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, March 11, 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

ANN PAGE, Acting Designated Federal Officer (DFO), Office of the Assistant Secretary for Planning and Evaluation (ASPE)
AUDREY McDOWELL, ASPE
STEVEN SHEINGOLD, PhD, ASPE

CONTRACTOR STAFF PRESENT

ADELE SHARTZER, PhD, Urban Institute

*Present via telephone

A-G-E-N-D-A

Deliberation and Voting CMS Support of Wound Care in Private Outpatient Therapy Clinics: Measuring the Effectiveness of Physical or Occupational Therapy Intervention as the Primary Means of Managing Wounds in Medicare Recipients Proposal submitted by Upstream Rehabilitation

PRT: Harold D. Miller (Lead),
Kavita Patel, MD, MSHS, and
Bruce Steinwald, MBA
Staff Lead: Adele Shartzer, PhD

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

9:34 a.m.

* CHAIR BAILET: All right. We're going to go ahead and open the meeting officially.

Good morning and welcome, everyone. This is the meeting of the Physician-Focused Payment Model Technical Advisory Committee, better known as PTAC. Welcome to the members of public, the public who is here in attendance today. We also have the live stream and some folks on the phone. So thank you all for your interest in this meeting.

PTAC can play an important role in bringing the voice of the stakeholder community to Washington as the Department moves forward on its value-based transformation agenda.

To transform the health care system physicians and other care providers need to be partners in moving forward. We appreciate the stakeholder input provided to the PTAC to date and look forward to continued feedback as we

continue our work.

We extend a special thank you to stakeholders who have submitted proposed models, especially those who are participating in today's meeting. Stakeholders who submit proposals to PTAC bring us voices from the field regarding new models for care delivery and payment.

This is PTAC's seventh public meeting that includes deliberations and voting on proposed Medicare physician-focused payment models submitted by members of the public. At our last public meeting in December we deliberated and voted on a proposal called Making Accountable Sustainable Oncology Networks, or MASON, submitted by the Innovation Oncology Business Solutions. Last month we sent a report containing our comments and recommendations on the MASON proposal to the Secretary.

Since our last meeting we have also updated our proposal submission instructions.

That document reflects some changes PTAC made based on public feedback we received last year. It also gives potential submitters a sense of what to expect after they submit a proposal.

In addition, our Preliminary Review Teams have been working hard to review five proposals, two of which are scheduled to deliberate at today's meeting. Both of today's proposals relate to wound care.

To remind the audience the order of activities for each proposal is as follows: First, the 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 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 the deliberation concludes, I will ask the Committee whether they are ready to vote on the proposal. If the Committee is ready to vote, each Committee member will vote electronically on whether the proposal meets each of the Secretary's 10 criteria. After we vote on each criteria, we will vote on our overall recommendation to the Secretary of Health and Human Services. And finally, I will ask the PTAC members to provide any specific guidance to ASPE staff on key comments they would like to include in the PTAC's report to the Secretary.

As a reminder, as we begin discussions today on -- relative to the proposals under consideration, there are a few points needing to be made.

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

ptac@hhs.gov. We've established this process in the interest of consistency in responding to submitters and members of the public and appreciate everyone's cooperation in using it.

I would also like to underscore that the PRT Report -- those reports are from three PTAC members to the full PTAC and do not represent the consensus or position of the PTAC. PTAC Reports -- PRT Reports are not binding. The full PTAC may reach different conclusions and from those contained in the PRT Report, so they're going to -- they could be different, and that's happened before.

Finally, the PRT Report is not a report to the Secretary of HHS. After this meeting PTAC will write a new report that reflects PTAC's deliberations and discussions 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 discussion today will accomplish this goal.

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

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

* **Bundled Payment for All Inclusive Outpatient Wound Care Services in Non Hospital Based Setting Proposal submitted by Seha Medical and Wound Care**

So let's go ahead and get started. We have one PTAC member, Harold Miller, who is on the phone. So I just want to make folks aware of that.

The proposal that we're going to discuss first today is called Bundled Payment for All Inclusive Outpatient Wound Care Services in Non Hospital Based Settings. That was submitted by Seha Medical and Wound Care.

* **PTAC Member Disclosures**

I'd like to start the process by introducing ourselves and then at the same time read disclosure statements on this proposal.

I'll start with myself. Jeff Bailet. I'm the Executive Vice President of Blue Shield of California and I have nothing to disclose.

DR. SINOPOLI: Angelo Sinopoli and I have nothing to disclose.

DR. WILER: Jennifer Wiler. Nothing to disclose.

DR. CASALE: Paul Casale. Nothing to disclose.

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

CHAIR BAILET: Grace?

VICE CHAIR TERRELL: Grace Terrell. Nothing to disclose.

DR. NICHOLS: Len Nichols, George Mason University. Nothing to disclose.

DR. PATEL: Kavita Patel. Nothing

to disclose.

DR. FERRIS: Tim Ferris, Mass. General Hospital. Nothing to disclose.

CHAIR BAILET: Harold?

MR. MILLER: Hi. Can everybody hear me? This is Harold Miller, Center for Healthcare Quality and Payment Reform. Sorry that an illness has prevented me from being there in person. And I have nothing to nothing to disclose.

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

CHAIR BAILET: Thank you, Harold.

I'm going to go ahead and turn it over to Bruce who was the lead on the PRT Report.

MR. STEINWALD: Thank you, Jeff. I'm the lead on the PRT. The other members of the PRT are Angelo Sinopoli and Grace Terrell.

In the course of my summarizing our PRT Report I encourage you to jump in at any time.

Also our principal staff person from ASPE is Audrey McDowell, who is also at the table.

The submitter, Dr. Farooqi, I believe is on the line.

Is that true, Dr. Farooqi?

DR. FAROOQI: Hello. That is correct. Good morning, everyone.

MR. STEINWALD: Thank you. You will have an opportunity after the PRT does its report to address the full PTAC Committee and respond to its questions. And thank you for being willing to participate.

Okay. Let's do the first slide. Okay. That's the proposal. It's already been described to you. We refer to it as the Seha proposal.

Next slide. This is the process that we go through, and I won't go into details because I think we have done so enough.

Next slide. Do we need to -- well, we've done this a lot, too, but there are always

two or three members of the PRT, one of whom has to be a physician. We review the proposal, we give questions and get responses from the proposer. We've asked our contractor to do some additional research on wound care, which I'll get into in a moment. And it's always worth emphasizing that the PRT Report is a report of three individuals, not the entire PTAC, and PTAC, as it has in the past, may come to a different conclusion than the PRT has.

Let's do the overview of the proposal. In other words, next slide. Dr. Farooqi has submitted a fairly straightforward proposal to provide fixed-price reimbursement per visit for wound care provided in the office setting. Eligibility would be for patients who have wound care, needs to be treated. The whole idea here is to encourage more treatment of wounds that can be treated in the office setting to be provided in the office setting instead of in the hospital outpatient clinic. And by doing so provide more convenience to patients, lower

cost both to the health care system and also a lower cost to patients who are required to pay co-payments.

Next slide. Dr. Farooqi proposes a $400 flat payment per visit for all services provided with a couple of exceptions, one of which is hyperbaric oxygen treatments, a fairly sophisticated service that perhaps needs to be provided in the hospital outpatient department and other services that are outside the realm of wound care such as physical therapy and other services. He proposes -- there are certain wound care measures that might be included as -- in the proposal, although there's not a lot of specificity as to how they might be.

Let's go to the next proposal. Sorry, next slide. We asked our contractor to do some preliminary research on the extent and cost of wound care services in Medicare. There's more detail on this in the PRT Report. We did find there are a significant number of Medicare beneficiaries who are diagnosed with

wound care needs, some of which are non-healing wounds, but we were actually somewhat surprised to find that three-quarters of those services that are non-emergent are actually provided in the office-based setting.

It is certainly less expensive to the Medicare Program for it to be provided in the office-based settings than in the hospital outpatient department. We found that the majority of wound care services provided in the office setting were provided by podiatrists. And in the hospital outpatient department there's a lot of variety in who's actually providing the services.

Next slide. This is a summary of our evaluation of the 10 criteria most of whom -- most of which we determined that the proposal did not meet the criteria. I'll explain why as we go through them individually.

Next slide. Scope. High priority. Our unanimous conclusion was that this was met. Our general sense; and this would be a good

place for our other members of the PRT who are physicians, and I am not, to weigh in here, is that there is a genuine issue that Dr. Farooqi has raised about how the way that Medicare pays for wound care services discourages many physicians from providing services in their offices.

A major part of that is the difference in reimbursement. And part of what Dr. Farooqi is proposing is that -- let's in essence split the difference. Let's pay more in the office-based setting, encourage more doctors to provide wound care services in their offices and it will still wind up being cheaper for both the Medicare Program and for patients to encourage more provision in the office setting. And we thought the issue was a genuine one. We observed that there still are -- a majority of services are provided in the office setting, but we decided that it was still significant enough in scope and there is no other proposal like this. There's no other model out there for

wound care services, so we decided that it met the criterion.

Next slide. However, on the quality and cost, even though it certainly may be less costly on a per-visit basis, there's no constraint on the number of visits. It's a visit bundle not an episode bundle. We had some concern that there could be inflation in the number of visits if there's a $400 payment per visit and a lack of assurance that there would be some cherry-picking of a number of doctors participating, picking the patients who are less expensive to care for.

Grace and Angelo, any additions, remember please jump in.

Next slide. Payment methodology. Certainly the simplicity of the model is appealing and yet we had a problem of justifying the specific amount of $400 per visit. And there's no risk adjustment or anything like that, no negative consequences for doctors participating in the model if the costs -- if,

for example, the patient is referred on for care in the hospital, the physicians participating in the model don't have any negative consequences of that.

Next slide. By the way, I've kept the slides very succinct. There's a lot more information, a lot more bullet points on the individual criteria. But the problem here is that a per-visit payment system doesn't control the number of visits.

Next slide. We decided it did meet the condition, the criterion of flexibility because if indeed it does encourage more office-based physicians to provide wound care services, it gives more options for patients to seek care in either the hospital Outpatient Department or in the physician's office.

Next slide. Although it certainly could be evaluated, the proposal didn't articulate a methodology for conducting an evaluation, and so we thought that it was a bit too thin on this criterion to say that it meets

the criteria, so our judgment was that it didn't.

Next slide. There's no specific plan for integrating the wound care services with other services that the patient may require, and although this certainly could happen; and Dr. Farooqi may explain why he thinks it would, there doesn't seem to be a guarantee or a part of the model that requires any care coordination for patients with wounds that need to be treated but also may have other conditions that need to be treated as well.

Next slide. Patient choice. In large part for the reason I just stated if there are more physicians providing wound care services in the office setting, it provides patients with more choice. This may be especially important in rural areas where hospital outpatient services are not as readily available.

Next slide. Patient safety we decided did not meet the criterion. It's pretty

much a fixed price per service without any genuine assurance that the patients will be provided the services they need or that the patients who need to be in the hospital would in fact be provided their services there if they participated in the model and they needed to be transferred to the hospital.

Next slide. We decided it did not meet the health information technology criterion because there's no real requirement of the use of health information technology to accentuate the exchange of information and the other information needs of the patient and the other providers of services who are provided services in the hospital -- in the physician office. No guaranteed exchange of information.

So those are the 10 criteria. Just to generally summarize, I'm not going to summarize the extent of the proposal, but what I am going to say is if Bob Berenson were sitting at his chair over next to Kavita and Tim, he might be at this point standing on his chair

saying isn't this a case where we should be -- if there's a problem, the problem is with the fee schedule, not necessarily the lack of a model to pay for wound care services? I'm not asserting that, but I am saying that's a topic that's worthy of discussion.

And another issue is a more general one of Medicare payment. Site of service, neutrality. I mean, it's an issue that goes far beyond just wound care services. And if we'd like to think of this as a special case of a site-of- care problem, it's actually a much bigger problem than just wound care and we might want to discuss it at some point in that context of being site-of-care issue, not just a wound care issue.

All right. I am finished with my summary. Please, Grace and Angelo?

VICE CHAIR TERRELL: You did a great job summarizing I think the PRT's thinking on this as it's reflected in our report.

There are a couple of things that I

think might be useful and one is we're going to get a different type of wound care proposal later this morning, and this is not deliberation about that, but there are certain themes that are being brought up that are slightly different, so it might be good to articulate how this is different in a broader sense. So you're exactly right, this one is about site-of-service differential and how that potentially impacts the delivery of care.

And the other one may be about that with respect to -- not the site-of-service, but the type of people who would provide certain care services. So I think it's important as we're thinking about this one as -- possibly as we deliberate independently on the other one to understand exactly what the problem is from the perspective of the proposer.

A larger point though is that when you start seeing the same thing over and over again as a theme to the PRT that probably means that many people are being very thoughtful about

something that is a real problem. And we've seen that now in several respects. We've seen it with respect to the provision of primary care where we had several proposals and where I think there's some more coming. We have seen that with respect to services such as nursing home or hospital at home or other things that may be further provided outside our traditional health care system. We've certainly seen it in oncology where we've had from two points of view, two very thoughtful perspectives. And today we're seeing it with respect to wound care.

So as we're deliberating we have to be very specific about the merits of this, but I think that this is an opportunity for the Committee and for the Secretary in general to say why do certain themes keep coming up over and over again? It probably means there's something that many people see as a problem and we ought to pay attention to it.

And the -- with respect to this

specific proposal, even though we got exceptionally good research done by our contractors, there was really to my mind a fairly limited amount of information we had to dig into it. We were surprised to discover that 75 percent of the actual provision of wound care was from -- was in the clinic setting, but we couldn't distinguish what was different about that which was provided in the outpatient hospital facilities versus that that was in the office-based setting.

Having provided wound care as a primary care physician in both the nursing home setting as well as an office setting and having led a multi-specialty group, one of the very first things we looked at when we started going down the ACO value route was where our wound care services were being provided. It is likely that having better data over time will help us figure out in more detail how we can better evaluate this, but some of these questions that are being identified in the -- by the

stakeholders in the communities getting underneath the data to understand the scope of the problem and what they're seeing is a little bit difficult even though we had exceptionally good research.

So I'm hoping that that will be useful in our discussion not only as we're dealing with the particulars of this, but as we're thinking in general about how we ought to approach themes that come over and over again. It usually means that there's a real problem.

*** Clarifying Questions from PTAC to PRT**

MR. STEINWALD: Thank you, Grace.

Questions from PTAC members for clarification?

(No audible response.)

CHAIR BAILET: All right. I think it's time to invite the submitters up to the table. And I --

MR. STEINWALD: He's --

CHAIR BAILET: -- think he's on the

phone.

MR. STEINWALD: Virtual table.

CHAIR BAILET: Virtually coming to the table.

MR. STEINWALD: So, Dr. Farooqi, you have -- how many minutes for --

CHAIR BAILET: Ten.

MR. STEINWALD: -- Ten minutes to address the Committee and then Committee members may have questions for you after that.

CHAIR BAILET: Thank you, Bruce.

Dr. Farooqi, welcome.

* **Submitter's Statement**

DR. FAROOQI: Thank you. Good morning, everyone. So number one, I would to thank the PTAC Committee members for considering and reviewing this proposal, and also the staff members people who send out the emails, who do the phone calls, who put everything together. My interaction has been very, I'd say, pleasurable and it looks like it's a very well-run program.

Okay. So I have been providing wound care, as I have put it in the proposal, for about 15 years, mostly to elderly people. Having a geriatric background that was the reason for starting the wound clinic, because at that time there were not many people providing this type of care in this area. So over the years I have learned a few -- or rather many issues that come trying to provide a good quality care in an independent setting aside from the hospital.

So the proposal was in response to those shortcomings in the system and limitations and difficulties. I do realize some of the weaknesses that have been pointed out in the system. One of the explanations is it's a limited resource in terms of time and otherwise, so this was a preliminary proposal that I could put forward.

One of the main reasons, and I think I have had some success, is trying to bring to light the different policies that make it

difficult to provide the care that is needed as well as prevent some of the recurrences. So that's why there was multiple times emphasis in my proposal about the different -- the LCDs or local coverage determinations, the global periods, periods which makes it harder to provide certain services or just basically eat up the cost if you do it.

The others are preventive services which mean, again, not directly in the proposal, but I'm just going to quickly say two points. One is pressure ulcers, as you've done your research, and there are charts that show the cost of different ulcers. Pressure ulcers are very costly and they can also lead to death. And I have seen it myself.

The reason people have pressure ulcers is because they are not able to move. They are constantly in the same position, especially the elderly people. So if they are in a nursing home or in a hospital, there is somebody who can change the position. But even

at the nursing home or especially at home it becomes difficult. So the way around it, you get special mattresses. They are air mattresses. There are two types. One in which just the air is blown. The other is like an egg crate where the pressure changes in different cells of the mattress. It's called low air loss mattress with alternating pressure.

So if somebody has ulcer at stage 3 or 4, which is it's gone too deep like muscle or bone level, the horse is already out of the barn and the cost increases. So the best thing would be to prevent it and put a mattress and other services to prevent to get to that state, but Medicare policy does not allow an air loss mattress unless there is a stage 3 or a stage 4 ulcer or multiple stage 2 ulcers. Doesn't make sense. To some degree, maybe it's a stretch, will be the example of telling people we'll allow colonoscopy when it's a stage 3 and a stage 4 cancer. So that's one.

The second in my current practice

the example would be compression stockings. So to prevent the recurrences it's recommended for people to wear compression stockings. The Medicare guidelines do not allow compression stockings unless there is an ulcer present, but by the time the ulcer is present it's late and typically you need -- a person needs compression bandaging and a whole lot of treatment.

Second, Medicare only allows 30 to 40 millimeters of mercury. I'm not sure if anyone there has tried that kind of compression stocking. I'm pretty healthy person. It's not easy for me to put them on, let alone the 80-year-old people who are -- who have arthritis, poor dexterity, they cannot bend over, they cannot -- they don't have enough strength to pull that kind of tight stocking on their legs, which they don't need anyways. About 20 millimeters of mercury is sufficient to keep something under control and something that they can actually practically do.

So they -- we end up sending them to

pharmacies, buy something over the counter which may or may not work. Some of the points in the proposal are related to those issues.

I will -- and then there is definitely a question about per-visit, a justification versus a bundled payment. So the per-visit, again due to limited resources and going through the literature trying to figure out how much actually it costs Medicare and then practically looking at a couple of bills that my patients were able to provide me when they were going to a hospital-based wound clinic. And those bills ranged anywhere from -- the payments, not the bills. The bills they can charge anything they want. The payments ranged anywhere from $700 to $1,400 per visit.

Total cost, in the literature that at least I searched, on an average wound care was about $5,000, anywhere from $5,000 to $5,600 to $7,000. So that's how -- and the average time to heal is anywhere from 10 to 16 weeks. The mean would be 12 to 13 weeks. So that's how the

proposal for $400 a visit was reached, that it would give at least 20 percent savings for the total healing of the wound.

Now the bundle -- the problem with the bundled treatment sort of payment is, say, on the average it costs $4,000 to heal a wound in terms of total number of visits whether the person is going to the hospital or coming to an independent provider. A lot of times, at least in my practice, I see people coming again. They come with a right leg wound, or it could be venous ulcer, could -- something -- they fell, something fell on them. They heal. They go back. Three months later, two months later something else happens.

A lot of trauma wounds are easy to heal because with the treatments they could heal anywhere from four, five visits to 10 visits. The treatments are relatively simple. Each time they come in it is a new episode, so that means each time the physician is getting a full payment of -- it has to be an average payment

that takes to heal the wound, which would be in thousands of dollars. So the total cost at the end of the year may be more.

