PHYSICIAN-FOCUSED PAYMENT MODEL TECHNICAL ADVISORY COMMITTEE (PTAC)

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PUBLIC MEETING

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

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Monday, June 17, 2019

PTAC MEMBERS PRESENT

GRACE TERRELL, MD, MMM, Vice Chair
PAUL N. CASALE, MD, MPH
HAROLD D. MILLER
LEN M. NICHOLS, PhD
ANGELO SINOPOLI, MD
BRUCE STEINWALD, MBA
JENNIFER WILER, MD, MBA

PTAC MEMBERS IN PARTIAL ATTENDANCE IN-PERSON

JEFFREY BAILET, MD, Chair

PTAC MEMBERS IN PARTIAL ATTENDANCE VIA TELECONFERENCE

KAVITA PATEL, MD, MSHS

PTAC MEMBERS NOT IN ATTENDANCE

TIM FERRIS, MD, MPH
RHONDA M. MEDOWS, MD

STAFF PRESENT

STELLA (STACE) MANDL, RN, BSN, BSW, PHN, Office of the Assistant Secretary for Planning and Evaluation (ASPE)
SARAH SELENICH, MPP, Designated Federal Officer (DFO), ASPE
SALLY STEARNS, PhD, ASPE

A-G-E-N-D-A

P-R-O-C-E-E-D-I-N-G-S

9:04 a.m.

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

We extend a special thank you to the stakeholders who have submitted the proposed model today, especially those who are participating in today's meeting.

I'm Grace Terrell of Envision Genomics and Wake Forest Baptist Health. I am the Vice Chair of PTAC. And I will be chairing today's meeting.

This is the PTAC's eighth public meeting that includes deliberations and voting on proposed Medicare physician-focused payment

models submitted by members of the public.

At our last public meeting in March, we deliberated and voted on two proposals related to wound care, one submitted by SEHA Medical and Wound Care and another submitted by Upstream Rehabilitation. Last month we sent a combined report containing our comments and recommendations on those proposals to the Secretary.

In addition, our preliminary review teams have been working hard to review several proposals, one of which we are scheduled to deliberate and vote on today.

To remind the audience, the order of activities for the proposal is as follows. First, PTAC members will make disclosures of any potential conflicts of interest. We will then announce any committee members not voting on a particular proposal.

Second, discussion of each proposal will begin with a presentation from the preliminary review team, or PRT, charged with

conducting a preliminary review of the proposal.

After the PRT's presentation and any initial questions from PTAC members, the committee looks forward to hearing comments from the proposed submitters and the public. The committee will then deliberate on the proposal.

As deliberation concludes, I will ask the committee whether they are ready to vote on the proposal. If the committee is ready to vote, each committee member will vote electronically on whether the proposal meets each of the Secretary's ten criteria.

After we vote on each criterion, we will vote on our overall recommendation to the Secretary of Health and Human Services.

And finally, I will ask PTAC members to provide any specific guidance to ASPE staff on key comments they would like included in PTAC's report to the Secretary.

A few reminders as we begin

discussion of today's proposal. First, if any questions arise about PTAC, please reach out to staff through the ptac@hhs.gov email. Again, that email address is ptac@hhs.gov.

We have established this process in the interest of consistency in responding to submitters and members of the public and appreciate everyone's cooperation in using it.

I also want to underscore three things. PRT reports are reports from three PTAC members to the full PTAC and do not represent the consensus or the position of the PTAC.

PRT reports are not binding. The full PTAC may reach different conclusions from those contained in the PRT report.

And finally, the PRT report is not a report to the Secretary of Health and Human Services. After this meeting, PTAC will write a new report that reflects PTAC's deliberations and decisions today, which will then be sent to the Secretary.

PTAC's job is to provide the best possible comments and recommendations to the Secretary. And I expect that our discussions today will accomplish this goal.

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

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

* **Deliberation and Voting on Community Aging in Place - Advancing Better Living for Elders (CAPABLE) Provider Focused Payment Model submitted by Johns Hopkins School of Nursing and Stanford Clinical Excellence Research Center**

The proposal we will discuss today is called CAPABLE Provider Focused Payment Model, which was submitted by the Johns Hopkins School of Nursing and the Stanford Clinical

Excellence Research Center.

*** PTAC Member Disclosures**

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

VICE CHAIR TERRELL: I'm Grace Terrell. And I have nothing to disclose. At this time, I'm going to go around to --

CHAIR BAILET: Sure. Thanks, Grace. Jeff Bailet, Chair of PTAC. I was formerly the Executive Vice President for Health Care Quality and Affordability with Blue Shield of California until the end of May.

Starting in June, I am now the CEO of NewCo. It's a new company that Blue Shield is spinning off to support physicians to provide physician support services, particularly for independent physicians. The company is two weeks old. And we're working on a name. So there will be more to follow. But --

(Off-microphone comments.)

CHAIR BAILET: It won't be NewCo forever. My disclosure is Blue Shield of California has been and continues to be a multi-year financial supporter of Stanford Medicine Clinical Excellence Research Center. While I do not know or have spoken to the submitters about this proposal nor have I been involved in any way with its creation, I recuse myself from deliberation and voting. So, Grace, I will be leaving after the disclosures.

DR. NICHOLS: I'm Len Nichols. I'm a health economist in George Mason University. And I have no conflicts.

DR. WILER: Jennifer Wiler, I'm an emergency physician in Colorado. And I have no conflicts.

DR. SINOPOLI: Angelo Sinopoli, Executive Vice President and Chief Clinical Officer of Prisma Health in South Carolina. And I have no conflicts.

MR. MILLER: I'm Harold Miller. I'm

the President and CEO of the Center for Healthcare Quality and Payment Reform. And I have no conflicts.

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

MR. STEINWALD: I'm Bruce Steinwald. I'm a health economist here in Washington D.C. And I have nothing to disclose, which means I have no conflicts.

VICE CHAIR TERRELL: And we have on the phone Dr. Kavita Patel. Can we open the lines? And is Dr. Patel going to give a disclosure?

DR. PATEL: Hi. It's Kavita Patel. I have no idea if anyone can hear me.

VICE CHAIR TERRELL: We can hear you.

DR. PATEL: Can you hear me?

VICE CHAIR TERRELL: We can hear

you.

DR. PATEL: Oh, okay. Great. I'll keep it short and sweet. Kavita Patel, I'm Vice President of Johns Hopkins Health System. I was not involved in the development of this proposal but have recused myself.

VICE CHAIR TERRELL: All right. At this time, we are going to start the deliberations. So I will ask those who have conflicts to leave the room.

*** Preliminary Review Team (PRT) Report to PTAC**

So I'm now going to turn the microphone over to the lead of the Preliminary Review Team for this proposal, Len Nichols, to present the PRT's findings to the full PTAC.

DR. NICHOLS: Thank you, Madam Chair. We're going to call this CAPABLE, but it stands for Community Aging in Place-Advancing Better Living for Elders Provider Focused Payment Models, submitted by Johns Hopkins and Stanford Clinical Excellence

Research Center.

The other members of the PRT who, of course, are both smarter than I am are Paul Casale and Jennifer Wiler. I note they are physicians. It's entirely interesting that they picked an economist to lead this thing. It must have been a random draw.

Anyway, so my first job is to go through the rules. And this is how we do this stuff, right. There's a Preliminary Review Team actually selected by the Chair every time a proposal comes in. And the staff reviews it for completeness. And then it's assigned out to this three-person PRT team. I think the only rule is there has to be at least one doc on each PRT.

I will go over our proposal overview very briefly. And then we'll talk a summary about what we thought were true, talk about the key issues, and then go through the Secretary's criteria specifically.

I think I just said all this.

Basically, as Grace said, I'll just iterate, in fact, what the PRT is doing is kind of like a preliminary review. It's designed to make the deliberation more efficient at this level.

This is the only time everyone has talked about the proposal. And certainly the PRT opinions, as expressed in the report, are not binding. They are merely informative hopefully.

And basically the process is the proposal is reviewed by staff. We then look at it in detail. Typically, and in this case, we did ask questions of the submitter to clarify things that we didn't quite understand.

And also, staff and their very capable contractors at NORC will give us supporting information, both things they know we ought to know, as well as questions we may have for them. And they will sometimes do data analyses as well.

And as Grace said, this report is not binding on PTAC. But it is here to help us

reach conclusions efficiently.

So this, first of all, comes with a history. This CAPABLE proposal was based on a pilot that was funded under a Health Care Innovation Award. And it also has been evaluated as an NIH-funded randomized control trial. So it comes with a good pedigree.

It's designed to improve the functional ability of older adults with chronic conditions and with functional limitations. When you think about the way the APM structure is set up in the statute, the APM entity would likely be an accountable care organization or some kind of equivalent entity.

The intervention or the actual essence of the program is listed on the left-hand side there. Think about it as a time limited intervention. There will be 10 home sessions, 60 to 90 minutes each, 6 with an occupational therapist, 4 with a registered nurse, over a course of 4 to 5 months.

In some ways, the key innovation is

the handyworker, which is basically somebody who knows how to fix stuff, and at the direction of the OT, would perform what we can call limited home repairs, which, of course, can be incredibly helpful for preventing falls and making daily life much more easy for the resident. And, of course, all these sessions do indeed have a patient centered focus.

In order to be eligible for the program, the applicants suggested that there should be some kind of either a self-reported or a positive screen for at least one limitation in activity of daily living.

Other features may be a recent stay or anything related to a fall or in-home accidents, debilitating chronic pain, polypharmacy, et cetera. You need to be living in the community, have minimal cognitive impairment because motivational interviewing is a big part of this, and not be terminally ill.

And while the applicants I thought made clear that this could benefit almost

everybody who satisfies those clinical conditions, given the nature of our need to target things, they thought folks under 200 percent of poverty were the ones that should be eligible for it out of the box.

The payment that was proposed by the applicants is essentially a flat fee like a bundle that was proposed originally as not risk adjusted. There's an asterisk there. And that is to remind me that in the back and forth between the PRT and the applicants, they agreed that they could certainly imagine that one might want to risk adjust that.

The reason they proposed it as not risk adjusted was because the cost of providing the CAPABLE services was relatively easy to predict and I think had been replicated in a number of different examples around the country, so they're pretty confident at this 2,882 number, interesting number. But, anyway, so that seems to be pretty easy to document.

But they propose it as this flat fee

for these services. It's important to understand, as if anyone in this building did not, that traditional fee-for-service doesn't pay for all the stuff that CAPABLE has envisioned in the intervention. And that's essentially the problem.

Things that might indeed be clinically useful are not currently in the fee schedule. And, of course, that means that it comes down to fee-for-service Medicare does not cover in-home modifications.

Medicare Advantage plans have a little more freedom, of course, than fee-for-service Medicare at the moment. But they are still bound by primarily health-related.

And so the serious conclusion was CAPABLE is going to expand services beyond what is today available. And that's why it's a proposed innovation payment model.

The model does not address total cost to care or risk sharing. The submitters are basically focused on providing these

services to folks in their home. They believe, in fact, there's some evidence that there would be cost consequences over time.

We'll talk about that in a little more detail later on. But that was not part of the proposal to talk about total cost to care or risk sharing.

And you could certainly imagine that this could be easily worked into an ACO framework as the ACO is sort of the accountable organization.

Like I said, the asterisks mean the submitter in the responses to our questions indicated a willingness to modify their proposal. But as we will discuss in a little more detail, we felt like, and I think they would agree, that there were still many details that would need to be worked out. And so that's a part of what the judgement had to be.

So, as far as evidence, there is a fair bit of evidence that there were significant reductions in functional

limitations at five months after baseline. But the published reports would suggest there was no significant difference in functional limitations at 12 months.

