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, September 16, 2019

PTAC MEMBERS PRESENT

JEFFREY BAILET, MD, Chair
GRACE TERRELL, MD, MMM, Vice Chair
PAUL N. CASALE, MD, MPH
TIM FERRIS, MD, MPH
RHONDA M. MEDOWS, MD*
HAROLD D. MILLER*
LEN M. NICHOLS, PhD
KAVITA PATEL, MD, MSHS
ANGELO SINOPOLI, MD
BRUCE STEINWALD, MBA
JENNIFER WILER, MD, MBA

STAFF PRESENT

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

*Present via telephone

A-G-E-N-D-A

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

12:53 p.m.

* CHAIR BAILET: All right. We're going to go ahead and get started. Good afternoon and welcome to the meeting of the Physician-Focused Payment Model Technical Advisory Committee or PTAC.

Welcome to the members of the public who are able to attend in-person, and welcome to all of you who are participating over the phone or over livestream. Thank you all for your interest in this meeting.

We extend a special thank you to the stakeholders who have submitted proposals, especially those who are participating in today's meeting, the PTAC's ninth meeting, that includes deliberations, voting on proposed Medicare Physician-Focused Payment Models submitted by the members of the public. So, this is our ninth meeting.

At our last public meeting in June we deliberated and voted on the CAPABLE

Provider-Focused Payment Model proposal which was submitted by the Johns Hopkins School of Nursing and the Stanford Clinical Excellence Research Center. Last week we sent a report containing our comments and recommendations on this proposal 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. And to remind the audience, the order of activities for the proposals are 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, discussions 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 proposal submitters and the public.

The Committee will then deliberate on the proposal. As deliberations conclude, I will ask the Committee whether they are ready to vote on the proposal.

If the Committee is ready to vote, each Committee Member will vote electronically on whether the proposal meets each of the Secretary's ten criteria. After we vote on each criterion we will then vote on an overall recommendation to the Secretary of Health and Human Services.

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

A few reminders before we begin. And that is first, any questions about the PTAC, please reach out to staff through the ptac@hhs.gov email. Again, the email address is PTAC, P-T-A-C, @hhs.gov.

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

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

The 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'd like to thank my PTAC colleagues all of whom give

countless hours to careful and expert review of the proposals we receive.

I also want to thank you again for your work and thank you to the public for participating in today's meeting via livestream and by phone.

Before we get started I just want to make a personal acknowledgment of Dr. Tim Ferris who has been on the Committee since its inception, four years ago. Dr. Ferris is the CEO of the Massachusetts General Medical Group.

We're very proud and privileged to have him on the Committee and we will miss him dearly. His last meeting is today. And hopefully, Tim, you'll continue to make a contribution today so you'll be memorialized forever going forward. So, thank you.

* **Deliberation and Voting on the ACCESS Telemedicine: An Alternative Healthcare Delivery Model for Rural Cerebral Emergencies Proposal submitted by the University of New Mexico Health**

Sciences Center (UNMHSC)

The proposal we're going to discuss today is called ACCESS Telemedicine: An Alternative Healthcare Delivery Model for Rural Cerebral Emergencies. This proposal was submitted by the University of New Mexico Health Sciences Center.

*** PTAC Member Disclosures**

PTAC Members, let's go ahead and start with introducing ourselves. At the same time, reading our disclosures.

I'll start with myself. I'm Dr. Jeff Bailet now with Altais, which is a physician services organization. I have nothing to disclose. Tim.

DR. FERRIS: Tim Ferris. I work at the Mass General Physicians Organization and I have nothing to disclose.

DR. PATEL: Hi, Kavita Patel, Johns Hopkins and the Brookings Institution. And I, I'm just going to read my disclosure.

I have never met or reviewed this

proposal previously, but I have been in contact with Dr. Sanjeev Arora and his team from the University of New Mexico around their program called Project ECHO which has similar features to this program.

While I was employed at Brookings full-time we did a report highlighting the ECHO Model.

DR. NICHOLS: I'm Len Nichols. I'm an economist from George Mason University and I have nothing to disclose.

VICE CHAIR TERRELL: I'm Grace Terrell. I'm CEO of Envision Genomics. I also do work for Kailos Genetics.

I'm an internist at Wake Forest Baptist Health System and I'm a senior advisor at the Oliver Wyman Health Innovation Center and I have nothing to disclose.

MR. STEINWALD: I'm Bruce Steinwald. I'm a health economist here in Washington, D.C. I have nothing to disclose.

DR. CASALE: Paul Casale, New York-

Presbyterian. I have nothing to disclose.

DR. WILER: Jennifer Wiler. I'm Professor of Emergency Medicine and Business at the University of Colorado. And I'm also founder and executive medical director of UCHealth CARE Innovation Center. Nothing to disclose.

DR. SINOPOLI: Dr. Angelo Sinopoli, Chief Clinical Officer of Prisma Health in South Carolina and the CEO of the Care Coordination Institute and I have nothing to disclose.

CHAIR BAILET: Thank you. And we have two of our Members on the phone. We have Rhonda Medows, Dr. Medows and Harold Miller. Rhonda, do you want to introduce yourself?

DR. MEDOWS: Sure. I'm Dr. Rhonda Medows and I am President of Population Health at Providence as well as CEO for Ayin Health. I have no disclosures.

MR. MILLER: Hi, this is Harold Miller. I'm the President and CEO of the Center

for Healthcare Quality and Payment Reform. I'm sorry I couldn't be there in-person today. I have no conflicts or disclosures on the proposal.

CHAIR BAILET: Thank you, Harold and Rhonda. And we'll be sure to make sure you get air time if you need to make comments as the Committee moves forward with our process.

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

I would like to now turn it over to Len Nichols to present the PRT's finding to the full PTAC. They'll just advance your slides for you.

DR. NICHOLS: Okay, great. So, this is an amazing team I had the privilege of leading. You know, they have this rule that you have to have at least one doc on these committees and they gave me two so it was a lot of fun.

But anyway, Dr. Terrell and Dr. Medows both were quite enthusiastic and you'll

see why. So, as Jeff told you, the way the world works, proposals come in. The staff reviews for completeness.

Then the Chair or the Vice Chair selects the PRT composition. What I'm going to do is talk about the overview of the proposal, the summary of our review, the key issues and then the specific criteria by which we evaluate every proposal.

I think I just said all this. Yes, after the Committee reviews the proposal, we do have a process whereby we're staffed by really smart people who bring us facts we should be aware of and we ask questions of the applicants.

They submit responses and they can do that along the way. And I think they sent us something last week, in fact, to clarify some things.

So, that process continues through today. And as Jeff said and it's very important to make clear, the PRT report is the report of

the PRT. It is not the judgment of the PTAC and all of us may change our mind before we're done.

So, this is a proposal based upon a pilot study that was done under the auspices of the Health Care Innovation Awards. And essentially the idea is to address what is perceived as, and apparently clearly is, an unmet need for cerebral emergent care management in rural hospitals.

And it's pretty clear that there's not financial resources to support this sort of thing nor is there a payment model at the moment that can successfully make it worthwhile.

So, what ACCESS does is it aims to expand essentially access to expertise of neurological and neurosurgical nature to docs in rural hospitals so that they could make more timely and maybe more accurate judgments about the need for hospitalization and the very costly and sometimes risky transfer of patients

to a more sophisticated hospital.

And so, the idea really is to reduce unnecessary utilization at the regional referral centers by equipping them with this access to the telemedicine expertise. The APM entity would be the rural hospital because the payment would go to them.

So, it uses this two-way audio-visual program to connect providers in the rural underserved areas to the experts in the teaching hospitals. The rural providers would request a consultation with an available specialist who consults with them using this platform.

And the consulting physician provides recommendations on treatment to the requesting provider who ultimately always has control of the patient and the course of action.

The submitter in this idea proposes that a bundled payment be made to the rural hospital, not to the entity that's delivering

the telemedicine services but to the rural hospital itself, so that in a sense you pay the hospital and then that rural hospital decides what to do with the money.

And then of course, the money would flow back upstream to the deliverer of the consulting services. The payment includes an element for the consulting itself, for the technology, and for ensuring provider availability.

And I would argue, staff education, program administration and quality assurance, the kinds of, if you will, infrastructure stuff that is not typically paid for in a fee-for-service context.

And that's partly why the bundle was seen as a necessary pre-condition for enabling these services to be provided as frequently as they should be. The payment covers the follow up consultation on the same case within 24 hours so they could call them back.

And the rural hospital is

responsible for paying the distant site neurologist or neurosurgeon and the technology platform provider. Now, here's a nice little chart which somebody made. Probably you all made it originally and ASPE made it pretty.