So from that perspective my feeling was a per-visit cost will be more cost saving compared to a full bundle payment every time a person walks in. And there are not a lot, but a good number of people who have recurrences, either same ulcer, which would probably be covered, but then they have ulcers coming in different area. They fall. They have arm skin that's soft. Their leg has skin that's soft. They walk into dishwashers or car doors and all that. So then every time Medicare is paying a full amount which could be much larger than really needed.

So then there is question of limit on the number of visits. So this is tricky, but my -- if a bundled payment is being made and there is in the -- if the Medicare is told that the average number should be say 12 or 14 visits, after visit it does -- or it will

somehow trigger that and a person is going there too much.

In the current system there is no limit. So my example would be somebody walks in with a venous ulcer and say it takes 10 visits or 10 weeks to heal it. Under the proposal it's $4,000. If the same person goes to a hospital-based clinic and it takes 10 weeks or 10 visits to heal, it's not less than $4,000. It's at least $4,500 onwards, but there is no upper limit there. In this system there is an upper limit there. In that system there is no upper limit there.

And if you go to wound conferences, and from what I see there -- the management companies are revenue-based. They need to maximize their revenue. That's why they're coming and managing for more or less free a wound clinic in a hospital. So there is definitely encouragement of utilization of more resources, which is what we are trying to limit here.

There was a question about severity and complexity in the payment model. Those indexes will probably have to be developed. There are not many indexes available. One of the criticisms about this is cherry-picking which has come up a few times. It is -- my example would be concierge practice. A lot of people are already doing concierge practices. So that is cherry-picking.

But the problem is especially in smaller towns, especially in rural areas. If the person walks in, they cannot be turned away. So cherry-picking becomes less of a relevant issue. In my own practice until the person is seen in the clinic, it's not -- it's difficult to know how extensive a wound is or how extensive a problem is. Sometimes the wound could be just a centimeter by centimeter but it turns out to be a pyoderma or something much more complicated. So unless you see it you cannot deny a person or turn them away just on the phone.

CHAIR BAILET: Dr. Farooqi?

DR. FAROOQI: Yes?

CHAIR BAILET: Are you wrapping up your comments?

DR. FAROOQI: Yes, I am wrapping up. So again, this was an attempt to bring the issues on the ground. And like you said, I see the issues and the weaknesses in the program, but I think it's -- at least in some way it's successful to bring it to CMS. I have I think in one of the summaries one of the lines says that this could be brought to local CMS to resolve some of these guidelines, LCDs and global payment issues. I actually tried to reach out to our local contractor when I made a phone call to who to write the letter. I was told the name of the medical director is not publicly disclosed. I could not have the name or the address to address the letter and the issues to. So that is not easy either.

So, but in the end I would again thank the members for considering this proposal

and hopefully something good will come out.

CHAIR BAILET: Dr. Farooqi, thank you. Compliment you for your efforts and submitting this proposal and working with the PRT Committee to get us to this point and bringing this issue forward. You're not alone obviously, because as it was already mentioned, there's another wound care proposal in the queue that we're going to deliberate on after yours.

I would like to open it up to the Committee members to ask Dr. Farooqi any questions based on his comments and thoughts.

Kavita?

DR. PATEL: So, Dr. Farooqi, thanks for kind of going through kind of your logic. Can I ask a question building off of what Bruce and it sounds like the Preliminary Review Team -- this is Kavita Patel since you're on the phone. It feels like there -- just explain to me because it feels like what really motivated you to put this proposal in was something that a lot of us who are clinically-oriented see, which

is a lack of getting to wound care kind of early enough or having wound care be involved in a sustained way. And part of this problem is that you're operating literally and figuratively in a very distinctly different setting than potentially the people who might refer you these patients or the settings in which the patient finds themselves like the emergency room, the inpatient setting, or even a primary care office.

How much of this is really the lack of going -- without confusing it with the name of the second proposal -- upstream, so getting to the patient earlier versus some of what you described where you're trying to -- it sounded like you're actually trying to calculate a 20 percent savings to the Medicare Program, but I think what's hard for me personally is that it doesn't feel like -- it feels like just adding dollars by having a per-visit fixed dollar amount doesn't actually solve the problem you're trying to address.

DR. FAROOQI: So there are two parts. One is there is a financial problem because as I explain in the proposal, if somebody goes to hospital -- so if somebody comes with a lower extremity or a leg ulcer due to venous disease or even due to trauma, they develop swelling and the swelling prevents the wound from healing, they have go to ER. They do a nice job trying to stitch it up, everything, but then the leg swells up as an inflammatory response or whatever reason and it just opens up. So you -- so we need to do a compression.

Now here's the problem: If I see the person, I do the dressing and under the Medicare current guidelines I can debride the wound or do the treatment, but they will not pay for me for the compression. If I put the compression on, I can only charge for the compression. I cannot charge for anything else. I can charge for only doing one thing at a time, which means basically -- I'm trying to do good quality care, so I'm basically eating up

the cost. So that's one.

And then there is definitely prevention. As the PTAC members did a review on literature search themselves, one of the articles does talk about lack of education and lack of training or awareness. Some of the wounds we see in every wound clinic are due to lack of awareness.

In metropolitan area like Boston it's -- there are many wound clinics, there are many specialists, but this becomes more important in smaller towns and rural or semi-rural areas where it's convenient for patients to go to their physician and some incentive for the physician to be able to provide the services. Otherwise, people will just send them somewhere else. I'm not sure if it answers your question.

DR. PATEL: No, that's fine. Thank you.

CHAIR BAILET: Jen?

DR. WILER: Dr. Farooqi, Dr. Wiler.

One of -- I have two questions for you: The first is one of the criterion we will be asked to look at is scope. So it's unclear to me after reading the proposal, how many providers and what type of providers would be eligible in this payment model? I saw specifically you described outpatient wound care clinic providers with a recommendation of two years of experience, but could you clarify who would be eligible?

DR. FAROOQI: Yes, so as I was doing my research before writing the proposal, there are a whole number of family practice and some internal medicine physicians who do provide the wound care in their office setting for various reasons. One, if there is no hospital-based wound clinic in the area, they have to do it, or the hospital is not interested in opening a wound clinic, they have to do it, or simply the patients prefer to go to their primary care physician. So it will be an incentive and those people would be included in this proposal.

And then I have a full-fledged freestanding wound clinic. If somebody is interested in narrowing down and just doing the wound care to meet the needs of their communities, those will be included.

DR. WILER: Thank you. My next question is as I read your proposal there is no -- you describe the importance of providing high-quality care to these patients, but in the model proposal there's no description of risk to the provider based on the quality measures that you have described, is that correct?

DR. FAROOQI: That is -- yes, that is correct. Well, so, I am trying to compare it with the current system in which I think one of the weaknesses of the program is somebody goes to the hospital, then -- and then comes back, then the program just picks it up again and there is no negative consequences.

It's -- in terms of risk, if the plan takes full consequence of everything including a hospital admission, then the cost

will simply not be worth it to do this proposal. And then my comparison is with the current system in which when people are going to say a hospital-based wound clinic and appropriate care is not provided, they end up in the hospital. They go back once they're discharged and restart where they left off.

So again, here at least there is a limit, upper limit to how much that can be paid and there will be -- the number of visits will after a certain point should or will trigger why the person keeps going there versus the current system where there is no limit, upper limit to how much is paid and upper limit to how many visits.

CHAIR BAILET: Thank you.

Tim?

DR. FERRIS: Good morning. Thanks for doing the work on submitting this proposal. This is going to be a slightly long question, but I think it builds off of what Kavita was asking but maybe using some different terms.

So the way I read your proposal, I see this as primarily a proposal to try to improve access to services. On this committee we have to consider at least three things conceptually: access, quality and cost. And I think what you're hearing is questions related to the other two elements of that triad: quality and cost, and trying to figure out how this improved access to care for patients who could benefit from it squares with the quality and cost problem. And I'm going to -- the specific question I have is related to incentives for referral.

So wound care is a classic situation where the vast majority of patients can be handled by a simple set of interventions, but in fact some patients need extreme interventions including for example lower extremity re-vascularization. That is not uncommon in the context of wound healing in the lower extremities. And that's a very expensive, very high-end procedure.

So you have a whole set across a continuum. And what your proposal is addressing is a very specific set on the lower end of that, decreasing costs and improving access at the lower end, but I'm still concerned along the line that Kavita was asking about barriers to referral when it's appropriate to refer. And specifically, if one were to create a bundled payment where everyone on the care team was part -- was contracted as part of that bundle, then there would be no financial disincentives for referral. But I -- the way this -- your proposal isolates a certain fraction of those patients without any a priori knowledge of whether or not they would end up needing a big procedure.

Does your proposal then -- how is -- how does your proposal either enhance or is impeded by the financial framework for referral to doctors who take care of more severe ulcers?

DR. FAROOQI: Part of the reason to keep it simple is participation and not to

overload people or burden people with too much work. That's one thing.

Second, the example you cited, some people do need extensive procedures because wound is a mere symptom or presentation of the underlying disorder. For example, neuropathy with diabetes, arterial disease or some other issue going on.

So once the person comes in, they do have to be referred to the specialist, as you cited, either to have a vascular intervention, whether venous or arterial, have to be seen by endocrinologist or primary care or the wound physician has to work with them to control the blood sugar because it's been cited in the literature blood sugar greater than 200 slows or prevents the wound from healing and similar issues.

So I personally -- and then if I keep the person who has an arterial disease for the sake of bringing him in for getting $400 every visit, this plus much more could be lost

once the person has to lose the foot or the leg and takes me to the court.

So, and then so there is clinical practice that when we see -- which happens everywhere -- when you see a problem that needs a specialist's attention, you simply send them there. So -- to the specialist like a vascular surgeon or somebody else. I don't see why this could be a hindrance to sending the people to the specialist for a specialist's help.

The cost of seeing the specialist, again if we're going -- if we have a proposal which takes on everything, then the cost and the work would spiral so much out of control that it will not be -- we will not simply be able to implement anything.

So that's the reason for keeping it simple, but I do not see why patients could not be referred to specialists when they need a specialist's services.

CHAIR BAILET: Thank you.

Do we have any other questions for

Dr. Farooqi from the Committee?

(No audible response.)

* **Public Comments**

CHAIR BAILET: Seeing none, the next part of our process is to get public comments. We have three folks who are registered. Dr. Christopher Pittman who's a board member of the American Vein and Lymphatic Society. He's on the phone. I'll turn it over to him.

DR. PITTMAN: Good morning, everyone. I'm just walking out of a patient room.

This is Dr. Chris Pittman from Tampa, Florida. Can everybody hear me?

CHAIR BAILET: Yes.

DR. PITTMAN: Awesome. I'm an interventional radiologist by training. I practice in my own office-based clinic and I'm devoted 100 percent to venous and lymphatic medicine. I'm board-certified in both diagnostic radiology and interventional radiology and I'm a diplomat at the American

Board of Venous and Lymphatic Medicine. I'm also a board member and chair of the Health Care Advocacy Committee of the American Vein and Lymphatic Society. The AVLS is approximately a 2,000-member professional society dedicated to advocacy, research and education in vein and lymphatic medicine.

I have no relevant conflict of interest; however, I wish to declare that I am on the Scientific Advisory Board of Tactile Medical, a company that develops at-home therapy devices that treat lymphedema and chronic venous insufficiency.

I echo the issues raised by the Preliminary Review Team, but I want to commend the applicant for initiating a very important discussion about wound care. I am sharing just two key points to underscore how important venous disease is in the clinical care of most wound patients.

Key point No. 1, venous leg ulcers are statistically the leading cause of a non-

healing wound. Chronic venous disease impacts up to 40 percent of the population and up to four percent of patients 65 and over will suffer from venous leg ulceration. Venous ulcers alone consume nearly two percent of the total health care budget in developed countries. Venous leg ulcers in the United States are a $15 billion a year public and private payer burden. To put this in perspective diabetic foot ulcers are only approximately a 10 billion a year burden because the prevalence of venous disease is much higher than diabetes.

Venous leg ulcer patients make up the majority of patients in wound care centers, however, the recurrence rate of venous leg ulcers without venous intervention is shown to approximate 30 percent per year even under the best medical management. Leg ulcer patients in wound care centers are often not properly screened for venous disease even though venous disease is statistically the leading cause of leg ulcers.

Key point No. 2 and I'll wrap up. A landmark *New England Journal of Medicine* study entitled, "A Randomized Trial of Early Endovenous Ablation and Venous Ulceration," published May 2018, concluded what every experienced vein care physician has understood for more than a decade, and I quote: Venous disease is the most common cause of leg ulceration. Although compression therapy improves venous ulcer healing, it does not treat the underlying causes of venous hypertension. Pathways of care for leg ulcers in general do not include a provision for early assessment and treatment of superficial venous reflux. The lack of standardized models of care for leg ulcers and the involvement of a range of specialists may contribute to the inconsistent care delivered.

The one-line conclusion from this study reads, and I quote: Early endovenous ablation of superficial venous reflux resulted in faster healing of venous leg ulcers and more

time free from ulcers than deferred endovenous ablation.

Forgive the analogy, but when a vein physician eliminates a leak in the venous plumbing, the hole in the skin drywall will heal. For venous leg ulcer patients who are properly referred for vein care leg wounds heal in weeks instead of months or years. I'd also like to highlight that these venous procedures are outpatient office-based procedures.

On behalf of the American Vein and Lymphatic Society I thank the PTAC for the opportunity to comment and our society is pleased to be of assistance to the applicant or the PTAC for further detailed discussion. Thank you for your attention.

CHAIR BAILET: Thank you, Dr. Pittman. Appreciate your comments.

Dr. Helen Gelly, HyperbaRxs. She's here in person.

DR. GELLY: Thank you. I would like to thank the members of the PTAC for examining

this issue and for allowing me to comment.

As a bit of background I have been practicing wound care and hyperbaric oxygen therapy in office since 1993. I am one of the founding fellows of the American College of Wound Care Specialists. So I've been doing this for a very long time.

A review of the quantitative analysis shows that the patients seen for wound diagnoses are more than twice as likely to have diabetes, heart failure, peripheral vascular disease, and in fact all comorbidities are more common. This identical patient profile exists in my aggregate report. So when you look at my HCC score, which is about 2.8, it puts me in a category where I'm treating patients that are significantly more complicated and complex than anyone except someone doing critical care and nephrology and infectious disease. So it puts me at least in the top 10.

Podiatry being seen as the primary deliverer of office-based wound care actually

only limits these wounds to below the knee and in some states below the ankle. So I think that although this is probably true looking at the numbers, the body doesn't end at the knee and so wounds are present everywhere.

Wound care has evolved since 1993 when wet to dry dressings were the standard of care. Currently maintaining a moist wound environment has become more costly as dressings and new products have been designed to create that environment. However, practice expenses as calculated by the AMA RUC have not kept up.

One question that was raised was whether or not we cherry pick patients. Well, I can tell you that in a private practice if I say no once, that referring physician will never call again. And I think that that's validated by my HCC score.

With my limited time I would like to offer some recommendations because I think that this is worthy of further discussion. As presented in this bundled model, it's not fully

explored to take into consideration all of the aspects that need to be integrated. For example, I would recommend removing the NCC edits that CMS has in place. As Dr. Farooqi mentioned, if I do a debridement I cannot put on a compression dressing, however, compression is the standard of care. So CMS is putting me in a quandary. Do I do one, do I do another, or do I ask the patient to come back for a second visit on the next day, which would be inappropriate on multiple levels.

They should also allow physicians to charge DME rates for the products that are used to maximize the moist wound environment, thus reducing the need for daily dressing changes.

In this proposal he has included CTPs. In my opinion those would need to be separate because CTPs are not appropriate for every wound care patient and should be applied towards the end of the wound care encounter and variably cannot be factored in over a 12- or a 16-week period of time.

That also brings up his reference to the U.S. Wound Registry. There the average patient stays in service seven months. And since the U.S. Wound Registry looks at predominantly hospital-based outpatient departments, although we also participate in that wound registry, seven months is really what we're looking at, not 14 weeks or four months. So this makes it very challenging to identify how we should make an average patient be put in one category of the length of time in service.

The other question of referral bias which was brought up would be addressed by using quality measures which physicians do do reporting for, and within the U.S. Wound Registry quality measures include appropriate referral for compression at every visit for a wound care patient that has venous stasis disease. It also includes vascular assessment and potential interventions for patients who have lower extremity ulcers including venous ulcers and diabetic foot ulcers, and the list

goes on. So there are quality measures that can be utilized which currently exist and are approved by CMS to be able to factor in whether physicians are appropriately utilizing the referrals that are necessary to get the patients healed.

And then the other question -- oh, excuse me, the other point I'd like to bring up is that the current ICD-10 codes are not helpful in identifying multiple wounds in one patient in the same anatomic area. And this is not uncommon in the area of venous ulcers where there might be multiple areas where one may be treated for a certain period of time, but then it kind of gets confused as to if someone then has a traumatic ulcer or a traumatic wound on the same extremity. You cannot really differentiate that.

And that's a coding problem that I don't think that we can resolve here. But it will be increasingly important in chronic elder care that we address this issue because it's not

just a matter of increased cost. It also is a matter of increased availability. And what we haven't addressed here because we're talking about traditional Medicare is that many of our patients are now in Medicare Advantage Plans and the actual cost to the patient is increasing because they have out-of-pocket costs of $6,000 to $7,000, which can easily be eaten up by a number of hospital outpatient department visits.

So I would like to thank PTAC for looking at this as a topic of interest, and if anyone has any questions I would love to be a resource for you all in your plans to expand or look at this in other applications. Thank you.

CHAIR BAILET: Thank you, Dr. Gelly.

Louis Savant, Director for Osiris Therapeutics? Thank you.

MR. SAVANT: All right. Thank you and thank the -- I'd like to thank the Committee for allowing public comments and to -- as Helen said, to address this issue of wound care, is really important. We just have a few comments.

Number one is we concur with most of the comments that the Committee had regarding the proposal.

The main comment that we would like to make is just to emphasize what's already been said, and that is that wound care is a very complex specialty and it's not treated as a specialty very often. We have cancer specialists, we have rheumatology. There's specialties for everything but wound care is one of those specialties where we don't have a true specialist. And because of that, the wound care itself often doesn't get treated like a specialty. So we would encourage the Committee and CMS to continue to explore wound care and continue to look at this very closely.

The final comment is just that what Dr. Farooqi is saying regarding standard of care. Standard of care continues to evolve and change and the payment methodologies often restrict doctors from what they can do.

Our company, Osiris, we've been around for 26 years researching cellular and tissue-based products. That's what our company does. And so we offer one of those advanced therapies. And in the course of our research it's become obvious that it's an adjunct to good standard of care. And when wound care specialists are restricted due to payment or guidelines restricting the treatments, it certainly impacts what our product is capable of doing.

So removing the edits and looking at new ways of paying for therapies together, multimodal therapies. Most of the time a physician is restricted. You can only do one treatment at a time. So if you put a cellular tissue product on a patient that has already failed a standard of care but they don't get paid for compression or they can't do negative pressure, they can't do these other therapies together, you're really hamstringing a wound care specialist.

And again, the final comment would be that other specialties like cancer, you wouldn't say to a cancer specialist you can only do this one treatment and not do this other treatment if the evidence shows that the treatments together might work better in concert. So that's our final comments. Thank you.

CHAIR BAILET: Thank you.

We have one additional individual, Dr. Brian Liljenquist, Managing Partner for Surgical Wound Care Associates. He's here on site.

Thank you.

DR. LILJENQUIST: I'd like to thank the Committee for the opportunity to speak. Thank you.

Dr. Farooqi, thank you for your work on this. It's important. Echo the comments that we've heard.

We're talking about access. Dr. Terrell, you -- did I say that right? Terrell?