The HCIA evaluation found no significant difference on spending, neither Medicare or Medicaid. Although, the samples were small. And so they clearly were underpowered.

There have been organizations who very strongly support CAPABLE. I think we got seven letters of support. I can't remember exactly. But it was, you know, a robust set, and from people who have respect around the country.

And it's true that there are 18 different versions of this going on around the country. And so clearly a lot of people are impressed with the model.

Now, this is a summary of our judgments of each of the Secretary's criteria as specified in the law. And you can see that,

you know, did pretty well, but it did not meet payment methodology, which is one of our high priority.

We also had concerns about integration and care coordination, although that was not unanimous in the PRT. And then we felt unanimously that it did not meet on health information technology.

So, basically, what we felt were the major issues are it's definitely innovative. It's definitely addressing a problem that is not currently well managed in the Medicare program. And for all those reasons, it's definitely worthy of consideration. It's got a lot of support and so forth.

However, it wasn't entirely clear to me or to us that we really need an alternative payment model to do this. That is to say if Bob Berenson were here, if the codes were adjusted appropriately, that is to say the CPT codes, one could imagine this being taken care of in a fee-for-service nature.

We talked about that with them. And since none of us, since we have no power to compel codes to be constructive and obviously the applicants don't either, that's why they proposed this APM.

And I will say they definitely were willing to entertain a modification proposal from the flat risk, flat bundled, no risk adjustment version that they proposed. However, there still, we would require CMS to do a fair bit of developmental work. And as our committee has learned, their bandwidth is limited. And so that's a high price to pay.

Some of the services are currently paid through Medicare, Medicaid waivers and so forth. However, like I said, we don't really have authority to require that in fee-for-service Medicare.

We were concerned about the lack of specific physician interactions. This is very much a contained intervention for non-physicians. Obviously, there could be

communication. And the submitters talked about examples of how that could happen.

But we felt like there was insufficient detail. And that was why the majority of our PRT thought it did not satisfy the care coordination integration criterion.

And the HIT problem fundamentally came from while Epic exists and Epic has a nice little module that could facilitate physicians getting access to the information recorded by the CAPABLE staff, there was no requirement for such information exchange. And if you don't have Epic, then there was no plan really for trying to figure that out. So that's why we felt like that did not get met.

So, on scope, there's no question this is not being covered by other programs. And it would be an innovative recognition of the fact that some things outside the specific clinical scope could actually have clinical impact. And so, in that sense, we felt like it met the criterion.

Quality and cost, there was enough evidence in our view that quality was improved even if cost might not have been reduced according to the evaluations that were done. And it's unambiguously true that if quality is improved and cost is not then that also is worthy of consideration. So we felt like Criterion 2 was satisfied.

Payment methodology was the one where we thought there really, you know, again, they understand the importance of risk sharing and accountability. But we felt like the flat payment not being risk adjusted was a problem.

They're open to thinking about how to do that in a different way. But those details were not able to be specified.

And we really felt like in a fundamental sense it's going to require a fair bit of work on CMS staff part. And that's why we thought this, as written and as modified, did not satisfy the standards we'd like to set for payment methodology.

Value over volume, we certainly agree that we thought unanimously improving the quality of care for these folks and the quality of their lives would make it, satisfy this criteria. It is nothing if not flexible, because go to people's homes and figure out what they need.

It certainly can be evaluated. The control groups that were constructed for some of the evaluations were small. And that's why the power wasn't so great. But it doesn't mean it couldn't be done. It's quite simple to imagine how that could be done.

Care coordination I talked about a couple of times. I'll just say the fundamental problem there we thought was a lack of very explicit coordination with physician oversight.

Patient choice, no question, satisfies that. Patient safety, we felt pretty good about that. The whole intent is to improve safety of living at home.

And finally, as I spoke, HIT, there

was no plan B if it didn't have Epic. So we felt like it did not meet those criteria.

So let me stop there and have my physician colleagues add anything they would like to clarify.

DR. CASALE: Sure. Thanks, Len, for that review. And, yeah, I would just, really just highlight what you've already said. I think the challenges are, as you stated, you know, is there a need for an APM for this to be implemented or is there an alternative way.

And as already alluded to, there are many other places where this is being done through other funding sources. And as you also highlighted, the Medicare Advantage has expanded in 2019 to potentially allow this.

So you could see, I think there's no question that it benefits the beneficiaries. I think the challenge is do we need a payment model, an alternative payment model in order to have this implemented. And, you know, I think that's where the biggest challenge is.

DR. WILER: Yes, thank you to Paul and Len for summarizing our thoughts. Clearly, this model has been impressive and successful. And it's scalability across the United States in pilot programs, again, is impressive, that this can be adapted not only at the MACRA system but also within patients' homes. So it's the right thing to do for patients and in a really important population.

That said, the three areas, just to highlight again, the payment methodology of creating an APM is one that we struggled with, because even though it's not currently paid in fee-for-service, you can, we'd like to hear in the comment period really understanding why this can't be an expansion of a Medicare Advantage program or why this can't be adapted into fee-for-service.

Even though that lift is hard, we have an opportunity to influence but not mandate those other programs, and why specifically an APM is one where this program

is one that would be most successful from a payment perspective.

The next is around care coordination and integration with a physician practice. We appreciated the comments that came back. But really a detailed understanding of how this might be part of a care plan for a patient would be helpful for us to hear about.

And then finally, although Epic, yes, is a dominant player in the health, electronic health record space, there obviously are others. So really understanding the digital care coordination aspect would be important. Thank you.

*** Clarifying Questions from PTAC to PRT**

VICE CHAIR TERRELL: So, if there are any questions from the committee for the PRT members, we will try to continue our practice that we've been doing the last couple of meetings of trying to limit questions to the PRT committee that might best be answered by the actual submitters themselves. But we will

do some. So I'm going to first go with Bruce.

MR. STEINWALD: Yeah, thanks. Nice presentation. It's pretty clear.

About your asterisk, I understood from the proposal that the submitter didn't really think it was necessary to risk adjust because they thought the costs were fairly constant across different kinds of patients. And yet you had stated that you weren't sure that an ACO would be willing to participate if there were no risk adjustment.

So my question is why did you come to that conclusion if the presenter presented evidence that the costs were fairly constant or did I get --

DR. NICHOLS: So really good question, Bruce, and I expect no less from my fellow economist.

I'll just say, look, so the proposal, as I understand it, was to provide services in the home for which the cost is relatively predictable. Boom. This is it.

That's why they proposed a flat fee.

Our point of view is an alternative payment model is meant to engender some kind of attempt to get at total cost to care, some kind of attempt to actually create, if you will, an incentive to reduce total cost to care. And this insertion, while it might very well have that outcome and in some cases was shown to, in other cases not so much.

And our thought was that an APM should be more globally focused. And, therefore, we thought in a world where, while the cost of CAPABLE is not going to vary by patient, the cost of those patients in the rest of the system will vary a lot.

And that's why we thought an ACO or any kind of sort of risk focused entity is going to want to have a risk adjusted payment. So that's where that all came from.

VICE CHAIR TERRELL: Are you wanting to respond to that or is this okay? Jennifer.

DR. WILER: I would also add from

the clinical perspective, when we think about how this APM might be scaled to other patient populations, this is about keeping seniors in their home safely. But there were very, from a pilot perspective, there was a necessary scoping of the patient population from an inclusion/exclusion criteria.

So we also discussed, in order to meet Medicare's expectation around high impact areas in total spend, that this program may have to be scaled to a larger patient population. And if that were to happen, that would mean sicker patients trying to keep them at home. So there would need to be some risk, our opinion was there needed to be some consideration for risk adjustment.

VICE CHAIR TERRELL: Mr. Miller.

MR. MILLER: Thanks. I just wondered if you could elaborate just a little bit more on your interpretation of the studies, because you've all said you think it's a really good program. And when I look at it, I think,

you know, really desirable set of services. But a question is does it, in fact, save money or is it just budget neutral or whatever.

And I looked at the studies but probably not in as much detail as you did. And I'm sort of wondering like how did you, what did you conclude from them. Were they, were all the indications were that it did save money but they were underpowered or --

And I guess part two of the question is to what extent do you think that the results are, in fact, extensible to a broader population, as opposed to they happen to pick, except for the one randomized trial, they happen to pick people who would be potentially benefit from this, and that if one started to do this more broadly, particularly if you had a billing code for it, that all of a sudden you would start to get lots of people who didn't really need it quite as much but were getting it because it would generate income.

DR. NICHOLS: I'll let my clinicians

speak to the sort of broader population question. I'll speak specifically to the evaluations, Harold.

The HCIA evaluation showed that it did indeed improve functional status after five months. And I take that as quality improvement for the person. But it did not show a savings in cost.

And the other study is Medicare and Medicaid, so it did not find impact on cost that were statistically significant. There were some sometimes but not powered enough or not significant in the standard way of thinking about those things.

So the way I would conclude it is it's a program that's highly likely to improve the health and well-being of the people but not necessarily to save money.

In my view, the statute says either improve cost or lower, improve quality or lower cost or both. This does one without hurting the other. So it did not increase costs.

MR. MILLER: Just to follow up, though, when I looked at the three studies that were, I think it was three studies that were quoted, there was one that showed sort of basically almost no change in spending, a sort of small increase. The other one showed decrease but with confidence intervals across zero.

So I'm wondering whether there was any -- did you draw any interpretation that said that the actual savings, you know, the mean, the mean savings that they showed seemed sensible given the other kinds of things that were showing up, that they, in fact, did see reductions in hospitalizations, et cetera, and it wasn't some other aberration?

I'm just trying to sort of sort out the issue of -- I mean, you know, the challenge is always statistical significance in underpowered study, right, what do we know. So you have to look for other things that might tell you whether all the other signals are sort

of pointing in the right direction.

And I just wondered if you saw anything else that says to you, yes, I think it probably saves money but they're underpowered, or whether I think that could have just been a random effect of the particular project.

DR. NICHOLS: I'm just going to speak for myself. My interpretation of the studies is that it very likely improves functional status. It very likely does not statistically affect cost. And the rest of it is commentary really.

VICE CHAIR TERRELL: And I --

DR. CASALE: Yeah, I'm sorry. I was just going to, because I was getting a nod from Len to say something.

Yeah, I had the same interpretation. I think the cost, I don't see this in the current as cost savings. But I think the benefit is keeping people in their home. And, you know, how you figure out if that's cost savings or not versus just quality of life is

really where I focused on particularly.

DR. WILER: I guess I'm going to answer just a little bit differently. And we had this conversation internally, in that does it improve functional status, yes, have other studies shown that improved functional status means decreased visits to emergency departments and in-patient hospitalizations, yes.

They started to go there from an economic modeling perspective but didn't go the full way.

So, from the clinical perspective, it makes sense that if we can keep people in their home and prevent them from falling that there will be cost savings. But the study, and the studies that were made as reference have shown that correlation. But this particular pilot does not yet have the power to show that in a robust way.

But from a clinical perspective, for me, it makes sense that it could. But that's one of the challenges that would need to be

addressed in order to affirm that there not only is this quality improvement but an opportunity for cost savings long term.

VICE CHAIR TERRELL: I have a question that's really about our scope. So we're supposed to be the Physician-Focused Payment Model Technical Advisory Committee. And within the context of that, we now know that MACRA includes a broader range of clinicians including the occupational therapists.

So I can understand the thinking about this within the context of that as a provider type that we can look at alternative payment models and, therefore, evaluate them with respect to whether they ought to be recommended to the Secretary.

But one of the things that you all were very, didn't score very highly was related to coordination with physician practices. So is this something that really ought to be within our scope? Did you all talk about that

at all at the committee level or not?

This gets kind of back into my concern sometimes about payment models versus care models. Everything that I've heard you all say and what we are asking about has to do with an excellence of a care model that may or may not be cost neutral.

