

**The PTAC Preliminary Review Team's Questions on
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**

Submitted by BenchMark Rehab Partners

Questions for the Submitter

APM Participants and Scope

1. The proposal states that the goal is to gather data to measure the costs and outcomes associated with delivery of physical and occupational therapy services for wound care. Do you see this as a one-time research study or as a pilot test of a long-term payment model? **My vision is a pilot test of a long-term payment model.**
2. How many physical therapists and occupational therapists do you believe would want to be paid under this model on a long-term basis? **Extrapolating from our population, I would estimate 1500 practitioners nationwide.** Do you believe that physical and occupational therapists in rural areas would be interested in participating in this model? **Yes; those clinicians are used to managing more “holistic” needs of patients and would be likely to be interested.** Would physical therapists and occupational therapists be equally interested in participating? **Yes** Would independently practicing PTs/OTs or those employed by nursing homes or home health agencies be more likely to participate? **I assume that those employed by nursing homes and home health agencies would be paid under different models, so I do not know how likely they are to participate in this program.**
3. Would scope of practice laws for PTs/OTs in any states limit their ability to participate in this model? **Yes; some states have been slow to adopt a stated policy allowing PTs and OTs to perform sharp debridement, despite the fact that both AOTA and APTA have those skills outlined in their national practice acts.**
4. Are PTs/OTs permitted to perform sharp debridement of wounds, and what proportion of wound care patients would require that service? **Yes; see response above. Both APTA and AOTA support sharp debridement in the context of physical and occupational therapy treatment. Note that in all settings, healing of the wound is not the end in and of itself; it is a means to achieve a functional end for the patient. As for the proportion, most, if not all, chronic wounds require the removal of non-viable tissue to convert it to an acute wound.**
5. What proportion of their total time during a typical week do you expect that a participating PT/OT would spend delivering wound care if this model were implemented? **This would vary by demographics of the area in which the clinician is treating. In rural areas with decreased access to hospital-based wound care centers and with a high population of adults with Type 2 diabetes, a clinician who specializes in wound care could spend 20 to 30 hours per week with these patients.**
6. Are there any important distinctions between the types of patients or wounds that PTs versus OTs would be likely to treat? **In typical practice, PTs tend to see lower extremity wounds (because functionally, they are the mobility experts) and OTs tend**

to see upper extremity wounds (because functionally, they are coordination experts); however, there is certainly cross-pollination between the two and nothing limits one from treating the other.

7. What are the minimum standards participants would need to meet in terms of training, experience, and/or certification in wound care in order to participate in the APM? **In addition to being a therapist-level practitioner (not an assistant), additional completion of a wound certification course and achievement of certification status by a recognized governing board of wound care (e.g., ABWM or NAWCO).**
8. Do you envision this model applying only to PTs/OTs, or could other providers like primary care physicians or podiatrists also participate? **PTs/OTs. I am not aware of any cost limitations that physicians or podiatrists are encountering to adequately provide these services.**
9. How did you select 200 as the maximum number of participants? **I extrapolated our pilot group to a national sample of 10 geographic regions. We have 20 therapists covering the southeast, so I expanded that to 9 additional pilot areas. I also felt like an *n* of 200 would give the power we needed to draw statistically significant conclusions.**

Target Patient Population

10. Please describe the specific kinds of wound care patients for whom you believe this payment model would generate significant savings and/or improvements in outcomes. **Rurally-based demographically (those for whom access to hospital-based wound care centers is challenging), those with significant co-morbidities (another or history of chronic wounds, Type 2 DM, renal failure, etc.), and those with concurrent functional limitations who would benefit from PT or OT following healing of the wound (compromised mobility or coordination).**
11. Please give at least two hypothetical examples of patients who would benefit from the proposed payment model and describe explicitly:
 - where and how they would likely receive care today
 - where and how they would receive care if the proposed payment model were in place
 - how the change in care would improve wound healing
 - how billable services and spending would differ between the two approaches to care
 - 1) **62 year-old male lives in a rural area 25 miles from the nearest hospital facility with limited access to public transportation and relies on friends/family for transport to/from medical appointments. He suffers from a wound on the plantar surface covering 1/3 of his foot; he has Type 2 Diabetes concurrently. He walks with crutches and is unable to reach the plantar surface of his foot due to limited range of motion in his hip.**
 - **Where and how he would receive care today: Due to the distance from the hospital-based wound care, he would either be admitted to the hospital for wound care or be seen at a hospital-based outpatient care center (if available in his area). Because of his dependence on others for transport, he might be seen 1 time per week to manage his wound. This limited intervention will significantly increase the time required for the wound to heal. Intervention**

will be focused on healing of the wound. His primary care physician may or may not be involved in the care plan.