Yes. You talk about going to nursing homes to do wound treatments, right? That's the access. We do that. We get in our cars, we drive there. That's the early access. We have a hard time at Surgical Wound Care Associates finding more doctors to staff our clinics that's growing.

What worries me is that we have this evolving specialty that's not even a specialty yet but it's very complex, like we've talked about. It worries me that we're being premature and putting limits on it. It's too early for that.

We find we have an average heal time of 5.2 weeks using the advanced grafts and these high-end procedures with the interventionalists.

Dr. Pittman, I love your excitement, if you're still on the phone. That's what we live every day, to see these patients come in with wounds that have affected their lives. They can't have a social life. Their kids, their grandkids won't come around them because

they're smelly and leaky. Physicians like Dr. Pittman, products that we see here, putting those together and getting that full closure with a pristine native tissue in six weeks is so cool, so rewarding.

And so as we talk about how to contain costs it has to be part of the conversation, but we're just not there yet. We're still exploring what are best practices. Interventional radiology has been such a powerful tool that we use -- 85 percent of our patient get a referral for vascular or arterial, or both, and they -- and 65 percent of those receive an intervention. That happens in the first week. When we see that patient for an initial visit, they come back re-vascularized from this percutaneous procedure and then we can get to work.

I always say we can't grow a garden without water. And we heard the drywall. I mean, it's the same thing. We have to treat the complexities of these very sick patients. It

concerns me that we're putting limits on wound care prematurely right now. Thank you very much for your time.

CHAIR BAILET: Thank you.

Oh, one more? Is there one more? Yes. Maybe two more. Okay. Well -- all right.

DR. TETTELBACH: I registered online. I guess there may have been a mix-up.

So my name is Bill Tettelbach. Appreciate giving me the time to speak.

My background actually is infectious diseases as well as hyperbaric -- understanding hyperbaric medicine and obviously wound care. And I currently am the Associate CMO for MiMedx and I'm also actively practicing as Medical Director for Landmark Hospitals. I also until recently was the Executive Assistant Medical Director for Intermountain Healthcare. I oversaw wound care for 22 hospitals, 10 outpatient clinics. For the last five years I was treating faculty for the podiatry residency. I also was involved in bringing up systems for

the Methodist Le Bonheur System in Memphis.

So this is obviously a passion. Everyone that's got up here is passionate about this. And so I agree with everything that has been said from the mic today. I thank Dr. Gelly, Helen Gelly for her comments.

The problem is -- looking at this in a broad perspective, I agree access is the issue here, increasing access. And having worked where we've had to increase access within a hospital- affiliated system from just two clinics to 10 clinics over five years, we still didn't scratch the surface. We worked very closely with the non-affiliated clinics, the referral systems.

And I've also been heavily involved in research. And so the last three years we've done venous leg ulcer studies, diabetic foot ulcer studies. And just looking at the standard of care, these are large randomized control trials. Put them all together it's over 300 patients.

The typical -- with standard of care meaning just like an alginate, compression for venous leg ulcers, off-loading, you get up to 50 percent healing rates. That's a good number, but the other 50 percent do not heal with standard of care. And so this model, this proposal will -- as mentioned before, will eliminate some of these advanced therapies that can be done in the non-affiliated outpatient setting by eliminating some of these Q codes and putting it into just a bundled payment.

The other thing is just even putting on a cast for off-loading reaches the ceiling and actually makes it a loss for seeing these patients when you can't charge for the cost of the cast that's bundled into the payment. So there's a very limited range of treatment that's going to be allowable within this. And so this is going to get into this system or what we say in the medical field, especially in epidemiology for infectious diseases -- this is going to be like squeezing the balloon.

So you're going to be squeezing the cost out in one area and it's just going to blossom in another area where there's going to be more patients or referrals going into hospital-affiliated clinics, which is -- if I was still there, would be great, but tell you the truth, we couldn't handle the volume. We would have to build more clinics. And it stresses that multi-specialty.

This is a multi-specialty. So this will also -- there's a trend for wound care in the outpatient setting to move back out into the outpatient setting. There are these multi-specialty clinics now where you have angio suites, MRIs, hyperbaric and the wound centers all in one. This is actually what we want and this is going to maybe inhibit this.

Traditional wound care with just someone treating the wound is really I think five, 10 years now is going to be the old standard of doing things. And this bundled payment will halt that.

So that's really my input having a broad perspective with evidence showing that you -- we still have 50 percent of these DFUs and VLUs, which is the major portion of these. I have to tell you I've also had the opportunity to -- over the last year to work with folks in the NHS, which they struggle with the same problem. They have a capitated system and a lot of the rural or community-based medicine has been a complete failure with these bundled-type -- or limitations on what can be done by who is treating them, which is in essence reducing the cost.

So we should not fall into that same trap. We need a different payment model as we talk to here, expanded maybe for putting on compression, keeping advanced therapies available, and at the same time I think you're going to have folks holding onto these patients for extended periods of time because this turns into a lucrative model.

It's going to take seven months you

hear, but really these folks can be 12 to two years if you look at the NHS data, I mean 12 months to 24 months. And now you're talking 20, $40,000 for one patient for closure, which is far less than allowing advanced therapies and sort of individual therapeutics to be charged within that patient visit. So that's -- I appreciate the time. Thank you.

CHAIR BAILET: Thank you.

And since I don't have you registered I can't introduce you. You'll have to introduce yourself.

DR. NUSGART: And I'm happy to do so. Good morning. My name is Marcia Nusgart. I'm the Executive Director of the Alliance of Wound Care Stakeholders. And you heard from Dr. Gelly, you heard from Dr. Pittman. They also represent -- they're some of our members. The alliance is a non-profit multidisciplinary trade association of physician specialty societies, clinical and patient organizations whose mission is to be able to promote evidence-based quality

care and access to products and services for people with chronic wounds through effective advocacy and educational research.

So our focus is on wound care research, developing of quality measures for wound care, as well as reimbursement. And we're happy to be able to work with you if you decide that -- as Dr. Berenson would probably say, there needs to be some changes in terms of prevention, changes in the coverage with the LCDs as well as payment. Happy to be a resource to you as well as education more in the wound care space.

So as some of the other presenters had mentioned that we appreciate that Seha Medical had brought up the subject of chronic wound care to the PTAC's attention. Since it was noted, our value and health study, that 15 percent of the Medicare population has a chronic wound and the total Medicare spending on wound care types could be anywhere from 28 to 96 billion depending upon whether wound care is a

primary or secondary diagnosis.

I have to tell you I was so impressed with what I had read from the PTAC Preliminary Review Team because they did an outstanding job of addressing some of the issues within this particular proposal. So we're in agreement with the preliminary results with the proposal as written that it has a number of structural flaws in it, and therefore the -- and elements that weren't sufficiently developed.

For instance, as stated in Criterion No. 3 of the payment methodology we have concerns that that proposed $400 per visit all-inclusive payment will not allow the providers to probably give the high quality wound care services to patients with diabetic foot ulcers, venous stasis ulcers and pressure ulcers. You already know; you treated these patients, they are sick complex patients and could be very complicated and have complex medical needs.

We agree with the assessment on Criterion No. 9 on patient safety. This low

payment could result in risks relating to stinting on care. Also the proposal didn't require the provider to adhere to a particular care model, follow a particular set of national guidelines or established protocols in order to achieve the desired cost and utilization objectives. It's also lacking on how the proposed quality metrics would be measured. We're concerned that the patients just may not be well served under this simplified model.

Wound care is really a symptom of a disease and these patients, as Dr. Gelly and others mentioned, have a tremendous number of comorbidities that need to be treated. In fact, some of the most prevalent comorbid diseases are hypertension, chronic kidney disease, diabetes, heart failure, ischemic heart disease, osteoarthritis and rheumatoid arthritis.

Noting the seriousness of treating these comorbid conditions we're in agreement with the PTAC's concern that this proposal doesn't include a severity or complexity

component to account for the comorbidities and other factors.

We are also in agreement; you already mentioned, wound care is multidisciplinary. There needs to be able to be an adequate team of physicians, whether they're surgeons, vascular medicine physicians, podiatrists, dermatologists, nurse practitioners, infectious disease experts, physical therapists, nurses, registered dietician nutritionists, lymphedema therapists and primary care physicians to be able to treat for these patients.

We're in agreement with the PRT's environmental scan underscoring that the multidisciplinary approach to treating a patient is a most important element to the success of treatment because no single health care provider is adequately equipped with the skills, knowledge and experience to provide the comprehensive care for all the chronic wound care types. And you'd want to make sure that

the PTAC -- that this proposal allows for this type of expertise.

It's very interesting and I was -- I had mentioned to a number of people in the audience that creating a bundled payment for any type of chronic condition, especially one that involves chronic wound care, it's very complex with many details and thus very difficult to not only create but also implement.

We just met with the CMS' hospital outpatient department because they're looking to be able to figure out payment for only a small portion in the wound care space. That's actually the application and the products of those, quote-unquote skin substitutes. The more clinically appropriate term is what Dr. Gelly mentioned, cellular and/or tissue-based products for skin wounds, otherwise known as CTPs.

But we -- it was very interesting because when we were talking with them they had mentioned the fact that they need to be very thoughtful about all of this. They were trying

to figure out whether there's something that CMMI might want to be able to do. We had thought that CMMI has probably bigger fish to fry.

Perhaps if there was something that was for diabetes, then you could probably have some type of episode for the diabetic foot ulcers, but again wound care being very complex and the fact that what we had mentioned is there needs to be taken into account not only the NCCI edits, but also the patient comorbidities.

So we are in agreement with the PTAC's preliminary recommendations. Don't believe the proposal should move forward as is currently written, but because of the 20 different clinical associations that we have as our members that we'd be pleased to be able to work with you to figure out if you want to be able move forward with something like this. Please use us a resource. And thank you so much for you time.

CHAIR BAILET: Thank you. I just

need to check to make sure there's no other unregistered, registered folks. We're good? Okay. Very good.

Oh, I want to again thank Dr. Farooqi for submitting the proposal, working with the PRT team to get us to where we are today, the public commenters and the folks on the phone. Appreciate that input.

Now unless any of my colleagues have any other additional comments, we are going to begin our voting process. I would like to alert folks that Dr. Rhonda Medows is now on the phone, who is a member of the Committee. She's been on the line.

Rhonda, you want to just introduce yourself and provide your disclosure?

DR. MEDOWS: Certainly. I'm Rhonda Medows. I am the President of Population Health Management at Providence St. Joseph Health. I'm the CEO for Ayin Health Solutions, a Population Health Management company. I have no conflicts of interest for this proposal. Thank you.

CHAIR BAILET: Thank you, Rhonda. We have one comment from Len.

DR. NICHOLS: So, Jeff, I'm all in favor of moving expeditiously, but shouldn't we deliberate a little bit first?

CHAIR BAILET: Thank you for picking up on that, sir. Of course we're going to deliberate. Like I said, please.

DR. NICHOLS: Okay. So I have one question for Bruce and the team and the Committee. It seems to me what we heard today, which is actually quite informative for my economist brain, would have been much better received, this proposal would have been, if it had been a risk-adjusted, episode-based bundle, right? So I was also really struck at how fundamentally the information that you all had, the PRT had about cost per I guess you could say visit or activity differed from the presenter's read of the literature.

Obviously, you didn't have access to what CMS could do for you, what NORC could do

for you, but the data we were shown was all per visit as opposed to per episode, and he seemed to be backing out from a per-episode estimate from the literature, some kind of average. And so I was really struck at how if you look at the outpatient portion of the per-visit cost that we were given, the mean was like $413 or something, but the 75th percentile was $215. You had to get up to the 90th percentile before you get into the thousands. So clearly the very common, the most common cost per visit is way less than $400.

So I guess my question is how much information did you all share with the presenter that NORC was able to give to you, and if there could be a price that you would put on this risk-adjusted episode bundle at this moment, what would it be?

MR. STEINWALD: Well, in response to your first statement, which is maybe if it was an episode-based, risk-adjusted model we'd be more favorably disposed, I think the answer is

maybe. It depends on what the particulars of that would look like.

You know, we had a couple of rounds on the data that we requested because we thought it would be useful for the entire committee to have an overview of what wound care looks like under Medicare, both in terms of volumes and services, who is providing them and the cost. And I agree there is a little bit of a conflict between what our presenter said and even what we just heard right now and what the data that we were provided seemed to suggest. So I'm not exactly sure how to resolve that.

It does seem clear that there is a lot of office-based wound care being provided right now, and the majority is being provided by podiatrists. Whether that's a good thing or not is hard to say.

We decided that there is still an issue even if it's not as big as we had thought about patients being treated in hospital-based clinics that could be treated in the individual

doctor's office, and that's partially an access issue because there might be more, especially in non-urban areas.

Beyond that, Grace, you might have something to say, but we -- I can't completely reconcile the differences in what we hear about the cost and prevalence versus the data we were provided by our contractor.

VICE CHAIR TERRELL: So there's a famous quote from William Osler, the famous 19th Century general internist that -- something along the lines of to know syphilis is to know all of medicine. And that was the 19th Century, but I suspect that for wound care that's a very, very good metaphor for the 21st Century.

And so if you think about the conversation that we've had this morning and put it within the context of what wound care is really about, there's a lot of different causes. I mean it can be a pressure ulcer, as was mentioned. It can be neuropathy from diabetes or some other neuropathic cause. It can be

venous insufficiency, which was talked about by one of our public speakers in great detail. It can be arterial insufficiency, which is a whole different thing. And many other causes including infectious disease or heart failure or renal failure.

So if we're able to actually think about what the actual problem is today, it's because lots of different people from lots of different angles are trying to attack something where this is the end stage or what we hope is not an end stage, but an outcome of various bodily processes. And so we've -- we have a system in place that's not a system.

I'm old enough in my own medical practice to remember the really, really bad old days when podiatry was not integrated into things and the vascular surgeons did not like them and they would say, well, these guys are just whittling away at things and eventually I'm going to amputate it anyway. And then we ended up with wound care centers at hospitals where

for the first time really you started seeing team-based care that you didn't see in the outpatient setting. And everybody complained about the cost, but it was the first time in my community that the vascular surgeons and the podiatrists were working together.

So I went back when we were looking at the PRT and spoke to one of those podiatrists, who used to not be part of the team and now is really integral with that but also has an outpatient practice, and I said why don't you do wound care in your practice anymore, and he said because it's so much better in the hospital setting. We can't afford it anyway in the outpatient setting, which was Dr. Farooqi's point; he can't afford it anyway.

So my point in bringing all this up in sort of -- in this way is that as we're thinking about payment models versus care models. There is no care model for wound care, and that might be something that all these very thoughtful folks could work on together to think

about what that would mean within the context of what a wound actually is. And as a result of that we don't have a payment model that actually makes sense either and it probably is premature to do so, but it probably is something where the entire ecosystem, if you will, of those that are providing wound care really ought to get together because it's a whole lot better than it used to be, but I suspect it's a whole lot better -- it can be a whole lot better.

So this is a real opportunity this morning to actually have a public conversation about it with respect to what the PRT can do. We can make comments on this, we can make comments on the next proposal, but I'm going to suggest that we're going to have to throw it back to you and there may well be the possibility of multiple people coming together and saying let's figure out what the care model ought to be and then let's figure out what a payment model ought to be.

CHAIR BAILET: Tim?

DR. FERRIS: I would just encourage our contractors to take a transcript of what Grace just said, which I thought was absolutely brilliantly expressed and perfectly aligned with the set of issues that this Committee is faced with, and everyone should read it four or five times because it is a statement that applies to our work much more broadly than this specific proposal.

CHAIR BAILET: Okay. Any other comments from the Committee?

(No audible response.)

CHAIR BAILET: All right. One more time with feeling. Are we ready to vote?

(No audible response.)

* **Voting**

CHAIR BAILET: Okay. So first we vote on how the proposal meets the 10 criteria. The member votes roll down until a simple majority has been reached. We have electronic devices for the purposes of being efficient. A vote of 1 or 2 means does not meet, 3 or 4 means

meet, 5 and 6 meets and deserves priority, and the asterisk is not applicable.

So we're going to go ahead and start voting. After we vote on the 10 criteria, we'll then proceed to vote on an overall recommendation to the Secretary. We will use the voting categories and process that we've debuted at our December public meeting.

We designed these more descriptive categories to better reflect our deliberations for the Secretary. So first we will vote using three criteria: not recommended for implementation as a physician-focused payment model; recommended; and referred for other attention by HHS.

So we need to achieve a two-thirds majority of votes for one of these three categories. So we're going to -- so maybe it would be better before I go through the Rules of Engagement for the rest of the process if we just go ahead and start with the first section of the process, which is to go through the 10

criteria, vote electronically. We're going to go ahead and get rolling on this starting with the first criteria. If we could put that slide up, please?

* **Criterion 1**

Okay. Scope 1. Criterion 1, scope. The aim is to either directly address an issue in payment policy that broadens and expands the CMS APM portfolio or include APM entities whose opportunities to participate in APMs have been limited. So let's go ahead and vote on this one.

All right. Very good. Ann?

MS. PAGE: Two members voted 6, meets and deserves priority consideration; one member votes 5, meets and deserves priority consideration; four members voted 4, meets; two members voted 3, meets, two members voted 2, does not meet, and zero members voted 1 or 0, not applicable. So we need a total of six votes, and so the majority six Committee members have voted that the proposal meets Criterion 1.

CHAIR BAILET: Thank you, Ann.

* **Criterion 2**

Let's go with Criterion 2, quality and cost. It's a high-priority criterion. Anticipated to improve health care quality at no additional cost, maintain health care quality while decreasing cost, or both, improve health care quality and decrease costs. So we're going to go ahead and vote.

MS. PAGE: Zero members voted 5 or 6, meets and deserves priority consideration; zero members voted 3 or 4, meets; five members voted 2, does not meet; six members voted 1, does not meet, so the majority has determined that the proposal does not meet Criterion 2.

CHAIR BAILET: Thank you, Ann.

* **Criterion 3**

Let's go with Criterion 3, payment methodology, which is a high-priority criterion, Pay APM entities with a payment methodology designed to achieve the goals of the PFPM criteria, addresses in detail through this

methodology how Medicare and other payers, if applicable, pay APM entities and how the payment methodology differs from current payment methodologies and why the physician-focused payment model cannot be tested under current payment methodologies.

Let's go ahead and vote.

MS. PAGE: Zero members voted 5 or 6, meets and deserves priority consideration; zero members voted 3 or 4, meets; three members voted 2, does not meet; eight members voted 1, does not meet. The majority has found that the proposal does not meet Criterion 3.

CHAIR BAILET: Thank you, Ann.

* **Criterion 4**

The fourth criterion is value over volume. Provide incentives to practitioners to deliver high-quality health care.

Please vote.

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

voted 2, does not meet; four members voted 1, does not meet. The majority finds that the proposal does not meet Criterion 4.

CHAIR BAILET: Thank you, Ann.

* **Criterion 5**

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

MS. PAGE: Zero members voted 5 or 6, meets and deserves priority consideration; one member voted 4, meets; eight members voted 3, meets; two members voted 2, does not meet; and zero members voted 1, does not meet. The majority finds that the proposal meets Criterion 5 on flexibility.

* **Criterion 6**

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

Vote, please.

MS. PAGE: Zero members voted 5 or

6, meets and deserves priority consideration; zero members voted 4, meets; two members voted 3, meets; seven member voted 2, does not meet; two members voted 1, does not meet. The majority have found that the proposal does not meet Criterion 6, ability to be evaluated.

CHAIR BAILET: Thanks, Ann.

* **Criterion 7**

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

Please vote.

MS. PAGE: Zero members voted 5 or 6, meets and deserves priority consideration; zero members voted 4, meets; one member voted 3, meets; three members voted 2, does not meet; seven members voted 1, does not meet. The majority finds that the proposal does not meet

Criterion 7.