But here's how the bundle breaks down. First of all, what you want to pay attention to probably and all the specialists in the room already have, the neurologist is paid differently than the neurosurgeon.

And then there's a payment to the consulting physician right there. The technical charge is the same depending on, regardless of who does the service. And then there's a residual payment, obviously, which is the difference.

And the idea behind the differential payment, of course, is that these people cost different amounts of money in real life and having their time on reserve, in essence is necessary. However, this is a deviation, as you'll see in a moment, from what Medicare has

always done.

That doesn't mean it's a bad idea. It just means it's a deviation from what Medicare has always done.

The other thing I want to call your attention to is the cost does cover the payment for the technology and includes this on call availability notion of keeping folks available. The HCIA evaluation basically concluded that there weren't enough people in the experiment to deliver a statistically valid, rigorous impact analysis.

And that was disappointing and obviously a fact we had to take into account. The evaluation that was done did report anecdotal evidence, of course, that suggested all the good stuff.

And I'll just say, I can't really pronounce that. But the point is that thing, that tPA clearly it's a good idea to get that sort of stuff quickly. Timing is everything.

I believe the phrase I heard on the

phone was, you know, time is brain. So, I did learn that.

And then what happened was because the HCIA evaluation was not able to do what we usually like to see in sort of statistical control group analyses, the submitter made available to us a number of different modeling exercises based upon real data that suggested the kinds of savings that you see here.

And there are some unpublished costs analyses from the submitter that estimates quite large savings over time, all of which in our view is plausible but could not be proven statistically at the time.

So, this is the summary chart. And you can see, if you just take a second, it's unusual in that we really liked this one. In fact, we liked every dimension of it and three of them meets and deserves priority consideration which might be a record.

But anyway, unanimous across the board. So, let's go through it. We basically

think this is absolutely a value add to the medical delivery system precisely because it makes the specific expertise available in that real time where time is brain.

And we believe that the program has potential to improve quality and outcomes for patients while saving Medicare money and reducing family stress. It's kind of a win-win-win.

The proposal is innovative. It is an innovative care delivery model in addition to an innovative payment model and it would in many ways bolster the ability of rural hospitals to continue to be viable and all of those are desirable things.

As I mentioned earlier, it is true that Medicare traditionally has not paid for this infrastructure sort of stuff, the education and training, the technology itself and keeping the provider available, et cetera. And the payments are made to the originating site which is a little different than paying

the people who are delivering the services.

And we went through this a couple of times. You know, I am an economist. My job is to be skeptical. And I must say at first I thought it was odd and now I think it makes sense.

So, that's sort of our evolution as we thought about this problem. We definitely think that the fair market value which was the methodology used to determine the price of the neurosurgeon versus the neurologist is probably reasonable.

But there wasn't a great deal of information about exactly how that was done. I mean, it does have kind of an implication. So, it could be that Medicare will want to look a little more deeply into how that might be done and maybe it should be different in different parts of the country.

Anyway, so the criterion as the Secretary laid them out, we start with scope which basically asks the question does it reach

patients that have not been reached before or providers who have not been reached before in a scale that's big enough to make difference?

Essentially, we said not only is it unanimously yes, but it meets criteria and it deserves priority consideration precisely because of the rural hospital nexus with the stroke patients. And so, there's no question here.

Quality and cost, again while the HCIA evidence wasn't tremendously convincing, the totality of the evidence presented led us to believe that it was quite reasonable to conclude it will indeed lower costs and improve quality. So, again we think deserves priority consideration.

The payment methodology, like I said, we did have a couple of questions here. We're not quite sure that the fair market value calculation was clear enough to satisfy CMS's normal healthy skepticism.

So, we think some of that is going

to have to be clarified. And there is no explicit risk sharing, although almost by construction a bundle involves some downside risk sharing. But in any event, we thought this did meet the criterion and not -- deserved priority consideration.

Value over volume, again we really had no doubt that this was moving in the right direction. And we thought it was sufficiently impactful, potentially deserved priority consideration in that way. We certainly think one great thing about paying the rural hospital is they have flexibility about what to do with this money and how to contract with the services and so forth.

And so, we thought that absolutely gave the right amount of flexibility clinically. No question that there's a question about coming up with a control group. But we're pretty sure there is enough patients out there to find one in real life.

And if you take it to scale like

they're proposing it should be much easier to generate a sample size large enough to get statistical validity. So, we think it absolutely is able to be evaluated.

Care coordination, the whole point is to better coordinate care of these complex patients in real time. And we're convinced that this application of technology and services would do that.

Patient choice is absolutely respected by granting that the local rural hospital physician have control over the basically plan of care sort of guarantees that patient conversation goes on the right way.

Patient safety, I will say that there is concern about that. But almost by construction this is better than the status quo and therefore it's enhancing the safety environment that we have today.

And of course it uses pretty sophisticated technology to make all this happen. So, for all those reasons, Mr.

Chairman, we have concluded that this proposal meets all the criteria the Secretary laid out.

Let me stop now and allow my physician colleagues. Rhonda is on the phone. We might want to start with her since she's on the phone, and Grace to see what I left out or should have said better.

DR. MEDOWS: So, Len, I don't think you left anything out. I think you just did a fantastic job describing what I thought was one of the best prepared proposals that we have seen as a Committee.

Quite frankly, I thought that they addressed a scope and span of need that was not addressed previously, observation of needs. They did a great job in describing both how they would actually measure and monitor quality, patient safety, patient outreach and engagement as well as how they would actually get coordination to occur amongst a significant group of providers and specialists for this much needed service.

I think you did a great job. I don't have anything else to add other than thank you for representing the PRT.

CHAIR BAILET: Thank you, Rhonda.

VICE CHAIR TERRELL: So, I forgot to say earlier when I was stating some of things that I do is that for the last several months I've been doing some telemedicine work for a telemedicine company.

A very different situation than this. But what I've learned from that experience having done about 4,100 telemedicine consults over the last six months is that there is a major access problem in rural areas, at least in the two states that I do that in, which is North Carolina and Alabama.

So, even though when you think of a state like New Mexico geographically speaking, there is a very different sort of structure. I think that the need for this is going to be universal, and this could be a very, very good and effective way to really solve some major

structural problems in the U.S. healthcare system, namely those in rural areas as well, quite frankly, making the expertise and experience of academic medical centers have an outreach that sometimes in the past has been constricted by geography.

So, I would agree with both of my colleagues and just want to talk about the experience that I've had, actually, since the review process started that would just confirm the enthusiasm I have for the work that they've done around this.

*** Clarifying Questions from PTAC to PRT**

CHAIR BAILET: Great, thank you. Before we have the submitters actually come to the table it's now time if we had clarifying questions that the Committee would like to ask of the PRTs. We'll start with you, Bruce and then Tim.

MR. STEINWALD: The elements of the payment, there are the payments to the

consulting physician. But then the other payments seem to be covering costs, many of which might be fixed costs.

And I was wondering if you had some discussion about that and whether if the volume wasn't sufficiently high, the ability to cover those fixed costs might be limited.

DR. NICHOLS: That's a good question. And in fact, yes, that's what I meant by infrastructure. Yes, there's a lot of stuff that is fixed.

And that's what I also meant when I said CMS might want to kick the tires a little bit more about exactly how to think about this. They made a set of price recommendations based upon anticipated volume.

And I think you might want to be able to adjust that if the volume turned out not to be there. I think that's right.

But again, I think what would happen if it goes through the process is CMS could bring more data together to perhaps get a more

precise estimate. But absolutely the notion is it's a fixed cost you're spreading over a lot of it.

CHAIR BAILET: Tim.

DR. FERRIS: My question had to do with the rural versus everywhere else. And the expertise necessary to make a decision to prescribe in real time a highly lethal, potentially lethal drug in order to prevent a stroke or the extension of a stroke is actually not commonly found in suburban community hospitals, either.

And so, I was unclear whether or not the payment model as proposed restricted the site of care to rural as, however defined, or was it just a payment model that happened to be particularly beneficial for rural but could be applied anywhere? That's the first half of the question.

DR. NICHOLS: I don't remember that rural was a requirement. I think it's more the way it was described and the way the HCIA thing

played out.

In fact, I think they said any hospital that didn't have the expertise should be able to connect and they're nodding. So, I think that's true, yes. All right. It ain't rural per se. It's rural-like.

DR. FERRIS: Rural-like, okay. And my second question actually had to do with, did they, and maybe I'll address it to them when they come up.

But did they address the issue of state borders? So, the licensing requirements associated with physicians delivering a recommended care across state borders has been, let's just say a bit of a conundrum.

And while some states are moving toward reciprocal agreements usually adjoining states that we're still a long way away from that as a country. And it is a big barrier to these kinds of telemedicine services.