But is it within the scope of what we are supposed to be commenting on? So did you all have that conversation at all with respect to our scope as opposed to this proposal?

DR. NICHOLS: So let me make sure I understand the question, Grace. Are you saying that, are you asking the question is this physician-focused enough to be in our purview or are you saying did we judge this thing harshly because we didn't see enough docs running around in Criterion 7? That's --

VICE CHAIR TERRELL: Is this a physician --

DR. NICHOLS: Okay.

VICE CHAIR TERRELL: -- focused payment model or not?

DR. NICHOLS: Yeah, okay.

VICE CHAIR TERRELL: I mean, if it is, it is.

DR. NICHOLS: Yeah.

VICE CHAIR TERRELL: But if it's not, I just wondered if you tackled that issue at all.

DR. NICHOLS: I think we, I think staff helped us think about this if I remember correctly. Sarah, don't, I'm not blaming you. I'm just saying I believe we asked the question, and they said, oh, but, Len, the statute says it's not just physicians.

VICE CHAIR TERRELL: Okay.

DR. NICHOLS: And so I think we settled that pretty quick. Well, that's the answer to --

VICE CHAIR TERRELL: Okay. That's all I wanted to know. Are there any other questions from the committee members? Okay.

Well, if not, I'm going to invite our submitters to come to the table up here. And we are going to let you all have your own say about this. And then afterwards, the committee will have an opportunity to ask you questions directly. And we appreciate that.

So which one of you is -- if you will introduce yourselves, and then whichever is going to speak or speak first.

*** Submitter's Statement**

DR. SZANTON: I'm Sarah Szanton. I'm a professor at the Johns Hopkins University School of Nursing and the School of Public Health.

DR. CANNON: I am Kendell Cannon. I'm an internal medicine physician as well as a clinical instructor at Stanford University. And I also am the medical director and primary care physician for a PACE program with WelbeHealth.

VICE CHAIR TERRELL: Okay.

DR. SZANTON: Great. Well, thank

you so much. It's such an honor to be here. Thank you for the work of the PRT and for just being able to have this opportunity.

So adjusting the function of older adults is imperative with 10,000 people turning 65 each day currently. And as Dr. Wiler alluded to, physical function is a modifiable risk factor for many bad outcomes, including nursing home placement and preventable hospitalizations.

I am a nurse practitioner with a PhD who provided a decade of house calls. And my patients often greeted me on their hands and knees because that's how they got around their home or dropped keys from the second floor because they were trapped on the second floor. And I would find the keys in the grass and let myself in.

I also had a 101-year-old who had to drop out of her wheelchair onto her knees to get into her kitchen because her doorway of her kitchen wasn't broad enough.

So, you know, this happens every day. And I am so pleased that we are able to bring forth the importance of this scope for traditional Medicare.

And you've heard about CAPABLE from the excellent report and also that there's been ten years of research. And HUD also has researched CAPABLE. Along with the Weinberg Foundation, they funded the first replication. It's now in 27 places in 13 states, including CMS recently approved adding it to the Medicaid waiver for Massachusetts for people who want to age at home.

And also important to part of your discussion prior, CMMI asked us to go through the PTAC process. They said this will be the next logical step for CAPABLE.

And also their evaluators that were assigned to us from being part of CMMI demonstration project published in Health Affairs in 2016 cost savings that was $2,700 per quarter per patient for eight quarters.

And CAPABLE costs about $2,800.

So, from that analysis, it would seem that it saves about seven times what it costs. So I understand that there's research all over the place because the samples are small. But I think from a conceptual point of view and from some of the data, it looks like it saves more than it costs.

I also, what data you don't have is Trinity, the accountable care organization that's multi-state, they adapted CAPABLE as an innovation to try out in one place, which was Muskegon, Michigan. And we recently presented those results together with them at Academy Health.

And there it saved more than it cost, even though they had a much smaller dose, if you will. The handyman was more about $120 than $1,200. And they found reduced ER, reduced admissions, and a lower length of stay compared to a matched comparison group of the rest of their ACO. And then subsequent to

those data, Trinity voted to scale it to two new places.

So I think, you know, there is good reason to think that it saves money. Although, it's not a slam dunk yet with the data we have so far.

I also just wanted to thank you for your words about our flexibility. The whole model is flexible. And we are flexible people as well and happy to consider a, you know, a graduated kind of payment in terms of the frailty and complexity of the participants.

As Mr. Steinwald mentioned, we had just envisioned it kind of the way you would envision a flu shot, right. It's just a thing. And it doesn't need modeling for how much you would pay for it.

But it does make sense as more frail and complex people come into it that you might want to add another nurse visit or -- so I think that makes a lot of sense.

And we think the best outcome would

be for, not to tell you what to do, but that I believe there's several options where PTAC can advise. And one of them I believe is option C, which is recommending a limited scale, right, a limited, testing it out a little bit more. And then we would all learn more about what makes sense in terms of costs and savings and how to pay for it.

In terms of the coordination, I think in your binders you all have the additional information that we presented. And some of that does address the coordination with primary care in a more robust way.

And, you know, we started as research separate from primary care and needed HIPAA waivers to be able to talk with primary care.

Now that more and more places are adopting it, and not just with Epic but also with Epic, the primary care providers are much more involved. And there's some quotations from some primary care providers showing how

it's distinct and separate but so needed and useful to address function.

You know, even just buying a refrigerator for someone who needs insulin, right, that you're not going to do that in primary care. But as CAPABLE, you know, the handyman budget is fungible across things. So it can be items or home repair.

And we also, in the additional information, talked about different ways of interoperability with health IT. So, you know, you're welcome to refer to that.

And Secretary Azar often mentions that he's the Secretary of Health and Human Services. And CAPABLE fits squarely in the stream of innovation of not just looking at diseases but looking at the total health of people.

And you're likely aware that the RAISE Act for Caregivers, which was passed in 2018, requires the Secretary to develop and maintain a strategy to help caregivers across

the country who are under a lot of strain. And CAPABLE fits nicely into a strategy like that.

Before I introduce Dr. Cannon, I wanted to just leave you with a story of a CAPABLE participant who finished recently who's a veteran. He's in a wheelchair. He's on, he has end stage renal failure. He's on dialysis.

And when we got to him, he had a completely flat affect, a depressed affect, was in a lot of chronic pain, and never left his home except for dialysis. He had a grown grandson who would come over and help him some.

And his favorite thing he liked to do was to sit on his back stoop to listen to the birds. And he couldn't do that in the wheelchair. His grandson would have to lift him up.

And in identifying his goals, he wanted to work on his pain, and he wanted to be able to shave standing up. Currently, he shaved in a wheelchair. And the gunk of it and the cream just dribbled into his lap.

And, you know, that may seem like a small thing to those of us who are able to take the train or the plane and get here. But that was really big to him.

And those aren't things you would ask in primary care, right. You wouldn't ask how are you shaving currently, right, or can you get outside, out into your backyard.

But we addressed his pain, his strength, and balance. We put grab bars around his sink. By the end, because of those, he could stand to shave. And that was a huge thing for him. He also, we put grab bars around his back entrance. And because of his strength and balance and the grab bars, he could get out into the back stoop and listen there without needing his grandson.

He longer has a flat affect. He's got a twinkle in his eyes. And now he's going out and doing other things besides just dialysis.

And speaking as a primary care

provider, if he had come into my office for a 20-minute visit in the beginning when he was depressed and in pain and not going anywhere, I wouldn't have thought I could do much for him, you know. But after an intervention like this, he's more engaged. He's more able. He feels more dignified. And then primary care can do more for some of his other issues.

So he went from being a socially isolated, depressed, and in pain person to someone who can navigate his home and his outside environment with confidence.

So I'd like to introduce my colleague, Dr. Kendell Cannon. She mentioned where she's been. And she contacted me after looking at all the programs for an aging society and thought that CAPABLE was worth more study.

DR. CANNON: So multiple people have asked me how did Stanford get involved in this, because this is very much Sarah Szanton and a Johns Hopkins project.

The Clinical Excellence Research Center is kind of a think tank for valued-based care and has fellows each year to study healthcare innovation and design with the primary goal of lowering costs and improving or maintaining quality and patient experience.

And so our year's topic was how to improve care in late life.

So we spent an entire year researching both what are, what is that, what does late life mean, which we came to define as the intersection between multiple chronic conditions, functional limitations, what are the primary needs for that population, and completed a very extensive literature review, and then from there tried to find everything we could both within industry, within academia, that served and met those needs.

And I have to say, by far CAPABLE was, had the best cost saving data. Although, as several people have mentioned, some of it was, is a little bit harder to interpret but

also had -- for me as a clinician, getting to learn more about CAPABLE ended up changing the way I think through medical care in terms of integrating other services and as a primary care doctor why it's so important to have and use the other people on the team, which to me was this CAPABLE team.

And so that was for me one of the biggest reasons I ended up actually in PACE and changing my philosophy was because of CAPABLE. And so very much understand there's not a doctor on the roll call for CAPABLE, but changed the way I practice.

VICE CHAIR TERRELL: We've exceeded a little bit your ten minutes. So I'm going to -- no worries. But I'm going to at this point open it up for my commissioner colleagues to ask questions. Mr. Miller, you've got a question?

MR. MILLER: I do, several actually. First question I guess is the question about risk adjustment. There's a couple different

purposes to risk adjustment. One is if you need different resources to be able to deliver a service for different patients. The other is if you're accountable for outcomes and the outcome risk differs.

In this case, though, I guess I'm curious. You say it basically costs $2,882 for everybody, because it looks to me like you follow in general a fixed protocol with everyone.

But I wonder whether that's necessary. And in fact, if in fact some patients could get it for less, then it would be a more scalable program for many people if you said, you know, the man in the wheelchair doesn't need five months of RN, OT visits. They need an OT assessment and the handyman and look what a transformation that will make.

So I'm wondering, first of all, whether you've thought about that, whether there is, in fact, a way to stratify the patients, not to say, yes, if it's risk

adjusted, we'll do more for some people, but whether some people could do quite well with just, you know, less.

DR. SZANTON: Sure. Thank you for that question. So certainly there could be less. The way it's designed is that the older adult picks three different goals they want to work on with the nurse and three different goals they want to work on with the OT. And those, they address a goal, after the initial assessment, they address a goal on a monthly visit for those times.

So someone could have fewer -- you know, unless you're going to have really long visits where the cognitive intake is going to be less, you'd have to have fewer goals, which could completely happen.

And, in fact, in the Trinity replication, they started with a community health worker and worked on some of the goals. And then, so then did have fewer visits. And that could certainly happen as well.

MR. MILLER: So you're saying in some cases it could be less and there could be a different level of payment.

DR. SZANTON: Absolutely.

MR. MILLER: Second question is could you explain to me how you see this interacting with home health.

Many of these patients, and I'd be interested in what your experience is in terms of how many of them would qualify for home health services. And I was concerned, I guess the concern was that we have the RN and the OT from home health showing up in the house as well as the CAPABLE RN and OT showing up in the house.

And the second is that if, in fact, the service was desirable, home health could pay for it. They're not restricted in terms of what they can spend money on. They get a prospective payment. They wouldn't necessarily want to spend more money on this under the current model. But they might.

And so tell me how you see this working with home health --

DR. SZANTON: Great.

MR. MILLER: -- in coordinating.

DR. SZANTON: Yeah. So some of the places that are adopting CAPABLE are home health agencies. And in fact, I think one of the people registered to give a public comment is an occupational therapist at a home health agency in Denver that has been doing a wonderful job with CAPABLE.

So home health, what Medicare calls skilled care is different than CAPABLE. It is, you know, with a specific something in mind, like wound care or, you know, new diabetic teaching or -- and the, it certainly, it could work through that if the skilled care definition was a little bit different.

