us will want to say not applicable because we didn't evaluate it. But I think that's the distinction we're maintaining.

CHAIR BAILET: Harold.

MR. MILLER: So my opinion is even if we -- I didn't -- I felt that the criteria were applicable, too, if it was a payment model, but even if we didn't feel the criteria were applicable, I don't think that that precludes us individually from saying whether or not we think that this should go forward in any fashion. You know, and I think the Committee as a whole can conclude that it didn't have the expertise or whatever to be able to evaluate that. I didn't -- I think we could have determined whether there was some merit to it. I read it carefully, tried to assess whether there was merit to it. Could not find any description of merit, and, therefore, to me, simply saying it's not applicable and that we don't know is different than what I felt. I looked at it and didn't see merit or didn't see enough detail to be able to determine merit.

So that's why I'm voting. I'm not suggesting everybody else has to vote that way, but that's my

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conclusion.

CHAIR BAILET: Bruce.

MR. STEINWALD: Materially, not applicable and do not recommend amount to the same thing. I mean, we are certainly not recommending it. So I'm thinking it's kind of a distinction without a difference.

But I will say this. We may have had the expertise to evaluate it. I don't know that we didn't. I mean, all of us, in some way or another, have been -- have seen models like -- models -- have seen proposals like this in the past and have seen the various debates that get very political very quickly. And that's what I think we should avoid getting anywhere close to.

And so I don't think it was lack of expertise. I think it was really, fundamentally, it's not the kind of thing that this Committee should be reviewing.

CHAIR BAILET: Tim and then Bob.

DR. FERRIS: I think I -- I think there -- I'm concerned that there is a difference between the two, although I understand they end up in the same place. One is an assessment of the proposal and one is a statement that proposal could not be assessed because it didn’t meet our criteria.

Now you can handle that in the comments or whatever, but I've seen proposals for changes in benefit

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structures and contribution plans. I know that I am -- it is -- it would be incorrect of me, because I do not have nearly the background required to make an assessment of that, and I would be so -- I am concerned for myself, just myself, that I could not vote number 1, because that is a -- that reflects an assessment that this should not -- at least how I understand it -- that this should not be recommended, because of some value judgment placed on the proposal. And I am certainly not prepared to place a value judgment on this proposal.

DR. BERENSON: Yeah, I mean, I think Tim said what I wanted to say. I don't -- but I agree with Bruce. We're not constituted to review this. If the Congress wanted us to be reviewing restructuring proposals, I think they -- if they wanted a body to advise CMMI, they would not have had our makeup. And so whereas some of us may feel confident in reviewing what is, in fact, not a very strong proposal, there could be a very good proposal coming through, and I don't think we want to set the precedent that we are reviewing on the merits of proposals that have to do with fundamental restructuring of the program.

CHAIR BAILET: Len.

DR. NICHOLS: I think, picking up on Tim and Bob, I think it would be a mistake for us to signal that we were open to consideration of these kinds of broader

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restructuring things. I actually think, Timmy, you could figure it out, but I also think it's a bad idea for us to try, because it's just too big for what MACRA set us up to do.

CHAIR BAILET: Harold.

MR. MILLER: So I think we have made a distinction all along that do not recommend doesn't necessarily mean bad idea, in general. It means that we do not -- are not prepared to recommend that. And we've made that distinction with others, sort of -- lots of good ideas there but needs work, and therefore we're not recommending it, but without prejudice.

In this particular case, I'm just saying, we asked the applicant what she thought this was. She said this is a payment model. If she had said this is a fundamental benefit design, then I would have said not applicable because that's not what this is. But she said it's a payment model, so I looked at it and I said is there a payment model here and I saw no payment model. So, therefore, I'm saying -- again, it's just me -- I'm not recommending because I don't -- I think, from her perspective, she doesn't think it's a benefit design. She thinks it's a payment model, and I don't think that we -- I can recommend that as a payment model. So that's why I'm making that distinction.

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DR. TERRELL: It's so weird when I agree with him, but I do.

CHAIR BAILET: I think this is the first time. Right. I think I'm going to go buy a Powerball ticket.

MR. MILLER: No, there was one other time. I marked it on my wall.

CHAIR BAILET: Did you? Okay, very good.

[Laughter.]

CHAIR BAILET: With all seriousness, we're going to go ahead and --

DR. CASALE: I'm so sorry. I just --

CHAIR BAILET: No, no. Please, Paul.

DR. CASALE: I'll just add on. I'm attaching my comments to Tim and Len. I mean, I think -- and Bob, too. Just because she said it's a payment model doesn't mean it's a payment model, at least the way I'm thinking about it. So even when I looked at it, I don't see it that way, so I don't feel comfortable to even consider one.

CHAIR BAILET: Okay. Thank you, Paul.

So I think we are in the process of voting on this. I think we should complete the --

MR. MILLER: Do you want to restart it?

CHAIR BAILET: Yeah, yeah. Why don't we -- can we reset it, Matt? Please.

That's just a test. Nothing to see here. Move

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along. Okay. Now we're going to vote.

[Electronic voting.]

* **Final Vote**

MS. PAGE: Zero members recommend -- zero members recommend the proposed payment models to the Secretary for implementation as a high priority. Zero members recommend proposing it to the Secretary for implementation. Zero members recommend proposing it to the Secretary for limited-scale testing. Three members do not recommend -- affirmatively do not recommend the proposed payment model to the Secretary, and seven members voted that this is not applicable.

CHAIR BAILET: Thank you, Ann.

And we're going to now just go around and see how we voted. Oh, what?

DR. NICHOLS: [Speaking off microphone.]

MS. PAGE: Two-thirds is seven when 10 members are voting, so --

CHAIR BAILET: It's okay, Len. I know you're an actuary, and yeah, yeah. It's okay. We'll get you a bigger calculator. Okay.

[Laughter.]

* **Instructions on Report to the Secretary**

CHAIR BAILET: So we're going to start with you, Rhonda, please.

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DR. MEDOWS: Okay. I voted that it was not applicable because I believe that it extends well beyond a payment model. That's pretty much it.

CHAIR BAILET: Bob?

DR. BERENSON: I support the PRT's views.

CHAIR BAILET: Len?

DR. NICHOLS: I voted that it was not applicable because I think it's dangerous to imply it is.

VICE CHAIR MITCHELL: I was on the PRT, and I voted do not recommend. I do think that the large majority of the criteria were not applicable, and I voted as such, but there were elements of the model that I would actually affirmatively vote against. And I did so.

CHAIR BAILET: I think it's not applicable for reasons already stated.

Bruce?

MR. STEINWALD: I agree with the PRT, too.

One thing I decided not to argue with the proposer, but she said a couple of times it's not a restructuring of the Medicare program; it's just a small-scale demonstration. Do you remember? And I was going to say, "Yeah, but it's a small-scale demonstration about restructuring the Medicare program." So you wouldn't do a demonstration unless you thought maybe that's where you were headed.

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So I'm not sure that that needs to be captured in the report. I don't know how others feel. Maybe just keeping it clean, cleaner, and simpler would be best.

CHAIR BAILET: Paul.

DR. CASALE: Yeah. I voted not applicable, and as I stated, although she declared that it was a payment model, I didn't see that.

CHAIR BAILET: Thank you.

Harold?

MR. MILLER: I voted do not recommend.

CHAIR BAILET: Grace?

DR. TERRELL: I voted do not recommend. My logic was very similar to Elizabeth's.

Interestingly, when I was going through the individual things, I was bobbling back and forth between some, which I thought you absolutely could evaluate within the context of our criteria that we're to go by and others that were absolutely not applicable.

But ultimately, I don't necessarily agree with the majority opinion, but that we shouldn't make a judgment one way or the other on these things. I think that this particular situation, we could. I don't think there has to be a strong minority opinion in the report back.

CHAIR BAILET: Thank you.

Tim.

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DR. FERRIS: I don't think what I'm going to say is a surprise, but I voted not applicable for the reasons already stated.

CHAIR BAILET: Thank you, Tim.

Ann.

MS. PAGE: Staff just has a question. So the Committee's vote is not applicable in the report to the Secretary. Do those of you who voted do not recommend, do you want that recorded as sort of a minority view and/or if you do, do you want to elaborate? So it's just a question how much is that --

DR. TERRELL: Whatever makes you happy.

CHAIR BAILET: I thought it was that you guys said no, that you didn't --

MR. MILLER: I would say -- I mean, I don't disagree with the Committee determining not applicable. I would just -- I personally would just note that in fact some Committee members felt that the applicant asserted that it in fact was a payment model, and therefore, some people -- some people's votes were based on the fact that -- because that's why it's based on that assertion in my opinion. I was not trying to evaluate its merits otherwise. It was asserted as a payment model, and that's why, but I'm happy to support the not applicable since most of the criteria came out that way.