And I just wondered if there was any reflection on that in the proposal. Okay, I'll

ask our submitters.

CHAIR BAILET: Jen, and then --

DR. WILER: Thank you. I want to make sure I understand. So, the episode starts with a request for consultation for an emergent, what I would describe as stroke consult rule in, rule out and a decision around administration of tPA.

And that it ends at transfer of the patient to a facility or within 24 hours if the patient stays within that rural location. Is that correct?

DR. NICHOLS: I think so.

DR. WILER: So, my question is was there any conversation about why transportation costs with EMS, which can be costly, weren't included in the bundle or radiology because in these rural facilities getting emergent reads of scans which could be done by a consultation expert in neurology or neurosurgery, but at least in my comprehensive stroke center that we actually have neuroradiologists who are reading

those.

And also then the hospitalist care or whoever is providing in hospital consultative services during those post 24 hours, why those weren't included in the bundle?

DR. NICHOLS: So, as I understand it and, Grace, I definitely look to you and Rhonda to weigh in here, the fundamental problem that was attempted to be addressed here was overly conservative referral to the regional hospital center.

So, the expertise was thought to essentially, and part of the training as well, was essentially designed to enable the local physician to feel more comfortable about keeping that patient in their own hospital.

And everything else you just described is sort of after that. So, if they're going to keep them they feel good with what they've got. If they're going to transfer them they don't feel good about what they've got

compared to what that patient needs.

And that's the expertise they're trying to bring to help them bear. So, the rest of it is all paid for as I understand it. So, I don't think it's relevant to the bundle per se. The bundle is to buy the expertise.

CHAIR BAILET: Angelo.

DR. SINOPOLI: So, first of all I like the idea that this is the rural hospitals' or the outlying community hospitals own this payment. Just a couple of questions that are really just more curiosity.

So, it was clear in the proposal that it started with the event and there was some payment for the 24 hour coverage. It wasn't clear whether there was payment for on call availability to be available when an event occurred.

Was that discussed a part of the payment? And as part of that, as a rural hospital has the events and sees their needs in a community that may have several hospitals

that do this type of intervention, can they on a given day or a week choose various hospitals or are you looking at this as being an exclusive contract with a tertiary care center that does that?

VICE CHAIR TERRELL: It wasn't, to my understanding looked as a bundle of, it's a really great question, a bundle of, you know, one payment that different hospitals would share. If you're talking about, it really was about covering the cost at the unit level of the rural hospital.

I mean, this may be some clarification that might want to be when you talk to the submitters with respect to their HCIA award because they were covering more than one hospital at a time.

CHAIR BAILET: All right, Paul.

DR. CASALE: Just to add on further to Jennifer's question which, again I think, the submitters could probably further elucidate. But so, part of it was around do you

transfer or not.

But if you give the tPA and you keep them, you still need a neurologist and you still need expertise. So, who is providing that? I presume if they had a neurologist on site they wouldn't necessarily need the telemedicine neurologist.

So, I'm trying to understand to Jennifer's point about that ongoing care and is that, why not include that in the bundle or is there a separate fee for that ongoing telemedical medicine care?

DR. NICHOLS: I definitely think we should ask the professionals. But I would just observe that what they're buying is the extra expertise for the decision making.

The monitoring neurology of an inpatient in the rural hospital would either be paid for through normal Medicare channels or not. I mean, that's a consult.

CHAIR BAILET: Angelo, and Jennifer.

DR. WILER: Sorry, just to preempt

the discussion with the presenters I'd like to hear, I'm sure the societies have considered why not requesting to add this to the fee schedule in some ways.

There are some examples of, you know, where these specialist consultation services might have been added. So, why that's not possible and why an APM would be a better arrangement would be a welcome discussion.

CHAIR BAILET: All right. I just want to make sure, check in with Rhonda and Harold before we open it up to the submitters. Do you guys have questions for the Committee?

DR. MEDOWS: I do not and I'm on the Committee, but, no.

MR. MILLER: I do not. I have questions for the submitter but not PRT.

CHAIR BAILET: All right. Thank you, guys. Let's go ahead and have the proposal submitters come on up to the table. We have one person on the phone, Susy Salvo-Wendt. She's participating by the conference line.

And if you guys could introduce yourselves. I know you want to make some opening comments which we limit to ten minutes and then we'll open it up for questions. Thank you guys for being here.

*** Submitter's Statement**

MR. STEVENS: Well, my name is Ryan Stevens. I'm an administrator with the UNM School of Medicine. And joining me today is Dr. Neeraj Dubey who is one of our consulting neurologists and a user of this platform.

Members of the PTAC, we thank you for your time and consideration of our PFPM proposal with the ACCESS model of delivering specialty telemedicine consultation in urgent and emergent settings.

It is fulfilling both personally and professionally to discuss with you today a service that has demonstrated tremendous value and is potentially a springboard for eliminating health disparities that are driven more by beneficiaries' zip code than any

socioeconomic or medical variable.

I also want to take a moment to recognize and thank the members of the ACCESS Team who are on the phone. And particularly Dr. Howard Yonas, whose extraordinary vision and leadership made possible this program that has now delivered over 6,000 consults.

We sent you updated statistics built on the data collected during the CMMI grant demonstrating the positive impact of the ACCESS model for patients, family, emergency physicians, facilities lacking specialty coverage, their communities, payers and referral centers.

It's difficult in today's healthcare arena to identify self-sustaining programs and services with so many stakeholders benefitting so much yet still with the purity of purpose that aligns everyone for the benefit of the patient.

The ACCESS Program has garnered support from hospitals, local payers and the

State of New Mexico based on the value proposition demonstrated through the grant and now perpetuated into a sustainable and ever evolving post-grant period.

Several unique aspects of the ACCESS Program enhance the value proposition that has contributed to the current level of support. So, I'll list those out.

First, hospitals only pay for specialist services as needed. This entirely variable cost structure is particularly favorable for low frequency, high acuity events such as cerebral emergencies. Because we bundle program costs into this variable rate, it does complicate a fair market value assessment.

Second, we propose facilities be reimbursed for physician services. There is far greater administrative simplification if the specialist is not required to bill the insurer or the patient for services rendered. Program resources that would be required for the specialist to obtain billing information are

better spent on education and quality assurance.

Third, the education component of ACCESS is a critical element of success. There is far greater, excuse me, and is a differentiator from many other telemedicine programs.

It is one thing to receive a recommendation from a specialist and another to be comfortable implementing. We believe the change in emergency provider and facility behavior from 90 percent transfer to 15 percent transfer for these conditions is a result of combining specialist availability with targeted education, ongoing training, and surveillance.

So, another differentiator for our program is its intent. ACCESS was set up with the specific goal of keeping patients in their home communities, not to capture cases for a referral center. And we left the decision for transfer as to where to transfer up to the local facility.

While we're confident in the positive results of the ACCESS model, we acknowledge that there are multiple aspects of this model that challenge existing CMS physician payment paradigms and we look forward to participating in a lively discussion today among the experts on how to best meet those challenges.

I'll call four of those challenges out now. Outcomes validations. So, the unfulfilled promise of interoperability between EMR platforms created a challenge to efficiently validate outcomes, utilization and any savings impact beyond tPA administration in stroke, which is well studied, and transport avoidance.

During this program nearly $100 million in transport charges have been avoided, a tremendous accomplishment. But intuitively, we know even more benefit has accrued via the improved timeliness of treatment delivered to patients experiencing a time sensitive clinical

event.

Interestingly, the majority of consultation requests are for neurological conditions other than stroke. For stroke consultations there's good evidence in the literature to support our findings of an improvement in lifetime quality adjusted life years of 2.8 and savings of $35,761.

However, other than transport avoidance, we have less evidence on the outcomes for non-stroke consultations. We now have an increasingly robust HIE within the department to better assess our clinical outcomes. We would still need to acquire a control population from the geography that did not have access to consultative service.

The second challenge, risk sharing. Incorporating risk sharing elements into the ACCESS model necessitates an expansion of the service from the focus on rapid access consultation delivery to management of the episode of care initiated at the time of

consultation.

Episode management requires a degree of coordination that exceeded the scope of our initial CMMI project. We do welcome collaboration with government and/or private payers to secure reimbursement for these services while exploring how our urgent, emergent specialist model can, could be expanded to other specialties and could be adopted in other markets in the risk sharing agreement even.

The third thing, variable reimbursement. So, we introduced in a platform a model that can work for frontier, rural, underserved, and even urban hospitals with each entity only paying when the service is used.

Each participating hospital has access to clinical education, quality reporting, and other resources being part of ACCESS. But we introduced in this model the market driven reality of the cost of a specialist on demand, 24/7 coverage, and the

variability between specialties of that real cost.