But just as a small example, an OT cannot open a case in skilled care. And they always do in -- you know, so there would have to be some tweaks.

Also, we've hired people from home health. And there's a real mind shift. CAPABLE is all about the older adult, what they want to be able to do, and that all of the ideas come from them in terms of what they want to do. The clinician uses their pattern recognition and, you know, clinical judgment to help brainstorm with them.

But when we hire people from home health, they really have to be retrained. It's a different model. So that's certainly possible. But it's not the same.

MR. MILLER: But it wouldn't necessarily be a bad thing to have it more integrated. And this could potentially be something under home health.

Third question is I wasn't sure I understood who you, this is related to the second question, who you envisioned ordering this service, because there was mentions in here of physicians submitting a billing code, but then there were we'll let the primary care

physician know.

And so I wasn't clear on does a physician order this service or are there RN/OT/handyman teams sort of cruising around looking for patients who might need their help and say, hey, you look like your porch needs fixed, hey, we've got a service for you. How would that work?

DR. SZANTON: We were envisioning a primary care provider ordering it. And right now nurse practitioners can't order home health as you know. And so, in the current set up, probably that would be a physician. Although, it probably makes as much sense for also nurse practitioners to be able to.

Just addressing your second, more comic point, currently there are CAPABLE programs that are started by Habitat for Humanity, for example, and they go to their wait list or, you know, there are -- but for what we're talking about today with Medicare, it would be starting from a clinical side.

MR. MILLER: Okay. Final question, there were a couple of mentions in your proposal about when you were talking about the model, et cetera, and I'm quoting from page 9 to page 10, that there would need to be strict limitations on quality and very close measurement of quality.

And I wonder if you could elaborate what you meant by that in terms of what you thought would be the quality problems that might arise unless it was strictly limited and very closely monitored.

DR. SZANTON: Well, I don't know if you want to talk about that also. But -- okay. Go ahead.

DR. CANNON: So one of the concerns that my team had was that this potentially could turn into, by creating a payment model, roving herds of nurses and OTs and handymen looking for work.

MR. MILLER: Herds --

DR. CANNON: And so we felt like in

order to maintain the quality that was shown, the improvement in the ADLs, the improvements and the decrease in hospitalizations and nursing home visits, that those would have to continue to be measured. You couldn't just put this out there as like a, hey, here's a new program.

And we also saw it sort of in the sense of concern the way hospice when it switched over became much more focused on that financial part rather than on improving the quality of care, although it does both.

MR. MILLER: So, just to summarize, so your concern would be that there could be overuse of the service unless there was some way to show that it was actually being focused on the people whom it would benefit. Okay. Thanks.

VICE CHAIR TERRELL: Angelo.

DR. SINOPOLI: I think Harold asked most of my questions. And I think you may have answered most of them.

But I'm still a little bit curious as to how you're thinking about this as being an alternative payment model as opposed to services to PACE, who's already taking full risk, or to an ACO, who may be taking full risk, and why it's not just a service that's integrated within the care model and the care management team.

DR. SZANTON: So I'll start, and you can add if you want.

Certainly we've shown by the partial scaling that it is possible to offer in different ways, but because traditional Medicare is still the bulk of service provision, that it would be a way of scaling it much faster, that if we just relied on Medicare Advantage and the very most forward-looking ACOs, this will be a, these problems, like the person in the wheelchair in pain, will take a lot longer to reach kind of saturation and scope.

VICE CHAIR TERRELL: I have a

question, and it's about the criteria from which you selected handymen. There's not, as far as I know, a lot of literature on that in the medical literature about what would make a good handyman.

Certainly, we've got occupational therapists that are licensed and governed and are professional. Certainly, that's true for registered nurses.

But a handyman is kind of a, or handyperson is kind of a pretty vague job description. And the types of people who have those skills might be quite variable in terms of their background. So I could envision a dystopic future where there's not hordes of handymen and nurses running around, but suddenly everybody's a handyman.

And so, as you're thinking about bringing in new services, I suppose, to the healthcare ecosystem, how are you all thinking about those non-traditional roles and making sure that there's no fraud, that there's

competency, and that it also doesn't actually inflate costs where suddenly everything out there, like diabetic shoes now, has to cost a particular price?

DR. SZANTON: That's a great question. Thank you. So the, some of the CAPABLE sites have hired their own handyperson. And they've made sure that they are licensed and bonded and they're under kind of their clinical supervision in a way.

And the handyperson implements a work order that the occupational therapist makes up or, you know, addresses. And it's based by the person's goals. And so it's not, so it's kind of under the occupational therapist's scope in a way.

The second thing is that in, I'm not sure as much in rural America, but in urban America, there's very often non-profits that have been long established that do small home repairs for low-income people. And a lot of the partners we've had have hired those and,

you know, licensed and bonded and drug testing.

And in fact, the one that we work with in Baltimore actually sends in two people, one who's getting job training skills through AmeriCorps and one who's a more senior contractor.

VICE CHAIR TERRELL: And just one more quick question, the cost of handrails they may put up or ramps or whatever the particular thing does, that would strike me in a lot of cases being much more expensive than, you know, $1,200. So where were those costs accounted for in this model? And was there variation in that?

DR. SZANTON: Thank you. So we've published a paper that I'm happy to furnish the PTAC about the kinds of modifications and how much they cost on average.

In our randomized control trial, on average 14 different things per house were done for that amount of money. They were often very small things like $7 bed risers that go under

the four corners of the bed to make it taller so it's easier to get out of or, you know, a cutting board.

The budget is not big enough for ramps. But grab bars and extra banisters cost about $80 parts and labor.

VICE CHAIR TERRELL: So this was a total bundle then.

DR. SZANTON: Um-hmm.

VICE CHAIR TERRELL: Okay. Thank you. Jennifer.

DR. WILER: So we previously raised some concerns about integration and care coordination. So I want to prompt you to give some thoughts on that.

So these services are triggered by a physician order. What in your pilots or what is your recommendation or what is your expectation around how this fits into managing health of a patient and that care coordination, and then specifically the health information communication component?

DR. SZANTON: Thank you. So, right, so, as we mentioned, this is kind of an adjunct to primary care and certainly not a replacement, and that the provider would order it and then would be getting updates from the care team, and that it doesn't exist -- so, you know, some primary care providers already have case management, in which case that case manager would be, you know, being kept up to date very often. And we have a whole case example of a woman in Maine and with a table of before and after capable.

I think the, Kendell and I were talking briefly beforehand, and I think so much of it has to do with decreasing primary care burden, you know, that everyone in primary care is overworked as it is as it relates to our visits and to take care of some of these other things that lead to hospitalizations or even just more calls to the primary care team is part of that.

If you want to --

DR. CANNON: In terms of the information exchange with primary care, again, was also one of my concerns and my team's concern. Epic, the fact that they were able to create a module in Epic kind of told me that we could at least expand that to other EMR systems.

And so I don't think we ever intended in our proposal to say Epic was the one and only, just that they had made one and it works. And so it could be duplicated.

Also, the idea that, as a primary care physician, I don't have the time to do the type of motivational interviewing and goal assessment that this team does. And so, if they can come out of these visits with a goal, some of them are functional, some of them are healthcare focused, then I can supplement that, whether it's polypharmacy is one of the major issues. People are primed to then want to talk about, oh, we're going to stop these medications.

And so a lot of what the CAPABLE team does is educate the patients on how to speak to a primary care doc, how to present themselves, how to share their ideas. And so, for me, really that increased patient interaction both improved the clinician experience and the patient experience.

DR. SZANTON: We provide a health passport that has a number of things in it, but part of it has questions that you wanted to ask your doctor. And so, even if someone feels too shy to ask them, they can at least hand it over and say -- so there's also care coordination just old school on paper as well as on the EHR.

And since it has been integrated into the EHR, in some sites we hear and we understand that, you know, providers are messaging through that to the CAPABLE OT or the CAPABLE nurse saying, oh, I see that you're working this goal. I'll reinforce that in my visit or -- and that that coordination has been happening.

DR. WILER: So, at non-Epic sites, it obviously makes sense if I'm going to get very operational, but just to make sure that we understand that they have Epic access. They can provide a report. It's all within one ecosystem.

Is your expectation in sites that don't have that digital platform that there is a traditional consult note? How is the primary care provider knowing what the assessments are, including the ADLs, IADLs, and PHQ-85 scores that you mentioned on page two? Where is that information then being transferred back to the primary care provider?

Is this only currently pre-post as described, or is there an expectation that this is a bundled consult? How would this happen if it was not in the current Epic platform as described?

DR. SZANTON: I think we're very open to how that should work, and I think different primary care practices would probably

have different views about how that should work, and we've proposed a model where, like, after the second visit, we let the primary care provider know about the goals, but I think after could work fine too.

We, in our research, what we ended up doing was after we were done, after the four months, we wrote what the goals were, whether they were achieved, what else they still want to work on, but, I mean, I hesitate to say this is how it has to be for the whole country.

But the principle of sharing back, and that it's under the primary care provider's purview, and doing it in the way that makes the most sense from their own health IT I think is probably as specific as it makes sense to get unless I'm misunderstanding your question.

DR. CANNON: I also wanted to share I think that part of the problem answering that question is that right now, a lot of the CAPABLE programs are being run through Housing or these different ways, and so you're trying

to get information back to a PCP who doesn't even know it exists, and so there's different, depending on who the doc is, different ways you can get information to those doctors.

Sometimes the best way is through a case manager. Sometimes the best way is a consult note. Sometimes the best way is a phone call, and the CAPABLE RNs have done all of those different things and tried all of them in order to get to it.

I think the idea as an advanced payment model was that this would be, it adds that medical component, and so then it would actually be thought about by clinicians, and so facilitate the communication as opposed to just the trials that are going on and trying to kind of spread it as is.

DR. SZANTON: And we have a paper published about the primary care provider feedback loop that I'm happy to provide the committee, and the CAPABLE nurses up to that point had done a number of phone calls, emails,

hard copy letters for the chart, and different providers preferred different things.

VICE CHAIR TERRELL: Harold?

MR. MILLER: One more question I'm thinking about. So if one were to try to do this, how would one implement and pay for it? And I can see several different potential approaches that I'd just be interested in your reactions to.

So one is CMS currently has a Comprehensive Primary Care Plus demonstration, and in that model, the primary care physicians get an additional care management payment with which they can do the kind of things that Kendell said I can't ordinarily do. They could hire nurses.

The amounts of those payments would probably not be enough to support the service, at least as you costed it, although it might be if it could be done for some patients less expensively.

But if you would say there is a

payment for this, then potentially you could say a primary care physician could now accept for this kind of patient that they would get this kind of payment and they could deliver this kind of service for it, and then they would also be accountable for the fact that it would, in fact, keep patients out of the hospital. So that's one model is that it could sort of be an enhancement to that.

Another model is CMMI has an Independence at Home demonstration where there are physician practices, groups that have decided to focus on trying to keep a patient population at home, but it's a pure shared savings model now.

And you might say ah, these are groups that are focused on trying to keep a patient population at home and this would be a useful service to add to them, and they're already, you know, upside accountable and maybe downside accountable for that.

You don't have to be a whole ACO,

but you're focused on this particular -- and if you look at the criteria for those patients, they are very similar to what you've suggested.

The third model would be that you make this an adjunct to the home health prospective payment system and you would say, particularly under the new system, a home health agency can do this. They get a prospective payment.

When I looked at the numbers, the numbers were on the order of, under the current system, it's on the order of $3,000 or so dollars for a 60-day period.

Under the new system, it's going to be about $2,000 base payment for a 30-day period, and then if you have functional status limitations, comorbidities, you get a higher payment.