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CHAIR BAILET: Rhonda?

DR. MEDOWS: I actually think it's important that your vote and the rationale behind it be included in the report.

MS. PAGE: Okay.

CHAIR BAILET: So, Ann, given that, do you have what you need to be able to represent that opinion?

MS. PAGE: Right. The only -- I've heard that there were a few people who voted do not recommend based on the assertion that it was a payment model, even though there was some potential disagreement on that. And I don't -- if you want to say any more -- okay. I'm going to leave it that way.

DR. NICHOLS: I don't think anybody thought it was a payment model except the applicant.

MR. MILLER: Correct. I agree with that, but the point was it was represented after even a question. It was represented as a payment model, and so, therefore, that was -- that was the basis of my vote. What I was trying to make clear earlier is I don't see it as a minority opinion that needs to be reflected in the report, per se, in terms of I didn't -- I don't disagree with what the Committee came up with.

CHAIR BAILET: All right. We are now going to move on to the final proposal for today, which is the Mercy

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Accountable Care Organization annual wellness visit billing at rural health clinics. Bob Berenson was the lead proposal review team.

UNIDENTIFIED SPEAKER: [Speaking off microphone.]

Mercy Accountable Care Organization: Annual Wellness Visit Billing at Rural Health Clinics

*** Committee Member Disclosures**

CHAIR BAILET: And we're going to do the disclosures, starting with me since most of my Committee is just stepping away. So, Jeff Bailet, Executive Vice President, Health Care Quality and Affordability of Blue Shield of California. I have nothing to declare.

Elizabeth?

VICE CHAIR MITCHELL: Elizabeth Mitchell, CEO, Network for Regional Healthcare Improvement. Nothing to disclose.

CHAIR BAILET: Len?

DR. NICHOLS: Len Nichols. I direct the Center for Health Policy Research and Ethics at George Mason University, and I have nothing to declare.

DR. BERENSON: I'm Bob Berenson. I am an Institute Fellow at the Urban Institute, and I have nothing to disclose.

DR. MEDOWS: I'm Rhonda Medows, EVP, Population Health, Providence St. Joseph Health. I have no

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disclosures.

DR. TERRELL: Grace Terrell, an internist at Wake Forest Baptist Health Integrated System and CEO of Envision Genomics. Nothing to disclose.

MR. MILLER: Harold Miller, CEO of the Center for Healthcare Quality and Payment Reform. No disclosures.

DR. CASALE: Paul Casale, cardiologist, Executive Director of New York Quality Care. Nothing to disclose.

MR. STEINWALD: Bruce Steinwald, health economist in Northwest Washington. I have nothing to disclose, but I would like Tim to turn his card right side up.

CHAIR BAILET: And Tim Ferris, Dr. Ferris, stepped out, but we have his disclosure. Nothing to disclose. He's one of the members of the PRT -- and I'm just speaking for you, Tim, which is a pretty weighty obligation on my part. So you might want to do it yourself. Thank you.

DR. FERRIS: Tim Ferris. Nothing to disclose.

CHAIR BAILET: Thank you.

Okay. I'm going to turn it over to Bob. Bob, you got the wheel.

*** PRT Report to the Full PTAC**

DR. BERENSON: So, we have another proposal in which we're going to recommend not applicable. It's the other end of the spectrum. This has to do with what we

considered de minimis changes to an existing payment model rather than an alternative payment model. Our Committee is me and Tim and Len.

So let me go through the [unintelligible] now, do we have the proposers on the phone?

MS. STAHLMAN: They are.

DR. BERENSON: Do we know they are there?

MS. STAHLMAN: We know that they are there.

DR. BERENSON: Okay. So very good. They're not here in person. So the presentation overview is the standard, the team composition. Has the proposers, do they know all this stuff, or do I need to go through it? The slides like this.

[Off-microphone discussion.]

DR. BERENSON: All right. Let me go through this real fast. The Chair and the Vice Chair assign two to three PTAC members, including at least one physician, to each complete proposal to serve as the PRT. One PRT member is tapped to serve as the lead reviewer. In this case I am that person.

The PRT identifies additional information needed from the submitter and determines to what extent any additional resources and/or analyses are needed for the review. ASPE staff and contractors support the PRT in obtaining these additional materials.

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After reviewing the proposal, additional materials are gathered and public comments received, and the PRT prepares a report of its findings to the full PTAC. The report is posted to the PTAC website at least three weeks prior to the public deliberation by the full Committee, which is taking place right now.

The PRT report is not binding on the PTAC. PTAC may reach different conclusions from those contained in the PRT report.

I'm not going to go through the details of this slide. The point of this slide, which I thank Tim for preparing for us, is to make the point that this is a well -- there is a well-defined payment model for rural health clinics. They are defined in statute. The basic payment model, which is on the right side, is called an "all-inclusive rate." Each beneficiary encounter, regardless of the number or intensity of the services provided, is paid a single rate. The AIR (all-inclusive rate) is calculated for each rural health clinic annually by the Medicare administrator contractor based upon each RHC's (rural health clinic’s) cost report. The RHC's AIR is subject to a national payment limit, which is updated annually.

There are a few exceptions to the AIR such as the Welcome to Medicare exam, which prompts a second AIR payment if performed on the same day as another covered

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service. This is a specific exception. There are a couple of other exceptions. Currently, the annual wellness visit is not such an exception to the all-inclusive rate.

So the proposal overview is that Mercy Medical Center's Round 2 HCIA project related to rural critical access hospitals, Mercy proposes that annual -- and these are quotes from the actual proposal -- that "annual wellness visits be eligible for an additional encounter payment at the all-inclusive rate similar to the initial preventative physical exam for patients that are new to Medicare, and that the annual wellness visits be categorized as an incident-to-carveout so that RNs (registered nurses) are able to provide the AWV (annual wellness visit) under direct supervision of a physician at the clinic. This is the precise request that Mercy came to the PTAC with.

Through these changes, they hypothesized and provided some data that more AWVs would be conducted and eventually cost savings would be realized by identifying health risks that can be mitigated.

In summary, the proposal summary is to make an additional payment for providing the annual wellness visit, and, again, I've been through that. So, basically one change is to include the annual visit just like they do the Welcome to Medicare exam as an exception; and number two

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would be to allow non-practitioners to provide an annual wellness visit, mostly RNs, rather than higher-level physician substitutes.

So, we summarized this and came to the conclusion, which I'll now get to after you'll see lots of "not applicables," that the payment method -- well, here are the issues identified by the PRT and why we came to the conclusion that we didn't really want to review the merits of the proposal. The PRT unanimously and unequivocally -- that was my word -- did not consider the proposal to represent an alternative physician payment model that PTAC should be reviewing but, rather, rules changes within a well-established payment methodology, and then say the Secretary may wish to consider the merits of the proposal as part of CMS' ongoing supervision of rural health clinics.

This, by the way, is within the authority or the jurisdiction of CM (Center for Medicare), not CMMI. They are the ones who administer the rural health clinic program and the AIR.

The PRT had a lengthy discussion before arriving at its recommendation, concluding that it lacked the expertise or standing to consider technical modifications of an existing payment methodology, such that any recommendations it would make regarding this proposal could

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have unforeseen and unintended consequences. At the same time, so that the public and future submitters more clearly understand the scope of PTAC's work, the PRT suggests that the PTAC develop criteria that distinguish proposals that meet tests of meriting review as alternative physician payment models and those that seek modifications and establish payment methodologies such as the all-inclusive rate approach for rural health clinics.

And then we have -- we would have -- for each of these, we have not applicable except for Criterion 3, which is the payment methodology, which pretty much repeats what I just went through.

The third bullet there, two of the PRT members point out that the proposed modifications do not include accountability for either quality or spending associated with the rule changes, and as such, the proposal does not meet what they consider hallmark expectations for physician-focused payment models.

And the third member, who was me, didn't necessarily disagree, but thought that this -- we needed a broader discussion of what the criteria would be and didn't want to just establish one at this point. So that's why the language here says "they point out" rather than "recommend" this as a criterion. But this could be one of the criterion that could be considered as meaningful in

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distinguishing between an APM and just an established payment model.

And I think that is it. We go through the rest of this, and we all say "not applicable" because we basically made a judgment that these were minor changes -- perhaps important changes but minor changes -- to a well-established payment model. They were not requesting a new payment methodology. They were establishing, they were requesting some rule interpretation modifications, and as such, we didn't think we wanted to review it.