So, for example, neurosurgery costs more to make available than neurology. Current telemedicine and E&M fee schedules do not take into account the significant cost variability between specialists nor the challenge of delivering services at all hours of the day instead of scheduled visits.

Last challenge, facility eligibility. The hospital criteria for eligibility for ACCESS services is conceptually quite simple. Does the facility need the service?

That need does not necessarily correlate to a population based ratio specialist, nor do HRSA, MUA or rural status reflect individual specialty availability. Through our Medicaid collaboration we continue to develop processes to validate the presence of program elements and outcomes data.

And we propose that the focus be on

developing a process of validating fulfillment of program objectives and not upon creation of facility eligibility criteria for participation.

So, we greatly appreciate the opportunity to collaborate with CMS and continue the discussion of how to take ACCESS model to the next level in other areas of the region, nation and into other specialties.

I'll conclude with a little story. During the CMMI Grant we collected many stories of how ACCESS affected patients and families.

Several were extraordinarily illustrative of the benefit of timely specialist availability, such as that of a woman who suffered a devastating hemorrhagic stroke in rural New Mexico and whose ED provider requested a consultation from Dr. Yonas amidst a scramble to transfer her elsewhere.

Our anecdotal pre-ACCESS experience and CMMI data both confirm that this woman with

great probability would have been transferred 300 miles away to a referral center likely in another state and with her prognosis would have certainly died in spite of the heroic efforts of her flight crew.

Instead, Dr. Yonas had the nurse turn the care to the family, explain the certainty of mom's prognosis and the woman passed away with dignity surrounded by those she loved.

So, what we propose is working with you to continue developing a physician focused payment model that enables tremendous fiscal and human benefits.

So, that concludes our prepared remarks. Thank you again.

CHAIR BAILET: Thank you, Ryan and Dr. Dubey. Yes, I know we're going to have a discussion, right.

But I wanted to turn it over to both Rhonda first and then Harold because they're already signaled that they had questions and

they're on the phone and then we'll open it up to the Committee Members in the room.

DR. MEDOWS: I actually don't have questions.

MR. MILLER: I do have questions.

CHAIR BAILET: Go ahead, Harold.

MR. MILLER: Okay. Thank you, Jeff. First of all, I'm sorry I couldn't be there in person and I want to commend you for this project which I think is an excellent service that clearly has had very good results.

I'm very familiar with the need for this kind of service in a variety of rural hospitals. But I did want to talk to you about, in more detail, about the payment model.

And I had really three questions. First of all, I'm interested to know how the critical access hospitals in New Mexico have dealt with this since they would theoretically be able to count the charge, your charge as a cost and receive cost-based reimbursement from Medicare for that.

Other critical access hospitals have tried to put these services in place have had this challenge that Medicare, they can basically cover the cost of the Medicare patients but not for Medicaid and commercial payments, whereas in New Mexico, you now have a payment for Medicaid.

So, I would think that the critical access hospitals would actually be able to support this that way. And I'm wondering what experience you've had differently with the way, are they in fact billing this service to Medicare now?

MR. STEVENS: Not that I'm aware of. They do have and I think, Susy, are you on the line?

MS. SALVO-WENDT: Yes, I am.

MR. STEVENS: Yes, Susy can speak better to the hospitals' experience with billing Medicaid.

MS. SALVO-WENDT: As of right now our critical access hospitals have not begun

billing Medicaid. We are in the process of developing that process.

And so, as they see it, they believe that their billing would be the same as the other hospitals as the benefit that they see is the same. So, we do not anticipate issues with the critical access hospitals other than they, during the grant we were supporting.

And so, that's why there hasn't been a crucial incentive for them to bill until now that we're off the grant.

MR. MILLER: Okay, thank you. But they would be able to count this as a cost and receive basically 99 percent reimbursement from CMS from the cost at least as apportioned to the -- and since you're charging them on a patient by patient basis they would be able to recover that.

The two questions I have really are about the, other questions are about the payment approach. And I understand why your structure when you're charging for the service

would be to have the hospital pay you on a patient by patient basis. That makes perfect sense.

I guess the thing though that I'm a little perplexed by is the notion that if Medicare were paying for it that the rural hospital would be billing Medicare for a service that you are providing.

Typically in most, almost virtually all payments that Medicare makes, the Medicare payment goes to the entity that provides the majority of the service.

But what you're having Medicare pay for here is a service that is provided by you, the remote provider with a variety of things that you provide as part of that.

Not only the physician consultation. But as you mentioned the backup, the standby service from the specialist, et cetera. And so, I don't understand why it wouldn't be you that would be billing Medicare for the individual service.

You would only bill Medicare for the individual service when an individual hospital actually used it. That part would make sense. But Medicare would presumably, CMS would want to know that in fact the service was being delivered appropriately, that there was high quality standards associated with it, that the specialists were in fact available and responsive and had the appropriate qualifications.

And it would be very difficult for the rural hospitals to do that whereas it would make, be far easier and more appropriate for you, the service provider, to actually do that.

So, can you explain why it would make sense for a rural hospital to bill Medicare and then have to somehow justify to Medicare that the thing that it was delivering in return for that payment met all of those kinds of quality and appropriateness standards?

MR. STEVENS: I'm going to let Dr. Dubey speak to that as one of our consulting

providers.

DR. DUBEY: So, typically what happens is we get consulted on a stroke patient or any kind of neurological emergency which reaches the ED. And we provide consultation within a very specified period of time frame, 30 minutes.

And we leave the recommendation and we discuss it with the ED physician. And we are available for the same consultation within 24 hours with no extra charge.

And if they approach us again after a 24 hour period then there's an extra charge, I believe. So, the service is such, it's so good because we get approached numerous times by the same patient within 24 hours of a critical time period when you see a patient.

And I think it's easier for the hospitals to bill rather than the physician billing for the services over and over again and adding administrative costs to it.

MR. MILLER: Well, I'm not suggesting

that the physician bills for the service because this service is not being delivered by an individual physician.

It's being delivered by you as a program that organizes a set of physicians and has physicians on standby so that you can deliver the services in a timely fashion.

No individual physician could do that. And what you're offering is not just that individual physician consultation. It's that whole backup program.

So, you're the one that's delivering that service. So, it seems to me that you would be the person that would be billing Medicare.

So, let me ask part two of the question because these two are related. As I read the proposal you did not include any kind of accountability for results or quality in the payment.

The payment gets billed if the service is delivered essentially regardless of what the quality is. You have some measures

that you defined that would be reviewed through an evaluation process.

But I'm curious again as to why most models that we review and that we have called for in our guidelines have some kind of where the payment is based in some fashion on the quality of the service delivered.

So, in fact if you were not delivering service in a timely fashion the payment would be lower. If you were making bad recommendations the payment would be lower, et cetera.

And so, I guess I'm interested in why you didn't include any accountability like that. But to relate just to part one of the question, is, if there were some accountability, the accountability would really be at the part of your program, not the individual hospital, because your program is the one that is assuring timely response and good recommendations, et cetera.

And you would need to be accountable

for that quality.

MS. SALVO-WENDT: Okay, can I intervene? This is Susy. And so, since I was on the inception of 2010 when we started working on telemedicine, our whole point was to keep the local rural underserved urban hospitals control of their patients.

And so to do that, we felt it was beneficial that they controlled the billing because our purpose was to provide the consult and the education and some quality objectives that we do as part of them being part of the ACCESS team of hospitals.

So, we thought about this in the beginning very intensely, why don't we bill? Well, because then we become that patient's doctor which we're not prepared to do.

When patients go to rural hospitals or underserved most times they know those doctors. They have a relationship. When it comes to billing it's, the patient can actually go to the hospital and understand the billing

process and work with that hospital.

We really wanted these hospitals to be the anchor institutions and not have us, the university being the big guy defining the billing, all of that.

We wanted to put this, all of this in the rural hospital so they could build upon their financial stability and they could control what happened to that patient both clinically and through the reimbursement process.

MR. MILLER: Okay, but if you could explain to me, can you explain to me though how if one wanted to tie the payment to the quality of the service being delivered how that might be done?

DR. DUBEY: I'll make a point to that because each of us who do consultations in different hospitals, we have to get credentialed at the local level, at the rural hospital level or suburban hospital.

So, their credentialing process is

done by every hospital. It's not a uniform credentialing process but it's done locally by every hospital.

They look at your credentials and they approve credentials based upon, you know, your training and your education. And that should serve as a quality measure.

MR. MILLER: Okay, Jeff. Thank you.

CHAIR BAILET: Thank you, Harold. Tim.