So, in fact, again, it seems to me that this model might fit there if there were some encouragement to do it, and it would be a logical thing to think that home health

agencies who employ RNs and OTs could potentially do this, or you could make it a free for all and say that anybody who wants to go out and start doing the service can, you know, bill for it.

If you could just give some reaction to where you think it's feasible? I mean, if those options were available, would primary care physicians say, who were already interested in doing care management, jump up and say, yes, I'd like to do this, or too complicated?

They might certainly contract with a home health agency, but it would flow through the primary care physician, or do you think it's better if it's sort of integrated with home health and viewed as yet one more thing that a primary care physician can refer to home health and then hold the home health agency accountable?

DR. CANNON: So a couple of thoughts on that, in terms of the primary care being

responsible for, I guess, hiring and coordinating the OT, the RN, and the handyperson, that's not really our skill set, and so my thought was that it could be seen more as an adjunct.

My concern -- I think that it does work within home health. My concern is that, having worked with multiple home health agencies, what this program is is very different.

And so to try to say that we would just put this with a home health team, it would change what I believe to be the most efficacious parts of the model, the person-centered goals, the motivational interviewing.

Because these people are thinking very differently than you do for a typical OT or a typical skilled RN experience, I would worry that you would lose the benefit.

DR. SZANTON: But that said, there are home health agencies that are successfully doing it. They just have a special team, kind

of like they might have a hospice team that thinks differently than the regular skilled health team, and so to me, they all sound good, and thank you for the roadmap, I would say, and I think that --

MR. MILLER: Do you think it would be good for home health to be more patient centered and motivational interviewing oriented, et cetera, than it is today?

DR. SZANTON: Yes, I mean, I'm sure we would both say yeah, but also their visits are longer, you know, like typically you'd do two or three visits in a day of this than the eight or nine you might do in home health, right, so it would take a team, I think, a CAPABLE team within the home health, but it could certainly work.

VICE CHAIR TERRELL: Len?

DR. NICHOLS: Madam Chair, I would like to call attention to I forgot something that's really important.

VICE CHAIR TERRELL: Uh-oh.

DR. NICHOLS: Yeah, I screwed up. So I just wanted to point out, in particular, Harold, in relation to your first question about the interpretation of the studies, I was supposed to, but forgot to make clear that the kind of most interesting one, the randomized trial study, the control group was not patients who got nothing.

It was patients who got sort of attention controls. They got like 10 visits or something, so they got like a smaller dose than the dose you were imposing in CAPABLE.

So think about it this way, instead of CAPABLE versus nothing, it was CAPABLE versus a small dose of CAPABLE, and that showed no cost impact. Well, one might infer, there probably is a cost impact compact compared to nothing, and that's probably important context I failed to make clear even though staff put it on the slide.

DR. SZANTON: Well, sorry, and if I can just also interject, actually the cost

results for that, we still don't have. The staff at CMS are working on the costs for the randomized control trial. The costs that are published are the one arm trial from the CMMI demonstration project.

But it is true that the attention control group, they had 10 visits. They were also goal directed, also got what they wanted to do, but it was sedentary goals, and so some people criticized that as being too strong, and that group did improve to an extent.

And when you say that we didn't keep improvement at 12 months, that was in comparison to that control group, but they were still improved compared to their own selves at the beginning.

VICE CHAIR TERRELL: Are there any questions from the commissioners? If not, let's go to the portion of the hearing where we hear from public commenters.

*** Public Comments**

VICE CHAIR TERRELL: We have six

that have registered, but it is open for others. There is one that is onsite, and we'll remind the public commenters that you're limited to three minutes, and the first one is Sharmila Sandhu. Oh, I'm being prompted that you all can sit back there. Thanks.

MS. SANDHU: Hi, good morning. Thank you for the opportunity. My name is Sharmila Sandhu. I'm the counsel and director of regulatory affairs with the American Occupational Therapy Association. I'd like to just make a brief comment.

The American Occupational Therapy Association is the national professional association representing the interests of more than 213,000 occupational therapists, occupational therapy assistants, and students of occupational therapy.

The client-centered, science-driven, and evidence-based services of an occupational therapy professional enables people of all ages to live life to its fullest by promoting

participation in daily activities. We appreciate the opportunity to provide feedback on the CAPABLE model.

The program evolved and developed through a series of studies and has clearly demonstrated the importance of addressing Medicare and Medicaid beneficiary problems related to everyday functioning in the home environment, which are both specific domains within the scope of occupational therapy practice.

CAPABLE has resulted in reduced disability and healthcare cost savings while promoting aging in place, outcomes which are increasingly desired by elders and their families as the baby boomer population continues to age.

CAPABLE interventions are consistent with the perspective role and scope of occupational therapy practice under, in community health and prevention. The skilled occupational therapy perspective is integral to

the fidelity of the CAPABLE intervention.

CAPABLE promotes safe and effective aging in place to positively impact population health, while at the same time meeting the unmet individual Medicare beneficiary needs that directly drive healthcare costs, but are not readily addressed in current care or reimbursement models. CAPABLE also is directly aligned with the goals of the Triple Aim in our opinion.

As the national professional association representing occupational therapy, AOTA asserts that the demand for these types of targeted, coordinated services for the Medicare and Medicaid population will only continue to grow.

The inclusion of housing and home modification considerations is critical at a time when payers, policy makers, and quality experts are recognizing the importance of social determinants of health or social risk in the overall health risk profile and recovery

trajectory for patients.

Services like CAPABLE which demonstrate reduced healthcare costs and health utilization through innovative preventative interventions offer the potential to greatly impact both the individual recipients and population health, as well as the caregiver needs for those beneficiaries.

AOTA continues to believe it is critical to weave key social determinants of health into the fabric of healthcare coverage and payment if wish to truly be more responsive to the needs and wishes of the elderly population. Thank you.

VICE CHAIR TERRELL: Thank you. We have on the phone now Samantha DeKoven.

MS. DeKOVEN: Thank you for the opportunity to participate. This is a great conversation.

I'm with BRicK Partners. We're a consulting and project management firm in the Chicago region, and we're supporting a CAPABLE

replication among our partners here, groups like the North West Housing Partnership, which is a housing organization that delivers a range of housing services, and their partner, Attuned Care, which is a home health agency that has on staff an occupational therapist and RN who participate in the training and are delivering this program to clients.

Another important partner for our office is the mayor's office because this effort was really led by municipalities who were concerned about our residents, and were seeing burdens on our first responders and our social services as we have an aging population, and our residents wish to remain in their community and remain in their homes and be able to live independently.

So this small demonstration is in the northwest suburbs of Chicago. We're underway, so I can't speak to any of the data, but I can tell you that in conversations and in early reporting, our clinicians note

significant depression and talk about how the participants really benefit from the program and find themselves and report themselves more able to do the things that they wish to do.

The handyman comes out sent by the housing organization and is able to do the minor repairs, as well as providing some of the tools and other needs identified by the client with the occupational therapist.

And our clinicians really talk about the benefits of having been trained and focusing on the client-centered approach to delivering care, and that it's a tool and an approach that they are able to bring into their other work and be able to speak to how they are benefitting from the training.

There is a lot of interest around the region. The Metropolitan Mayor's Caucus has surveyed municipalities, and the communities around the region identified aging in place and identified helping their communities with an aging population as top

priorities that the municipalities want to identify.

So there's a lot of interest in growing and scaling this program, and so we're eager to see you identify sustainable funding mechanisms so that we're able to replicate this program locally. Thank you.

VICE CHAIR TERRELL: Thank you. And now is Amanda Goodenow on the phone?

MS. GOODENOW: Yes, I am. I'm Amanda Goodenow. I'm the occupational therapist and the program manager in the Denver area. I work at the Colorado Visiting Nurse Association.

We are a home health agency that are implementing CAPABLE. We do have separate OTs and nurses that only do CAPABLE, so we do both CAPABLE and home health services though also.

And it has, like Sarah has said, has been challenging to get into the CAPABLE mindset versus the home health mindset, but with a lot of work and time, we were able to

transition and we are thriving.

We have seen about 126 clients so far in the CAPABLE program and I just wanted to give you some clients' perspectives of the program. We had one gentleman that his main goal was he wanted to be able to get in and out of the house safer.

He really wanted to be able to get to his AA meetings. He was a recovering alcoholic and drug addict. And just by the simple modification of rearranging the way the door swung open to get into the garage made it feasible for him.

And that's not something that he had thought of previously, but through the OT's expertise and with the work of Habitat for Humanity of Metro Denver, he was able to have that done.

We also had a gentleman who, kind of like Sarah has talked about, was stuck in his house for years. He was wheelchair bound and did not have a way to get in and out of the

house. In order to get to appointments, he would have to have people lift him up in the wheelchair to get down the stairs or go via ambulance, which, as we know, is extremely expensive.

So we were able to build him a wheelchair ramp, and he just started crying because it was the first time he was able to get himself in and out of his house. Not only is it feasible for him, but now it's also a safety improvement in case of fires and things like that.

We, at the Colorado VNA, have noted some significant changes in depression, increased independence and ADL, decreased pain, and decreased fall risk.

Some of the data that we have pooled ourselves, we do the PHQ-9 right before admission into the CAPABLE program, and then after the CAPABLE program has been implemented, we do it again.

And we've noticed a 57 percent

decrease in depression. We've noticed an increase in independence with ADL by 77 percent, and pain has improved by 53 percent in the little bit of data that we have pooled ourselves. So overall, we, at the Colorado VNA, have shown some major improvements in these clients.

The other thing that we have noticed is just community reentry. A lot of people are getting back out into the community, so they're no longer just staying at home all day and isolating themselves.

I had a client personally that she had fractured her humerus, and we, as a home health agency, had actually seen her from home health, and she had progressed through the home health side of things and was discharged to outpatient therapy, so she then qualified for the CAPABLE program.

And she really wanted to be able to drive her car, but it was a standard, and she broke her right humerus, so shifting the

standard wasn't feasible for her at the time.

So she started, towards the end of the program, actually calling friends and getting rides, which previously she thought that was a burden, but through the program, without us even addressing this as an issue, because this was not one of her goals, through the program, she started reaching out for help, which is fabulous. It shows those behavioral changes that occurred through time.

She was then going to cards once a month with friends and back to her book club once a month with friends, which is just absolutely huge.

The other thing we've noticed is people getting involved in going to the senior center for different activities or getting involved with SilverSneakers. Again, these aren't necessarily their goals. These are just some of the outcomes that occur as a side note of the program.

So we have thoroughly enjoyed

implementing this program, and as an OT, it's really fun to be able to see them over this expanded period of time.

It's only six visits, but you truly get to see major change because it's not six visits in three weeks. It's six visits over four to five months, which has been really, really nice, and it's been a joy to be able to implement this program. Thank you for the opportunity to speak.

VICE CHAIR TERRELL: Thank you. Is there anyone else on the phone or in the audience who would like to comment at this time?

We are a little bit early relative to where we usually are, so I just want to ask my colleagues, do you want to have any further discussion at all before we go into voting? Hearing none, let's begin the voting process.

*** Voting**

VICE CHAIR TERRELL: First, we vote on how the proposal meets each of the 10

criteria. Member votes roll down until a simple majority has been reached. A vote of one or two means it does not meet, three and four means meets, five and six means meets and deserves priority. The asterisk means not applicable.

After we vote on all 10 criteria, we will proceed to vote on our overall recommendation to the Secretary. We will use the voting categories and process that we debuted at our December 2018 public meeting. We designed these more descriptive categories to better reflect our deliberations for the Secretary. First, we will vote using the following three categories, not recommended for implementation as a physician-focused payment model, or recommended, or referred for other attention by HHS.