That's it. That's my report.

CHAIR BAILET: Thank you, Bob.

Comments from the remaining PRT members? Harold? Oh, well, maybe questions for the PRT.

DR. BERENSON: The other two [off microphone].

DR. FERRIS: I think Bob did a great job representing us, so --

DR. NICHOLS: So, wait. I'm on this Committee, too.

CHAIR BAILET: Like I said, Len, I --

DR. NICHOLS: And I have something to say, and it is that Tim had this really cool two-part test he proposed, and I was enamored of it, but Robert was not. And what he thought actually was it made sense, but he thought the full Committee should discuss it, and I agreed with that. And

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that's why we didn't push harder to get it in the PRT report.

So I would just point out, Mr. Chairman, it might be useful, after we finish this proposal discussion, to come back to that two-part test as a starting point for how to start drawing these lines.

CHAIR BAILET: And I agree, Len, not even knowing what the two-part is. I think we need --

DR. NICHOLS: I can't remember it, but it was really cool.

CHAIR BAILET: I think we need to have a discussion after this -- we're done with this proposal, before we adjourn.

DR. NICHOLS: Just sometime [off microphone].

CHAIR BAILET: Okay. Very good. So we've got Bruce and Harold.

*** Clarifying Questions from PTAC to PRT**

MR. STEINWALD: Just to clarify, under current law the Secretary would have the authority to make these changes and it would be subject to a rulemaking process. Is that how you --

DR. BERENSON: Tim, that is correct, right? This is regulatory, right? The decision about the AWV is a regulatory decision and could be modified by -- through rulemaking, correct?

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MR. DUBE: That's our understanding reading the regulations.

DR. BERENSON: Yeah, we looked into that some, and that's what would have to happen. So as I understand it -- and maybe this, I shouldn't be saying this, but I'm going to say it anyway. They got to us because CMMI referred Mercy to the PTAC for their proposal instead of referring them to CM, which would have been the, I think, the logical first place to go. We referred them to CM, and those conversations are happening or have happened. So that's how this proposal came to us, as I understand it.

CHAIR BAILET: Harold and then Grace.

MR. MILLER: I want to disagree in the strongest terms with my colleagues on the PRT about this. If the payment model proposal is problematic, then we should say that we don't think that it's a good payment model. But I think the notion of saying that this whole thing is not applicable is really inappropriate.

This is how health care is delivered in many rural communities around the country. This is how physicians are paid in many parts of the country. And so to somehow categorically suggest that anything that is involved with rural health clinics is off the table I think is inappropriate, or to suggest that somehow this is a well-established payment model, I think that the physician

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fee schedule is a well-established payment model. Anything that people come in and want to do differently could be done regulatorily by the Secretary if he or she wanted to, depending on which gender is in office at that particular point. And so for us to somehow say that there is something different about coming in and proposing a change to the way rural health clinics are paid, from saying that there should be something different about the way physician practices under the physician fee schedule are paid is just, I think, wrong.

The most predominant alternative payment model that exists out there is called an ACO, which changes absolutely nothing about the way physicians are paid other than giving them a bonus or a penalty, depending on the structure. So the notion that somehow changing the way a rural health clinic is paid is somehow off the table I think is completely and totally inappropriate.

I think that this proposal could be evaluated in all these respects. We may conclude that we don't think that it meets the criteria, but I think it absolutely can be evaluated against all the criteria. We can say, does this, in fact, enable practitioners -- i.e., people who practice in rural health clinics -- an opportunity to participate in something that they don't otherwise have an opportunity to participate in? Will it improve quality and

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cost? Will it encourage value over volume? Will it give more patients choices? All of those things could be evaluated against a rural health clinic payment change, which this is.

Now, again, I'm not saying that I think that this is the best model, and we'll talk about that. But the notion that somehow it's not applicable I think is just wrong.

CHAIR BAILET: I think Bob has a comment on that.

DR. BERENSON: Yeah, now, I don't think we have ever said that because it’s dealing with the rural health clinics and there's an established payment methodology that we wouldn't consider proposals. We've considered this one a de minimis modification in the established payment model. I could imagine any number of proposals for changing how fees are calculated in the Medicare fee schedule, which I would consider real and substantive, as opposed to coming in and saying we want to get paid a little more for doing an appendectomy, which is a change in the payment model but -- so it does -- so I don't think we are in any way arguing that rural health clinic payment is off limits. I think we are arguing -- and I'll look to my two colleagues -- that this particular proposal was nominal -- would have a nominal effect on behavior, on incentives. It might be a good one, but it would -- it's not a payment model. It is

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just a tinkering with an established payment model.

DR. NICHOLS: I think the key phrase is "de minimis," and I would take exception, Harold, to saying that we're saying don't touch rural. That's not what we're saying. We're saying that this proposal is a de minimis change in the existing structure and not worthy of what PTAC is intended to do.

MR. MILLER: It may be, but that's -- my point is to say that all of the criteria are not applicable because you think it's a de minimis change I don't think is the right -- I think we should go through and say whether or not we think it meets the criteria or not. I don't think -- and I think the impression that this will create is that somehow because there is a statement in the PRT report -- I'm challenging two things here. One is the notion that saying that all these things are not applicable and then this statement that says this is an established payment model, the rural health clinic payment model, that implies -- in this statement in the PRT report -- that implies that somehow we view rural health clinic payment as something different than what this Committee addresses. And my point is that is, in fact, how physicians in many parts of America are paid. Whether this model itself is a good model is a different question. But we deal with that with everything else.

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CHAIR BAILET: Okay. I think this is an important point. Grace?

DR. TERRELL: Mine are a couple of questions, actually, for the Committee, and one of it was with respect to the things that they were asking for, how many of them were absolutely related to it being a rural -- or did you not even evaluate their -- because I don't believe an RN can do this in other settings either. So there are certain aspects of it that were just a policy change that was above and beyond that, which is relevant only in the sense of where Harold was going in the conversation that I disagree with, that this was specifically about that particular proposal.

Relevant to that is the issue that we talked about earlier in the day, and it's sort of the extremes and in the middle, where there are probably physician-focused payment models for which certain changes in the way things are paid for, whether there's a code or not a code, whether we need to -- you know, someone needs a co-pay, would be relevant to the physician payment model.

So it would be nice to understand, since we've had the extremes today, what the middle might be. I will agree that this is not applicable relative to what I understand about it, but I do think a conversation that we ultimately have around what makes those distinctions, maybe

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it's going to be, you know, Dr. Ferris' two-part solution or something, but are we saying that certain aspects of payment of the fee schedule will never, you know, be part of something that's a physician-focused payment model or not? I think we probably are going to come across that there are criteria that's going to let us be that.

So two questions. Was this only about the rural, you didn't even have a chance to evaluate that? And the second one is: Did you talk about what might or might not be criteria that would be inclusive?

DR. BERENSON: Well, in the latter one, you know, Tim proposed a criterion, a two-part test. Part of my reaction was that that would handle this proposal, but it wouldn't handle any number of other proposals that we might want to also not consider to be APMs. We can remove offensive language that may imply that we somehow think that rural health clinic payment is off limits to the PTAC. That's not what we meant at all.

I guess the point I would make here is we have to be able to distinguish between a model and just a small change in a model. I think we are -- it is incumbent on us to do that. And if ever there's an example of a de minimis change in a model, this is it. They haven't asked for a restructuring of the AIR to promote -- permit physicians and staff to transform how they practice and help patients.

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They've asked for, "We want to get paid for an AWV." And so I think we came to the judgment that that was -- didn't qualify as a model, but we do not want to imply that for some reason rural health clinic payment is off limits or that even the Medicare fee schedule is off limits for a real structure -- restructuring that would change incentives in a substantial way. If that -- I don't know if that's responsive.

CHAIR BAILET: Tim and then Len.

DR. NICHOLS: I need to answer --

CHAIR BAILET: Go ahead.

DR. NICHOLS: Tim's on the -- he may answer, too. I was just going to say there were two dimensions of ruralness that were relevant here. One is people have to travel a long way to get to the clinic, and they would prefer to do all the stuff when they're there, and having them go back and come back for the second visit was problematic from the patient's point of view. So it was convenience and, therefore, access and, therefore, ultimately probably good patient care.

Second, staffing issues and having the RN perform the wellness visit under the supervision of a physician in the clinic was a scope of practice kind of issue that is often met in rural America. So to me, those dimensions were why this proposal made sense to them and, in fact,

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they do make sense, but it's just not a --

CHAIR BAILET: Tim and then Harold.