DR. FERRIS: Going directly to the point of assurance, did you think about requiring the provider of the service to be a certified stroke center because certified stroke centers have to go through extensive evaluations about their ability to provide high quality services in, specifically in the telemedicine context?

So, I just wondered if that might serve as a proxy for like some, there's an existing certification system that exists in the United States for Comprehensive Stroke

Centers.

MR. STEVENS: Actually we're familiar with the fact that there are several different certifications. And I think one of the challenges would be landing on which one.

DR. FERRIS: Just there are some that are available, yes.

CHAIR BAILET: Grace.

VICE CHAIR TERRELL: So, we often talk about payment models as being either about value or about volume. And one of the things, I believe I just heard from your colleague on the phone is that this is both potentially at the same time.

And the fact that the motivation for the hospital in the rural area would be keepage, they're able to keep the patient locally and keep the beds full as opposed to shipping out somebody in a way that may be dangerous, you know, for the patient as well as inconvenient for their family and also not necessarily the way things would necessarily

appropriately be done if the services could be done locally.

So, within that context of value and volume the value would seem to be the overall lower cost of care secondary to keeping someone local.

But the value proposition for the rural hospital is actually increased volume for, because it increases their medical appropriateness if -- am I getting the value proposition for the rural hospital correct in the way that I'm understanding why they would be motivated to do this, as opposed to just shipping them out because of risk or lack of resources?

MR. STEVENS: Yes, absolutely. In fact, we have a CFO from one of the hospitals that had relayed to us that this was the difference between them shutting down and staying open.

The 100 patients that they were able to retain was the difference in their bottom

line. It kept them open.

CHAIR BAILET: Thank you, Paul.

MS. SALVO-WENDT: Another aspect is that we do, we review 30 percent of the consults every month in a vigorous review by specialists who review each consult for diagnosis and appropriate treatment.

And so, we also, I mean just as an example, as we were doing some research on our epilepsy patients, realized that not all consultants were up to date on treatments in epilepsy which then we were able to send out to our consulting physician and do some more education, some pointed education in our hospitals.

So, that's another way where we're trying to make sure the quality is appropriate and that the education is up to date.

CHAIR BAILET: Thank you, Paul.

DR. CASALE: Great. So, one of the, with bundled payments in general there's always a question of if you now get paid for a bundle

what prevents you from just doing more bundles?

So, in your list, there's a list of diagnoses that can trigger this. But, of course, when payment is tied then there's a potential for some to maybe trigger a bundle for a diagnosis unless, I didn't see, is there a clear list of diagnoses that are prescribed or is there a potential for sort of unintended consequences of other sort of neurologic conditions like severe headache or something that could, you know, sort of trigger bundles?

And how do you assure or guard against that?

DR. DUBEY: As you can see in the data, there were only 27 percent of the consults were provided for stroke. A lot of times when the patients hit the emergency room as, you know, they're considered a stroke patient if they have some kind of a deficit or a headache, unexplained headache.

So, it's a process of ruling in and ruling out. Clear cut strokes are always

included. But there is always such a gray area in medicine that some of these neurological emergencies which roll in have to be ruled in and ruled out.

So, there's not one consensus, one diagnosis that you --

DR. CASALE: I understand that. I just didn't know if there's a way to guard against, again, an unintended consequence of someone sort of just triggering more and more bundles potentially?

DR. DUBEY: I think there is. It would be hard to do so.

CHAIR BAILET: All right. We want to thank both of you for coming and, Susy, you on the phone. Obviously, you can return to your seats and we're going to open it up for public comments.

*** Public Comments**

We've got three folks who have signed up for public comments. So, again, Dr. Dubey and Ryan, appreciate your coming and

submitting this.

MR. STEVENS: Thank you very much.

CHAIR BAILET: So, I want to open it up to Mr. Dick Govatski who is the CEO of Net Medical Xpress. You're calling in.

MR. GOVATSKI: Thank you very much.

CHAIR BAILET: Yes, go ahead.

MR. GOVATSKI: Thank you very much. Just a brief explanation of the technology that we developed for medical purposes. In 2001, we developed FDA-cleared software to remotely diagnose x-rays. It's called XREX.

By 2005, we were the early pioneers in telemedicine and started discussing how we could build products for not only x-rays but larger solutions to get hospitals to be able to transmit information from their EMRs.

Today our proven technology had to undergo many innovations to provide solutions for not only radiology, but by 2011, we had developed a way to help remote doctors assist in neurology, cardiology, critical care and

most important, neurosurgery.

We had to have a way to combine medical imaging and videoconferencing technology. So, we could place a specialist in a remote location in minutes instead of physically placing them in the emergency room and our average time to do that is about 17 to 18 minutes.

We had to have a way to combine medical imaging for the rural hospitals because while this all seems commonplace today, there are still hospitals that are grasping at how to do this, how to do telemedicine.

And we also had to develop licensing and credentialing programs for remote specialists, for example. A call center had to be created. And it wasn't just to answer the telephone. We needed the call center operators to be able to troubleshoot the technology if things went wrong with the consultations.

And we had to learn how to integrate the information required by the remote

physician without having to have someone tell that specialist what was happening to the patient.

We successfully integrated with multiple EMR systems including Epic, Allscripts, NextGen, NovaScan and many other smaller EMRs. In addition to the software and hardware, Net Medical employs our own specialists that work in conjunction with the university specialists.

This is absolutely necessary and here's why. If you have specialists in the hospitals and you're limited to five, six specialists perhaps in neurology, how would you populate those specialists at ten, 20 or even 100 hospitals?

And how do you train those specialists to work with perhaps over 100 different work flows at each hospital? So, you have to centralize the technology to be able to do telemedicine.

And it gets more complicated as you

integrate FDA-cleared image viewers, interoperability conditions, security, encryption, HIPAA, customized program management solutions and to operate 24/7, 365.

So, our technology is very advanced, it's complex, but yet it's also in the same breath easy to use by the hospital customers. We strive for good patient care by providing an operational program for many different modalities and customers.

And this is important, what I'm about to say. And that is we are open to license this technology to others as needed because even the big EMR vendors have not figured out how to do telemedicine across multiple facilities, multiple modalities and multiple specialists all at the same time.

So in conclusion, we support the model you're reviewing because it allows small business and independent physicians to join a group to provide clinical services where there were none before. Thank you very much.

CHAIR BAILET: Thank you. The next person on the phone is Deirdre Kearney. She's the clinical educator for the University of New Mexico.

MS. KEARNEY: Good morning. I wanted to talk about the impact of clinical education and quality just as things change.

One of the intentions of the ACCESS Program is to not only deliver a versatile efficient healthcare technology based product such as telemedicine but to encourage lasting change in provider behavior and practice with a positive impact on health outcomes.

This change is rooted in clinical education and clinical quality. We want the rural hospital staff to not only see telemedicine as an external convenience but a real learning partnership with the telemedicine specialists.

A significant barrier to adopting change is if that new technology, skill or approach is, the change involved is a process

and not an event. It takes time to develop mutual trust and respect between rural providers and specialists.

This professional relationship is the basis for an informal but critical exchange of knowledge such as in the ED when a patient with a devastating neurological deficit now has the advantage of two physicians collaborating on his care.

It's one thing for a specialist to consult on a head injury patient in ED to provide a presumptive diagnosis and treatment plan and another to now ask the rural hospital and the nursing staff to admit and take care of the patient.

This calls for an educational bridge whereby fundamental clinical knowledge is shared with staff to provide a basic comfort level and competence in the care of a neurological patient. This is what ACCESS is addressing through formal education offered on site with clinical staff workshops and remotely

by livestreaming neuroscience grand rounds and physician to physician outreach.

Education reached between clinician increases trust and builds a comfort level with patient care and confidence in that care delivery.

Quality with ACCESS is driven by many metrics, such as accuracy of ED presumptive diagnoses, appropriateness of clinical recommendations, mortality, morbidity, length of stay, cost, and function of status at discharge.

I would like to consider another more personal metric of quality. And that is what does the rural community, the patient, the physician, the nurses, therapists or techs really see as valuable.

A quote by Richard Doll, epidemiologist who was addressing healthcare patient satisfaction exactly hit this point when he noted no point providing clinically effective and economically efficient care that

no one wants.

Care needs to be personal and relational between a patient and a doctor, between collaborating physician and clinician, between a town and their hospital. Thank you so much for giving me this opportunity to share my thoughts today.

CHAIR BAILET: Thank you. We have Sandy Marks who is the assistant director for the Federal Affairs with the American Medical Association. Sandy.

MS. MARKS: Thank you and good afternoon. The AMA is very encouraged that in the last several months the Center for Medicare and Medicaid Innovation has taken important steps to implement several of the PTAC's recommendations.