- **If the proposed model were in place: He would receive intervention at a rural outpatient physical therapy clinic, which are often much more accessible for community members. He would have access to care 3 to 5 times per week, and would be simultaneously improving his hip ROM to allow him to achieve his goal of independent foot hygiene and application of footwear. His wound would be healed in much less time, and his primary care physician would receive notifications of his progress every 10 visits.**
 - **How the change in care would improve wound healing: Accessibility to attend visits regularly is a huge factor in improving care and wound healing rates for these patients. Often, specialized dressings that are applied need to be monitored daily or several times per week. Additionally, this patient would receive intervention to improve his overall functional status in addition to healing the wound.**
 - **How billable services and spending would differ between the two approaches to care: According to the studies cited in the original proposal, if he were admitted to the hospital, the cost to manage the wound would be above \$14k, not including the increased risk for exposure to secondary infection; a hospital outpatient episode would cost more than \$5k (and his functional limitations would not be addressed simultaneously, possibly necessitating the need for “regular” PT/OT following healing of the wound to manage his functional issues); this proposal would aim for management within 35 treatment sessions plus a \$250 allowance for supplies. If the patient is in need of skin-substitutes, the physical or occupational therapist would be able to make that judgment and apply the dressing (whereas under the current plan, the patient would require an additional visit and intervention by another provider, often not even the referring physician, but a plastic surgeon or wound care specialist familiar with the application of these dressings).**
 - **Savings for this one patient vs. hospital stay: approximately \$10,000**
 - **Savings for this one patient vs. hospital outpatient visit: ~\$1000**
- 2) **83 year-old female who suffered a burn of her right hand referred to outpatient Occupational Therapy to address wound healing, functional loss of her right hand, and pain control.**
- **Where and how she would receive care today: Patient would be seen in an outpatient clinic, most likely with a Certified Hand Therapist. No supplies would be paid for by Medicare, so the therapist will utilize the most cost-efficient, though not necessarily the most effective, dressings to manage the wound. Lack of access to adequate supplies could lengthen the time required for the wound to heal and could be ineffective in managing her pain. Following 20 visits, the therapist would be subject to a focused internal review; she would be required to explicitly state on each note going forward why the continued care is medically necessary. Should the patient require a skin-substitute, she would be referred back to her primary care physician to request he apply the dressing, who may or may not be comfortable with the application and might involve a further**

referral to a plastic surgeon. Once the patient heals and scarring begins, adhesions over the dorsum of her hand are often a complication of treatment. Because supplies of this nature are not covered by Medicare, the patient would complete an ABN and the cost of the scar management gel (pad or cream) would be out-of-pocket for the patient. Because the patient may not be able to afford the scar management pad/cream, full ROM may not be achieved and function limited.

- **If the proposed model were in place: The patient would be seen in the same venue, but because the allowance is available for wound management, the patient would be seen for less total visits due to faster wound healing and more effective scar management.**
- **How the change in care would improve wound healing: The allowance of \$250 allows for the choice of the most appropriate dressing/scar management item to allow the wound to heal faster and ROM, strength, coordination, and other functional goals approached and achieved quicker (with less total visits).**
- **How billable services and spending would differ between the two approaches to care: Faster healing and more effective scar management means less overall visits, at a savings rate of \$100 per visit, plus the cost to the patient of transportation to the clinic each time and any out-of-pocket costs she would incur to purchase the scar management pad/gel.**

12. **Would all of the patients included in the APM come to the PT/OT practice for wound care based on a physician referral, or would the PT/OT practice be able to diagnose a wound itself and initiate wound care directly? Currently, Medicare does not pay for PT or OT services without a physician referral and signing of the Plan of Care, even in states with Direct Access laws in place.**
13. **How would patients be informed about the different options for wound care available to them? In the same way they are informed about their options for receiving physical and occupational therapy currently—reliance on the physician to inform them of their choice. Would they be given the choice to opt out of receiving physical or occupational therapy services other than those directly related to wound care? As stated earlier, wound care within the context of physical and occupational therapy is a means to an end of functional improvement. So, partaking in PT or OT just to heal the wound would not satisfy the definition of physical or occupational therapy.**
14. **Are there any types of wounds or patients with specific characteristics that should not be treated by physical and occupational therapists and that should be excluded from participation in the APM? Physical and occupational therapists who are certified to perform wound care are also educated in the types and stages of wound care that are beyond their scope of practice and would refer to physicians and surgeons in these instances.**