DR. FERRIS: So, I'm interested in learning more about the basis of Harold's objection, but I want to make what might be a bridging point, which is in response to my proposed criteria, Bob's main objection to endorsement of that was establishing case law that would prevent some things that we do want to see.

I wonder if that isn't part of Harold's objection, and I would say I share that concern. And we had a conversation specifically about this proposal in the context of not wanting to -- because we are establishing case law here, and I hear that we may be setting a threshold and that that's a scary prospect.

What I would say is that's a scary prospect in both directions, which is we may be dissuading potentially useful proposals and good proposals that we want to see. We may be simultaneously -- if we go the other way, we may be simultaneously encouraging everyone who wants to change a V code or a, you know, the dollar value on an ICD-9 code or whatever it is, to come with their thing as a new payment model. And so I think this is -- to me it's a legitimate argument to have, or legitimate -- "argument" is not the right word -- a legitimate discussion to set the framework. I think we agreed that this proposal for us,

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for the PRT -- reminding us and everyone else that the PRT does not determine the PTAC's decision -- was helpful because we all agreed this was on the other side of what we want to see, that it was too small a change for -- and I think it would be -- that was the main.

CHAIR BAILET: Bob.

DR. BERENSON: I'm just wondering for process, should we hear from Mercy --

CHAIR BAILET: Well, they're on the phone.

DR. BERENSON: -- and then come back to this discussion?

CHAIR BAILET: Right, but I just -- Harold, you have a closing comment or --

MR. MILLER: I was -- well, Tim said he wanted to hear more. I mean, I agree with that. I think we need to have a policy about what we're going to do. We have in the -- whatever we call it now, the RFP -- a statement about things that -- submitter instructions, a statement that we developed way back about things we were more likely to recommend, but that's how we framed it. We said more likely to recommend, which says, in fact, that there needs to be some accountability built into the thing. We didn't say, though, that we were not going to consider something else. We just simply said we're not going to recommend it.

So my point is here I think that if we want to

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say it doesn't meet the payment methodology criterion, we should say that. But we shouldn't say everything else is inapplicable. And if we want to change our rules and say you have to pass the payment methodology test first before we'll consider any of the other things, which I wouldn't necessarily disagree with, but that would be a prospective change to people before they -- before they come in on our process.

I was going to answer the question about the nurses, and we can ask them, but my impression is the issue is you can have a nurse do it in other places under -- anywhere under the supervision of a physician. The concern here is that if the patient just comes in and sees a nurse, they will not have -- it's not a billable encounter because you have to have seen the practitioner, a billing practitioner who is not a nurse, on that visit. So you can't just come in for an annual wellness visit --

DR. TERRELL: That's not a rural health issue. That was my point. That's not specific to rural health.

MR. MILLER: It is in this particular case because this -- yes, this -- they can't bill that as an encounter; whereas, you could bill the visit to the physician practice -- maybe. I don't know. But, anyway, that's what we need to resolve, but that's the thing you're trying to solve. But we can ask them.

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DR. NICHOLS: It's not a technical billing difference for rural, but it's a practical issue because of the staffing reality of their world.

CHAIR BAILET: All right.

DR. TERRELL: RNs do it in my office, okay? But I go in and see the patient as the provider. Are you saying that an RN can't ask the questions and then they go in and do that with the provider seeing them?

DR. NICHOLS: We should ask Mercy [off microphone].

DR. TERRELL: Okay.

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

CHAIR BAILET: Right, and I think that's a perfect segue to actually inviting our submitters, Anne Wright and Sandra Christensen, who are on the phone, to address the Committee. Can you guys hear us?

MS. WRIGHT: Yes, we can. Thank you for the opportunity. This is Anne Wright, and I am the Director of Rural Operations at our Mercy Accountable Care Organization, and as somebody on the Committee had indicated earlier, we were the recipient of a Round 2 HCIA award. So, as you'd alluded to, we had indicated in our payment model, in developing our project, that we were going to have our rural participants join our ACO, and they

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would join a Medicare shared savings contract. And this is one of the challenges that we uncovered as we got into our project a little bit more, that right now all of our participants are kind of living in two worlds -- in a fee-for-service world and in a shared savings world. And with our rural health clinics getting reimbursed under their cost-based methodology, essentially if you work to decrease utilization, all you do is -- your costs stay the same, so you increase the cost per visit; thus, we don't have any opportunity with our rural sites for achieving shared savings, or we have minimal opportunity.

So that encourages the rural sites to live more in the fee-for-service world, and obviously our ACO, along with others, a huge strategy of ours is to get preventative services completed, and one of those big ones being annual wellness visits. And so when we are doing that, we've encountered that -- I think it sounds like the Committee understands correctly that with the all-inclusive rate method of reimbursement, a patient comes in for a medical service of some kind; they're not able to get the annual wellness visit completed that same day or at least able to bill for that service the same day. And that is -- it's a challenge for us because, as the group inferred, the patient would need to come back and transportation is a huge issue in a lot of our rural communities. They would

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need to leave and come back a separate day for that separate service. So this was a challenge that we've uncovered. Sandra -- I'm going to introduce my colleague here who's also joined us. She has more expertise than I do related to rural health clinic billing. Sandra Christensen, can you introduce yourself since you're on the line as well?

MS. CHRISTENSEN: Thank you, Anne, and thank you to the Committee. I am Sandra Christensen, and I am the finance exec for our rural network. So I work closely with -- across the State of Iowa with all of our critical access hospitals who many own and operate rural health clinics, as well as provider-based clinics.

Many of your points -- and Anne alluded to -- this topic does become access issue, and, you know, how do we -- and that issue as well as one of the Committee members pointed out, you know, the rural health clinic model of payment, which is cost reimbursed, and really what I'm going to call a "safety net reimbursement." And it's so important to continue to -- that we maintain that in our world so that we retain that access to care for patients across rural Iowa and in other states.

But I think our proposal talked about we have done a lot of work with the CMMI grant and our Health Coach Program, that we're looking to how do we create the

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sustainability of that position? You know, our rural health clinics have not mentioned it, but we have a concern that once the grant dollars go away to support that position, how do we have a billing mechanism or something that supports that health coach's role? And I think this proposal starts to address that, that if we can create a billable visit, one that the patient doesn't have to come back to, is -- supports the health coaches, which is an RN today, the role that he or she does, and also being mindful about in our rural communities access to physicians, mid-levels, just physician shortage, this helps expand those services and be able to meet the patient's needs.

And, you know, through wellness and prevention models, we are trying to move that patient care out of the ED into our clinics. But if we don't have access to more providers, we've got to create capacity somehow. And I think that was also one of the drivers behind this proposal.

MS. WRIGHT: Thank you.

Just one additional point of clarification that the group seemed to have in your discussions, the RN billing for the service, and in our clinics that are in our urban locations that are under the physician fee schedule, we do have RNs that their specific role is to actually do annual wellness visits. So they do it from start to finish

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in our urban clinics and are able to bill for that service as an incident. So it is a difference. My understanding of the rural health clinic legislative statute is that if a physician -- in order to bill for the service, a physician needs to see the patient, and because of the scheduling challenge in doing so with our -- with the physician shortages that we experience in our rural communities, that makes it challenging to get these annual wellness visits, which are huge drivers of quality, to be completed.

So I hope that helps to answer some of your questions. If there's any more, we're happy to address those as well.

CHAIR BAILET: Thank you.

We're now going to open it up for questions from the Committee members, and Harold Miller is first.

MR. MILLER: Hi, this is Harold Miller. Three questions for you.

First of all, I was a little perplexed. It sounded to me as though most of your rural health clinics are part of critical access hospitals. Is that right?

MS. WRIGHT: That's correct.

MR. MILLER: So you could, in fact, pay for the nurse simply as a cost to the rural health clinic because there's no limit on the per visit amount for a critical access hospital-located rural health clinic? Right?

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MS. WRIGHT: Correct.

MR. MILLER: So this really shouldn't be a problem for the rural health clinics at the critical access hospitals. I mean, in other words, you can't bill separately for an annual wellness visit, but you could hire a nurse; you could have the nurse doing those visits and simply count the cost of that towards the cost of the rural health clinic. You couldn't do that in an independent rural health clinic, but you can do it at a critical access hospital-based clinic because there's no limit on the per visit payment for a critical access hospital clinic. Correct?

MS. CHRISTENSEN: Correct.

MR. MILLER: Second question -- So this would be an issue for an independent rural health clinic, but it wouldn't necessarily be an issue for the critical access hospital-based clinics.