This includes the new Primary Care First Model for primary care and palliative care and the Kidney Care First Model. The AMA has been working closely with the primary care specialty societies and CMMI to better

understand the details of Primary Care First and provide feedback to the Agency.

We're anxious to see this work continue to advance. It's been a long time since PTAC recommended a number of other models to the Secretary. But we haven't yet seen a response.

This includes two models that the AMA strongly supported. The American College of Emergency Physicians' proposal for the Acute Unscheduled Care Model and the oncology model known as MASON, Making Accountable Sustainable Oncology Networks.

We urge PTAC to advocate for prompt responses to its recommendations. Timely responses are needed so that other applicants won't be concerned that they may be wasting their time developing proposals that are unlikely to be implemented.

We also wanted to comment on the issue of PTAC providing technical assistance to submitters. It has become clear that the

changes to PTAC's authority that Congress made in the bipartisan Budget Act of 2018 regarding initial feedback did not really accomplish what was needed.

In a joint letter to Congressional leaders last spring, the AMA and 120 state and national medical societies recommended that Congress make a number of technical improvements to MACRA, including providing authority for PTAC to provide technical assistance and data analyses to stakeholders who are developing proposals for its review.

We are continuing to work for these changes and urge the PTAC Members to support them. Thank you.

CHAIR BAILET: Thank you, Sandy. We are, I guess I'll check with the operator. Are there any other folks on the phone who wanted to contribute?

Hearing none that is the end of the public statements. Any other questions to the Committee or with the Committee before we would

move into deliberation?

*** Voting**

Hearing none, are we ready to go ahead and vote on the ten criteria? All right. So, let's just review real quick how the voting works.

We're going to ask through each of the criteria we're going to have the Committee vote electronically. And you'll see the results here as we go through the process.

A vote of 1 or 2 means does not meet the criteria. A vote of 3 or 4 means meets. A vote of 5 or 6 means meets and deserves priority.

There's an asterisk also which can be chosen which means it's not applicable. Once we vote on the ten criteria we'll then proceed to vote on the overall recommendation to the Secretary.

We will use the voting categories and process that we debuted in December of 2018 when we designed these more descriptive

categories to better reflect our deliberations for the Secretary. And I'll go through those categories when we get to that point.

So, it's going to be a little, a little more clumsy this time around because we've got two people on the phone who have to submit and then those votes have to be tallied.

* **Criterion 1**

So, we appreciate your patience as we go through the process. So, let's go ahead and start with the first criteria, please, which is scope.

It's a high-priority criteria and the aim is to either directly address an issue in payment policy that broadens and expands the CMS APM portfolio or include an alternative payment model entity whose opportunities to participate in APMs have been limited.

So, let's go ahead and vote, please. Okay, hang on. We're almost there. No, no, I think we're good. Just Grace has got to tally one.

Rhonda, could you please text your vote to Grace, Grace's cell which you have? Thank you.

VICE CHAIR TERRELL: I'm not on the guest Wi-Fi. Do I need to get on the guest Wi-Fi___33?

CHAIR BAILET: I don't think so. Yes, could you just call her back and we'll hand the clicker to you and you just stay in communication and you vote for her?

Could you do that please, Amy? Grace, do you want to give her one of yours. That's hers. Thank you. I did say it was going to be a little clumsy.

So, as soon as she records it you'll see the number go from ten to 11 and then the totals will tally and we can move forward. She's on, okay. So, you voted? It hasn't --

VICE CHAIR TERRELL: I got it.

CHAIR BAILET: You need her, okay --

VICE CHAIR TERRELL: Did it come through?

CHAIR BAILET: Yes. No, it's going to. Hang on, Grace. Here you go. Okay.

So, we're ready for the results. Sarah.

MS. SELENICH: Okay. So, four members voted 6, meets and deserves priority consideration. Three members voted 5, meets and deserves priority consideration.

Three members voted 4, meets. One member voted 3, meets. And zero members voted 1 or 2, does not meet and zero members voted not applicable. The votes roll down until a majority is met.

In this case a majority is eight so, sorry, I'm thinking two-thirds. In this case the finding of the Committee is that the criterion or the proposal meets and deserves priority consideration of this criterion.

*** Criterion 2**

CHAIR BAILET: Thank you, Sarah. Let's go with Criterion number 2 which is quality and costs which is also a high-priority

criterion.

Anticipated to improve the healthcare quality at no additional cost, maintain healthcare quality while decreasing cost or both, improve healthcare quality and decrease costs. Could we please vote?

All right, very good. One more time with feeling. Hit it again, Grace. Everybody revote. Just hit your number one more time in case it wasn't captured. There we go, thank you.

MS. SELENICH: One member votes 6, meets and deserves priority consideration. Five 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 finding of the Committee is that the proposal meets this criterion and deserves priority consideration because of it.

*** Criterion 3**

CHAIR BAILET: Thank you, Sarah. Criterion number 3, payment methodology, again high-priority criterion. Pay the alternative payment model entities with a payment methodology designed to achieve the goals of the PFPM criteria.

Addresses in detail through this methodology how Medicare and other payers, if applicable, pay alternative payment model entities.

How the payment methodology differs from current payment methodologies and why the Physician-Focused Payment Model cannot be tested under current payment methodologies. Please vote. All right. Here we go.

MS. SELENICH: Zero members vote 5 or 6, meets and deserves priority consideration. Three members vote 4, meets. Seven members vote 3, meets.

Zero members vote 2, does not meet. One member votes 1, does not meet and zero members vote not applicable. The finding of the

Committee is that the proposal meets this criterion.

*** Criterion 4**

CHAIR BAILET: Thank you, Sarah. And Criterion number 4, value over volume. Provide incentives to practitioners to deliver high-quality healthcare. Please vote. Sarah.

MS. SELENICH: Zero members vote 6, meets and deserves priority consideration. Four members vote 5, 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 finding of the Committee is that the proposal meets this criterion.

*** Criterion 5**

CHAIR BAILET: Thank you, Sarah. Criterion number 5, flexibility. Provide the flexibility needed for practitioners to deliver high quality healthcare. Please vote.

MS. SELENICH: Zero members vote 6,

meets and deserves priority consideration. Two members vote 5, meets and deserves priority consideration.

Seven 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 finding of the Committee is the proposal meets this criterion.

*** Criterion 6**

CHAIR BAILET: Thank you, Sarah. And Criterion number 6, ability to be evaluated. Have valuable goals for quality of care, costs and other goals of the PFPM. Please vote. Sarah.

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

Seven 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 finding of the Committee is the

proposal meets this criterion.

* **Criterion 7**

CHAIR BAILET: Thank you, Sarah. And Criterion number 7, integration and care coordination.

Encourage greater integration in care coordination among practitioners and across settings where multiple practitioners or settings are relevant to delivering care to the population treated under the PFPM. Please vote.

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

Five members vote 4, meets. Zero members vote 3, meets. One member votes 2, does not meet. Zero members vote 1, does not meet and zero members vote not applicable. The finding of the Committee is that the proposal meets this criterion.

* **Criterion 8**

CHAIR BAILET: Thank you, Sarah.

Criterion number 8, patient choice. Encourage greater attention to the health of the population served while also supporting the unique needs and preferences of individual patients. Please vote.

MS. SELENICH: Zero members vote 6, meets and deserves priority consideration. Five members vote 5, meets and deserves priority consideration.

Six 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 finding of the Committee is the proposal meets this criterion.

*** Criterion 9**

CHAIR BAILET: Thanks, Sarah. And Criterion number 9, patient safety. Aim to maintain or improve standards of patient safety. Please vote.

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

priority consideration.

Six members vote 4, meets. Zero members vote 3, meets. Zero members vote 1 or 2, does not meet. Zero members vote not applicable. The finding of the proposal is that -- or finding of the Committee is that the proposal meets this criterion.

*** Criterion 10**

CHAIR BAILET: All right. Here we are at number 10. Health information technology encourages the use of health information technology to inform care. Please vote.

MS. SELENICH: Four 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 finding of the Committee is that the proposal meets this criterion and deserves

priority consideration because of it.

CHAIR BAILET: All right. Do you want to summarize the voting and then we'll get to the next phase on the ten criteria?

MS. SELENICH: So, all the criterion are met. I just know that a couple were meet and deserves priority. So scope, and quality and cost, and health information technology.

CHAIR BAILET: Thank you. So, the next part of our voting we're going to again vote electronically.

*** Overall Vote**

But the three categories that we're going to vote on first are: not recommended for implementation as a Physician-Focused Payment Model, recommended, and, lastly, referred for other attention by HHS.

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

recommendation to the Secretary.

And the second vote is for the following four categories. First, the proposal substantially meets the Secretary's criteria for PFPMs and PTAC recommends implementing the proposal as a payment model.