Payment

15. **Is it correct that probation or termination of the provider would only be triggered if the Medicare payments averaged \$3,500 per visit? In what circumstances would a payment**

- per visit be this high? **I apologize, not per individual treatment session. It is \$3500 per episode (aggregate net amount of reimbursement for all visits in a treatment span).**
16. How did you determine that the maximum spending limit should be \$3,500? **Taking the average of net Medicare payments (100/visit) and multiplying by the outer bell curve of the average number of visits required to heal wounds (35).**
 17. How would the APM prevent creating an incentive for the participants to avoid treating patients who needed more than \$3,500 in services? **You could employ an exceptions or manual review process, much like the current process in place for the therapy cap exceptions.**
 18. Does the number of visits, and the number and types of services per visit, needed for good wound care vary based on the type and severity of the patient's wound? In the proposed model, the payments and spending limits would not vary based on the severity of the patient's wound and other factors that could make healing more difficult. **It does, and that is true. For permanent use of the model, you could certainly employ a staging and severity calculation much like the RUG system used in long-term care admissions.**
 19. Do you believe that the current Medicare payment rates are adequate for all of the services that would be used for wound care services, as long as the one-time supply credit is paid and the therapy cap is lifted? The study you cited on page 18 stated that the breakeven cost is higher than the reimbursement rate; can you provide any analysis demonstrating that physical and occupational therapy practices could afford to deliver the services you propose at current Medicare payment rates with the changes you propose in the APM? **That is what this model is hoping to determine. Clarification of the CPT codes that outpatient PTs/OTs can use as suggested in the model, as well as the ability to charge for skin-substitutes, will allow for a better economic return and ability to practices to actively engage in wound care without it being a loss leader.**
 20. Do you believe that the payment amounts for services are sufficient to enable physical and occupational therapists in rural areas to participate? Do you have any financial analysis to support that? **See my comment in #19 above; I think it will take all of the proposed measures to allow it to be an incentive for rural-based therapists to participate. I am hoping the pilot study will provide the financial analysis needed to make that determination.**

Wound Care Products

21. What data did you use to determine that the one-time supply credit should be \$250? **Examining our usage over the trailing twelve months.**
22. Please give examples of the kinds of wound care patients who need wound care products that physical/occupational therapists cannot currently bill for. (Do not provide any patient-identifiable information in the examples.)
 1. **Venous insufficiency: Primary dressings would be collagen, calcium or iodisorb. Secondary dressing would be foam product. Then 2, 3 or 4-layer compression wrap. The compression wraps are sold either as a package or individual pieces (cast padding/unna boot/coban)**

2. Diabetic patient: Primary dressing would be the same as above. Secondary is typically the same. No compression but we have to off load. Gold standard is a total contact cast, but most patients refuse. Next option is a walking boot. Third option would be adhesive felt with a post op type shoe.

23. Would physical/occupational therapy practices be able to purchase the proposed wound dressing products for amounts equal to or less than the Medicare reimbursement? **For the skin substitutes—yes. This would be much like an L-code for DME suppliers, where the skill of the application and monitoring of the wound is factored into the reimbursement.**

24. Does the proposal intentionally limit reimbursement for skin substitutes to those within codes C5271-C5278 and Q4100-Q4172? **No, we are asking for the Medicare allowable on these codes.**

Therapy Caps

25. Are you proposing that the therapy cap be lifted for all visits with the patient, or only for visits where wound care is performed? **All visits, as wound care would take up a significant portion of the overall care. Due to the recent permanent repeal of the therapy cap, this may be a moot point.**

26. Have you found the therapy cap to be a significant barrier to delivering good care? Can you provide examples of the kinds of wound care patients who need services beyond the therapy cap and where Medicare payment for the additional services is being denied? (Do not provide any patient-identifiable information in the examples.) **Due to the recent permanent repeal of the therapy cap, this may be a moot point. With the new process, it will remain to be seen how often patients are being denied or placed under Managed Medical Review.**