CHAIR BAILET: Thank you.

* **Criterion 8**

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

MS. PAGE: Zero members voted 5 or 6, meets and deserves priority consideration; one member voted 4, meets; eight members voted 3, meets; two members voted 2, does not meet; zero members voted 1, does not meet. The majority finds that the proposal meets Criterion 8, patient choice.

CHAIR BAILET: Thank you.

* **Criterion 9**

And Criterion 9 is patient safety. Aim to maintain or improve standards of patient safety. Please vote.

MS. PAGE: Zero members voted 5 or 6, meets and deserves priority consideration;

zero members voted 4, meets; one member voted 3, meets; seven members voted 2, does not meet; three members voted 1, does not meet. The majority finds that the proposal does not meet Criterion 9, patient safety.

CHAIR BAILET: Thank you.

* **Criterion 10**

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

Please vote.

MS. PAGE: Zero members voted 5 or 6, meets and deserves priority consideration; zero members voted 4, meets; two members voted 3, meets; five members voted 2, does not meet; four members voted 1, does not meet. The majority finds that the proposal does not meet Criterion 10, health information technology.

CHAIR BAILET: Okay. So here's the summary:

So, Ann, did you want to summarize

those results for --

MS. PAGE: All right.

CHAIR BAILET: -- the 1 through 10?

* **Overall Vote**

MS. PAGE: The Committee voted that the proposal meets three criteria: Criterion 1, scope; Criterion 5 on flexibility; and Criterion 8, patient choice. For the remaining three criteria the Committee voted that it does not meet those criteria.

* **Instructions on Report to Secretary**

CHAIR BAILET: Thank you. Now we're going to go ahead and move onto the recommendation to the Secretary, the first part of that, one through three: not recommended for implementation is one; two is recommended. And if that's the case, there will be two parts to that or three, referred for other attention by HHS. So we're going to go ahead and -- is the Committee ready to vote? Looks -- sounds like we are. We're going to go ahead and vote here.

MS. PAGE: Four members voted refer

for other attention by HHS; zero members voted to recommend the proposal; and seven members voted one, which is not recommended for implementation as a PFPM. In this vote we needed two-thirds majority, which would be eight votes. And so we've got seven on not recommend and four on refer for other attention by HHS, so I don't know if you want to have more --

CHAIR BAILET: Yes, I think we need to have a discussion about this. I have a comment. I guess I would make a comment.

What I'm hearing today clearly is that the payment -- and as Grace pointed out, the clinical design for wound care, there's definitely a disconnect. The design for -- the payment design is not caught up with the multidisciplinary approach to this problem. And the technology that's -- also comes through in either it's a procedure or a wound dressing, the fact that there is compartmentalization of payment and physicians have to decide even though there's a series of clear -- not just

physicians, but clinicians have to decide there's a series of things that would make -- would be appropriate at the time the patient is there and have to decide because the payment doesn't recognize their efforts, that's a problem.

And so to me it's clear that this is a significant problem given the comorbidities that are involved here and the drain on the system that this needs to be addressed. And so as I sort of think about -- the way I think about this part 1 is this -- are we saying that we're -- the challenge is, the balance is that we're not recommending -- the sense of the group is we're not recommending this for a PFPM, but I don't want to lose sight of the fact that this is a problem that should be attended to and that CMS and CMMI should explore and address the challenge that our submitter and also the public commenters have raised.

So that's sort of the frame in which I think the question is posed because if it's

referred on for other attention, it doesn't necessarily say that we're not -- we're still not recommending it as a PFPM. And I think we need as a committee to sort of understand that distinction.

Len?

DR. NICHOLS: So I think you framed it right. I think that Grace said it so beautifully. The question to me between not recommending and refer is the old question we've been asking from the beginning: When is it worth CMS attention? Seems to me the people who spoke today and some on the phone and some others they know should go work among themselves and come back with a much more concrete proposal that spans the care model and a risk-adjusted, episode-based payment model and come to CMS with that as opposed to say, okay, we think you should pay attention to this.

Because, Jeff, what I worry about, we have so many proposals that we've recommended and none of them have been implemented yet. We

have so many other priorities that CMMI is pursuing independent of us to say go think about wound care when they've got all this other stuff going on. It would be better if the professionals came up with a more concrete proposal and then they could evaluate that. That would be the time to refer.

CHAIR BAILET: Thank you, Len.

Harold has his tent card up; he's on the phone. And then we'll go with Paul and Bruce.

MR. MILLER: Yes, I'm glad you can see my tent card. Thank you.

I really strongly agree with what Jeff said and I am in some ways most proud of what the PTAC does today because we really I think unearthed an issue that's clearly on the minds of a number of physicians and providers that will come up again this afternoon, but which hasn't been addressed to date. And I think critically the issue is I'm not clear that it can be very effectively addressed simply by

asking individual physicians or individual specialty societies to come up with an idea, partly because it is multi-specialty and therefore it needs to have attention in a different way.

And second, because of the issues raised earlier about the data, is that in order to be able to propose something better, there needs to be a lot more analysis of data in a much different way that is not easy to do for anybody and certainly I think impossible to do for any individual provider, specialty society or otherwise. So that to me really justifies special attention or a different attention in order to be able to do what needs to be done to even enable someone to propose a better payment model.

CHAIR BAILET: Thank you, Harold.

Paul, Bruce and then Tim.

DR. CASALE: Yes, I'm in Len's thinking around this. You know, as I was debating how I voted, I really was thinking

through that piece. I really think the advantage of the entities coming together with a more comprehensive model may not be perfect, but I think it's a better place to start ultimately whether they come back here or go right to CMS as opposed to referring at this point.

CHAIR BAILET: Bruce?

MR. STEINWALD: My thinking was more along the lines of yours, Jeff. I'm sorry we don't have the advantage of having reviewed the second proposal because we might have a richer discussion of what our options are and we also might want to consider a single report rather than two separate reports. But I guess I'm of the belief, as you stated, that the -- both proposers have identified what appears to be a genuine problem. And although it would be a good idea to have a more comprehensive proposal, it still might be a good idea to raise to the Secretary why we believe that this is a genuine problem and deserving of additional attention.

CHAIR BAILET: Tim?

DR. FERRIS: I was just going to speak to the fairly narrow issue of the rural and access issues. It does sound like we're -- there -- I heard a relatively -- I don't want to ascribe consensus where there isn't any, but the votes seemed like we had consensus feeling about this issue, about the issue of the proposal overall, the complexity of payment in the context of where ideal care is multidisciplinary and the requirement for a payment model to reflect that multidisciplinary nature.

But I do think our submitter had a very good point about access to providers in rural settings where the existing payment codes don't actually cover the ability to take good care of wounds. I can't say whether that is a real problem or not; it sounds like it might be, but that's a fairly narrow question and it is entirely within the scope of CMS to address that issue all by themselves without any help from anyone outside.

And so I guess with Bruce I'm not --

whether it's refer or not recommend, as long as the message goes to CMS that: (A) we think this issue deserves attention because it is a big issue in U.S. health care wound care itself and that it is most susceptible to a multidisciplinary team bundled episode payment approach which needs to be developed maybe by submitters or not, but also there's a more narrow issue about access and coverage for rural providers, that they could just fix on their own.

CHAIR BAILET: Thank you.

We're going to need -- well, we need to re-vote just to confirm people's positions. We may not get two-thirds. And if that's the case, we can also send that signal to the Secretary as well. And I guess maybe to just summarize the conversations, referring this proposal on does not automatically say we think that it is -- we're recommending it as an -- that it's ready for prime time, I guess; my words, but the way I see it is we're referring

it because it's clearly an important issue that we feel -- if that's our collective, we feel needs attention because there is definite incongruences between the way payment and clinical delivery right now link up on this particular disease.

So that's again the frame in which I'm going to go ahead and vote on this one, that it's clearly a significant issue. This particular recommendation, this particular proposal is insufficient, but the issue itself warrants the stakeholders to come together and put together a robust proposal.

So does anybody else want to clarify the --

DR. CASALE: I'm just -- I think the way you just said that, this is insufficient, but we think it needs -- you could vote that either way, right? I mean, you can put the -- say not recommend and then say but we think it needs more attention. So I'm struggling a little bit because I --

CHAIR BAILET: So maybe we get there by landing on -- it looks like where the Committee's landing right now on not recommend, although we don't have enough votes. And then we can get to the refer on based on comments that we would make. Perhaps that's the way to thread the needle.

Len?

DR. NICHOLS: Yes, I think the letter can handle the spirit of what you're trying to do, and all I'm saying is; the boy who cried wolf, if we have no threshold for saying it deserves attention, hell, everything deserves attention. We're trying to rank these things and I fundamentally believe we have a limited -- very limited claims have so far zero success getting them to pay attention to what we've said, and so I think we really ought to be careful about using that bullet.

CHAIR BAILET: Okay. So we're going to go ahead and vote one more time. One, not recommend; two, recommend; and three, referred

for other attention.

MS. PAGE: One member voted refer for other attention by HHS; zero members voted to recommend; and ten members voted to not recommend for implementation as a PFPM. So the majority has found that the proposal should not be recommended to the Secretary for implementation as a PFPM.

CHAIR BAILET: Thank you, Ann.

And just to be -- check me on the process, but given the fact that we've landed here, we now have the opportunity to go around, share our respective votes and make sure that specific comments are made so that the ASPE staff can capture them and incorporate them into the letter to the Secretary.

And staff has a question already? Did someone have a question?

MS. PAGE: Staff. I do.

CHAIR BAILET: Oh, Ann?

MS. PAGE: Yes.

CHAIR BAILET: Please.

MS. PAGE: Just as we will capture the comments that have already been made, but as you comment please direct us to what extent we -- you want us to capture comments that may have been made by a public commenter.

CHAIR BAILET: Okay. So why don't we start with you, Dr. Ferris?

DR. FERRIS: Thank you, Jeff.

So I think -- so I voted to -- I voted first time to refer and second time to not recommend. Thank you, Len, for clarifying my position.

(Laughter.)

DR. FERRIS: I think we've said what needs to be said. I actually don't think we have -- I didn't -- I don't see any things that -- they haven't already pointed out that need to be highlighted, that need to be highlighted in addition, but I would say that the general issue of the promotion of multidisciplinary teams, and it seems to be a common theme in our deliberations. And Grace uses the term care

model and financial model or payment model, and I think that's very useful. It's very important to start with what is the care model that we think best takes care of patients and then work toward the payment model that best supports that care model.

This is an example of a proposal that worked in the other direction and it was in response to a legitimate problem in the payment system, but I think it is useful to take this opportunity since it came up during this to sort of highlight that issue, that what we'd really like to see in a proposal first is what is the care model that would provide ideal or optimal care and then how do we support that care model with a payment model?

I would go further; and I don't know if the rest of the Committee would come along this journey with me, but one of the things that comes up more and more frequently is the simple fact that optimal care is very frequently identified as multidisciplinary. And we have a

system of payment in our country, the fee-for-service payment system, which inherently divides our specialties because people are paid based on what they do in their silo.

To the extent that disciplines are brought together under a single legal and financial framework, then payment model construction is fairly straightforward because you can move in between those silos all you want, move patients all you want and it doesn't affect the income of any one player in that system.

It is also possible to do that in a world where our specialists practice in isolation, financial isolation from each other, but in order to succeed at that you actually have contractual relationships between them. And the contractual relationships between them inevitably become very complicated because the biology that we're dealing with is very complicated.

And so it would seem to me

suboptimal to build a payment system that encourages siloed delivery and siloed payment. I actually think that worked generally, and not in every case, but in most cases that works against a multidisciplinary model, which is almost always the right solution for optimal care model. So thank you for the opportunity to grandstand.

CHAIR BAILET: All right. Very good.

Dr. Patel?

DR. PATEL: I voted first to refer and also got course corrected to not recommend, and the only areas of emphasis from the public comment: (1) was just a comment about payment not keeping up with CTP, which I think is a theme we'll also see in a future proposal; and No. (2), kind of the comment both public and what was made here about the lack of adequacy of the physician fee schedule. That seems to be something 100 percent that the Secretary could probably send that to CM pretty quickly to say

here is some kind of lack of parity and also looking at what the -- what CMS has authority to do around kind of undervalued codes. It strikes me that we've identified potentially a host of undervalued codes for some of these things.

And then the third would be actually directing -- I think the lady that spoke last from the public comment made the point that in and of itself this topic might not be enough for CMMI to kind of chew on. I'm not 100 percent clear what exactly meets the threshold of what CMMI will do or not do except that we know they need to reduce cost and improve quality and improve morbidity and mortality, but I would say that within some of our more chronic care models, certainly our comprehensive primary care model, next generation models, things that have more partial or large capitated payments, that having an area of emphasis on this clinical condition or -- it's not even one condition, which is the problem -- would actually be a very good one.

And then finally this comment that was made about innovation and that this field is actually very analogous to potentially medical oncology where we see innovation far outpacing any payment mechanism that that would be -- that this actually would be in -- kind of fitting with other areas where we're struggling right now with kind of innovations that have yet to be determined even, but are certainly not being -- the access to those innovations are actually currently being denied to Medicare beneficiaries unintentionally because of a lack of evolution of the payment model.

CHAIR BAILET: Len?

DR. NICHOLS: So I voted not to recommend both times. Only two things I would emphasize. One, I definitely agree with what Tim said earlier about setting aside the rural question. We should mention that in the letter and say that's a separate question.

And then to me it's sort of obvious and therefore I would like the letter to reflect

it if the Committee agrees that we should say work on the care model among yourselves and come back with a risk-adjusted episode bundle. That's got to be a much more appealing frame to solve the problem.

I would say -- and I don't know if we're allowed to do this, but it would seem to me that it would have been very helpful if when NORC was asked to do the analysis for the PRT they had produced a distribution of cost by episode. Because what I heard from my clinician friend is that there's a set of wound care that's fairly straightforward and there's a set of wound care that's is extremely complex, and there's obviously stuff in between.

But if you just look at the distribution of per-visit cost, it's big. Per episode must be really big and it would seem to me that set of -- that table would be extremely helpful to the clinical teams that ought to get together to work this out and then come to CMS for real. But I don't think you can expect them

to come up with a number or even a coherent precise model without having them be aware of the distribution of costs that vary. But NORC could do that. It would probably take them, oh, an hour. But anyway --

CHAIR BAILET: Grace?

VICE CHAIR TERRELL: We actually asked them to do some work on that. It ended up being I remember getting some questions back relative to actually how to understand how to define the episode relative to the current Medicare data. And so the PRT did think through that and NORC did attempt to work on that within the context of the data they had. So if that is something that's important within this issue or others, we probably need to understand a little more detail what the capabilities are to do that.

I voted both times not to recommend really within the context of the spirit of the way Len was thinking about it. Having said that, I just want to publicly commend Dr.

Farooqi again for bringing this issue forward and being the first one to do it in a public meeting in a way because it's so important.

With respect to your question, Ann, about things that were said in the -- among public comments this morning, I heard some data points that we didn't have: the two percent of the total cost of care among Medicare, that if some of that could be captured, oftentimes -- and it goes to show that oftentimes the specialty societies and groups have more interesting data sometimes that we don't necessarily know to acquire within our usual ways. That might be effective.

There was a comment made by one of the public speakers with respect to when they looked at it at the National Health Service. We actually did ask for some data relative to other international systems because we wanted to understand how much of this was related to our idiosyncrasies of our fee-for-service system versus others. And so somewhere buried in that

report may be some information that we got from NICE and the British efforts that if it makes sense to bring that up or not, it would be something for you all to look at before you're preparing a draft report.

And finally, the issue that again Tim brought up a little bit that we ought to be thinking about is as one of the public speakers challenged whether bundled payments actually suppresses innovation. And if that's the case, that's a really important issue that needs to be thought about publicly in many different circumstances. And you can make -- I think he made the argument and you could make the argument that that's what some of the nationalized focuses have been. If that's true, then episodic bundles for comprehensive care have issues with respect to innovation that need to be thought through.

And so again, my final challenge, which I hope will be part of our letter, whether it's a combined letter or a single letter, is

that I would challenge all the stakeholders who spoke today and any others involved in this part of the health care ecosystem to get together to come back either with a proposal to us or to CMS directly addressing the care model and the payment model in a way that would be comprehensive to solve this problem.

CHAIR BAILET: Thank you, Grace, and you took the words out of my mouth. That was going to be my recommendation, that clearly there needs to be more coordination as a proposal would be constructed. The viewpoints from the commenters was very helpful for me in sorting this out. And also again commend Dr. Farooqi for blazing the trail and bringing this to our attention.

I voted not to recommend, but clearly I've already made comments earlier, so I don't think I want to reiterate those in the interest of time.

I'm going to turn it over to Bruce.

MR. STEINWALD: Like Tim and Kavita,

I was re-channeled from refer to not recommend largely because I thought the sentiment among the members of PTAC was pretty consistent. I didn't sense any major disagreement about how we view the issue, so I'm fine with not recommending but then raising for -- the issues we've discussed.

Also since I raised the issue myself in the PRT Report of whether this is a problem that could be fixed by amending the fee schedule, I think maybe that needs to be addressed a little bit. There certainly could be improvements. And I don't mean to say that that's not an issue at all, but I guess I'm convinced in large part because of the discussion here that this is not just a fee schedule issue. And a major part of that conclusion is that if we believe that the way -- the care model should be a multidisciplinary team approach, just adjusting the fee schedule won't get you there.

CHAIR BAILET: Paul?

DR. CASALE: Yes, I also -- well, I voted not recommend both times. And I guess the only other point I'd make is that I -- which is what I think, Jeff, you and Grace and others have said, is I would encourage them to bring it -- get all together and bring it back here. And although, as Len points out, we're 0 for 18, or whatever, I do think there's value. I mean, yes, we could refer it to CMS and see what happens. I would really encourage them to come back here with a more comprehensive model that we then deliberate on and presumably move forward as opposed to -- so I'd really emphasize that in the --

CHAIR BAILET: Yes, and I just guess I should have been more clear.

DR. CASALE: Yes. You did, yes.

CHAIR BAILET: I think that that is the path, right --

DR. CASALE: No, I agree, but --

CHAIR BAILET: -- that we come back. Yes.

DR. CASALE: Right, but we're also going to make some comments about, well, we could refer to CMS as well, so I'm just balancing those two. I would strongly encourage the return here with a comprehensive payment model, as you said.

CHAIR BAILET: Thank you, Paul.

Jennifer?

DR. WILER: I'm going to echo a couple of the comments that have already been made.

First, again thank you to Dr. Farooqi for bringing up what obviously has sparked a really interesting conversation and highlighted an important issue that will carry into the second session.

My first comment will be to echo the recommendation of the specialty societies that some of these issues may be resolved within the current fee schedule, and I think in our letter we should specifically describe what some of those are. If there's currently a disincentive

to provide patient-centered care on one visit and extend it over multiple visits, that should be addressed in addition to the mis-valuation or as a description by a specialty society or societies undervaluation of current codes.

I too voted not recommend both times, but agree and would really encourage the specialty societies again to get together and describe what ideal care looks like. It sounds like the distribution is a bimodal distribution, not that ill versus highly specialized care. And we heard in the public comments the care team could include hyperbarists, infectious disease providers, interventional radiologists, podiatrists, primary care providers, general surgeons. And I'm sure there's many that I have left out. And that's only the specialists and doesn't describe the interventions of which those specialists use in addition to these skin substitutes.

So understanding a care model and then developing a payment model that addresses

these two what sounds like very different patient populations would be important.

And finally, I will -- sorry, not only payment model, but then I will go deeper. That would help us to better understand then what we are looking to judge, and that's the cost and quality metrics, because those -- the quality metrics in particular may be different for those two distributions. And then also I would encourage the societies to clearly describe what care coordination looks like and make sure that they include this technology component that we're asked to evaluate. As was described before, I think the experience in the oncology space is a good one to refer to. Thank you.