The second question was: It sounded like your ACO felt it to be valuable to do -- have the annual wellness visits done. I'm curious as to why the ACO then didn't pay for them itself in order to be able to achieve the savings that would be -- that you showed. You showed that the clinics that had the higher number of AWVs had lower spending, so I would think that if the ACO was trying to reduce spending, it would have decided to invest in

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those visits itself.

MS. CHRISTENSEN: And I think on that one -- this is Sandra Christensen -- they were running up against the whole methodology of cost reimbursement and, as Anne mentioned, decreasing the cost per visit, because as you -- and when you're looking at rural health clinics and they're aligned with critical access hospitals, as you're decreasing those number of visits, you're driving up the cost per visit. So in a rural health clinic, one of your points was that, yes, the cost of that health coach should be covered in the rural health clinic, cost reimbursement, and, yes, it is. But it's also spread across all of the payer mix in that clinic. So you're not getting 100 percent of that health coach's cost --

MR. MILLER: Well, it would be -- I mean, if you had -- if only Medicare was paying for it, then you would have the health coach or the nurse doing it just for Medicare patients. Maybe there's not enough volume to support that, but, in fact, because it's cost-based, if you restricted it that way, it would still be covered because there's no productivity requirement associated with that.

And I guess the third question was: Did you think at all about in terms of putting a proposal together to us or to anyone having some kind of a performance measure tied to paying for the annual wellness visits? For

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example, actually achieving a percentage of the population, actually having the annual wellness visit; as opposed to just saying we want to be paid for the annual wellness visits, actually having a percentage of the population screened or any other kinds of results associated with that? Because I think that's one of the things we're struggling with, is simply adding a payment for a service without any kind of quality or cost measure attached to it. Have you thought about whether there could be a measure of some kind you could attach to the payment?

MS. CHRISTENSEN: You know, I'm going to answer from my perspective -- this is Sandra -- and then maybe Anne, because, you know, that's a very good thought because that might be some of the answer on -- you know, we have challenges with the cost reimbursement methodology and what are the incentives to drive quality and compliance from the patient. And, you know, I'm not aware that we did put that in, but that might be something to consider in this model, that that is the benefit or an incentive payment for a rural health clinic provider that, yes, X number of patients meet these annual wellness visits, and that might be a model to consider.

MS. WRIGHT: And some of our sites do – they’re all of the providers are employed by their own critical access hospitals. So several of them have included in the

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provider compensation model as an incentive to complete annual wellness visits, that -- but those are the ones, you know, we're struggling, too, with a lot of our sites pay their providers based on RVUs (relative value units), and so they see this as a big time sucker to do annual wellness visits, which decrease their productivity.

So it's hard for us to mandate that they -- that they do employ a productivity model for their -- or that they do employ a compensation model change for the physicians that they employ. But it has been done, I guess, in several --

MR. MILLER: Every provider organization has to face the issue that if they're going to be paid differently on the outside, they have to pay differently on the inside. But I would just be thinking about whether there was some way that you could ensure that, in fact, the patients, the highest-risk patients were being reached, et cetera, through that model, because I think you actually could do something different like that given the kind of cost-based payment you have.

CHAIR BAILET: Thank you, Harold.

MR. MILLER: Thank you.

CHAIR BAILET: Paul.

MS. WRIGHT: Thank you.

DR. CASALE: Yeah, hi. Just a clarification, and

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I may have this wrong. It was my understanding that wellness visits in rural areas could be completed through a telehealth visit. Is that true? Or do I have that wrong?

MS. WRIGHT: I think -- no, I do think that that is -- I agree, that's a proposal in 2018 with the -- it's a proposal change effective in 2018.

DR. CASALE: Yeah, okay.

MS. WRIGHT: So that actually has kind of come about. Since we've submitted this application, we saw that that was in the proposed regulations, and it may be an opportunity. Some of the things that we need, we'd need to just work through operationally. For an annual wellness visit, you do have to take some just preliminary vitals that would -- you know, it's challenging to do that via telemedicine. But certainly portions of the annual wellness visit could be completed via telemedicine.

DR. CASALE: Yeah, that might help with the revisit and the travel.

MS. WRIGHT: Yes.

CHAIR BAILET: Thank you.

Any other questions for the submitters from the Committee?

[No response.]

CHAIR BAILET: Great. So, Anne and Sandra, we thank you for the time and effort to put this proposal

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together and answering our questions.

* **Comments from the Public**

CHAIR BAILET: I do not see that there are people who are in the queue to make a public statement, so I would open it up first for the phone. Anybody on the phone making a public comment?

[No response.]

CHAIR BAILET: And then anybody in the room wanting to make a public comment on this proposal before we move to the next phase?

[No response.]

* **Committee Deliberation**

CHAIR BAILET: Okay. So are we ready to go through the criteria? It looks like we are. Matt has queued it up.

So, again, just to reiterate, there's 10 criteria. We're going to go through them one at a time. The numbers 1 and 2 do not meet, 3 and 4 meets, 5 and 6 meets and deserves priority consideration, and then for criteria that the Committee member feels it not applicable, pushing the zero key will illuminate the asterisk column.

* **Voting**

CHAIR BAILET: So we're going to go ahead and start to vote on Criterion 1, which is Scope, which is a high-priority item, aimed at either directly address an

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issue in payment policy that broadens and expands the CMS APM portfolio or include APM Entities who has opportunities to participate, and APMs have been limited.

Please vote.

[Electronic voting.]

CHAIR BAILET: Ann.

* **Criterion 1**

MS. PAGE: Zero members voted 5 or 6, meets and deserves priority consideration. Zero members voted 4, meets. One member voted 3, meets. Zero members voted 2, does not meet. One member voted 1, does not meet; and nine members voted not applicable.

So the majority has determined that Criterion 1 is not applicable to this proposal.

CHAIR BAILET: Thank you, Ann.

Criterion Number 2 is Quality and Cost, high-priority item, anticipated to improve health care quality at no additional cost, maintain quality while decreasing cost, or improve health quality and decrease in cost.

Please vote.

[Electronic voting.]

* **Criterion 2**

MS. PAGE: Zero members voted 5 or 6, meets and deserves priority consideration. Zero members voted 4, meets. One member voted 3, meets. Zero members voted 2,

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does not meet. One member voted 1, does not meet. Nine members voted not applicable.

The majority has determined that Criterion 2 is not applicable to this proposal.

CHAIR BAILET: Thank you, Ann.

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

Please vote.

[Electronic voting.]

* **Criterion 3**

MS. PAGE: Zero members voted 5 or 6, meets and deserves priority consideration. Zero members voted 3 or 4, meets. Zero members voted 2, does not meet. Five members voted 1, does not meet; and six members voted not applicable.

The majority has found that six -- that the proposed -- that Criterion 3 is not applicable to this proposal.

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CHAIR BAILET: Thank you, Ann.

And Criterion Number 4 is Value over Volume, providing incentives to practitioners to deliver high-quality health care. Please vote.

[Electronic voting.]

* **Criterion 4**

MS. PAGE: Zero members have voted 5 or 6, meets and deserves priority consideration. Zero members voted 4, meets. One member voted 3, meets. Zero members voted 2, does not meet. One member voted 1, does not meet. Nine members voted not applicable.

The majority has determined that Criterion 4 is not applicable to this proposal.

CHAIR BAILET: Thank you, Ann.

And number 5, Flexibility, provides the flexibility needed for practitioners to deliver high-quality health care.

Please vote.

[Electronic voting.]

* **Criterion 5**

MS. PAGE: Zero members voted 5 or 6, meets and deserves priority consideration. Zero members voted 4, meets. One member voted 3, meets. One member voted 2, does not meet. Zero members voted 1, does not meet; and nine members voted not applicable.

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The majority has determined that Criterion 5 is not applicable to this proposal.

CHAIR BAILET: Thanks.

And number 6 is Ability to Be Evaluated, evaluable goals for quality of care, cost, and other goals of the PFPM.

Please vote.

[Electronic voting.]

* **Criterion 6**

MS. PAGE: Zero members have voted 5 or 6, meets and deserves priority consideration. Zero members have voted 4, meets. One member voted 3, meets. Zero members voted 1 or 2, does not meet; and 10 members voted not applicable.

The majority has determined that Criterion 6 is not applicable to this proposal.

CHAIR BAILET: Number 7 is Integration in Care Coordination, encourage greater integration and care coordination among practitioners and across settings where multiple practitioners or settings are relevant to delivering care to the population treated under the PFPM.

Please vote.

[Electronic voting.]

CHAIR BAILET: There we go.

* **Criterion 7**

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MS. PAGE: Zero members voted 5 or 6, meets and deserves priority consideration. Zero members voted 4, meets. One member voted 3, meets. Zero members voted 2, does not meet. One member voted 1, does not meet; and nine members voted not applicable.