We need to achieve a two-thirds majority of votes for one of these three categories. If the two-thirds majority votes to recommend the proposal, then we vote on the

subset of categories to determine the final overall recommendation to the Secretary.

The second vote uses the following four subcategories, the proposal substantially meets the Secretary's criteria for a PFPM and PTAC recommends implementing the proposal as a payment model, number two, PTAC recommends further developing and implementing the proposal as a payment model as specified in PTAC comments, number three, PTAC recommends testing the proposal as specified in PTAC comments to inform payment model development, and number four, PTAC recommends implementing the proposal as part of an existing or planned CMMI model, and we would need a two-thirds majority of one of these four categories.

*** Criterion 1**

So let's get ready now and vote on the first criteria which is scope, which is considered a high priority item.

MS. SELENICH: Okay, so two members voted 6, meets and deserves priority

consideration. Three members voted 5, meets and deserves priority consideration. One member voted 4, meets. One member voted 3, meets.

A majority vote in this case is four, so the committee has determined for this criterion that it meets and deserves priority consideration.

* **Criterion 2**

VICE CHAIR TERRELL: Moving on to Criterion 2, quality and cost, also a high priority.

MS. SELENICH: Zero members vote 6, meets and deserves priority consideration. Two members vote 5, meets and deserves priority consideration. Three members vote 4, meets. Two members vote 3, meets. Zero members vote 1 or 2, does not meet, and zero members vote not applicable. The committee finds that this proposal meets this criterion.

* **Criterion 3**

VICE CHAIR TERRELL: Moving on to

Criterion 3, payment methodology, also high priority.

MS. SELENICH: So zero members vote 5 or 6, meets and deserves priority consideration. Zero members vote 4, meets. One member votes 3, meets. Six members vote 2, does not meet. Zero members vote 1, does not meet, and zero members vote not applicable. The committee finds that the proposal does not meet this criterion.

*** Criterion 4**

VICE CHAIR TERRELL: Moving on to Criterion 4, value over volume, providing incentives to practitioners to deliver high quality healthcare.

MS. SELENICH: Zero members vote 5 or 6, meets and deserves priority consideration. Four members vote 4, meets. Three members vote 3, meets. Zero members vote 1 or 2, does not meet, and zero members vote not applicable. The committee finds that the proposal meets this criterion.

*** Criterion 5**

VICE CHAIR TERRELL: Criterion 5, flexibility, to provide the flexibility needed for practitioners to deliver high quality healthcare.

MS. SELENICH: Zero members vote 6, meets and deserves priority consideration. Two members vote 5, meets and deserves priority consideration. Four members vote 4, meets. One member votes 3, meets. Zero members vote 1 or 2, does not meet, and zero members vote not applicable. The committee finds that the proposal meets this criterion.

*** Criterion 6**

VICE CHAIR TERRELL: Criterion 6 is the ability to be evaluated, have evaluable goals for quality of care, cost, and any other goals of the PFPM.

MS. SELENICH: Zero members vote 6, meets and deserves priority consideration. Two members vote 5, meets and deserves priority consideration. Three members vote 4, meets.

Two members vote 3, meets. Zero members vote 1 or 2, does not meet, and zero members vote not applicable. The committee finds that the proposal meets this criterion.

* **Criterion 7**

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

MS. SELENICH: Zero members vote 5 or 6, meets and deserves priority consideration. Zero members vote 4, meets. Two members vote 3, meets. Five members vote 2, does not meet. Zero members vote 1, does not meet, and zero members vote not applicable. The committee finds that the proposal does not meet this criterion.

* **Criterion 8**

VICE CHAIR TERRELL: Criterion 8,

patient choice, encourage greater attention to the health of the population served while also supporting the unique needs and preferences of individual patients.

MS. SELENICH: Three members vote 6, meets and deserves priority consideration. Two members vote 5, meets and deserves priority consideration. Two members vote 4, meets. Zero members vote 3, meets. Zero members vote 1 or 2, does not meet, and zero members vote not applicable. The committee finds that the proposal meets and deserves priority consideration.

* **Criterion 9**

VICE CHAIR TERRELL: Criterion 9, patient safety, which aims to maintain or improve standards of patient safety.

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

members vote 1 or 2, does not meet, and zero members vote not applicable. The committee finds that the proposal meets and deserves priority consideration based on this criterion.

* **Criterion 10**

VICE CHAIR TERRELL: And finally, Criterion 10, health information technology, encourage the use of health information technology to inform care.

MS. SELENICH: Zero members vote 5 or 6, meets and deserves priority consideration. Zero members vote 4, meets. Two members vote 3, meets. Four members vote 2, does not meet. One member votes 1, does not meet, and zero members vote not applicable. The committee finds that the proposal does not meet this criterion.

* **Overall Vote**

VICE CHAIR TERRELL: So now we are going to proceed with the overall voting, the recommendation to the Secretary part one. A vote of one is to not recommend as an

implementation as a PFPM. Number two is to recommend, and three is referred for other attention by HHS.

MR. STEINWALD: Could you remind us what, under two, what the two-part voting is before we vote on this?

VICE CHAIR TERRELL: Sure, we need to achieve two-thirds of the majority of votes for one of these three categories, and if a two-thirds majority votes to recommend a proposal, then we have a subset which is the proposed meets the criteria and it recommends implemented, or number two, recommends further developing and implementing, or number three, recommends testing the proposal as specified, or number four, recommends implementing as part of an existing model.

MR. STEINWALD: Thank you.

MR. MILLER: Grace, I wonder if it would make sense just to have a couple minutes of discussion about where we're going next with those things that Bruce just asked about

because it seems to me it's kind of hard to say should it be in --

VICE CHAIR TERRELL: Okay.

MR. MILLER: -- two or three, you know, and then how we're going to vote on the next one without sort of at least talking through a little bit what everybody thinks about those things, because that's kind of what I've been struggling with is, so where's it going to go next?

And if it's logical to fit into one of the other four categories, then it's logical to vote for two. If it's not, then it's logical to vote into three, and it might make sense to talk about that a little bit before we vote.

MR. STEINWALD: Yeah, thanks, Harold. You're thinking much more comprehensively along the same lines as I was.

VICE CHAIR TERRELL: Okay, discuss away. Do you want to start with Harold?

MR. MILLER: Well, I guess as I've

been thinking about this, I'm somewhat concerned by the -- I mean, I like the service. I think it's a very desirable service to have.

I am concerned about trying to fund or pay for the service or call it an alternative payment model as sort of just a freestanding thing because it seems to me that it should be connected to other things, and that if the patient needs this, they should be able to get this, but the patient needs something else, they should be able to get something else, and if they need two things, they should be able to get the two things in coordination.

So, I mean, this is what I've been struggling with on the home health side is that if the patient needs or is eligible for and needs home health services, they should be getting home health services, and if they also need this service, they should be getting that, and we shouldn't end up having two sets of nurses and OTs running around the house, you

know, doing stuff simply because that's what they're paid for.

So I have trouble sort of thinking about it as a freestanding thing. On the other hand, I don't necessarily think it's a good idea to just say, you know, good luck. Hopefully maybe some ACOs will take this up.

What I do think that there is, for example, the Independence at Home demonstration, which was created by Congress, and that Congress continues to reauthorize, but is limited in terms of its ability to what it can pay for, and so this could be a potential adjunct for that.

So at least the way I'm thinking about this is that I think that it could certainly be -- there needs to be a payment model for it. I don't think there's a payment model really adequately described in this document.

But I think there could be a payment model for it, and that it would make more sense

to me to see it hooked up with something else, whether it's like is this a test of how to do home health in a different way?

Is this an adjunct to an Independence at Home demonstration or does it help a hospital at home initiative where somebody is trying to do something else to be able to keep patients at home and this is one more thing that would be a part of that?

So at least where I'm leaning is with one of those part of other things. I guess I'm struggling a bit as to whether one says this should be a part of an existing CMMI demonstration.

It seems to me that the only one that really fits well for it is Independence at Home, or whether it should be somehow just refined in some way, but anyway, I'm sort of leaning towards a two here, and then the other part of something else when we get to the second phase.

VICE CHAIR TERRELL: Shall we just

go around the table, yeah?

DR. CASALE: We can also describe, we can all describe our struggles. Yeah, I think I was similar, you know, thinking through. Should this just simply be referred to HHS and have them try to sort out where it goes? I mean, are we the ones to sort of -- because I'm not sure. Yeah, I mean, I conceptually agree with the concept of having it as part of something else. I'm not sure what it should be, and so that's why I'm not sure I could do the -- if it should be part of another model since I'm not sure what model that actually should be part of.

But I certainly think given the way Medicare is moving and the Medicare Advantage world around all of this, et cetera, it would be logical that HHS should be thinking about this for the future service world, so I'll stop there.

MR. STEINWALD: I also think it seems like an extremely worthwhile set of activities

for the population that's large and probably being somewhat under-served with these kinds of services.

I liked Dr. Cannon's description of it being adjunctive to primary care, which seems to me could be a primary care physician independently deciding that this is the set of services that a given patient needs as opposed to traditional home health or any other nursing home kind of thing.

And, you know, a well-informed primary care physician could make that decision, and that primary care physician could be part of an ACO, could be part of a Medicare Advantage plan. I'm not sure about Habitat for Humanity, but --

And just to end where I started, I kind of like the way of thinking of it as being an adjunct to primary care.

VICE CHAIR TERRELL: So I guess my thoughts about this are that we spent the last two years differentiating between care models

and payment models, and this is actually a social care model as opposed to a medical care model, which is, you know, adding yet another level of complexity, but also potential benefit.

And so where I'm struggling with it is that there -- it appears that what has happened with this is it's trying to put something that is actually quite unique and different, which is to look at social care and a broader range of services than what we traditionally think of as being medical care, into our analysis infrastructure that has been around payment models as it relates to typical medical care.

And so we're really broadening in many ways the way that we are thinking about what a healthcare system should do, and this may well be, as someone said, what the Secretary's aims are, the human services part of things, not just the health, but it's not what we have been particularly focused on thus

far here at PTAC.

I thought one of the most important things that was said was that they were told to bring this to us, okay. So we, as a PTAC, need to think about that within the context of our own role as it relates to nontraditional ways of thinking about things, not only with this one, but in the future.

I'm not sure that we have that fleshed out adequately yet at the commission level in terms of being able to literally think about social care, but within the context of the data that's out there, we know that countries that spend more on social care spend less on healthcare and vice versa. When you put it all together, that may actually be the way that you actually start to make a great deal of difference of things.

So, I'm encouraged to see this in front of us. I think we're probably inadequate to completely answer it, but that's sort of where I am with it.

DR. NICHOLS: Well, that's great, Grace, because I'm pretty sure we're never going to adequately answer anything, but I will observe that, you know, I was really taken with the parallel nature of Dr. Cannon's description of how this is very different than home health, and the home health lady from Denver, I think, visiting nurses or whatever, so they have different human beings who do this, very clear sort of this is one thing, okay.

So I would address the spirit of your inquiry to say look, we probably shouldn't be pigeonholing this into one little corner of what we can make it adjunct to. Let's just pay for the damn stuff and see what happens.

I mean, I think at the end of the day, why I find this frustrating is because I made a promise to my profession that I would never vote for a proposal that didn't have a payment model that satisfied our criteria, but I'm about to do that, and the reason is because these people need this and, you know, I mean,

that story you told, good lord, I just almost cried, and I'm a fairly hard-ass guy.

(Laughter.)

DR. NICHOLS: So I think at the end of the day, you know, we ought to be doing something here, and I would submit seriously that thinking upstream, I mean, it's certainly what I've been spending the last two years doing, I think it's where we have to go.

And we've got a population and a model that seems quite well tailored to be adjunctive to everything you could imagine if we created it, and I'm not sure CMS would go through the extra work.