CHAIR BAILET: Thank you. Angelo?

DR. SINOPOLI: So thank you. Some great comments around the table, and I voted twice to not recommend. And I was on the PRT Committee and had a lot of great discussion in the PRT Committee with Dr. Farooqi, and just

again want to thank him for bringing this issue to attention.

And as I hear the comments though, nothing around this table I disagree with. I do think some of the issues may be site of service or undervalue, some of the codes. My biggest concern is that this is such a broad issue, to Grace's points, that we would have to assume to create an accurate bundled payment model that we know exactly what the bundle covers, what the care model covers and that we could actually create a bundle that would include every specialty that might theoretically be involved in that bundle.

And so to Tim's point, this really to me is best paid for in a population health type of broad payment model as opposed to a bundle, and maybe the bundle just needs to be very limited in scope if there is a bundle.

I think the first thing that needs to happen, I agree that the specialists and the commenters in the room; Dr. Pittman, would be

best served by helping us understand what a care model would look like, what aspects of care are most common, what would be used most commonly, how that would get paid for? Then how the peripheral specialists that need to be involved could be involved in a payment model that weren't maybe part of the core bundle. But certainly something that from a scope standpoint needs to be addressed, and hopefully we can get CMS' attention for that. Thank you.

CHAIR BAILET: Thank you. And we've got two of our members on the phone.

Rhonda, if you could go first and then follow up with Harold?

DR. MEDOWS: Okay. So I am the sole person who voted for referral to HHS. I will tell you that I initially vacillated back and forth between do not recommend, which I believe is correct for this particular version of the proposal. I voted to recommend to HHS because I believe that HHS is not limited to CMMI. It is a big and vast place that could address some of

the questions, concerns and the need to convene multiple stakeholders to address a complex set of conditions that result in wounds. So there are other places within HHS that could address model of care.

The fee service, I'm not really sure that the fee schedule is actually the issue. I think it's more a matter of understanding the multitude of conditions that can cause these wounds, the differences in their therapy, the need for multiple stakeholders to weigh in with their expertise.

I was really impressed with the work of the PRT. I have to give great kudos to the physician who led the proposal itself because it takes a lot of courage to go out there and to do this, in addition to a lot of work.

But I will tell you that the stakeholders who spoke today actually influenced my decision the most. Thank you.

CHAIR BAILET: Thank you, Rhonda.

Harold?

MR. MILLER: I was -- I voted not to recommend. I was one of the ones who changed. I was persuaded by my colleagues in fact that I think it does need to ultimately be a payment model and PTAC is the relevant venue for that to come back to.

So, and I agree with most everything that's been said so far. What I don't agree with is I don't think we should be stating or recommending that this should be a risk-adjusted episode payment model. That doesn't mean I agree with Angelo either. I don't think this should only be a population model. I think there are a variety of things that could be done by improving the fee schedule. I think there are ways to introduce some episode cost and quality accountability without necessarily making it an episode payment model.

And one of the reasons why I feel that way is because I think that it seems clear that there is significant diversity around the country in terms of the resources that are

available and trying to come up with a one-size-fits-all program could be -- take longer and be more challenging without achieving the kind of quick results that I think are really deserved here.

The one thing I want to emphasize is I do think that it is critical though for -- if stakeholders do come together to plan something different that they have to have better data to be able to do that. And I would like to see our report reflect that while PTAC could potentially provide such data, has the mechanics to provide such data we are not technically authorized, we are prohibited from providing that kind of information.

So I do think it has to come in some fashion from HHS and I think it is important that that data analysis be careful, comprehensive and iterative. And I think it particularly needs to be stratified, it needs to stratified by part of the country so that one can see where there are differences. I think it

needs to be stratified by type of patient, and that doesn't just mean diagnosis. For example, I think there are issues in terms of end-of-life patients with wound care that need to be addressed separately that we haven't talked about today. But I think it's critical that that kind of data analysis be made available in order for the stakeholders to come up with something that is a realistic both care delivery model in multiple places and a payment model that would support that.

CHAIR BAILET: Thank you, Harold.

And again I want to thank the commenters, the folks on the phone, Dr. Farooqi and the process. And we're going to go ahead and adjourn until 12:30. So we don't have a lot of time, but appreciate it. Thank you.

(Whereupon, the above-entitled matter went off the record at 11:54 a.m. and resumed at 12:49 p.m.)

CHAIR BAILET: Okay, we're going to go ahead. Please take your seats. And we're

going to go ahead and start the second part of the public session today.

I have the distinct honor of introducing our guest speaker, Adam Boehler, who is a Senior Advisor to the Secretary as well as the CMS Deputy Administrator and Director of CMS Medicare and Medicaid Innovation, CMMI.

Mr. Boehler brings with him experience with many innovative ventures across multiple facets of the private healthcare industry, including healthcare information technology and lab management services. He founded and led one of the largest home-based medical groups in the country, Landmark Health. And we had, actually, one of the public commenters who works for Landmark.

Mr. Boehler became the CMS Deputy Administrator and Innovative Center Director in April of 2018, and added the role of Senior Advisor to the Secretary on Value-Based Transformation and Innovation in July of last year.

Secretary Azar, CMS Administrator Verma, and Mr. Boehler have been very engaged with the committee. They were all here to give public remarks about the important role the PTAC can play in the value-based transformation of the healthcare system at our public meeting in September of last year. And we are fortunate to have Mr. Boehler return today.

Please join me in welcoming Adam Boehler to learn more about his work at HHS. Thank you.

(Applause.)

* **Adam Boehler, Deputy Administrator and Director of CMMI - Remarks**

Mr. BOEHLER: Thank you, Jeff. And good afternoon to you all. I am delighted to be able to join you today, if only for a short while.

As Dr. Bailet mentioned in his introduction, the Secretary, Administrator, and I were fortunate enough to be here for the beginning of the PTAC public meeting last

September. We were eager to continue to work with the PTAC and with proposal submitters as we move forward with transforming our healthcare system to one that is based on volume to one that is based on outcomes.

Today I am grateful for the opportunity to speak directly with you about how the CMS Innovation Center is working toward that goal. I will begin with our vision to transform healthcare into a patient-centered, consumer-driven model where providers compete for patients on the basis of lower cost and quality.

To achieve this, we at HHS are concentrating on four areas which we have publicly shared in a document called the Value Considerations for Model Development and Testing Fact Sheet that we published with PTAC not too long ago.

The four areas that HHS and the Secretary have focused for value-based transformation are patients as consumers. We will empower patients as consumers by enabling

access to competitive pricing and allowing patients to share financially in the benefit of choosing high-performing providers for high quality, affordable elective procedures.

The second is providers as accountable patient navigators. We will pay providers for their patients' outcomes, and remove unnecessary burdens so that they can focus on delivery of care and not on administrative tasks.

The third is payment for outcomes. We will test ways to modernize outdated payment rules that pay providers different amounts for the exact location that's based solely on that location in which the service is delivered. We are also going to expand our efforts to pay for successful episodes of care, rather than discrete services.

And fourth, prevention of disease before it occurs. We will consider a patient's health holistically and focus on early life interventions to deliver improvements over the

course of a lifetime.

We are working to develop payment models that are transparent, simple, and accountable. We are looking for transparent models that empower consumers. We're looking for simple models that reduce complexity so that participants can understand them. And we're looking for accountable models that encourage providers and others to take accountability for their population.

Finally, we're looking for multi-payer collaboration. We want to ensure that it's not us alone. We may, in Medicare and Medicaid, represent a lot of payment and a lot of concentration and scale, but this will happen if done together. And we are engaging other payers, other providers to work in unison. We want to have a system that fully transforms from volume to value. And that will be done together, not alone.

For example, we recently introduced the ET3 Model. This is the Emergency Triage,

Treat, and Transport Model. And one item that I'd recognized publicly when I started in the outcomes area is that today in Medicare we only pay a 911 provider if somebody is taken to the hospital. It's a silly incentive, and it means lots of people are taken to the hospital. I guarantee, you get what you pay for.

We have introduced a model that has neutralized that incentive. We, in cooperation with other municipalities, with Medicaid, are accepting applications where we would pay a neutral amount of money if the patient is treated in place, if they are taken to an alternative destination, like a physician's office, of if they are taken to the hospital. The goal is to do what's best for the patient and to pay people in a way where they are compensated no matter where they take the patient and where they're focusing on the best outcomes.

We also recently introduced an updated version of the Value-Based Insurance

Design, or VBID Model, and a new Part D modernization model. Together for Medicare Advantage and Part D plans we expect that this will improve care and lower costs, both to the Federal Government but, more importantly, to the beneficiary directly.

I call these models our opening act. We have more to come. We are working on other proposals, many that build on the concepts and the proposals that have been announced by this committee sitting with me here today. Their work has been invaluable in informing us and driving our models.

You may recognize common themes from prior proposals. One, we're exploring ways to reform primary care by simplifying the patient -- the payment system, reducing administrative burden, and focusing on patient outcomes.

For advanced groups we're looking at full accountability models, similar to what you'd see in private Medicare Advantage. These are built on concepts and proposals introduced

by this very committee where we've had significant engagement with those that have presented to this committee as a result.

We're looking at ways to optimize care for seriously ill beneficiaries, and to reduce burdens for organizations that want to focus on that population. This work is directly based on a proposal from this committee.

We're continuing to evaluate and look at how hospital-based care can be delivered at home. We would like to define care on the basis of the care delivered, not based on the basis of physical walls, which we consider largely irrelevant going forward. This is directly based on a proposal from this committee.

Finally, we're looking at ways to support better patient-centered kidney care. The current system cannot continue as it is. We need to provide the right incentives. We need to focus on kidney care before end stage renal disease, looking at chronic kidney disease four,

five, looking at a combination model. We want to create avenues for all to participate, whether they be a large dialysis group, whether they be a single nephrologist. And that, this proposal directly came from this committee that we are significantly evaluating and hope to have more news in the not too distant.

We've relied heavily on PTAC's rigorous review. I will say that at the Innovation Center we have no shortage of ideas that come. We take a lot of stakeholder meetings. That's important to our process. We are very focused on making sure that stakeholders have the ability to interact with us. And those stakeholders include providers, payers, hospitals, members of Congress, committees, a wide variety of stakeholders that we engage with. And we think that's important and it's part of our mission.

But the role of PTAC has been enormous to us. You have a serious amount of experience across this table and the ability to

understand and give us recommendations on where to focus. Because, as in most of life, time is your most valuable resource. And we need their experience to guide us, to let us know where to focus our efforts so that we can further our mission of improving quality and reducing costs for Americans.

Thank you very much. Thank you for having me. I appreciate it. Thank you for all the work you do.

(Applause.)

CHAIR BAILET: Thank you, Adam, we appreciate all your support. Thanks.

*** CMS SUPPORT OF WOUND CARE IN PRIVATE OUTPATIENT THERAPY CLINICS: MEASURING THE EFFECTIVENESS OF PHYSICAL OR OCCUPATIONAL THERAPY INTERVENTIONS AS THE PRIMARY MEANS OF MANAGING WOUNDS IN MEDICARE RECIPIENTS SUBMITTED BY UPSTREAM REHABILITATION**

All right. So we're going to go ahead and key up the next proposal, which is Upstream Rehabilitation: CMS Support of Wound

Care in Private Outpatient Therapy Clinics: Measuring the Effectiveness of Physical or Occupational Therapy Interventions as the Primary Means of Managing Wounds.

MS. McDOWELL: Jeff.

CHAIR BAILET: Yes?

MS. McDOWELL: Excuse me. We didn't do the final summary for Seha.

MS. PAGE: We did, actually, yes.

MS. McDOWELL: Okay.

CHAIR BAILET: Did you -- Well, what do you want to do?

MS. PAGE: I think the last round of the Committee comments captured it.

MS. McDOWELL: Okay. All right.

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

CHAIR BAILET: All right. So, we're going to go ahead and turn it over to Harold Miller who is on the phone. He is the lead for the preliminary review team. It was also comprised of Kavita, Dr. Kavita Patel and Bruce

Steinwald.

MR. MILLER: Thank you, Jeff. And I apologize to everyone, particularly Dr. Probert and the submitters, for not being able to be there in person. Some illness got me down.

But, and I want to thank, as Jeff mentioned, my colleagues Kavita Patel and Bruce Steinwald who are on the PRT, and also Audrey McDowell and Adele Shartzer who staffed us.

I'm going to jump to slide 3 here to start out.

Slide 3 describes this proposal went through two, two stages. The proposal you're reviewing today is a resubmission from an original proposal that was submitted last year. And, in fact, this is on wound care. This actually preceded, came in earlier than the wound care proposal that we talked about in the morning.

We went through an extended process with the submitter. Had a series of questions about the original proposal, which they

answered. We developed an initial feedback report to them. Had a conference call about that.

At that point, they agreed that they should withdraw the original proposal and submit a revised proposal to try to respond to some of the issues that were raised in our initial feedback report. So, we then received that. In that revised proposal this fall we requested some additional information on that. We received responses to that.

And so the PRT report that you have is really based on our review of both the original and this now-revised proposal and the responses to it.

Slide 4, the proposal overview. This is a important, potentially important piece of background. The submitters did not necessarily view themselves as coming in and designing a national payment model. They wanted to do a pilot project to evaluate the ability to deliver better wound care through physical and

occupational therapists. But, as in many cases, without a payment model to support that, it's impossible to deliver the different services.

So they proposed a payment structure to be able to support that, but with recognition that they didn't necessarily have all the answers to how things could be structured.

The goal with this is really to enable physical therapists and occupational therapists to do wound care, and particularly to manage chronic wounds for Medicare beneficiaries. And this was viewed as, by them and by us, as being potentially valuable, particularly in rural areas, because rather than having to travel a long distance to a hospital outpatient department when no one is available, that physical therapists and occupational therapists might be able to improve access for patients in those areas, as well as potentially other areas.

So, the idea was that physical therapists and occupational therapists, that I

will refer to from here on as PTs and OTs for simplicity, would be eligible if they had advanced training in treatment of wounds. And they already do get training in treatment of wounds, and the ability to track and report on outcome measures.

Beneficiaries would be eligible if they needed wound care, but also if they needed therapy. And that's one of the unique aspects of this is that it isn't just about wound care, it's about people who need wound care and who need wound care from someone who can also provide physical or occupational therapy.

So, the referrals would come from a primary care provider to be able to deliver these services by the PT/OT. And then the PT/OT under the proposal would basically stay in touch with the primary care physician, as they do today, for physical or occupational therapy which is somewhat irregular. That was one of the issues that we identified in the proposal.

Slide 5. The payment methodology

here is unique and has many beneficial aspects to it or desirable aspects to it. And I want to commend the submitters for having developed something that goes beyond the run-of-the-mill payment model.

This was proposed as actually a true outcome-based payment in that this physical or occupational therapist would only be paid or would have to repay if they -- would only be paid if they achieved an outcome, or would have to repay their payments if they didn't achieve an outcome. Exactly what that outcome is I'll come back to in a second.

But that's very different from the kind of models that we have received from many other proposers.

The only other real change in terms of the structure of payment was that the PT/OT would be able to bill for a new one-time $250 payment to cover wound care supplies that would not otherwise be separately billable to be able to encourage that additional cost to be covered.

They would also get the ability to use existing billing codes for more advanced skin substitutes. Those codes already exist but it is not always clear that physical therapists or occupational therapists can bill for those codes in giving wound care.

The other unique aspect of this methodology was that there was an episode cap on the payments that was risk stratified, somewhat along the lines of the notion of a risk-stratified episode payment we were talking about this morning in that for low risk patients the cap would be $3,500; $4,500 for moderate risk; and $5,500 for high risk beneficiaries. And that would be average. It's not an individual patient cap, it's an average across all the patients in a quarter. And if the PT/OT practice exceeded that cap in a quarter they would be placed on probation. And if they exceeded it in two caps, in two quarters in a row then they would potentially be dropped from the program.

They would also have the same

phenomenon of probation and then being dropped if they failed to achieve patient satisfaction scores of 80 percent, which is another outcome-based aspect to this.

We were somewhat confused initially but found that this is not really, it's not a full episode cap, it was simply a cap on the PT/OT billing, which raised some question about things like wound care supplies or referrals to other specialists as to whether they would be included or not. So that was one limitation that I'll come back to in terms of the proposal.

There was also the question was, well, how, what's the incentive to spend below the cap? Well, there's a bonus if the average Medicare payments per episode are below the cap over a two-year period, then the PT/OT can retain three percent of the savings.

And then they originally wanted to have a waiver of the what's called the outpatient therapy cap in Medicare that has now been repealed. But they would like to have it

as part of this also exemption from having to add additional modifier codes whenever outpatient therapy billings reach a certain threshold.

They proposed outcome measures using both a wound assessment tool, which would measure progress in wound healing, as well as one from a menu of different functional progress measures, obviously depending on where the -- what the nature of the wound is, where it's located or whether pain was more the issue, and then patient satisfaction.

But the practice would have -- and this is one of the challenges with the model -- would have the choice of which outcome measure to use. And they would not be required, the outcome-based payment would not necessarily be based on wound assessment, on the wound progress, it could be based on other issues.

So, slide six, just to give you sort of our overview of our conclusions, the three members of the PRT were unanimous in all of our

ratings. We felt that it did meet the scope criterion, which is one of the high-priority criteria, but did not meet the other two high-priority criteria. And that it met four of the other seven criteria. And I will go through those all briefly to explain why.

But first, slide seven, I want to just give kind of the overall, the big picture issues that we identified. Very similar to the discussion this morning, we felt that this proposal also focused on an area where there are really significant opportunities to improve access to care for patients, improve outcomes, achieve savings for Medicare. And moreover, it also brings in a payment model to support the work of physical therapists and occupational therapists, which we had not had before.

In terms of a care delivery model, we thought that there was some potential there to improve patient access to wound care because of giving patients access to a different kind of provider than they might otherwise be able to

have. And there was a lot of discussion about the opportunity this presents in rural areas.

Our concern, though, was similar to the concern raised this morning was that this was also fairly narrowly siloed on the services that could be delivered by physical therapists and occupational therapists, which would not include all the services many patients with chronic wounds need. And, in fact, PTs and OTs are precluded under some states to do what's called sharp debridement which may be necessary for many patients who have wound care.

The payment model, as I mentioned, had several desirable novel features. The fact that it's outcome-based and that there would be some kind of a cap on the average payment per patient. But we had several major concerns about that. That doesn't diminish the fact that those were desirable features because in fact it's challenging to develop an outcome-based, episode-based model. But the model that was proposed really didn't address all of those

issues.

So that, as I mentioned, the cap on the payments only applied to the services delivered by the physical, the occupational therapist, not the total cost of wound care. It was a very weak incentive, to spend below the cap, the three percent of the savings. And those savings really would relate to the payments to the physical or occupational therapist, so in a sense you'd be getting three percent of what you didn't bill for.

There's no requirement explicitly to continue to serve the patient when the cap is reached, the dollar cap is reached, or when a desirable outcome is not being achieved. So, one of the concerns would be if in fact the patient isn't doing well they might simply be dropped. And at the other end there was no requirement that every patient who needs services would have to be accepted. So, it could raise the concern about some cherry-picking in terms of patients.

And then finally, as I mentioned before, the outcome measures are based on functional status, not wound healing. It's not bad to have outcome measures based on function, but since this is a payment model focused on wound healing, we felt it was important that wound healing be measured as part of this.

Okay, just to briefly go through each of the criteria. Slide 8, in terms of scope we felt that this met the scope criterion because it was addressing a really important patient population and because it was also a payment model for practitioners that had not had an opportunity to participate in APMs.