The majority has determined that Criterion 7 is not applicable to this proposal.

CHAIR BAILET: Thank you, Ann.

Patient choice, encourage greater attention to health of the population served while also supporting the unique needs and preferences of individual patients.

Please vote.

[Electronic voting.]

* **Criterion 8**

MS. PAGE: Zero members voted 5 or 6, meets and deserves priority consideration. One member voted 4, meets. Zero members voted 3, meets. Zero members voted 1 or 2, does not meet. Ten members voted not applicable.

The majority has determined that Criterion 8 is not applicable to this proposal.

CHAIR BAILET: Thank you, Ann.

Patient Safety is number 9, Aim to Maintain and Improve Standards of Patient Safety. Please vote.

[Electronic voting.]

* **Criterion 9**

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MS. PAGE: Zero members voted 5 or 6, meets and deserves priority consideration. One member voted 4, meets. Zero members voted 3, meets. Zero members voted 1 or 2, does not meet; and 10 members voted not applicable.

The majority has found that Criterion 9 is not applicable to this proposal.

CHAIR BAILET: Thank you, Ann.

The last criterion, Number 10, is Health Information Technology, encourage the use of HIT to inform care.

Please vote.

[Electronic voting.]

* **Criterion 10**

MS. PAGE: Zero members voted 5 or 6, meets and deserves priority consideration. Zero members voted 4, meets. One member voted 3, meets. Zero members voted 1 or 2, does not meet; and 10 members voted not applicable.

The majority has determined that Criterion 10 is not applicable to this proposal.

CHAIR BAILET: And, Ann, just to summarize the voting, please?

MS. PAGE: The Committee determined that all 10 criteria are not applicable to this proposal.

CHAIR BAILET: Okay. So now the next and final phase is actually voting on the recommendation to the

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Secretary. So if we could get that up, Matt?

Thank you.

So we have four numbers, 1 through 4: 1, do not recommend the model to the Secretary; number 2 is recommend the model for limited-scale testing; 3 is recommend the proposed model to the Secretary for implementation; and 4 is recommend the proposed payment model to the Secretary for implementation as a high priority. Again, we the fifth category, which is not applicable, and that is by pressing the key zero will get you the asterisk here.

So we're going to vote electronically first, and then we're going to go around the room. So please vote.

Ann?

[Electronic voting.]

* **Final Vote**

MS. PAGE: Zero members voted 4, recommend proposed payment model to the Secretary for implementation as a high priority. Zero members voted recommend proposed payment model to the Secretary for implementation, and zero members voted recommend the proposed payment model to the Secretary for limited-scale testing. One member voted to not recommend the proposed payment model to the Secretary, and 10 Committee members voted that that proposal is not applicable. And that would be the recommendation to the Secretary.

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* **Instructions on Report to the Secretary**

CHAIR BAILET: All right. So we're going to start with Tim, and we'll just go around the room.

DR. FERRIS: I voted not applicable, and it was for the reasons that we had discussed. Maybe if I try to articulate them briefly, it was because we considered this proposal to be a technical change in regulations that did not represent a new model but represented a change in technical regulations related to an existing model, and with concerns about the difficulty of drawing a clear line between those things, I felt that this fell clearly on the side of that, of that line, where this was not a new payment model.

CHAIR BAILET: Grace?

DR. TERRELL: I voted not applicable, and with -- I agreed with the PRT's logic. And with respect to the fact that we established -- we're calling it case law, but we need to make sure that our public understands it is not case law. It's a metaphor that we're using, but we established a logic at the Committee level with the last one around this issue of applicability and how we vote.

I, therefore, flipped from my opinion last time and voted not applicable because I believe now that that would be where the Committee's consensus was, so I will do that in the future if something is deemed not applicable.

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CHAIR BAILET: Thank you, Grace.

Harold?

MR. MILLER: I voted do not recommend. I would like to be recorded as a very strong minority opinion. I do not believe it was appropriate to say that these were not appropriate. I think all of the criteria were appropriate for this model. I did not feel that the payment methodology was something that we should recommend, but I think that all of the criteria are applicable. And I would like to have that recorded.

I do think that we should be defining more clearly what kinds of things we want to see and what characteristics we want to have, but I think that ultimately, if someone -- unless we are going to say, which we have not said so far, we will not accept applications, then I think if someone sends us an application, even if we have said clearly what we are not inclined to recommend, then we should review it and review it and recommend against it or don't recommend it, but not simply punt on the evaluation of it against all the criteria because I think it is helpful to the applicants. I think it is ultimately helpful to the Secretary to CM, to CMMI or anyone else to know that we said we felt that something, in fact, might improve quality and reduce cost, et cetera, but that we didn't even think the payment methodology was

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adequate versus something that we didn't even think was a payment at all.

And I think this was a -- is a payment model. It just does not meet the kind of criteria that we should approve.

CHAIR BAILET: Paul?

DR. CASALE: Yeah. I voted for not applicable, and I respectfully disagree, Harold. I just didn't see this as a model to -- that I could evaluate each criteria.

I think some of your suggestions to the submitters about, well, if you're going to be paid differently on the annual wellness, you're going to tie it to some cost or outcome or other measures. And I just didn't see enough to see that this was, indeed, an actual model other than just a change in payment.

CHAIR BAILET: Bruce.

MR. STEINWALD: I voted not applicable. I think since there is an established rulemaking process for a change like this that it's not necessary or desirable for us to evaluate it.

And furthermore, given the volume of proposals we're getting and the volume of materials we have to review for meetings like this, I certainly wouldn't want to encourage more proposals of the kind that are -- let's call them "de minimis changes" in payment methodology.

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CHAIR BAILET: I also voted not applicable and for the reasons already stated.

VICE CHAIR MITCHELL: I voted not applicable for every criteria and for the overall model.

DR. NICHOLS: I voted not applicable because I think it's important not to prejudice the Secretary against the idea that he might want to -- or she might want to consider this coding business they're asking for because, in fact, it probably does make sense in their context, but it's not a model that rises to the level I think we should be -- we should be concerned with.

DR. PATEL: I also voted not applicable for reasons already mentioned.

DR. BERENSON: I largely -- I voted not applicable, and Bruce stated my view pretty exactly. I don't think our job is to administer -- tell CM how they administer established payment models that they have authority to do. We're supposed to be identifying important new alternative payment models that fundamentally change incentives, change behavior, and if we spend all of our time deciding on the merits of a code change, we will not have any energy to do what we're supposed to be doing.

DR. MEDOWS: I voted non-applicable because I believe it is a rural health clinic reimbursement issue for annual wellness visits. I also believe that it is

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something that needs to be addressed with respect to expanded scope of practice for RNs in rural communities where there is a real need to actually have providers available.

Thanks.

CHAIR BAILET: Thank you, and thank Anne and Sandra for submitting the proposal and staying with us, even though it's on the phone, while we ask clarifying questions and finished our process.

Any final comments because --

MS. WRIGHT: Thank you for the --

CHAIR BAILET: Go ahead, please.

MS. WRIGHT: No, I just -- I just wanted to say thank you for the opportunity.

CHAIR BAILET: You're welcome.

I think it's important, Tim, if you could just summarize where we are as it relates to the Secretary's report specifically in the comments, please.

MR. DUBE: Certainly.

So, at this point, 10 of the PTAC members voted that it was not applicable. One PTAC member voted that it -- that all 10 criteria should be evaluated, and I did want to just probe the PTAC members to see if there was a direct response to Dr. Miller's assertion that all 10 criteria be [unintelligible]

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DR. TERRELL: Mr. Miller.

MR. DUBE: Oh, Mr. Miller. Sorry.

MR. MILLER: Harold.

CHAIR BAILET: He plays one on TV.

[Laughter.]

MR. DUBE: I didn't hear any direct responses to his assertions, and I wanted to make sure that if there were any, that we recorded those.

DR. CASALE: Well, I responded. I said I respectfully disagreed that it could be evaluated on all the criteria because I didn't feel there was enough in there, particularly around --

MR. MILLER: I think it's a minority opinion. I think everybody does disagree with what I said. That's why I said I think it -- I want to be recorded as a minority opinion.

DR. BERENSON: But I would want to put in the record that the PRT did not review those 10 criteria on the merits, so that I would have no basis for voting one way or another for those 10 criteria because we didn't establish -- we didn't discuss them at all. We took the position that since the proposal wasn't applicable, we had no judgment. And I think that needs to be repeated. I think it represents the majority view as to why they voted -- that we voted non-applicable.