The second category is we recommend further developing and implementing the proposal as a payment model as specified in PTAC comments. Thirdly, PTAC recommends testing the proposal as specified in PTAC comments to inform payment model development.

And lastly, PTAC recommends implementing the proposal as part of an existing of planned CMMI model. So, we need a two-thirds majority vote for these four categories.

But now let's go ahead and vote on the first three categories, not recommended, recommended, and/or referred for other attention. Please vote.

MS. SELENICH: So, all 11 members

vote to recommend the proposal. So, we move into the second stage of voting.

CHAIR BAILET: So, let's take a minute just to make sure we're all square on the categories. And then as you're ready we can go ahead and vote. Yes, Len.

DR. NICHOLS: Mr. Chairman, could I just say what I think the difference between 2 and 3 is and see if I get it right? As I read 2 it says you're probably going to need to work on this but it's substantially knowable what you should do.

CMS has the data. They just don't have it in the hands of the people. Number 3 says we like it. There's uncertainty here. You need to test it before you set parameters to do it. Is that --

CHAIR BAILET: That's my understanding, yes. I interpret it the same way. I think we're ready to vote. I'm not seeing any action here.

Here we go. He's got it on now. Yes,

he turned it on. He was shutting us out there for a second.

MS. SELENICH: So, four members voted to implement the proposal as a payment model. Five members voted for further developing and implementing the proposal as a payment model as specified in PTAC comments.

And two members voted test the proposal to inform payment model development. And zero members voted to implement the proposal as part of an existing or planned CMMI model.

So, under the new voting categories, unlike the criterion categories that roll down, you all are looking for a two-thirds majority here which would be eight. So, right now you don't have eight votes in any bucket.

CHAIR BAILET: Please, I think it would be great to inform ourselves which may lead to revoting. We'll have to. Len.

DR. NICHOLS: Okay. So, I voted for number 2 because in my opinion it's close. And

what it needs to be fleshed out is a richer data set which I believe CMS either has or could acquire without a great deal more work.

And therefore, you could take this thing to the street with CMS, if you will, using its own data to test the parameters of the payment. It's all about the premise of the payment model.

I didn't vote for Number 1 because I don't think you want to take those numbers in that chart and throw them to the world. I think we need more volume considerations.

There's just too much uncertainty. What's called fair market value.

CHAIR BAILET: You're talking about the economic numbers?

DR. NICHOLS: That's all that matters, Jeff.

CHAIR BAILET: Spoken like a true economist. All right, Jennifer.

DR. WILER: I'll make my list of comments now and so I'll have limited ones when

we're done with voting. I had the privilege of taking care of three acute stroke patients, actually, on my last shift with my neurology colleagues.

I think some specialty access to high quality care especially for time critical diagnoses, especially when the diagnoses at times are challenging, is critically important and that regional centers should leverage their expertise by remote consultation.

And that's sorely needed currently in our care delivery models. The reason for the program that we're reviewing today was a pilot to prevent unnecessary transfers.

But it's unclear to me how this example may scale, specifically how many facilities are in need of this unique large need in the rural communities with one academic center.

And also the presenters discussed in their materials an opportunity to scale in the suburban/urban space. But to me that is why I

voted for more testing because it's unclear what that scalability looks like.

Digital mediated services are demonstrating high value to patient care. But there are real fixed costs that are associated with it.

And the impact on cost could not be modeled because the N in this sample size was too small.

So again, that's why I think that testing of this pilot needs to be determined to see if a payment model that's being recommended is the right one, if the bundle needs to be expanded to include EMS, emergency care providers, drugs, clinical education as we heard, radiology and imaging services, or if there need to be defined quality measures.

What it looks like in terms of the bundle to access longitudinal consultation or maybe a development of codes for emergent patient consultation and management services?

In addition, CMS could consider

meaningful use like infrastructure dollars be paid for the creation of telehealth infrastructure services without limited fixed costs in developing APMs.

That's why I recommend -- or that's why I voted for 3.

CHAIR BAILET: Thank you, Jen. Bruce.

MR. STEINWALD: I was the other person who voted 3. And largely based on what Len said before we started voting which was that 2 should be based on information that's not known but is knowable.

So, I wasn't confident that information was in fact knowable. But I'm more than happy to change my vote to a 2.

I think based on applying the standard that we've applied to other proposals that this is pretty well developed. As Len said, very close.

Needs a little fine tuning with respect to volume and specific payment numbers. But I'm also influenced by the weight of the

scale going to the left as opposed to the right.

CHAIR BAILET: Thank you, Bruce. Tim.

DR. FERRIS: So, I just want to say that Dr. Wiler's comments I completely agree with, and that is going to move my vote from the 1 to a 2 for exactly the reasons that she said.

I'm also reminded of Harold's pointing out the critical access hospital cost-based reimbursement issue. I think that is a, that needs to be worked out here as well. That is a real issue. And so, I will -- on revoting I will be moving my vote to a 2.

CHAIR BAILET: Thank you, Tim. Paul.

DR. CASALE: Yes. I voted 2 and, yes, I didn't really have any concerns around the clinical need.

It was more aligned with Len around the payment part needs to be worked out and to Jennifer's comments that amongst the payment, I think, maybe the bundle could be considered

more broadly in terms of what's included and even beyond the first 24 hours.

So, I think there's opportunity to development there. But I think on the clinical side there's no question that it would, there's a need.

CHAIR BAILET: Thanks, Paul. And I just wanted to make a couple comments about the model, having supported an integrated delivery system over the state of Wisconsin and Northern Illinois where many of the communities are extremely rural.

Towns of 3,000 to 7,000 individuals getting neurology coverage for the 15 hospitals within that system was incredibly challenging. Neurology recruitment is a national challenge just given the numbers of available physicians.

And when you're talking about a condition which again hangs in the balance measured by minutes, it's incredibly important to be able to have experts at your side to be able to help you in these smaller communities

where that's often a challenge.

That said, there are a tremendous number of elements of this model that would need to be worked out, not the least of which is the technology deployment and getting all of that established and the connections made with the clinical community.

So my overarching point is I think there is more work to be done. But I think this is awfully close to the pin for the reasons already stated.

The last comment I will make is it's not entirely clear, although I think it's clear, that the technology is not proprietary. You have multiple solutions. So, hearing that, that's the end of my comments. Grace.

VICE CHAIR TERRELL: So, there is the statement that only, close counts only in hand grenades and horseshoes. But, you know, Len started off saying this is close.

My feeling is close actually counts in something besides hand grenades and

horseshoes which is why I voted to implement because the nature of us as economists and clinicians is we will never find anything perfect enough.

And it sounds like CMS is sort of the same way. And so, if we don't have a standard for stating vote to implement that includes something this well studied to the HCIA award, the data backing it up, the results that they have, we will never have a Number 1, in my opinion.

So, I would put this in the category of horseshoes and hand grenades and that's why I'm going to not change my vote unless I have to, to get it to go forward.

DR. NICHOLS: I'd just like to point out Grace's mother voted for Nadia Comaneci to get a 10 when the French would never do it.

CHAIR BAILET: Well, that was relevant, Len. Okay. I think it's time to revote. I think so. No, wait, Rhonda and Harold, did you have any comments before we

vote again?

DR. MEDOWS: What Grace just said, I think this should be implemented. And I think we can actually count on CMS to actually do the work that needs to be done to get it ready.

I honestly don't think this is a 3. I'm worried about putting it in a 2 category and it never seeing the light of day. This actually needs to move forward. Thank you.

CHAIR BAILET: Harold.

MR. MILLER: I voted a 2 and I'm sticking with it. I think that the, I think the clinical model is badly needed. I think that trying to do it across the country broadly is necessary because many places need it and the only way to really be able to get enough scale to tell what's going on is to do it broadly.

But I do think that this particular payment model that's proposed was designed to work for this particular situation where we have the University of New Mexico that is willing to do the service in this particular

fashion.

And in that circumstance I think that it doesn't really matter quite who is billing for it. But I do think that if one extended this across the country there would be real issues as to what it is that a particular hospital was using the money to pay for.

And I think that it's putting truly an inappropriate burden on the hospital to say that they would then have to try to justify to CMS that they were using the service, they were using the payment for an appropriate service.

I think the service provider needed to do that. That does not disagree with the applicant's proposal that this has to originate from the hospital.

I think that the central provider should only have to, should only be able to bill for it if in fact a hospital, rural hospital has requested the service. But that's why I put it into Category 2.

I think it needs to move forward. I

think it needs further development. I don't think it needs to be tested. I think it's been tested.

I just think that the particular payment model that's being proposed is not adequate or appropriate for implementation across the country.

CHAIR BAILET: Thank you, Harold. And, Jen, you had another comment.