On Criterion 2, slide nine, we felt that it did not meet the quality and cost criterion, not because there wasn't a potential to be able to lower costs and improve quality, in fact, this would shift wound care services for some patients from hospital outpatient departments to physical therapy practices that would reduce spending. And it could well be

that with greater access that patients would be able to be more likely to get care, and thereby do better.

However, as I mentioned, the safeguards really weren't there to make sure that the patients were being selected properly. There was nothing that would make clear to the patients that in fact a physical therapist was the right provider for a patient who needed wound care and/or that the physical therapist could provide a comprehensive set of services.

And it wasn't clear that simply giving physical therapists the ability to use expensive wound care products would necessarily result in improved quality versus simply an increase in spending.

Criterion 3, slide ten, is payment methodology. We felt that it did not meet the payment methodology criterion. Again, very positive aspects of this in terms of outcome-based payment and some risk-adjusted type of a payment cap. But not a strong incentive to

spend below the cap, no adjustments for the actual amounts of payment, the supply credit. We did not see any clear justification for the proposed supply credit. And, again, the payment methodology really only involved PTs and OTs rather than an entire multidisciplinary team.

Slide 11, Criterion 4, value over volume. We felt that on balance while there were positives and negatives that it met the criterion, given that there was in fact a requirement that you couldn't simply bill for the services without achieving some improvement in outcome. So that has a much stronger value-based component than current pure fee-for-service payments do. And there was also a potential to shift care delivery from higher cost settings to lower cost settings.

But we were concerned that there were no minimum thresholds for patient participation or strong enough mechanisms for keeping the number of services below the cap.

Slide Number 12, Criterion 5,

flexibility. We felt that this did improve flexibility because it gave the physical therapist and occupational therapist additional kinds of resources, the supply credit and additional billing codes to do things that they cannot or may not be able to do today, and potentially thereby enable them to help patients who might not otherwise be able to easily get those services.

Slide 13, ability to be evaluated, this is an interesting one in that there were going to be outcome measures collected, which is unusual, and the ability to measure that. The challenge then would be to, though, compare these practices to other practices or other wound care providers that aren't collecting similar measures. And, moreover, the fact that there was no one single outcome measure or set of outcome measures that everyone will be using also somewhat complicated the ability to be able to evaluate this.

Slide 14, Criterion 7, integration

and care coordination. We felt that this didn't meet the criterion because it really didn't specify clearly how there would be close communication between PTs, OTs and PCPs and/or other wound care practitioners.

And I should say also this applies to many of our applicants, this is not a criticism of Upstream Rehabilitation and how they do their care. What we have looked -- have to look at in all of these models is what would happen if this were used broadly by a variety of providers? And the concern was that there was nothing built into the model that would ensure that there would be good integration in care coordination by any participant, not necessarily just the applicant.

Slide 15, Criterion 8, patient choice. We felt that this met that criterion because it could well enable patients in many parts of the country to be able to get wound care more easily and more affordably than they can today if they currently have to travel to a

distant site hospital outpatient department.

So we felt that it would improve patient choice. But we also thought that if something like this is done it would be very important to have good information for the patients so that they understood what they were choosing and that they were making the best choice about their particular needs.

Slide 16, Criterion 9, patient safety. We felt that it didn't meet the criterion. In some ways, obviously better wound care would be better for the patients' safety. But we were very concerned that without the appropriate kinds of protections to make sure that patients were getting the right mix of services for their needs that there could potentially be some safety issues, and the fact that there could be some potential incentive to drop patients who weren't improving could also lead to some problems.

And, finally, slide 17, the final slide, Criterion 10, health information

technology. We didn't feel that it met the criterion. This, and probably the one this morning, if people were working as a team on these kinds of things it would certainly encourage and maybe require the use of better HIT to be able to coordinate care. But there was no description of that here.

The one thing that was strong about this model was that it actually was requiring that outcomes be measured and tracked systematically for patients. But on balance we felt that it really did not meet the HIT criterion as it stands right now.

So, that summarizes the results. Let me turn to Kavita and Bruce to see if they have any additions or clarifications.

MR. STEINWALD: I don't, Harold. Good summary. Thank you.

DR. PATEL: Nothing to add except, Harold, we had a pretty robust kind of back and forth with the submitter and tried to kind of appreciate between what was originally submitted

and then the revisions as we are moving this. So I think for the rest of the PTAC to hear and maybe for the submitters to respond to it, really did feel like this was originally intended, as stated, as a pilot, not necessarily to be kind of this, I don't know, like full-blown CMMI model so to speak.

And that was really something I just wanted to underscore when the submitters come.

MR. MILLER: Thank you, Kavita. I just want to add I think, I think this is in fact consistent with what we've seen in many cases about the limited-scale testing issue is that many people really need to have the ability to try something in order to be able to work out some of the details. And it's really challenging for them to think through all the details or specify them without having been able to do it at all.

* **PTAC Member Disclosures**

CHAIR BAILET: Thank you, Harold.

We're going to open it up to

questions.

Oh, we need to, we need to have for the record we need to have disclosures. So I'll start with myself.

Jeff Bailet, I have nothing to disclose.

Tim?

DR. FERRIS: Tim Ferris. Nothing to disclose.

DR. PATEL: Kavita Patel. Nothing to disclose.

DR. NICHOLS: Len Nichols. Nothing to disclose.

VICE CHAIR TERRELL: Grace Terrell. Nothing to disclose.

MR. STEINWALD: Bruce Steinwald. Nothing to disclose.

DR. CASALE: Paul Casale. Nothing to disclose.

DR. WILER: Jennifer Wiler. Nothing to disclose.

DR. SINOPOLI: Angelo Sinopoli.

Nothing to disclose.

CHAIR BAILET: Harold and Rhonda?

MR. MILLER: Harold Miller. Nothing to disclose.

DR. MEDOWS: Rhonda Medows. Nothing to disclose. Thank you.

*** Clarifying Questions from PTAC to PRT**

CHAIR BAILET: All right, thank you.

So, if the committee members have questions for the PRT, this would be a good time to ask them. Otherwise we can bring up the submitters.

Grace?

VICE CHAIR TERRELL: Just a few questions.

We didn't really touch on this morning, per se, but this particular proposal I think may be a time to understand how much you dug into it. And then there may well be a need for the submitters to have more data for us.

One is around this whole issue of

the licensing. Obviously, some states will not permit certain aspects that others would, and how that actually would impact a federal policy with respect to the way you did your decision making around things.

The second one is are there examples of this outside of Medicare where oftentimes there's more freedom in certain of the commercial plans where this has been tried before? And did you all get any data with respect to that?

And then the third one is a larger question that really is around some of the things you pointed out here that could have been part of the broader discussion this morning, which is how much evidence-based medicine work has been done within the context and the field of wound care by the societies and all the different provider stakeholder communities in wound care that can be put together to come up with comprehensive models of care?

So, I think that those three

components if you all could just talk about how much you looked into it and then maybe get some color from the submitters, that would be useful for me.

MR. MILLER: Well, I'll start and then Kavita or Bruce can add on. And I think some of that will need to come from the submitter.

The conclusion that we drew was, first of all, the state practice act requirements differ across states. The idea would be that the physical or occupational therapist would not do anything that they were not permitted to do. They would be -- if they are permitted to do sharp debridement, and there's variations of what that means, then they, and if a patient needed it then they could do it. In other states they might not be able to do the same thing.

The challenge is that what a patient needs will vary. Some of them may need sharp debridement, some of them may not in terms of

what's going on with their wound. And what wasn't clear at all to us, and is I think at this point probably impossible to define from claims data, is how many patients there are in those categories and what's happening to them now because that's not really, you know, tracked very effectively.

So, what we concluded was that this was not requiring any violation of state practice acts, but it could potentially result in differences by state in terms of the number and types of patients that could be served.

Second, I don't think we really had any information. As you know, it's incredibly difficult to get any information about what private payers are doing. And I think the submitter may be better able to answer that than we are.

In terms of we did look into the evidence about wound care, and particularly about the advanced wound care products. And it's, it's unclear. There is some, there is

evidence that of improvement of many kinds of wounds with the more advanced wound care products.

But there is, as I recall the research -- and Kavita and Bruce may remember this differently -- but I, my recollection of the research was that it was equivocal in terms of cost effectiveness. That the cost of many of the products is very high. And unless they were used narrowly on the patients who were really having difficulty improving, that use of them might not be cost effective.

And, obviously, under Medicare the patients' cost sharing stays the same no matter what.

So, I think that is one of the issues that we struggled with here was lack of a clear evidence-base that if you did this it would work versus if you did something else it wouldn't work.

Kavita or Bruce, any, do you recall anything differently than what I stated?

MR. STEINWALD: I don't. Since I was a member of both PRTs it might be worth stating that the way in which the two proposals are most similar probably is found in the criterion scope where we all determined that there's no existing model and, second, that the current payment system is less than ideal.

After that they depart significantly in different directions, as we know.

CHAIR BAILET: All right. Kavita? No. Okay.

So, why don't we invite the submitter up to the table. And as you guys get seated we'd like you to introduce yourselves. And then you have 10 minutes to address the committee. Thank you.

* **Submitter's Statement**

MR. VAN NAME: I'm David Van Name. I'm the President and CEO of Upstream Rehabilitation.

DR. PROBERT: I'm Krisi Probert, Senior Vice President of Clinical Development

for Upstream Rehabilitation.

MR. HUNTSMAN: Stephen Huntsman, Vice President of Clinical Services and Chief Compliance Officer for Upstream Rehabilitation.

DR. BENNETT: Hi. I'm Greg Bennett. I'm a clinician and an Executive Vice President of Upstream Rehabilitation.

CHAIR BAILET: Thank you.

DR. PROBERT: Great. So, first of all I want to thank you guys for just the countless hours. I've been watching in my spare time, videoed sessions here. And I'm fan-girling a little bit because I've seen all of you guys on camera.

(Laughter.)

DR. PROBERT: So, the amount of time, and hours, and effort. And just, you know, in my experience with Bruce, and Harold, and Kavita, the time and effort that you guys put into that even though we come from a different discipline in a different area, I just want to thank you for giving us this

opportunity. We appreciate it.

So, this is not simply a proposal to address and solve the problem of wound care alone, it's a proposal that seeks to launch a prospective analysis of the patient experience, functional outcomes, and reduction of cost per capita for those patients who would have received similar or even identical care in hospital-based settings versus in private, freestanding rehabilitation clinics which, as you know, directly targets the triple aim of healthcare.

Those of us representing Upstream today, which we're the third largest private outpatient rehabilitation company in the nation, we are not wound care experts. Though, between the three of us clinicians we have treated hundreds of wounds that stood in the way of our patients achieving functional independence, from the patient with a venostatis wound that was pain free but prevented him from enjoying outdoor walking, or weakened him so that he

could not ambulate to the kitchen or stand long enough to make a bowl of soup, to the gangrenous, amputated dominant hand digit that kept a young mother from brushing her daughter's hair or made her fearful to brush her own teeth.

So, where we find ourselves now, advanced and veteran clinicians -- can I call you guys veterans? Is that okay? All right. And we're privileged to be able to view a broad landscape of patients we serve. And we're standing in awe of those clinicians coming after us who are incredibly skilled and fulfill our vision so much better than we ever could.

It is from that vantage that we were able to recognize our wound care certified clinicians who live in rural settings and who make a difference in their communities, extending wound care services to patients who would not otherwise have been able to receive those services at the level and intensity needed to return to full participation in their communities.

None of us could have finished our careers without having said that we did our very best to leverage our collective influence to extend a basic service to the communities we serve to allow our patients in rural communities parity in the treatment for the wounds that preclude their living full lives.

Admittedly, what this proposal cannot measure is the amount of money this program saves Medicare, because people are getting the services they need in the amount they need with the intensity they deserve without the inevitable, costly complications and readmissions that will result from wounds left untreated, merely because of the hassle that we're seeing that care entails.

Our mission is to leave our communities better than we found them, to interact with our patients with honor, and provide them with solutions to allow them to live better, independent lives, achieving outcomes and a quality of life they could not

have otherwise achieved.

So I wanted to address some of the weaknesses specifically and kind of dig into how we came to those.

So, therapists in the private outpatient space operate under very prescribed requirements as participants in the Medicare B program. Interdisciplinary intervention is at the very core of our practice. Physicians or physician care extenders must prescribe therapy intervention based on their judgment that the patient would receive benefit from our services. That requirement helps control the review committee's fear that therapy would be over utilized or consumed inappropriately by patients who do not require it, who simply have a chronic wound and no other issues.

However, I do have a hard time imagining any situation where a patient who has a chronic wound doesn't somehow have any other part of their functional independence being interrupted. Maybe a forehead wound, right?

But other than that I think, you know, these patients are going to have function interrupted.

Wounds by their very nature require some sort of special attention or environment that would increase the amount of time that self-care and participation in life activities would normally take. If they are painful, the patient's quality of life is interrupted and significantly impacted.

Rehabilitation is not simply about getting a patient back to lifting weights or playing tennis again or, in this case, just healing of a wound, it's about treating whatever it is that is preventing that patient from their normal, fully participatory role in life. When a wound is preventing the full, normal participation it's the responsibility of the therapist to treat that wound within the confines of their ability and their capacity in order to achieve the patient and the caregiver goals.

Just as a primary care physician

would not ignore an obvious case of psoriasis in a patient who consults with him for his diabetes, therapists are bound to serve the entire patient to the capacity at which they're able to do so.

Physicians, therefore, are the very foundation of the care coordination process. They're integral in not only prescribing that care initially, but in approving the plan of care and revisiting that plan every ten visits or any time a significant change occurs in the patient's status. The work of the therapist is in tandem with referral guidance and oversight of the physician and the physician care extender.

The physician/therapist relationship is the very embodiment of the third goal of the CMS quality strategy and, frankly, I think should be imitated by all specialty practices.

Careful monitoring and reporting on functional outcomes, consistent communication with the referral source, and the inherent

requirement incumbent on all occupational therapy services to demonstrate progressive improvement and progress toward the patient goals, fully satisfies requirement for multidisciplinary intervention, and ensures standards of quality care are followed.

Now, as to the concern that other disciplines such as surgeons would not be contacted as needed, physical and occupational therapists are well trained as a fundamental tenet of our profession to treat within the confines of our practice acts and our capacity, and to involve other healthcare professionals when necessary. To imply that a model would be needed to enforce that specifically is analogous to saying that a primary care physician would need a payment model to enforce their involvement of a surgeon or other specialists when the condition evolves beyond their expertise.

Additionally, we're highly trained in and fully understand our respective national

practice standards to which we are sworn to uphold upon entering this profession, and fully understand that we must demonstrate the skills, education, and certification needed to participate in any practice area.

Again, it would be analogous to having a patient model needed to remind a primary care physician without further training and board certification that they're not qualified to perform surgical procedures.

The additional concern that there are certain state practice acts that do not permit sharp debridement for therapists is not new to our industry. It is inherent to the practice of our profession that we must consult the most restrictive guidelines to practice. Often, the state practice act does limit certain activities that the payment sources actually permit. In those situations, we always adhere to the stricter limitations set by the states under which we're licensed.

Now, highlighted as another weakness

of the model was the lack of data to support the assertions. I fully agree. The data that we have to pull from is limited to our own practice of 20 clinicians in a geographically isolated area in the Southeast.

For example, to arrive at the $250 of payment for supplies I took a trailing 12-month look at one of our busiest clinics. And they spent about $26,000 in supplies. And over that period of time they saw 103 unique patients. So, from that I said, okay, that's $250 bought, so that's where I had to come up with that. You know, again, a starting point because I just don't have any other starting point.

But what we do as practice directors is our success depends on our ability to deliver the highest quality care with a focus on achievement of functional outcomes and superior care to our patients, while ensuring that they get that just-right care. Right? We don't want to over utilize, we don't want to underutilize.

So we have to manage those practices appropriately.

This proposal would allow for specific, open sharing of data in a prescribed format, in a collective data warehouse for a period of two years precisely to achieve the goal of demonstrating savings under the private rehabilitation clinic model versus hospital-based models. Admittedly, the difficulty will remain to ascertain and analyze comparative data from hospital-based settings. But, again, we're going to have to lean on our friends at CMS to whom we're providing this data to help us analyze and make recommendations based on comparable settings.

So, as for the incentive for clinicians to manage patient episodes under the maximums prescribed in this model, we proposed a three percent savings for each patient claim under that maximum threshold as a carrot. And then the stick of removal of the program for two consecutive years if they're not meeting those

goals.

Therapists under this model are going to be required to meet the provisions of the MCIDs for outcomes and patient satisfaction. And we can certainly address those MCIDs, but those are, you know, basic, they're based on research. NIH has developed the MCIDs for multiple models that we proposed. And we're going to lean on those recommendations.

So, there are always patients who will not show functional improvement quickly enough during the prescribed time line. Again, it's incumbent upon us as part of our training and oath as clinicians to continue to provide care for these patients as long as they're showing improvement, even if it means possible probation if the clinician has multiple patients who exceed the stratified amount.

But keep in mind, again, this proposal doesn't fundamentally replace the Medicare payment system. It's intended to track and monitor those patients within the tiers set

forth in this program in order to justify a more fully fleshed out overhaul of the program.

As for the separate payment for the cellular and tissue-based products, again we're asking that those be separate, not an in addition to. Those patients would probably be getting these CTPs anyway. We're just asking to allow us to go to that program. And I would suggest that we do a DME-based type program for that as well for initial separate certification.

So, finally, we own and champion the realization this proposal is more than about healing wounds. In fact, that's the point. As we're firmly embedded in our patients' lives, we understand that it is more than wound healing. It's more than the achievement of a certain range of motion or being able to lift the poundage. It's more about the so what? You know, this wound precludes them from so what?

And certainly we want to address wound care centrally in this program, but we also want to look at how is that then precluding

their lives. And we feel like that therapists are well positioned to do so.

So, thank you for viewing this model through the lens that this is our profession's only route to seek the opportunity to measure and prove out our effectiveness in this arena. Thank you for allowing us to achieve our mission, which is to leave our communities better than we found them, to interact with our patients with honor and provide them with solutions to allow them to live better, independent lives, and achieving outcomes and a quality of life they could not have otherwise achieved. Thank you.

CHAIR BAILET: Thank you, Krisi.

I'm going to open it up to my colleagues for questions, starting with Len Nichols and then Bruce.

DR. NICHOLS: Great presentation. And not just because I like your accent.

(Laughter.)

DR. PROBERT: I like Grace's accent,

too.

DR. NICHOLS: Well done. Well done.

So, obviously this is creative. And we applaud that. And I heard from Harold that you originally proposed it as a pilot, and the 200 sort of cutoff makes a lot of sense.

Did you all go to CMS and ask them directly or CMMI, like what pray tell led you to our door?

DR. PROBERT: What pray tell led us here. Right.

We actually did do that. We went to the Innovation Center first.

DR. NICHOLS: Okay.

DR. PROBERT: And that's probably, what, two years ago I guess?

MR. VAN NAME: Yes, about two years.

DR. NICHOLS: Okay.

DR. PROBERT: And they said, this is fantastic, we love it. But we're kind of the end goal.

DR. NICHOLS: Yeah.

DR. PROBERT: So, you guys go through this process.

DR. NICHOLS: Yes, we're used to that. Okay, fine. We're happy to play that role.

DR. PROBERT: Great.

DR. NICHOLS: So, at this point, knowing what you know, and who you know, and what you've learned, and what you'd like to learn, can you imagine working with a larger group of folks focused on wound care to come up with what I'm going to call a really cool demo, a really cool pilot? Because that seems to be kind of where we all are.

Like, I love your actual using of algebra to compute the 250, and that you had real numbers. But, you know, it's -- so, so how do we get to do that in the quickest possible way?

My sense is, my sense is telling you to go back and figure that out is not an option. You've done what you can do now. We've got to

figure out how to take it from here.