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CHAIR BAILET: Harold.

MR. MILLER: I guess one thing I would propose is I -- for the language into the final report, I guess I would suggest wholly independent of my point, I would suggest that we not include the statement that is at the beginning of the last paragraph, where it says concluding that it lacked the expertise or standing to consider modifications to an existing payment methodology because I think everything we are doing is modifications to existing payment methodologies, and that's to me an odd thing to say.

It's a completely different thing to say, I think, in terms of some technical changes to something, but that statement as it's written, it seems to me to be overly broadly sweeping.

DR. BERENSON: I am more than happy to take that statement out.

* **Discussion on Atypical Proposals**

CHAIR BAILET: Any other comments, Tim, at this point?

[No response.]

CHAIR BAILET: No?

So that concludes our fourth proposal, and I just wondered, given the fact that this was the second, what we were classifying as atypical, whether we could spend a

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minute as a Committee and actually deliberate to some degree or discuss amongst ourselves with the public listening in on what do we do futuristically, what's our -- do we have a methodology, whether it's Tim's, you know, bifurcation, two-part model? I don't know. But I think if we could spend a minute, it would be helpful.

So I don't know if you want to open it up, Tim, or, you know, you've got a point of view on it.

DR. FERRIS: Well, I think to me, framing this conversation in the context of maybe -- maybe the term for this is the "Goldilocks Dilemma" for the PTAC, which is we reviewed -- or we're asked to review a proposal that seemed in some ways too large for PTAC.

We also reviewed a proposal, which we -- some of us felt was too small for PTAC, and I have to say I have some degree of discomfort establishing -- and I think this reflects what I have learned from Bob -- establishing what -- where the cutoffs are based on criteria because I worry that any criteria we come up with -- we haven't seen enough proposals to know whether or not if we establish criteria.

On the other hand, it might be beneficial to us to put some strawman, straw-person criteria out, not as a rule, but as a test of our own process to see whether or not proposals that we think are too large or too small, if the criteria work.

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I worry that if we don't propose something that our process for figuring out what guidance to give the public will be delayed even further.

So in that spirit, in the spirit of that context of the Goldilocks Dilemma for the PTAC, the criteria was actually -- it's not a mystery. It was actually in the language of the PRT report under the payment methodology, which is there has to be some accountability for quality, very general, just some accountability for quality, and some accountability for cost.

I believe that the last proposal that we reviewed would not -- there was -- I didn't see it; maybe it was there -- either accountability. There was a -- there was a statement that they believed quality would get better, but there was no measurement of quality, and there was no proposed accountability for quality.

There was also a statement that they believed cost would get better, but there was no -- in the methodology itself, there was no accountability for that. They didn't pay any penalty if they didn't -- if it didn't get better.

So that was the framework that it seemed to apply, that didn't seem particularly limiting, although it might be. I worry that it might be -- and seemed to apply to at least this proposal. So that was the -- that's all I

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have to say.

CHAIR BAILET: All right. So I have Harold, Bruce, Bob, and Grace.

MR. MILLER: So I agree with everything Tim just said, and in fact, we have that already in the document for the submitter instructions where we said that we were more likely to recommend. That's how we phrased it.

I recall that we ended up with that language because we concluded through the counsel process, et cetera, that we were not able to refuse to accept proposals. Now, we could revisit that, but that's my recollection, was that we were -- we talked about saying we don't want to review proposals of the following character, and I believe we concluded at that point -- and that -- or at least the concern was that we didn't have -- this is another one of those under-the-statute things. We didn't have the ability to somehow say we were precluding certain proposals from coming in.

My concern is that saying, sort of using the round-about way of saying that we don't think that the criteria are applicable, it seems to me that what it's leading us to is some sort of a statement about an order of the criteria that we will -- that we will review in, that we will not review the other criteria if we think that it doesn't meet the payment methodology criteria.

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It seems to me, as I reflect on a lot of the things that we've been looking at, is that some of those other criteria reviews end up being somewhat -- I don't know -- perfunctory, anyway, if we think that the payment methodology really is fundamentally flawed, and again, my concern is I guess the semantics of somehow saying the criteria isn't applicable.

So it seems to me that the solution would be to say we're going to review the payment methodology first and if the payment methodology doesn't count -- now, we had -- at least in my mind, we had put some of the other things sort of first in order because we fundamentally didn't want to just be changing payments. We wanted to be improving quality, and we wanted to be improving cost. And that was kind of the threshold first.

But as a practical matter, what has turned around is that somebody might have really great goals for quality and really great goals for cost, but if they don't have a payment methodology that works, then we say, fundamentally, no, we're not going to recommend it.

So it just seems to me that a practical reflection of what we are is that we are saying that the payment methodology is kind of the first criterion, and if it doesn't pass on that, we're not going to recommend the model. And we might recommend changes to it or whatever,

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but that to me might be the way to sort of split the Gordian knot, in my opinion.

CHAIR BAILET: Bruce is -- So it's Bruce, Bob, and Grace.

MR. STEINWALD: Yeah. I'm not sure we've learned enough from these two proposals to establish criteria. I'm a slow learner, so take that into account.

There's another proposal. There was three atypical proposals, and the PRT decided to actually go through the criteria on the proposal we were looking at tomorrow. And we may learn something from that discussion, but fundamentally, even though I agree with the points about accountability, I think we need more case law, Grace.

CHAIR BAILET: Bob.

DR. BERENSON: Yeah, I agree with Bruce there. I can think of at least two other circumstances in which I would say it doesn't qualify as an APM. One is if it's a payment model that isn't physician-focused. Somebody has a new payment model for home health care, and physicians are peripheral or not involved at all, I would say it's not something we should be reviewing. Even though it is a payment model, it's not a physician-focused payment model, and we would need to establish what we think is physician-focused.

And then the one that's going to come up tomorrow

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has to do with Medicare. It's a Medicare payment model, and my hunch is we will come up with their criteria as they present. So that would be, number one, I don't think we're ready, but I agree with Harold that we should send a signal out that maybe we want to be a little more -- maybe we want to be stronger, that we will not consider some models that are -- and fill in the blank -- that are just mere -- I don't know what we would say, but I do think we have to figure out how to communicate this.

And then the second point I want to make is I happen -- and while I went along reluctantly with it months ago -- to not agree that accountability for cost and quality is the hallmark of an APM. I think one can make dramatic improvements in value in a physician fee schedule through coding and payment, and I don't hold to that criterion. I do understand that the PTAC did establish that, but I would want to reconsider it.

It was the CMS formulation. It was Patrick Conway's formulation. I don't think it's right, and I can imagine substantial changes to fee-for-service that improves value. And I would not want to say, "Oh, no, those are not value-based payment models because it doesn't have explicit process measures for measuring quality."

CHAIR BAILET: Len. Like I said, Grace.

DR. TERRELL: There was discussion of a strawman,

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so I wanted to just put out the things that I think we have learned so far today as we broaden the discussion tomorrow with respect to how we might actually find Baby Bear.

[Laughter.]

DR. TERRELL: What I believe we've learned is that it -- and maybe this would be partly out of tomorrow -- it's got to be relevant to the Medicare population as opposed to other populations. So that would be something that, you know, could be an a priori criteria.

The second one is -- it was just alluded to, which is it has to be relevant to the way physicians and the other qualified providers in the regulations are paid.

The third one that we talked about today was an overall change to the Medicare benefits at the MACRA level is not what our job is, and we could probably get language around that, that we could be clear about.

And then what we just learned, I believe, is that it's got to be more than just a change to policy with respect to how certain fees are paid or not paid today, with the scope issues -- so it's got to be more than just a fee schedule change.

The next one is that it -- and Bob has brought this up in several cases before, is there -- and we talked about it today briefly to. It ought not to be -- if there's some other way it can be done in the current

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situation, for example, the chronic care codes, then we can -- then that needs to be fleshed out. I mean, if somebody comes with a new way, but there's already a way it can be done, there's got to be something more than just it's a different way of getting to the same results. It's got to be something better. And maybe that's the place where the cost, quality could be articulated in a way that we could get to consensus.

And then my final concept, which is not that, which is Harold's proposal that if it doesn't meet the payment methodology in these criteria or any others that we come up with, we just don't go forward and review, the problem is that's a PRT that's making that distinction as opposed to the full PTAC, which may not agree with it. And so we would have to come up with a way of addressing that.

If there was a consensus at the PRT level that three out of three said isn't applicable, could there be some process there that got directly to the full PTAC or not, it would slow things down potentially up front, but it may actually decrease the amount of work downstream. So that component of this proposal, if we went in that direction, would have to go PTAC first and then PRT.