That's the other thing. There is work involved in making this operational, and that's unfortunate because we know that's requiring resources in a contested world.

But I'll just say to me, the idea that handyperson services could be finally considered worthy of being paid for by fee for service Medicare is a really good idea because

I am convinced we're not going to get where we want to be until we reach upstream.

And we're not going to have the perfect answer and draw the perfect red line, a bright line between this and that, but if we know there's likely to be clinical impact on functional status and we think there's a chance there could be an impact on cost, my opinion, it's worth experimenting.

DR. WILER: Thank you for the opportunity to have this discussion. It's been helpful for me to process as I'm in the same situation that many of you are.

I think what's interesting is that this is not only preventative services in that social component, but it's also doing screening, so there's an assessment that's happening, and then there's passive information that may be informing active treatment with some of these scoring tools.

So it's actually interesting from a clinical care perspective because it's also

this continuum of preventative to actually therapeutic intervention, both potentially passive and active, which makes it challenging.

Home health might not be, even though the description on the ground is that there would be two different teams, what I'm struggling with is where should home health be versus where is it today, and does it require, per our recommendation, a whole new focus, or really should we start pushing our policy makers to be thinking about care delivery models in a more holistic way and creating payment models that do that?

So at the end of the day, these are important services. They make a difference in peoples' lives and it's saving cost. We should be incenting this care model.

And at the end of the day, whatever way we do that, I think that -- well, I appreciate the presenters coming here and also the Secretary for recommending us to have an opportunity to evaluate it.

DR. SINOPOLI: Yes, thank you, so I'll say the same things. I've really enjoyed the discussion today and it's been very enlightening. And as a pulmonary critical care physician that has practiced for decades and taken care of a lot of patients with debility, I appreciate the interest in addressing those specifically, and I can't imagine any more powerful study that there's not going to be savings associated with this kind of model.

And I do believe that there's a difference between what you described as OT and your nursing model from today's traditional home health systems, and that may be very appropriate and need to continue in that manner, but there is a difference.

I do have some still confusion about how it gets paid for and how, as lots of bundles do, how they then incorporate into those practices that are taking other types of downside risk.

And I think there is some work to be

done there in how it fits into a broader care model, which I do believe needs to include all social determinants of health, including housing, et cetera, and that docs need to be responsible for identifying those and driving those issues.

And so I think it's a good direction and worthy, and just how then do we fit that into something that's got a bigger picture to it?

VICE CHAIR TERRELL: So in my faith community, which is Quakerism, we have this thing at the end of a session after a consensus or not where we say are all minds at ease? So are all minds at ease? Shall we vote? All right, let's go.

MS. SELENICH: So three members voted to refer the model for other attention by HHS. Four members voted to recommend the proposed model, and zero members voted to not recommend. We need a two-thirds majority, so, and that's five with the seven members voting,

so I guess I would ask the Chair if you all want to talk some more and perhaps --

MR. MILLER: Apparently the minds are at ease in different places.

VICE CHAIR TERRELL: All minds are not at ease.

MR. MILLER: They're at ease. They're just in different places where they're at ease.

VICE CHAIR TERRELL: So Dr. Nichols said he nominates the refer people to explain why. I was one of those. I'd be happy to do so. I actually was listening to you, and I know you probably voted in the other direction, but you convinced me to vote refer after you made your comments because I don't think this is a physician-focused payment model.

And although -- but I also think it's very, very worthy and needs to be incorporated into the overall payment ecosystem in fee for service medicine. It's just not a physician-focused payment model.

So within that context, I'm thinking about okay, you know, CMMI told them to come here, they did, and if we basically say, oh, yes, we recommend this, then we're saying it's a physician-focused payment model.

And I actually think that that might be a disservice to them because I think that actually what needs to happen is a broader play as it relates to incorporating the overall social determinants of health and social care into the way payment is thought about.

Some of the new proposed models that we don't have a lot of information about yet that have come out of CMMI are talking about primary care taking on risk, and so you could potentially see this as something that would be a service underneath another physician-focused payment model, but I just don't think that it is itself a physician-focused payment model, so that's why I voted as I did. Jennifer?

DR. WILER: I agree, Len, you were very compelling, and that's why I chose to vote

for refer.

I think at the end of the day, we're actually probably all advocating for something similar, and that's that this needs to be looked at, and there needs to be a real assessment to determine is this a new practice and therefore requires its own model or can it be integrated into current programs?

And there's been a number of suggestions about where that could land, and I think that depends not only the national landscape, but also state and community-based resources and programs.

So I agree, as constructed and described by the presenters, that this does not meet the criteria of a physician-focused payment model writ large, but I still think ultimately it would be ideal to have this pilot expanded as one of the recommendations under number two.

So that's where I personally struggled because that's where I'd like to see

it go, but if we, based on our rules and bylaws, say that we must first define if this is a physician-focused payment model, I did not think it met that threshold.

VICE CHAIR TERRELL: Angelo?

DR. SINOPOLI: So I was obviously the third who voted to refer, and I'm very supportive of this model, but I think it just does have some questions around it in terms of how does this connect through a patient-focused payment model and fit into a broader care model, or is it something just totally different outside of the physician realm that fits into some other model? And those questions were just not clear to me, which is why I voted to refer.

VICE CHAIR TERRELL: So for those of you who actually voted that it was a physician-focused payment model, I would throw a question out for you based on something you said, Len, which is this needs to be paid for, by golly, so I'm going to vote for it, and is

that the reason, or do you think it's a physician-focused payment model?

Because if that's really the reason you, you know, you put the scale on that side, then that basically implies something about us, which is we have to vote that to actually have any influence on policy at HHS, and to refer for other purposes may not actually be effective.

DR. NICHOLS: So --

VICE CHAIR TERRELL: So that's sort of something we need to talk about.

DR. NICHOLS: Oh, I agree completely, Grace, and I would go back to the, I believe, legal interpretation of the language in the statute, and that is since Medicare does pay for some non-physician practitioners, it is okay to have a proposal that is not in a physical sense physician-focused, but is in a way a provider-focused payment model, and that's kind of what this is.

So that's why I believe we were

given the assignment to review it in the first place because we did raise the question in the first conversation.

So I take your point. Your point is not incorrect that it's not very physician-focused, but it is provider-focused, and more importantly, in my opinion, it is patient-focused, and that's why I think it does meet the threshold. Could it fit in all of these different ways?

And I hesitate to speak any more since I lost votes the last time the longer I went, but I'll just say look, you could put it lots of places, and if I had confidence that referring for other attention would indeed engender the kind of effort that I think we could get if we recommend it, I would be perfectly happy with that, so that's kind of where I am.

VICE CHAIR TERRELL: Bruce?

DR. NICHOLS: I just think we've got to fight for attention.

MR. STEINWALD: So Len covered at least two of the three things that I was going to mention. One is that it doesn't have to be strictly speaking an MD physician.

VICE CHAIR TERRELL: Yeah, I wasn't meaning that in that way, but, yes, okay.

MR. STEINWALD: And when we've used referral for other attention in the past, in my mind, it's mostly been in cases where the proposer has identified a real problem that ought to be addressed, but they don't have really the wherewithal to address it in the model they propose.

Well, I think in this instance, they've identified a real problem and they do have a methodology for addressing the problem. It's missing a few important elements, mostly on the payment side, but I think I would distinguish this case from past cases where we've referred and with much less feeling of support for the care model itself.

VICE CHAIR TERRELL: Okay, Paul?

DR. CASALE: Yeah, not to -- so, again, I keep struggling with it, but to Len's point to your question, I do think that to get the attention, I think one of the categories are recommended and I think hopefully will get more attention. I think there clearly should be support for this.

To Bruce's point, I think the things we've referred have often been where it's clear they just need a CPT code for, you know, and HHS can fix this kind of thing, and I think there's more opportunity under the recommended than the other categories to move this forward.

And, you know, I think the physician-focused is a bit of a misnomer for our committee given, you know, where things are going.

VICE CHAIR TERRELL: Harold?

MR. MILLER: So first, just to be technically accurate, the statute does not define it at all. The HHS regulations that were promulgated said that physician includes

non-physician providers.

I think in this case, we don't really have a payment model at all, which is why we said that it didn't meet the payment methodology criterion, so, which is not different than other things.

And I think the second thing is it isn't quite clear at all who would be, in fact, getting the payment if there were a payment model. So right now, it's hard to say. I mean, it's not --

That's why I was asking the question about is this going to home health agencies, in which case it might be something we would refer because we would say, oh, it's just a change to the home health payment system, which is different than saying that.

But it at least feels to me that this is, in the way it's being described, more of an extension of what is being done today in terms of encouraging physicians to have nurse care managers, to have social workers, to make

home visits, to be able to do things like that as an extension of what is the traditional face-to-face only with the physician in the office approach.

So when I look at it from that perspective, it seems to me it certainly can be a physician-focused payment model in the sense that other physician-focused payment models exist and that we have approved, which is that it's a service that a patient needs that is beyond the traditional face-to-face service with the physician in the office that could be beneficial to the patient and help keep them out of the hospital, et cetera.

So I think in my mind it absolutely could qualify given that, I mean, to me, we're going to recommend that it needs to have a payment model that it doesn't have right now, and that that payment model, to me, should be in fact something that would be a physician-focused payment model similar to the other things that we have recommended.

I think that's a separate issue to me than should it be a freestanding physician-focused payment model where we would suddenly say any primary care physician who wants to deliver this service, there will be a new billing code for it and/or some accountability for keeping patients out of the hospital.

My personal feeling is it needs to be part of something that's bigger than just this particular service, but I don't see any problem with it being physician-focused. It's my personal opinion. Again, I don't see on both counts that it could turn into -- I think it could turn into -- it could be a physician-focused payment model and I think, the applicants could comment on this, but I don't think that if it were done that way, that it would be inconsistent with what they're trying to achieve, which is to enable patients to get this service following a physician's order in a way that would help the patients.

VICE CHAIR TERRELL: Angelo, did you want to say something? You just forgot, okay. Len?

DR. NICHOLS: So I was just going to say in the spirit of Harold's first remark which got us to this conversation, which is incredibly productive, can we look at the categories behind two before we vote again just so we have an idea?

VICE CHAIR TERRELL: Just so you know, I'm going to flip my vote.

DR. NICHOLS: Okay, then I'm going to shut up right now.

VICE CHAIR TERRELL: Okay, so unless somebody flips it in the other direction, okay.

(Laughter.)

VICE CHAIR TERRELL: I'd be happy to look at them again. Okay, all right.

MR. MILLER: So wait a minute now. Len convinced you to vote the other way. Now maybe you're going to convince other people to vote the other way. Is that right?

VICE CHAIR TERRELL: So shall we vote again? All right.

MS. SELENICH: So zero members vote to refer for other attention by HHS. Seven members vote to recommend, and zero members vote to not recommend for implementation as a PFPM, so the committee finds the proposal should be recommended, and then that will now go into the next part of voting to specify which category of recommend.

VICE CHAIR TERRELL: Okay, so this is actually the four categories that you were discussing, and just as a point of clarification, I want to make sure that people understood when I was saying before that I didn't think it was a PFPM, it wasn't the emphasis on physician. It was just the emphasis on the structure versus not.

But be that as it may, the four categories are it substantially meets the criteria and recommends implementation, number two, recommends further developing and

implementing the proposal as a payment model, number three, recommends testing the proposal as specified in PTAC comments to inform payment model development, or number four, recommends implementing the proposal as part of an existing or planned CMMI model.

So with that, I'm going to suggest that we all have an opportunity to vote again. Is everybody ready? Consensus? Everybody is at ease, okay.