DR. PROBERT: Sure. And it is hard.

DR. NICHOLS: So what's your -- yeah.

DR. PROBERT: And, as you know, the bundled payments space, right, has been attempted --

DR. NICHOLS: Right.

DR. PROBERT: -- not successfully; right? So it's very hard I think with, you know, multiple systems. We have lack of interoperability between our health information systems that's not been successful in our industry. So, really that's why we focused on let's control what we can control, our piece of this.

DR. NICHOLS: Right.

DR. PROBERT: Right? And so, I agree, I don't know how.

DR. NICHOLS: But do you have natural partners you can think of, and maybe some of your clinicians can point you to, so

that you could make this, if you will, a larger conversation?

DR. PROBERT: I think we could, yes.

MR. VAN NAME: I think the key here is that we do have comparable industry partners, other companies that are in the same space. And this proposal was really born out of a need.

This was for us, when we started to do business in central Tennessee where there was a great deal of distance between our clinic and the nearest community hospital, that the need was there from our clinicians that were saying we really have to provide these services between these Medicare patients otherwise would have to drive more than 35 miles to a hospital. And, therefore, they wouldn't do it. And they wouldn't get care. And that would create other comorbidities that would be problematic.

And so that's where this really, really came from for us. But we have similar companies in our industry that also have the same problem of rural clinics that have a need

for their patients. And so I think it would be pretty easy to actually source the patients.

The comparability of the data is what we need to do. But there are industry standards that could be established for measuring the quality of outcomes. And almost every one of our providers participate in some outcomes measurement tool today as, you know, most healthcare providers are aiming for that anyway.

MR. STEINWALD: Krisi, you used the analogy a moment ago about how you wouldn't need to have a model or a set of rules to persuade a primary care physician that he should refer a patient to a surgeon if the patient needs surgery.

And yet, an awful lot of medical care is sort of right at that nexus of do we continue to treat without a major intervention, or do we need to refer the patient on for an intervention that's different from what we're providing ourselves.

My question is since your organization that's submitting the proposal is oriented to physical and occupational therapy, how do you ensure that the services that a patient gets for wound care are sort of neutral with respect to the discipline of the various providers who could be providing care, and not too much focused on physical and occupational therapy at the expense of other providers?

DR. PROBERT: So, you know, when we set out from the onset of the treatment of the patient, you have certain goals that you need to meet. And those goals really guide the plan of care that we write and how we're going to achieve those.

In order to really be paid and receive payment from Medicare, we have to show progress in those areas. So it is, it behooves us if something is happening with that patient that they're not improving, and I realize that another, you know, another source needs to be consulted, I really have to do that or I can't

achieve my goals. Right?

As a hand therapist if I have a, you know, a tendon injury that's not -- that should be healing, that I've made all the appropriate adjustments and I've treated the wound, and there's a, you know, a suspicion of infection, well, guess what? I'm not going to meet those goals that I have set. I'm not going to get paid for that service if I don't refer them back to the plastic surgeon, if I don't refer them to further care.

So I think it's all part of that inter -- you know, the interplay of that plan of care with the physician that you're partners in making that patient better.

CHAIR BAILET: Jen.

DR. WILER: Thank you very much for your presentation and for continuing to highlight what is clearly a problem with the current Medicare fee schedule. My question's going to be similar to one that I asked this morning of the other group, and that's with

regards to our evaluation of Criterion 1, which is scope.

We're asked to consider the overall potential impact of the proposed model on physicians or other eligible professionals and the beneficiary of participation. Obviously, the space with regards to beneficiary participation is large, both in number of beneficiaries affected, in addition to total spend.

But do you have any sense of with your proposed model should it be scaled beyond a pilot, what the total number of occupational therapists or physical therapists who might be involved in these models, acknowledging that there is this concern about state scope of practice rules?

DR. PROBERT: No. And that's an interesting question. I did try to look at some of the specialty organizations that certify physical therapists as wound care specialists and occupational therapists as wound care

specialists. And there's not a lot of data out there.

Now, just like anything, once there becomes an opportunity in this space that it's not a loss leader, that would probably encourage more folks to go down this route and get that certification.

Matter of fact, when we saw success in our small little model in Tennessee, we then had more clinicians stepping up to say, you know, I want to go this route.

So, so it, I think if you build it they will come if we do that. So, but I don't have any ideas of what numbers we'd be looking at.

You know, I know you guys saw in the proposal that for 200 clinicians that I proposed to be in this, they could touch 18,400 lives over the course of two years. So, you know, taking those basic numbers and try to extrapolate I think, you know, at that ratio we can have a significant impact on those

beneficiaries.

MR. HUNTSMAN: And to that point as well I might add, we have, in the profession we have therapists who this is almost all they do. It's a passion, it's a love. They really enjoy wounds. And having been trained in that in PT school on my end we had several therapists that really enjoyed that aspect of it and really wanted to treat wounds. But they're limited on where they can work because it's harder to be able to deliver that care in a rural setting when you're not getting paid for it.

So, where do they gravitate towards? The larger metropolitan areas. And then, guess what, the patients follow them there.

So with them not having the resources out in the other communities because they're not getting paid for it, well then that's a challenge for us. So, we want to recruit them into these areas. They're like, gosh, I really love wounds. We're like, we don't really have that option here for you. And so

they stay where they are.

CHAIR BAILET: Grace.

VICE CHAIR TERRELL: I don't know how much of the conversation you all were present for this morning with the other wound care proposal, but one thing that was not really particularly brought up that I'm thinking as part of a report at some level we might need to give some thought to, so I'd love to hear your comments, relates to wound care as it relates to palliative care and how these models need to think about that.

So, I will tell you one of the greatest failures I ever had in my clinical practice was a call I got from a nursing home patient that I took care of from an ambulance driver who had taken him to a wound care visit and they died in the ambulance on the way there.

They did not need that wound care. I don't know, I don't remember anything about the circumstances other than I just felt like the entire system was a clinical failure.

So, there are people that have wounds that need palliative care. And they're probably a fairly large portion. So what you all are doing, I love the name Upstream for all the reasons because it's about, it's about preventing bad things. And we heard a lot this morning from some of the public speakers about getting people back to a level of function, and improving, and having, you know, better outcomes. But the truth is that a wound sometimes is an end stage when somebody is at the end of life.

So I would just be, I would find it useful if you could give me any thoughts you all have with respect to payment models and/or care models and how we actually think about palliative care as it relates to medical appropriateness and utilization in something where there's a spectrum clinically and there's a point where clearly services are not going to be preventative but they're going to be palliative.

How do we bring that into our models of care?

DR. PROBERT: You know, I think this issue surfaced for us as a profession with Jimmo v. Sebelius where if they have a declining system, a declining disease, right, that doesn't mean that they should not get care to maintain the level that they're at. Right?

So I think that speaks to this, this segment of the population, you know, what does function mean? What does improvement mean? That's one of the great things that I love about OT, it's like what is the role for this person right now? How do I return them to that? And if that means dying in a pain-free manner, if that means this portion of their life at the maximum capacity that they can be I think that's very appropriate. So I think that has to be considered in this, you know, what does improvement in function mean?

Sometimes, sometimes that does mean maintaining a life without pain. And so I think

that's really important to have the pain measure in this. You know, if nothing else, if they're not improving in anything else am I improving their pain? Am I improving their, you know, basic standard of life they have at this point? So, I think it's a great point.

DR. PROBERT: Yes.

CHAIR BAILET: Harold is on the phone. He has a question as well.

MR. MILLER: I do. First of all, I just want to also again commend Krisi and the team from Upstream for having done all this work and tolerated all the many questions that we have asked over the past year.

Krisi, when I listen to you talk you originally, your proposal is titled Physical or Occupational Therapy Intervention as the Primary Means of Managing Wounds in Medicare Recipients. But, when I hear you talk what I hear you talking about is patients who are coming to you for physical and occupational therapy to restore functional status of some kind where the wound

is an integral part of that and where failure to treat the wound effectively, or failure to treat the wound in a coordinated way reduces your ability to achieve what is really the functional outcome that you're trying to achieve.

And we have been evaluating this model all along based on that title, which is that this is using PT/OTs as a primary means of managing wounds in Medicare recipients. And I wonder if you could comment on those two different ways of sort of characterizing the issue and whether you would be comfortable with something that was more focused on patients who really had a functional need first and foremost, with the wound care being secondary to that, rather than something where wound care is primary?

DR. PROBERT: Is that what you're saying, Harold, I screwed up on the title there? Is that what you're saying?

MR. MILLER: No, no, no.

DR. PROBERT: I'm teasing. I'm

teasing.

MR. MILLER: Maybe you, maybe you didn't screw up, that's what I'm asking here. So that you might have thought that that char -- but at least it led me to believe something about what you were trying to achieve.

DR. PROBERT: Sure.

MR. MILLER: But I want to verify whether that's true or not.

DR. PROBERT: So, you know, I don't think that we're looking at really changing the role that the physical and occupational therapist plays in the wound care setting. I'm trying to characterize what it is the physical and occupational therapist does in the outpatient setting, which is we're the person that sees them every day, right, we see them most often, we can make those recommendations. We see the changes that take place.

So, you know, from my lens I see myself as the primary person who's interacting with this patient, certainly in terms of

frequency. But I don't see this as being a change in the role that's taking place right now in the outpatient setting or even in the hospital-based setting.

So your point is well taken. I think it does beg the question of do we need to change this title should it go forward into something that more accurately reflects what it is we're trying to do here.

MR. MILLER: So let me, can I just follow up then? And just to be clear, would you be comfortable -- and I'm just throwing out a concept, I'm not making a recommendation to you -- if this, if this were about limited to patients who were in need of physical or occupational therapy and where you're proposing to give the PT/OT some additional tools to be able to achieve, namely related to wound care, to be able to achieve better outcomes in physical and occupational therapy would that -- would you say yes, that does characterize what we're talking about?

DR. PROBERT: Yeah. I -- yes, it does, Harold. That's a great suggestion. It actually it would characterize it better.

MR. MILLER: Okay, thank you very much.

CHAIR BAILET: All right, thank you.

Tim.

DR. FERRIS: I am coming late to the party here.

So, I'm just thinking about the nursing home setting. And we talked earlier about, you know, the way forward in terms of models of care as likely multidisciplinary. And here we have a single discipline proposal. And I'm just reflecting on the fact that actually there is another clinician in the nursing home that sees the patient every single day. In fact, every single person in every single nursing home gets their medications from a nurse. That might be why they call it a nursing home.

And I just wondered why nurses in

the nursing home aren't part of the team here in this proposal. Maybe you could --

DR. PROBERT: Well, because it was focused basically in outpatient settings is why. So it's not for skilled nursing settings. We were looking at primarily in the outpatient space, so.

DR. FERRIS: Okay.

DR. PROBERT: Yeah.

CHAIR BAILET: All right. Krisi, your team, thank you so much for your contribution and sticking with us through the process that's taken us to this place.

* **PUBLIC COMMENTS**

So, as you're taking your seats I'm going to invite up William Tettelbach, who is the Associate Chief Medical Officer for MiMedx.

We've got to turn that mic on.

DR. TETTELBACH: Are we on? There we go.

All right, just to be transparent I'm going to reintroduce myself again. I'm Dr.

William Tettelbach. I am the Associate Chief Medical Officer at MiMedx. I'm also Medical Director of Landmark Hospital in Salt Lake City. Actually have an appointment with Duke University through the Department of Anesthesiology, hyperbaric medicine.

So, just recently over the last eight years I was the Executive Medical Director over all the wound care that had to do inpatient for 22 hospitals and 10 outpatients. We are an interesting institution in that we are a hybrid patient- or population-based system as well as a fee-for-service. So we've been heavily driven to find ways to support, you know, population health or, you know, keep people out of the system but healthy at the same time.

So we for years now have done a similar model like this. So I'm actually up here in support of this proposal for a number of reasons.

One, we need more access, more access to wound providers, PT and OT. At least

PT has been well established as wound care providers. But we were able to up and improve the ante by bringing in collaborations with physician wound specialists, as sort of was implied here today.

And we did that through a number of mechanisms. So, concerns about safety, concerns about integration of technology, there's great tools, affordable tools out there that will let you do this now.

There is a, when you are measuring metrics for success in this model, when you are measuring wounds and how they're percentage-wise healing over time there is a 40 percent error rate from hand-measured wounds every time you measure. So there are now handheld devices, you know, there are apps that are integrated into EMRs that have consistent measurement every time that can be seen by the person taking the picture and whoever is collaborating with them.

The other is using telemedicine that is, like, HIPAA compliant, through Skype for

Business. So if you can integrate clinician or wound care specialist critical care access, or even if Upstream had a dedicated wound physician who was able to do consultations weekly or based on a risk stratification, high risk was once a week, and then maybe, you know, lower encounters needed, part of the problem is, is when you're paying a DRG or a bundled payment we had great success in the home care setting with this. But Intermountain brunted the cost of having us go into the home with the home care nurses who were also doing wound care. Similar model but we were able to do data analysis and actually publish abstracts to show that we had significant reduction of utilization of admissions, also bringing folks into the outpatient clinics.

So if we had paraplegics who couldn't come in and we were able to go to the home and do debridements and notice infection, and work with our home care nurses, we could do the prescriptions. And even the scope issue, most PTs are allowed to do a level of

debridement that doesn't get into viable tissue. But some don't have the comfort level of doing it.

But when you are there walking them through a super -- you know, a sharp or superficial debridement it becomes more effective.

So, I think there are modifications that need to be done, or at least introduced. I think this is a worthy model, very worthy. And if there is a way -- and I know CMS has introduced new telehealth billing codes to allow for more variation or expanding the utilization of this, but we still run into the fact that, like, with home care coming in at the same time there is not a code that allows for a simultaneous consult. So that's something that would have to be addressed.

And then the sense of hospice. A lot of hospice care, you know, there's codes for that. So a GW, a GV or a GW, I think that could be another level of, say, risk, you know, risk

associated with the cost. So if someone is now put into hospice it's really kind of back -- even though complicated, it's back to simple basics: just comfort, and making sure that we're not going overboard.

So this is, you know, so I'm, I feel from a practicing clinician, someone who is really a proponent for population as well as supporting the fee-for-service side at the same time, this model fits that. It's something that we need to think about moving forward.

And I appreciate the time and consideration. Thank you.

CHAIR BAILET: Thank you for your comments. Appreciate it.

Is there anyone on the phone?

DR. TETTELBACH: One other thing was the Q codes with this. They need to be expanded to allow because there are basically data that support, there is, there is published data on the cellular or acellular products that are bioactive that actually improve outcomes. As

long as the wound bed is appropriately prepared, say a debridement was done by a primary care doc and they went back to the PT, anyone can put this on as long as the wound bed is prepared.

And so that's the other statement on this. I think the advanced tissues is actually a good point on this, so keep the patient at home, conserve on transportation costs. But there has to be confirmation that it's ready for that. It's not effective if the wound bed's not ready for it.

Thank you.

CHAIR BAILET: Thank you.

No other commenters? All right.

Turn to my committee colleagues. Are we ready to vote? Any deliberation? I'm just calling for -- Harold?

MR. MILLER: Yes. I guess an issue that I'm sort of struggling with based on the answer to my question earlier is we might have evaluated this model differently. Can't say for sure because we didn't do it. But I -- a lot of

the concerns were related to the idea that this is going to be open-ended, anybody with a wound coming in.

And if there had been sort of a eligibility criteria at the beginning that said that this was for patients with significant functional limitations due to whatever, and that had a wound that would potentially preclude good outcomes and to enable physical therapists to be able to deliver additional services to do that, we might have said, well, wow, this is pretty good because, see, you're having, you're adding an outcome measure to this, to the payment, and measuring functional outcomes, and patient satisfaction and everything else. A lot, not all, but a lot of our concerns are really driven by the fact that this could be attracting patients who might otherwise go to someplace better or who might think that this is the full solution to their problems.

And some of those issues still exist, but they're mitigated to me at least

personally, dramatically if you would have kind of a limitation at the beginning.

And so I'm just, I don't know quite what it means, but I think differently about how do I evaluate the model if I think that one change to it, and again it's a change to the model, but it would be an eligibility limitation would have significantly mitigated some of the concerns about it.

CHAIR BAILET: Thank you, Harold.

Any other comments before we start the voting process?

(No audible response.)

* **Voting**

CHAIR BAILET: All right, let's go ahead. And just wanted to make up, so Rhonda Medows who is still on the phone, may still be on the phone, she's going to abstain from voting. So just so we know what the count is, appropriate count. And we're going to go ahead and get started.

If you could flash up the first

criterion.

So, 1 and 2 means don't -- it does not meet against the criterion; 3 and 4 is meets; and 5 and 6 meets with and deserves priority consideration.

* **Criterion 1**

So, the first criterion is scope. It's a high priority item aimed to either directly address an issue in payment policy that broadens and expands the CMS APM portfolio, or include APM entities whose opportunity to participate in APMs has been limited.

So let's go ahead and vote, please.

MS. PAGE: Two members voted 6, meets and deserves priority consideration. One member voted 5, meets and deserves priority consideration. Four members voted 4, meets. Two members voted 3, meets. One member voted 2, does not meet. And zero members voted 1, does not meet.

The majority has found that the proposal meets Criterion 1, scope.

CHAIR BAILET: Thank you, Ann.

* **Criterion 2**

The second criterion is quality and cost. High priority criterion anticipated to improve healthcare quality at no additional costs, maintain healthcare quality while decreasing costs, or both improve healthcare quality and decrease costs.

Please vote.

MS. PAGE: Zero members voted 5 or 6, meets and deserves priority consideration. One member voted 4, meets. Zero members voted 3, meets. Nine members voted 2, does not meet. And zero members voted 1, does not meet.

The majority finds that the proposal does not meet Criterion 2.

CHAIR BAILET: Thank you, Ann.

* **Criterion 3**

And Criterion 3 is payment methodology, high priority criterion. Pay the APM entities with a payment methodology designed to achieve the goals in the PFPM criteria.

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

Please vote.

MS. PAGE: Zero members voted 5 or 6, meets and deserves priority consideration. One member voted 4, meets. Two members voted 3, meets. Seven members voted 2, does not meet. Zero members voted 1, does not meet.

The committee finds that the proposal does not meet Criterion 3, payment methodology.

* **Criterion 4**

CHAIR BAILET: Criterion 4, value over volume, provide incentives to practitioners to deliver high quality healthcare.

Please vote.

MS. PAGE: Zero members voted 5 or 6, meets and deserves priority consideration.

One member voted 4, meets. Nine members voted 3, meets. And zero members voted 1 or 2, does not meet.

The majority finds that the proposal does meet Criterion 4, value over volume.

CHAIR BAILET: Great.

* **Criterion 5**

Criterion 5 is flexibility, provide the flexibility needs for practitioners to deliver high quality healthcare.

Please vote.

We're missing, still missing one person.

All right.

MS. PAGE: Zero members voted 5 or 6, meets and deserves priority consideration. Five members voted 4, meets. Five members voted 3, meets. And zero members voted 1 or 2, does not meet.

The majority finds that the proposal meets Criterion 5.

* **Criterion 6**

CHAIR BAILET: Criterion 6, ability to be evaluated, have evaluable goals for quality of cost care -- quality of care cost and other goals of the PFPM.

Please vote.

MS. PAGE: Zero members voted 6, meets and deserves priority consideration. One member voted 5, meets and deserves priority consideration. Three members voted 4, meets. Five members voted 3, meets. One member voted 2, does not meet. And zero members voted 1, does not meet.

The majority finds that the proposal meets Criterion 6.

CHAIR BAILET: Thank you, Ann.

* **Criterion 7**

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

Please vote.