But it could be appropriateness that came out of the PRT, so those are the things that I learned, I think we learned today.

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CHAIR BAILET: All right. So go ahead, Len. Sorry.

DR. NICHOLS: So I think of life as a Google doc, and I don't know why we can't put stuff up there now, even though it's not going to be final, because we have learned a lot in the last couple of days. And what I'm most concerned about is that we send signals to the community about where our rank order and what our priorities and what our -- so forth -- really is.

I personally would be quite happy if the payment model criterion did get elevated up to an uber level because my suggestion of triggering Grace's mechanism here is if the PRT thinks this thing they're reviewing doesn't rise to the level, in my view, the payment model is the right thing to shop around.

I agree the whole PTAC has to judge that. We can't depend on a three-person PRT to do it for us, but I don't know why we couldn't do that in expeditious manner, and then we have an agreement.

I understand why we can't do it legally.

MS. PAGE: It has to be in public.

DR. NICHOLS: But I'm just saying -- well, I'm happy to do that. Let's do it on the phone in public, but I'm just saying the notion of we've got to wait and go through and yadda yadda, bing, bang, bong, we've got to do

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every -- that's silly. We can do better.

CHAIR BAILET: So, Harold, do you want to -- I'll let you go in front of me.

MR. MILLER: Well, I was -- I guess two points. One is to Grace's list. When I look at -- the regulations have two parts to them. At the beginning, they say Secretary has said payment model is Medicare, and its physicians, you know, and/or other providers. So that's kind of like the first thing, and then the criteria follow that. So, in my mind, there's a distinction between saying -- I mean, it's almost like to me it's backwards if it doesn't meet the Medicare criteria, then the criteria aren't applicable. But on the other hand, if it does meet those two things, the criteria are applicable, whether we think it's good or not.

So, anyway, I would just -- I would -- I think there's a distinction there between that list of things that we've been talking about that we have to relate back to what our charge is.

I don't agree -- I don't see any problem with us saying if a model comes in and the PRT looks at it and says, "Boy, we think the payment methodology is so bad here that we really don't think it's" --

DR. TERRELL: Not applicable.

MR. MILLER: No. Bad. I'm saying if we think

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the payment methodology is sufficiently bad, that we don't think it's worth the time to look at all the other things, then take that to the PTAC, have a discussion about that, and if, in fact, the PTAC disagrees that it really ought to be reviewed, then go back and do that.

But what we're talking about is people struggling to try to figure out what to do when we know that the groups are overloaded, and, you know, it depends on the volume.

Anyway, that's just, again, my opinion.

CHAIR BAILET: Okay. So here's my -- My caution is I don't think that the payment model in a vacuum can impugn our ability to review a proposal, and what I mean specifically about that is that there are some very elegant proposals that address seven or eight of the criteria potentially.

I can reflect on one or two that we've already reviewed, and there are some in the queue. So I think that if we have specific points of view relative to it, it could be -- it might not be the payment methodology. It may be something else that deems it not applicable, but to stay the course on payment methodology, since that's the theme of the day --

DR. TERRELL: It's also the name of our Committee.

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CHAIR BAILET: Pardon me?

DR. TERRELL: It's also the name of our Committee.

CHAIR BAILET: Right.

[Laughter.]

CHAIR BAILET: But I think we could telegraph that if it's a small change to existing payment, we're going to have a particular point of view and maybe activate a review on whether it should go forward or not, or the opposite, to Tim's analogy, that it's so transformative that it's really out of the realm of our Committee's purview. That's another opportunity.

And we may find, as we do more of these reviews, there may be other trip wires that will force us to maybe aggregate, come together, and come up with a determination on whether we should push it forward or not.

But I guess I just want to make sure that we're not walking out of this meeting that you could have an elegant, very elegant clinical model that is meritorious that has some flaws in the payment methodology that we would not support, right?

MR. MILLER: I wasn't suggesting that it always be a two-step process. I was more saying that if the PRT looks at it and basically doesn't think that it meets the payment methodology and has no other reason to bring it

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forward, but rather than having to go and evaluate every criterion completely, that it would make that judgment. But that's --

CHAIR BAILET: I completely agree with you, Harold, but it's that last qualifying comment that you made, that had you made that, I probably wouldn't have raised my placard.

So, Elizabeth, bring us home.

VICE CHAIR MITCHELL: I don't know about that, but I want to own any contribution made to our inconsistent case law. And I am not prepared to go with the payment model criteria at this point because that was where I really parted company on the big Medicare proposal.

But I like this sort of Baby Bear idea, and I'm not sure we're there yet. We don't fully recognize what it would look like, but --

DR. TERRELL: Just right.

[Laughter.]

VICE CHAIR MITCHELL: Just right.

But the two things that I think were entirely consistent on the two proposals that we -- on two of the proposals we didn't support was that it could have been done elsewhere. There was another way to do it. Whether it was the CCM or whether it was, you know, the last proposal, there was an alternative approach, and so we

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weren't needed for that. So maybe that's sort of a threshold that we can start to apply as we identify the others.

CHAIR BAILET: I think you finished it off.

Oh, Harold.

MR. MILLER: We haven't finished it because we haven't talked about what we're going to do with this.

I mean, it seems to me that we -- I'll just make a proposition. We need to -- well, we'll have -- but I think we should think about either having a discussion -- we could do it by phone and have kind of an open -- invite people in to comment or put out a document. We did that before. We haven't done that in a while, but to basically, back to the earlier point, is not just to have a document out that says we have a non-applicable category, but to say we are considering the following things or we're considering the following options.

We're thinking about we might do this, we might do that, and see what people say to -- has input to all of us. That would be a concrete next step that would kind of move us forward on that, get some feedback, find out whether other people see there's a problem with that before we try to make any decision.

CHAIR BAILET: So, Harold, that's a slightly different direction than where we were going because I

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thought what we were going to do is what we just did, meaning we -- As a Committee, we're going to develop a point of view. We weren't necessarily opening it up to the public for them to comment. I thought it was an opportunity -- well, I thought it was an opportunity for us to determine whether we move forward with a full evaluation or not.

MR. MILLER: Well, but we're -- if we're -- that's a change in process, we would have to -- that's all I'm saying, is I think we --

CHAIR BAILET: Understood.

MR. MILLER: -- we need to say here's what we're thinking about --

CHAIR BAILET: I got it.

MR. MILLER: -- and get feedback on it, and I was just suggesting that maybe we could also have some options in there if there are certain things that we're not all fully in agreement on.

CHAIR BAILET: Len?

DR. NICHOLS: I would support getting comments from the Secretary, from CMMI, from everybody we know, including the public, but I think we need to know what the rest of HHS thinks about us deciding these are beyond the pale because people may say no, no, no, you have to -- and I would like to hear -- I mean, first of all, I'm not

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qualified to interpret statutory language, in my opinion. I don't always like what general counsel does when they take that hat on, but they're better at it than I am or at least they're more experienced. So I'd like to know what they think about us deciding this and we're looking for Baby Bear here, and she said, "Oh, no, no. You're looking for all bears." I want to know if Baby Bear is okay.

DR. CASALE: I think that's a good point, and I wanted to ask the submitter, but I didn't. What Bob said, apparently the submitter was sent by CMMI to us, not to CM, right? So how did --

MR. MILLER: They must think it's applicable.

DR. CASALE: So to Len's point about having some discussion with them, CM -- CMMI.

CHAIR BAILET: So, in summary, do we -- no, I don't think we're done. I think we need to circle back.

So, Harold, your proposal, is that --

MR. MILLER: My proposal would be I think we need to write something up, circulate it amongst ourselves, with the idea being that it's going to be posted as a modification or proposed modifications to our process --

CHAIR BAILET: For comment.

MR. MILLER: -- for comments. That's what we did before.

CHAIR BAILET: All right. So that's the next

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step.

MR. MILLER: That would be the next step.

CHAIR BAILET: All right.

Do we need motion on that, or are we good to go?

MR. MILLER: I'd like to make a motion that we do that.

DR. MEDOWS: Second.

CHAIR BAILET: All in favor?

[Chorus of ayes.]

CHAIR BAILET: Alrighty, then. So, we've got that captured. We've lost --

MS. STAHLMAN: No, we lost the DFO.

CHAIR BAILET: We lost the DFO.

So I'm going to go ahead. I want to thank everybody for hanging with us this entire day, and we'll see you back again tomorrow.

* **The meeting is adjourned.**

[Whereupon, at 6:34 p.m., the PTAC meeting was recessed, to reconvene at 9:00 a.m. on Tuesday, December 19, 2017.]

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