MS. SELENICH: So zero members vote to implement the proposal as a payment model. Zero members vote to recommend the proposal for further development and implementation as a payment model. All seven members vote to test the proposal to inform payment model development as specified in PTAC comments, and then zero members vote to implement the proposal as part of an existing or planned CMMI model.

So the committee finds that the proposal should be recommended to test the

proposal to inform payment model development.

VICE CHAIR TERRELL: So now let's just offer the opportunity for any particular comments that people would like to make sure we emphasize in the Secretary's, the letter that we do to the Secretary. Len?

DR. NICHOLS: So the only one that I think adds to what we've had, which is a fairly rich discussion, I thought, was I just wanted to say why I was so persuaded by the testimony of Dr. Szanton, and that was when she described the effect of the patient as he would have presented in her office without this intervention with the depressed affect and how you would have thought you couldn't do much for him.

And it seems to me, while this is going on outside of the clinician's office, it is affecting patient care in that way, and I think we should be mindful of and point out to the Secretary why we think that therefore links it to healthcare and not just social services.

VICE CHAIR TERRELL: So Mr. Miller said that he wants to go around and do all of the votes verbally, which confuses me since it was a consensus, but that's okay. Do you want to have a continued conversation first or shall we do this? All right.

MR. MILLER: I apologize. That was that simply was our normal procedure is to go and ask --

VICE CHAIR TERRELL: Okay.

MR. MILLER: -- everyone what their vote is, but you're right. It's unanimous, so we don't need to do that.

VICE CHAIR TERRELL: Okay, just there's nothing else in particular, so, all right. Yeah, that's next on here, but any further comments? I wanted to do this before we had a summary from Sally, that anybody who wanted to make sure it was emphasized in our report.

MR. STEINWALD: I'm -- this is already in the conversation, but it just seems

to me that one of the nice features of this model is that it puts another arrow in the quiver of things that a primary care doctor or any other doctor in charge might consider for a given patient, and this arrow in the quiver -- don't use that metaphor. That's a crappy metaphor.

(Laughter.)

MR. STEINWALD: The tool, thank you, sir. This tool doesn't presently exist in most of the armamentarium and would really add some richness to the range of choices that could present for a given number of patients.

DR. CASALE: Sorry, just, and I think it's already been said many times, but just to emphasize, you know, there's a lot of discussion around social determinants of health and how to address them, and this clearly is one that actually would impact it significantly.

VICE CHAIR TERRELL: Harold?

MR. MILLER: Two comments if others

agree to put them in, I guess. One is I think that part of the testing is needed to get some greater experience on this issue of does everybody need the same thing, and is there is a way to have some different kind of stratification associated with that?

So, because I think the notion that there has to be a $2,882 payment for every single patient in all circumstances is going to make it a little bit more challenging to get this implemented.

But I think that if it has not been -- up until now, that has not really been a focus. It's been a focus of we have a protocol, and we want to follow that protocol, and we want to see if that protocol works. There has not really been a systematic effort to say, okay, let's try to understand better who might need more or less than that.

Because if the conclusion is really everybody ought to get exactly the same thing, it would be useful to know that, but you don't

know that if you haven't tried that, if you simply say we've always done it this way, you know, and that's the only way to do it.

I think the second thing is I do think it will be faster and more likely to happen if it can be done as part of something like Independence at Home. Independence at Home is the one that strikes me that's most appropriate for it.

That doesn't mean -- what I wanted to say is I don't think that means simply okay, let the Independence at Home people try it and see if it works.

I think it means saying okay, we'll create a payment for this, but have it done in a context where people are more systematically focused on keeping people at home, and have some accountability associated with that.

Because that's my worry is that the standard thing doing this payment model is let the ACOs try it and see what happens. So I just want to say I think it does need a payment

as opposed to simply being thrown into a shared savings model and kind of hope that it will get done as part of that.

So those would be my two comments, if other people would agree with that, that we could put in.

VICE CHAIR TERRELL: Jennifer?

DR. WILER: A couple of comments, so the first is obviously I changed my vote. I was persuaded by the concern around how we prioritize this proposal in front of the Secretary, but that said, I'm still reluctant to call the model as described as a physician-focused payment model, despite the lack of definition acknowledging that eligible professionals are actually within the legislation or the regulation acknowledged, and these are obviously eligible professionals per the Medicare definition.

But that said, I have three comments. The first is there still needs to be some development within the pilot around the

digital communication plan and integration from a care coordination perspective.

If we just throw these services out into the community, they may be successful, but the problem is we aren't going to be able to demonstrate their full impact if we don't have a way to track services on a digital platform, especially for health services research, so I think that's important.

You're doing great things. It has good outcomes. I think you're going to show great outcomes. And if we don't prioritize not only digital communication, but digital tracking, you're going to lose the opportunity to show that impact.

My second comment is around triggers for evaluation. It's still unclear to me who is the right person, or maybe there's many folks, who could trigger this kind of assessment for ultimately what is the physician order.

So it would be helpful in piloting

to understand, you know, is it the home health agency evaluator who creates a trigger? Is it a case manager? Is it a social worker? You know, the laundry list could be long as we know in these areas of these social determinant factors.

My last comment is akin to Harold's comment and that's around customization. As you know, there have been many pilots, and in full disclosure, I participated in a CMMI project where, although we published what was a standard program, ultimately after years in practice, customization was cheaper and showed the same outcome.

So I think you already know that, but just to say it for the record, that in the pilot, some type of customization is probably ideal to maintain quality, maybe improve it, but ideally from a cost perspective.

And then akin to that, any program from an implementation perspective needs a post-implementation assessment. And although

it was mentioned in here, I want to highlight it again because, from a tracking perspective and a health services research perspective, knowing what the intervention is and then looking at a post assessment is going to be really important as we move into this new frontier around assessment, excuse me, interventions that may be pre-need, i.e., this fall risk assessment space. Thank you.

VICE CHAIR TERRELL: Angelo?

DR. SINOPOLI: So I don't have a lot additional to add because everything has been said around the table, but I particularly agree with Jennifer's comments.

And it's still a little unclear to me from a physician standpoint, is the physician the initiator of this evaluation? What other community-based organizations, agencies, et cetera are also enabled to trigger these consults, and then who gets paid for those?

And I do think it's highly likely in

a lot of communities that this data will get fragmented across multiple community-based organizations and agencies, and you'll never be able to determine whether it was effective or not.

So I think that point in terms of centralizing the data and doing the post evaluation is going to be extremely important.

VICE CHAIR TERRELL: My final comments before we ask Sally to summarize -- oh, Harold, okay, go.

MR. MILLER: I guess I was going to respond to Angelo. I mean, our recommendation was tested and consistent with PTAC recommendations, so you make a good point. We should say what we recommend, and I would suggest, again, if other people agree, I would propose that we say the applicant said this.

It should be something that should be initiated at a physician's order, and I would say that it needs to be, however it's designed, it should be part of an overall plan

of care that the physician and the patient have been involved in approving, not kind of a go do it and let us know what happened kind of thing.

I mean, and I don't see why we can't say that's what we think would make sense. If there is an effort to try it in some different way, that's okay, but at least we would say that we think that the model should, in fact, involve a physician's referral.

Whether it's primary care or otherwise, I'm not sure, but, you know, because it could be a specialist saying, you know, as you said with, you know, a higher risk patient population that a specialist is managing. I've got my COPD patients at home. They need this kind of help, or my heart failure patients at home, that they need this kind of help, et cetera, so I think, to me, coming from a physician's order.

But I am concerned about the notion that this would just become one more thing that a home health agency could go bill for and get

somebody to sign off on, or that it would be freestanding entities doing it, but that would be my recommendation as to what we should say.

VICE CHAIR TERRELL: So my comments were probably congruent with that as well as what Jennifer articulated in that if you think about the three things that didn't meet the criteria, one is the payment model, but the other two were about information technology and care coordination.

And so what we probably are all saying in various versions is that the information integration, which I think is part and parcel with care coordination, must be solved for it in addition to the payment model for this to have the impact that we all think that it would require.

So, you know, we voted very consistently along those lines on the criteria, and it was also consistent with the PRT, so that might be a way of actually summarizing without getting into the details of, you know,

physician, or specialist, or whatever.

But, you know, anything ought to have solved the problem for information integration, care coordination, and the payment model for this to be as impactful as we want it. And Len?

DR. NICHOLS: I think that's right, but I think if we take Harold's suggestion, which I'm comfortable with, and that is to say the PTAC believes it ought to be triggered by a physician's order, that sets in motion the processes that will accomplish the goals you just set out because then there's much more physician involvement than it appeared to us when we read the first proposal. I'll say it that way.

DR. CASALE: Well, it may or it may not, or sometimes it does, so I'm not -- yeah, but I think to Grace's points about just emphasizing. I'm just not sure that that will -- well, I know it won't automatically create that integration and, yeah.

VICE CHAIR TERRELL: I don't know that I agree with that necessarily, which is why I wanted to keep it fairly open. I mean, I don't think we've had enough information to think about it as opposed to coming up with solutions on the, you know, in this part of the process. That may well be something.

We're going to have some time to think about it before the report is written and make some revisions, but I'm not comfortable, at least I'm not right now, saying that we -- that I would say it must start with a physician's order. It may be a good idea, but I need more than two seconds to think about that.

MR. MILLER: I would agree with you, Grace. I support what you said, although I would just enhance it by saying that not just sort of a vague notion of care coordination, but to say --

VICE CHAIR TERRELL: Sort of a very --

MR. MILLER: -- coordination with the patient's primary physician or whatever, whoever is managing their care. Because that was a thing I was troubled by in some of the initial responses from the applicant was that their definition of care coordination was coordinating their own care --

VICE CHAIR TERRELL: Right.

MR. MILLER: -- not coordinating with someone else. So I worry that if we don't make it clear that we're talking about coordinating with the patient's primary physician, and I'm not sure what the right term is we want to use for it because it's, you know, their primary physician may be the specialist who is managing the condition that they're dealing with, but I think, you know, that's what I was trying to get at in terms of the physician's order.

VICE CHAIR TERRELL: And I'm totally in consensus with that. Does anybody else have any further comments that they'd like to make

before we have Ms. Stearns, who is still rapidly scribbling our comments, summarize for us what she thinks we said?

*** Instructions on Report to Secretary**

DR. STEARNS: Okay, I think I've got actually a lot of great material to work with. I'm going to be very brief in my summary. I think that overall, PTAC has found this to be a very important and needed service.

It emphasizes both the human and health components based on different arguments in terms of health and human services. It's a well thought out program with very meaningful examples and a lot of interest.

That said, it's important to remember as this is recommended that there are still three very important criteria that are not fully addressed by the model in its current form. That would be first and foremost the payment model, and then although the submitter has indicated willingness and flexibility, focus on integrating information and care

coordination, and lastly, the potential for electronic health records to be integral in that and to be a formal part.

So I think there has been some discussion and debate in terms of the payment model and what that should constitute, whether or not there is a clear role for an APM, not clear that it needs to be an APM. There is clearly going to be some physician involvement, but what should that be?

And so without being proscriptive in the report to the Secretary, I think we'll be able to raise many of the issues from the discussion and put those forward for the Secretary to consider.

*** Adjourn**

VICE CHAIR TERRELL: Thank you very much. So I want to thank the public and particularly the stakeholders and applicants for bringing this forward to the PTAC today, and I'm ready to adjourn the meeting.

(Whereupon, the above-entitled

matter went off the record at 11:19 a.m.)

C E R T I F I C A T E

This is to certify that the foregoing transcript

In the matter of: Public Meeting

Before: PTAC Advisory Committee

Date: 06-17-19

Place: Washington, DC

was duly recorded and accurately transcribed under my direction; further, that said transcript is a true and accurate record of the proceedings.

Neal R Gross

Court Reporter