MS. PAGE: Zero members voted 6, meets and deserves priority consideration. One member voted 5, meets and deserves priority consideration. One member voted 4, meets. One member voted 3, meets. Seven members voted 2, does not meet. And zero members voted 1, does not meet.

The majority finds that the proposal does not meet Criterion 7.

CHAIR BAILET: And I would ask, given the diversity of opinion here on this one, do we want to talk about this or should we move on?

All right, like I said, we're going to keep going.

Okay. Well, just checking, Len.

* **Criterion 8**

Yeah, Criterion Number 8 is patient choice, encourage greater attention to the health of the population served while also supporting the unique needs and preferences of

individual patients.

MS. PAGE: Zero members voted 6, meets and deserves priority consideration. One member voted 5, meets and deserves priority consideration. Six members voted 4, meets. Three members voted 3, meets. And zero members voted 1 or 2, does not meet.

The majority finds that the proposal meets Criterion 8.

* **Criterion 9**

CHAIR BAILET: All right. Criterion 9 is patient safety, aims to maintain or improve standards of patient safety.

Please vote.

MS. PAGE: Zero members voted 5 or 6, meets and deserves priority consideration. Zero members voted 4, meets. Six members voted 3, meets. Four members voted 2, does not meet. Zero members voted 1, does not meet.

The majority finds that the proposal meets Criterion 9, patient safety.

* **Criterion 10**

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

Please vote.

MS. PAGE: Zero members voted 5 or 6, meets and deserves priority consideration. Zero members voted 4, meets. Three members voted 3, meets. Six members voted 2, does not meet. And one member voted 1, does not meet.

The majority finds that the proposal does not meet Criterion 10.

CHAIR BAILET: Thank you, Ann. If you want to just summarize for us, please.

* **Overall Vote**

MS. PAGE: Yes. The committee finds that the proposal meets six of the 10 criteria.

The four criteria that it does not meet are Number 2 pertaining to quality and cost; Number 3, payment methodology; Number 7, integration and care coordination; and Number 10, health information technology.

CHAIR BAILET: All right, thank you, Ann.

Any comments from the committee members before we move to the next phase?

(No audible response.)

* **Instructions on Report to Secretary**

CHAIR BAILET: Okay. So this is where we're making the recommendation to the Secretary. There's two parts to it.

The first part is deciding whether it's not recommended as a PFPM for implementation recommended. And we're going to vote additionally if that's the case. Or referred for other attention by HHS.

So, same lens applies. I guess the same approach applies as we did this morning. So if we could just go ahead and vote now. Thank you.

(Voting.)

CHAIR BAILET: Ann.

MS. PAGE: Zero members voted to refer for other attention by HHS. One member

voted to recommend the proposal. And nine members voted not to recommend the proposal for implementation as a PFPM.

So that does meet the two-thirds majority criteria, so the decision is to not recommend it to the Secretary for implementation as a PFPM.

CHAIR BAILET: We're now going to go around the room for comments. And include precise comments that you would like incorporated in the letter, and share how you voted.

Starting, Angelo, why don't we start with you.

DR. SINOPOLI: Sure. Because I'm the other Southern accent here on the table in committee.

So, first of all I'd like to comment that I actually like the model. And I think the comments made earlier about how this could fit into a bigger wound care model and the ability to leverage other healthcare workers in the care

of wound care is important and significant.

And so, although I voted not to recommend, I do think the Secretary needs to hear that this is an important piece of a more integrated care model. And as we mentioned to the other wound group this morning, if you can figure out how to propose something that is broader and more inclusive, then I think that would bring a lot of value to the industry today, so.

CHAIR BAILET: Jennifer.

DR. WILER: Again I'd like to thank the presenters for bringing up a challenging issue that's currently not being addressed within the fee schedule, and really being innovative in using what your organizations' best practices are to help figure out how to scale that nationally. So thank you for doing that.

I will refer to my comments from earlier today, although will repeat only a handful of them if there are members of the

public who weren't present before. And that's this idea that the committee described in-depth this morning about a care model really needing to be described so that a payment model could be ascribed to that body of work. That's just critically important.

And a number of the stakeholders are here in this room today, and it is my personal hope, and I think the committee's hope, that your groups will get together and really work to describe what does best practice look like for these patients so that we can better understand how we can incent from a payment model perspective how to do the right thing for the care of Medicare beneficiaries.

My other comment, and we said this this morning but I will repeat it now, is that it seems this rural care issue is one that is unique and we should call it specifically in the letter because a scalable payment model might not address that issue and might need a different solution, as it has with other payment

models. So I'd like to call that out.

Thank you.

CHAIR BAILET: Thanks, Jen.

Paul.

DR. CASALE: I also voted not recommend. And, again, I would also reflect on comments I made earlier today, and made by others, certainly around the multidisciplinary approach. And I think this also, so I think, I think the idea of bringing others into the -- being sure that it's truly multidisciplinary is really critical. And as we pointed out, this is a very complicated patient group.

And so, as Grace always points out, and now she has a Rubik's cube around care models, payment models, and there's also the population. So, defining the populations of patients who would fall under the care model. And as Jennifer pointed out, you know, last time it was bimodal. It could be tri. There's multiple populations, some of which this model would fit under. And then we've already brought

up some others where it wouldn't apply, again reflecting the complexity of this group of patients.

So emphasizing that I think to the Secretary, and also what we've already reiterated around developing a model amongst the various constituents who provide care for this group.

CHAIR BAILET: Bruce.

MR. STEINWALD: I also voted Number 1, although I think there were a number of admirable qualities to the proposal. And I also think that its emphasis on functioning is indeed appropriate.

But I also think that the ultimate approach that we're looking for is multidisciplinary where we're neutral with respect to the nature of the provider. What we're not neutral about is we want it to be the right service, provided by the right provider at the right time. It's both efficient and enhances quality and prevention of wounds from not

healing.

CHAIR BAILET: Thank you, Bruce.

I, too, voted not recommend. But I want to be clear, that's not a rejection. We have the position, you heard Adam Boehler speak earlier, we're here to help influence the process and evaluate these proposals with the hope that they will actually ultimately be implemented.

And so I know your group has done tremendous work in creating this proposal. More importantly, you do tremendous work every half day taking care of the patients with wound care. So I applaud the fact that you're putting this in a very precise way relative to your specialty and how to address this population. And I compliment you for your efforts.

And what we are going to do is we want to make a recommendation to the Secretary that puts this in the appropriate frame for them to address this issue with you and other stakeholders who were in the room today and are

represented by association members who are here as well, to put together a comprehensive wound care new payment model that will actually be effective and can be implemented, and can be measured, and meets the criteria that you just saw us review.

So what we, I guess my final comment would be this is a -- in a lot of these instances because of the complexity of the disease and the care that we're trying to provide, it's tough to bite this off in one shot. But you have -- hopefully, you're hearing the committee support the need for this to get wrestled to the ground and put out effectively a new payment model to take care of the patients that are behind this model.

And so my comments earlier, there's a disconnect today between the way the payment is delivered and the care that's needed. And that's a barrier to providing the care. And your proposal highlights some of that effort.

And so what we know is there is more

work to do. And we hope that if the stakeholders can get together and take the feedback that was shared today, but also shared from there's a lot of, a lot of folks working on this problem. And I've heard from Adam Boehler himself that they, too, see the need to put a model on the ground out in the field that is effective.

So, I think it's coming but it is not going to happen in the model as it's currently proposed. Thank you.

Grace.

VICE CHAIR TERRELL: I voted not to recommend, but it was a toss-up between recommend and not recommend. And I went with not recommend, mostly because I think the scope and scale of this is too small relative to the conversation, and that this is part of a solution that we need to make sure that actually gets out there.

And part of the way that PTAC has been constructed, you heard about that earlier

today, is that we're supposed to just evaluate what's in front of us and make recommendations to the Secretary. There were many things in this proposal that nobody else has done, and you did it well in that you were focused on accountability for outcomes. You came up with payment that was correlated and connected with models of care around that. And you did it in ways that were creative and unique that we haven't seen before.

So it was really hard for me not to vote for it. But it's only because I want a bigger win. And I'm afraid because of the scope and scale of our committee's, you know, mandate that if we just say, yeah, do this, that it actually will die. And what I want it to actually do is not die but be part of a larger solution that involves a comprehensive solution for wound care that takes into account all the things that we have been discussing all day.

This could be the model, the disease model if you will, or the problem, that solved

more than just this throughout the healthcare ecosystem because it requires multiple people for a complex problem that the payment system right now doesn't work for at all. And it may be big enough to actually get CMMI and Medicare's attention but may be small enough that they'll actually, you know, give some thoughtful design around it in a way that can be successful.

So I'm hoping that when you heard what Adam said today about the types of things that they are prioritizing right now in the administration such as providers being accountable, payment for outcomes, prevention, payment for successful episodes, that you realize how much of that was in your proposal relative to some of the others we've seen through the years, and how important this is that we get it right.

So I'm going to go ahead and make a recommendation for that we're going -- that we need a larger report that involves the entire

conversation in both models today where we can make this point so that the appropriate action occurs. And as part of that report I am, I'm going to again reiterate that getting all the stakeholders together, creating a recommendation that it may be a white paper, it may be a group that gets together that convenes and says, we've got this, we're going to, we're going to work on one of the biggest under-recognized problems in healthcare and Medicare, and fix it together, would be an extraordinary win.

And so I hope your leadership will continue in that way.

CHAIR BAILET: Len.

DR. NICHOLS: So I would like us to think about having three dimensions of sort of what to say. I voted not to recommend as well. And the three dimensions are what we could do for rural.

I heard a crisis in the rural. I grew up in rural, so I can relate. And I can definitely relate to people not getting what

they need because it's too far to go and takes too long, we'll just go home and change the bandage with Cousin Sally. And it ain't going to work.

So here we are.

So, rural should be addressed distinctly and perhaps immediately. And I'm going to say, what we could do now, which is payment, which is actually access to payment code for different providers. And maybe, maybe some simple payment code changes.

And then the third is obviously the nirvana of the optimal wound care dream. And I would just say this may be one rare case when the perfect is the friend of the good. Because I agree with you, Grace, if we recommended it as is it would get killed. And it would be better to make it stronger. And I believe it would be stronger if Upstream Rehabilitation is involved in all these people that we've been talking about getting together.

And that guy over there with the

grey hair who worked at Intermountain, he's got to be involved, too. So there I'll stop.

CHAIR BAILET: Thank you, Len.

Kavita.

DR. PATEL: Thank you. I also voted not to recommend. And I'll just kind of say for the report, I agree, we should combine this morning and this afternoon's in some way to show that we think that this is not just two -- they're two different proposals but similar issues.

I just want to make sure the record reflects something around the feedback that Harold was kind of getting to when he kind of asked the proposal submitters if there were to have been certain defined triggers. And so I think there are modifications that could potentially improve even the proposal, and then thinking about combining that to make it more feasible.

And then the second piece, there was some back and forth we had as a PRT with the

submitters about this concept that Krisi alluded to around, you know, you wouldn't tell a primary care physician, you know, when to send someone to the surgeon if they needed something surgical.

So I think what she's getting at is that there are standards of practice that everyone has to adhere to kind of within their training and their licensure, but I think there was a feeling, and certainly we had some feedback from the public, that there should be some definitions around that. And all we probably need to do is be more clear about that in any language.

And then the third is I think this taught me, I was the token physician on the PRT, and I was commenting, I feel like it's been months ago, Bruce and Harold and I were talking about kind of what the pitter--patter of getting a physical or occupational therapist who's involved. And I said that, you know, usually it's a little bit of like a hot potato where I

say, okay, let's just send them to PT/OT, and I do this blanket referral. And I'm praying on the other end that you get people half as smart as the people who put this proposal together.

But I would offer that, you know, probably none of us can really appreciate the really complex work that is done. And, if anything, I think I heard from our CMS colleagues on various conversations that they, too, feel like this is a "priority area." But I would submit that this is an area that, unlike other ones, primary care, kidney care, cancer care, this is one where we need a lot more education. And I would say that that's respectfully also true of our CMS colleagues, and HHS as well more largely. They probably under this roof don't have anywhere near the PT/OT expertise.

So I would encourage the Secretary from his team somewhere to Adam's team to reach out to the submitters of this morning and this afternoon's proposal to actually offer kind of a

convening of sorts in understanding exactly what are we talking about, like what is a practical experience of a physical therapist, or an occupational therapist, or a hyperbaric physician, or any of these people who deal with patients that are often kind of an end referral of sorts but aren't necessarily something that most of us have experience with.

CHAIR BAILET: Thanks, Kavita.

Tim.

DR. FERRIS: So I also voted to not recommend and would underscore what you said, Jeff, about that not being a rejection of the idea but more a reflection of the scope within we are asked to deliberate.

And I would also underscore all the other comments. I agreed with everything everyone said. I would add one comment, this is a reflection about our work, and the fact that it's interesting to me that, particularly in statute but also in our criteria, that access to services doesn't come up anywhere.

And, in fact, in the United States the United States has by far the best access to services of any country on the planet. And that's partially part of our problem. That's why we are being asked to address cost and quality.

But it is also true that in very specific areas -- and I'll highlight a couple -- wound care being one, mental health obviously being another, where actually underfunding in our system does create an access problem. It's just that in our system it is, it's generally pretty delimited. And I would just ask us to maybe that's something that we should reflect on as a committee is what is the role of access, and specifically access deficiencies, in our deliberations?

I suppose one could throw it under quality, because you can always throw everything under quality. Or it could go under scope.

But I just highlight that this, reviewing this proposal has really highlighted

for me that issue.

The other one is a workforce issue. And fundamentally what I hear going on, maybe incorrectly characterizing it, is basically expanding the scope of a certain set of professionals because they are in the right place at the right time to do this work.

So, expansion of scope is a fraught issue in all industries because of guild protectionism. And I would just say we -- and this is my own personal position here -- is that we should generally be -- look positively on expansion of scope. All the fearmongering associated with -- and I contribute to that fearmongering -- but associated with expansion of scope rarely plays out.

I think Krisi did an excellent job of highlighting the fact that it is your professional obligation to refer when it's time to refer. And that you -- you actually are putting your licensure at risk to not do that, and potentially personal financial peril.

So there are checks in place in the system. But in general, expanding scope such as in Europe pharmacists can prescribe. We don't allow that here. In other countries nurses have much more expanded scope than here. I think in general our solutions to our healthcare cost crisis are going to involve expansion of scope of the activities of professionals that are currently hindered by guild protectionist issues.

So I'd just highlight those two meta issues that came across strongly in my, in this excellent presentation.

CHAIR BAILET: Thank you, Tim.

Harold, take us home.

MR. MILLER: Well, I had the same struggle that Grace had, but I came down in the opposite way. I was the lone vote to recommend.

And I voted that way not because I disagree with most of what anybody has said so far, I absolutely believe that there needs to be a bigger approach to wound care and that we

should encourage all of the stakeholders to get together, including those from Upstream. But I don't -- I am concerned, I guess, that it's a big issue and it will take a while to be able to get to some kind of broader solution.

And I am worried that what may come out of that is a big, risk adjusted total cost of care bundle for wound care that may end up actually not working very well in some of the communities where access is limited.

And what I saw here is something that could be ready to go much more quickly and that could actually address with a much narrower area, but something that exists today, and where PTs/OTs might be available to do something in some of those areas that they can't do today.

I kind of viewed it as inappropriate for a recommendation that I would then have voted for a limited scale testing model because in many other cases we have had models that we thought were -- had problems. But if the problems could be resolved with a fairly clear,

simple change then we'd lean toward recommending them in several cases. And in this case it seemed to me based on Krisi's response to my questions that, in fact, narrowing the model's eligibility would be one simple way to be able to make that worthwhile.

And if we actually had physical therapists come in and say we simply want to be able to deliver wound care, and we're going to take accountability for outcomes and everything else, we would have said that's really great. And I -- I think we would have said that's really great. And I'm really disappointed that we can't sort of encourage that to move along further through a recommendation. But I hope that we can do that through the report and not have some testing of this model have to wait until the big thing gets done.

Because I agree with Tim, I think that this is a perfect case where a fairly limited expansion of scope, if in fact it's not turned into be comprehensive wound care for

everybody, but to be able to expand the ability of physical therapists to provide essentially two services rather than one, and two services that are related to each other, I think that actually could fairly quickly improve outcomes, et cetera. And I would like to see that be able to move forward on its own quickly.

So, I hope that we can sort of make it clear that this could be one piece of a broader solution, not simply one big model, but that a comprehensive approach to wound care could have this as being one component to it.

CHAIR BAILET: Thank you, Harold.

We do need to, I think it would be helpful to clarify. Grace mentioned combining into one letter. Tim, you agreed. But I think it would nice if the -- I'd like to have directional sense, is the committee supportive of combination and actually having a combined letter just by -- I see everybody's head nod.

MR. MILLER: I agree.

CHAIR BAILET: Does anybody not

support that?

(No audible response.)

CHAIR BAILET: So, it sounds like it's unanimous.

We were pretty precise in our conversation this morning in our comments. And I think we just carried that through for the second session.

I guess at this point I'd turn to you, Ann. Is there anything else procedurally that we need to do before we adjourn today?

Oh. Grace? Why don't you do that real quick, Grace, and then we'll turn to you, Ann.

VICE CHAIR TERRELL: So in our administrative sessions PTAC has been having a conversation about how we could improve or how we could actually improve our impact.

The legislation that put this in place, I think this was one of the most genius things to ever come out of Congress recently because we get the incredible good work of

people that are stakeholders like, like all of you. And then we get the thoughtful conversation in public like we've had today.

And what I've heard from Adam Boehler today, and he said it publicly, is how much that's actually impacting, you know, what they're doing from a policy point of view. Based upon what he said that there are getting ready to be some models to come out where we may actually see what that means in terms of how it impacts models of care or new payment models that are coming out, we had been thinking that June may well be a very good time to have a meeting that will focus on these broader issues.

There was a paper that came out in Health Affairs that our former colleague Bob Berenson and Paul Ginsburg just did where they were thinking about how PTAC could have a different role. It might be a very useful time for all of us to say, okay, here's where we are. Here's where things have been. Here's the outcome. Now what could we be?

So we believe that there may well be the opportunity to have that in public in June. There will certainly be announcements about that. Any of you all who have been through the process that wants to participate, either in commentary or public, as we design this out, we encourage you to do so. But, you know, today I believe is a perfect example of what is possible. But we need to make sure that the actual overall outcome of that is actually what we're all working so hard to achieve.

CHAIR BAILET: Thank you, Grace.

Len?

DR. NICHOLS: So I don't want to give ASPE too much instruction because they make us look a lot smarter than we are. And I'll just leave them alone. But I did want to suggest that when we combine these letters we start with what's in common, or the big picture stuff. And then have a specific section for each one.

Because I think it is precisely

describing to the Secretary the commonality of the big picture here that's the value of combining them. I just wouldn't want to get lost in making sure of that.

CHAIR BAILET: Yes. I agree, Len.

Ann, anything else procedurally before we adjourn?

MS. PAGE: No. I think the conversation that you all have had amongst yourself as well as with the submitters, and as the public comments and testimony that we got, I think was very rich. And so we typically base this, you know, when we get the transcript so we have a strong record of everything that's said.

I think we do have precedent of a former joint report that we sent to the Secretary which I think worked pretty well. And I agree to start out with here is what is in common, and here are some strong points in particular, and then here were some areas of concern, and then an overall message, you know, what, what we think should be the next steps.

* **Adjourn**

CHAIR BAILET: All right. So, I want to thank my committee colleagues, Harold on the phone, for sticking with it, and the submitters and the public commenters as well, and everyone on the phone.

Thank you all. We're going to adjourn.

(Whereupon, the above-entitled matter went off the record at 2:41 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 Advisory Committee

Date: 03-11-19

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