DR. WILER: Although I love suspense, it is Tim's last meeting. So, I didn't want him to worry about which side of horseshoes or hand grenades that I was on.

So, I'm persuaded, I think we're splitting hairs, personally. We've talked about this before with other votes between 3 and 2. Testing, in my definition, is the scalability component.

Where further development and implementation and scaling, I can be persuaded, frankly, mean the same thing. I am not persuaded to vote for 1. But I will move to 2.

CHAIR BAILET: All right. Before we vote, the DFO has reminded me that Kavita and Angelo, you've been radio silent.

DR. SINOPOLI: I'm more than happy to speak. So, I'll remind people that I come from South Carolina, if you can't tell by my accent, which is a very rural state.

And so, we have about maybe three centers that can provide this type of neurological support and all the rest of the hospitals across the state are very small, rural hospitals.

And they wind up sending tons of stuff to these three hospitals that could have stayed where they were and/or should have gotten intervention even if they were going to be transferred ahead of time.

And so, I agree with Grace's comments that this isn't perfect but it's better than what we've got today, and as they develop it and refine it over time, I think this is the direction we need to go. And I

voted 2 to begin with and that's what I'll vote again, probably.

CHAIR BAILET: Kavita.

DR. PATEL: I can't believe you're encouraging me to talk. The reason I haven't said anything is because I voted Number 2 mostly for the exact same reasons Len kind of articulated.

This is probably our biggest crisis in this country. Not just the rural issue but this divide between access to resources vis-a-vis kind of sub specialists and super specialized treatments.

So, I think this just needs to be something CMS does even if PTAC didn't exist. And I'm just happy that someone got, put a model in front.

I didn't, I'll say the only reason I didn't put it as 1 is I don't want someone to interpret that we think these economics translate for the critical access and all these other pieces. So, that's it.

CHAIR BAILET: All right. So, having heard from the full body we're ready to vote one more time with feeling.

Is this it, we're good to go? All right, here we go. Sarah.

MS. SELENICH: So, two members have voted to implement the proposal as a payment model. Nine members vote to further develop and implement the proposal as a payment model.

And zero members vote test proposal to inform payment model development. And zero members vote implement the proposal as part of an existing or plan model.

So, the finding of the Committee is to recommend further developing and implementing the proposal as a payment model as specified in PTAC comments.

*** Instructions on Report to the Secretary**

CHAIR BAILET: Thank you, Sarah. And we have, who is recording the comments for the Secretary's response? Great, Sally. So, let's

just make sure I know a lot of us have made some pretty direct comments.

But if there are any comments, and I'll start with you, Tim, that you haven't made already that you want to make sure get read in. Tim.

DR. FERRIS: I have no additional comments.

DR. PATEL: I have no additional comments.

CHAIR BAILET: Len, you're good?

DR. NICHOLS: Well, I don't know how to say this. But I'll just say the two clinicians on the PRT voted 1. So, that's pretty strong I would just say.

VICE CHAIR TERRELL: One of the speakers who was talking about the technology that underlies this really talked about it being a unique solution to vis-a-vis the current technology we have with disparate EMRs and integrated solutions.

So, the point was made and needs to

be put in the comments that it's not exclusive to that particular vendor. But the actual problems that the vendor talked about in those public remarks I think were good with respect to the portion that's on the health information technology component.

In the past we've had proposals where the HIT was almost -- and also this one, actually, is highly dependent on it. And actually, the technology itself until it was developed and existed, you know, this type of thing wouldn't be possible.

So, I think that as we're talking, communicating with the Secretary it would be useful to listen to the comments that were, that the vendor talked about, particularly as it relates to the types of things, this type of technology, not necessarily their technology, solves for that previously had not been solved for.

CHAIR BAILET: Thank you, Grace. And there's a small housekeeping issue. We just

need to know who voted in the 1 category. And I think it was you, Grace and possibly Rhonda. Yes, I thought Rhonda did.

Yes, like I said, Sarah, I told you it was Rhonda and Grace. All right. I have no additional comments other than this is a really elegant model and I want to compliment the submitters for your hard work to make this happen.

And the impact that you're describing is tremendous when you can go from 80 percent being referred out to actually reversing the numbers. It's amazing.

And this model, this kind of approach can be used for lots of other disease states. And again, once these rural hospitals collapse, you will never have them come back into the community.

So, these are assets that really we need to be very prudent about trying to preserve. So, I compliment you again for your efforts. Thank you.

MR. STEINWALD: I'd also like to compliment you and it's something I wasn't, I'd like to compliment you for using quality adjusted life years as a measure of impact. I wish we would do that more often.

I wish others would do it more often. And then last, Sally, when you write up the things that we've identified as need to be developed please do it in a very positive way. That we think it's good the way it is.

It can be made a little bit better and it's very doable.

DR. CASALE: I have no other comment other than to say, as I think pointed out by Tim and others, that this is not just rural that is in need but suburban and even in Manhattan I can see a need for this.

CHAIR BAILET: Jen, anything else?

DR. WILER: My only last comment is around scalability to other clinical conditions. I think we should comment that we see that the opportunity as is described to

provide subspecialty expertise in two facilities, doesn't even have to be regional or geographical or based on census.

But access to facilities don't have those resources. We should be thinking about payment models that incent that delivery of knowledge for all of the reasons that I loved that Grace explained why this is patient centered.

CHAIR BAILET: Thank you. Angelo.

DR. SINOPOLI: Just to again to compliment the team, I think it was a great proposal, something that's hugely needed across the country.

And at least in our systems we're trying to figure out how to decant our tertiary centers and keep as many patients out in the rural hospitals and community hospitals as we can. So, I think this is a good first step toward that.

CHAIR BAILET: Thank you, Angelo. Harold and Rhonda?

MR. MILLER: Rhonda?

DR. MEDOWS: I want to thank the presenters, the persons who actually created the proposal itself, the clinicians and the caregivers who are taking care of a population that is both vulnerable and in great need.

I really, really hope that this proposal does not get bogged down, that it does not get lost and that the efforts are made to do whatever study is thought to be needed to get it out the door and actually taking care of patients.

I think the expansion to other areas to, both geographically as well as clinically, would be a great thing. But I hope that we would not delay the actual delivery of this type of advanced care and coordination to individuals in rural communities today as well as those who have a time-limited response to cerebral injuries that need to be addressed now. Thanks.

MR. MILLER: I would just like to

both endorse, this is Harold, what Rhonda said. I think that this needs to move forward quickly.

We have not had a good experience so far in terms of proposals that we have even recommended strongly moving forward. And I do think that this is really urgent for CMS to take action on.

I do want to though emphasize I think that more attention needs to be given to incorporating the quality component to this. That one can evaluate it in the short run as to how well it works.

But in the long run there has to be some way of assuring that it continues to deliver quality care. And I don't think that simply relying on either accreditation or certification does that.

I think that there is the potential for harm from this as there is with any service. And I think that if we're approving a payment model rather than simply an addition to

the fee schedule that there needs to be some component in it specifically that tries to assure that there is high quality care being delivered. That's all, thanks.

VICE CHAIR TERRELL: And this is Grace Terrell again. So, in response to what Harold just said about quality, one of the things that happens in the non-Medicare private payer world is the concept sometimes of centers of excellence where they have proven expertise and excellence around a particular set of skills for which only they are contracted until something becomes more widespread.

And perhaps we could talk about in our comments to the Secretary that CMMI or Medicare explore the concept of centers of excellence with respect to this as part of a payment model to actually address some of the issues around quality that Harold and others have brought up.

CHAIR BAILET: Thank you, Grace. And I would just like to check in with you, Sally,

and make sure that you don't have any questions for the Committee before we sign off here.

DR. STEARNS: No. I think the discussion and points have been very clear. There's unanimous enthusiasm both -- given the importance of the problem there is a lot of enthusiasm for the submitter's model as a possible solution.

I will note the need for testing or development, specifically with respect to many aspects of the payment model, amounts, the issue of replicability, all of the issues about quality. And I'll make reference to the centers of excellence.

Also, definitions of the bundle. And then I will make two points in particular. The value of the technology platform for this particular application and the potential for extensions to other areas.

CHAIR BAILET: Okay. Thank you, Sally. And thank you for your support of the PRT and getting us to this point. I want to

thank everybody on the Committee for helping us get through this important proposal review.

Again, my acknowledgment of the submitters for putting this forward. I think it's fantastic and look forward to hearing more about it. And we'll use our best efforts to make sure that the Secretary understands the importance of moving forward on this.

*** Adjourn**

So again, thank you everybody for that. We're adjourned.

(Whereupon, the above-entitled matter went off the record at 2:43 p.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

Date: 09-16-19

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