27. How often do you believe that wound care patients would need services that exceed the therapy cap solely for an episode of wound care, versus for multiple episodes of services for different conditions during the course of the year? **Patients exceed the cap within approximately 20 visits, so with the average number of sessions needed to heal chronic wounds, yes, the cap would be exceeded for patients with wound care issues as well as those needing multiple sessions of care.**

28. Please provide more detail about the burden PTs/OTs encounter when applying for exceptions to the therapy cap, such as the estimated time involved. **Again, this may be alleviated with the recent permanent repeal, but currently, therapists must add a KX modifier once patients approach the cap; they must ensure they are adding an additional layer of documentation in their notes that clearly outlines the continuing medical necessity of the services. Once patients reach the threshold for medical review, each chart is independently audited through 3 approval layers to ensure documentation reiterates continued medical necessity beyond the normal and customary documentation practices.**

29. Would PT/OT practices be willing to participate in the APM if the therapy cap could not be lifted? **Due to the recent permanent repeal of the therapy cap, this may be a moot point.**

Quality/Measurement

30. Why did you choose the Bates-Jensen Wound Assessment Tool for measuring wound healing? **This is the research-backed assessment our wound care experts find to provide the most accurate measure of healing.**
31. How much time do you estimate it will take the participants to complete the Bates-Jensen Wound Assessment Tool for each patient? Are the current wound care payments adequate to cover the additional time required to use the Tool properly? How much do you estimate that it will cost for participants to track the other outcome measures that are required? **Completion of outcomes is a standard practice for all our clinicians, as is completed as part of the evaluation and progress process. Skilled and veteran clinicians can complete it in approximately 10 minutes. The other required outcomes should take an additional 5-10 minutes. It remains to be seen if the current wound care reimbursement is adequate to cover that additional time; that will certainly be a factor to consider.**
32. Are you proposing that the score on the Bates-Jensen Wound Assessment Tool would be considered one of the outcome measures in the APM? If not, how will changes in that score be used as part of the payment model? **Yes, the scores will be part of the outcome measures.**
33. Is there any mechanism for ensuring that participating providers accurately and consistently use the Bates-Jensen Wound Assessment Tool? **We would ask that participants model our training process and employ an EMR that utilizes reminder systems for consistent use of the tool.**
34. Do you currently use the Bates-Jensen Wound Assessment Tool and the functional outcome measures for the patients you treat in your practice? What kinds of improvements on those measures have you seen for wound care patients? **Yes, we do. In 139 visits from 11/17 to 2/18, 93% had an “excellent” return to function and 100% were “very satisfied” with their treatment. Ninety-three per cent also had their goals fully met.**
35. Is the Bates-Jensen Wound Assessment Tool routinely used by wound care specialists to measure wound healing? **Yes.** Are other tools used, and which are used most frequently? **Currently, the Bates Jensen (BWAT) along with the Pressure Ulcer Scale for Healing (PUSH) and Sessing Scale, Sussman Wound Healing Tool (SWHT) are used most frequently.** Are results from these tools currently submitted to any clinical registries? **None are currently submitted to the QCDR.**
36. Why are you using measures of functional status as outcome measures when the focus of the model is on wound care? **As noted above, wound care in the context of PT/OT is a means to an end (functional independence).** Would all of the patients participating in the model have wounds that affect their functional status in a significant way? **Yes, that is why they would be seeing a PT/OT.** Could it be possible to improve a patient’s functional status without actually healing their wound? **Yes.** Would there be a disincentive for therapists to provide wound care to patients for whom it would be difficult to achieve improvements in functional status? **Wound care is seen as one of the many barriers to functional independence. Specially-trained therapist incorporate techniques needed to heal wounds in order to achieve functional goals. Therapists**

who participate and specialize in treating patients with chronic wounds are not frightened or dis-incentivized to treat difficult-to-heal wounds.

37. Is it correct that you are proposing to allow the provider who is participating in the model to choose among four different measures of functional status and pain to measure outcomes? **Yes.** How would CMS or patients compare outcomes and quality across providers? **Each measure has a MCID (minimal clinically important difference). We frequently use these measures for different diagnoses, and simply measure a percent of improvement against the MCID for each tool.** Are you proposing that each provider could use a different measure for different patients, or would each provider need to choose a single measure for all patients? **Each provider would use a different functional measure, plus pain, plus BWAT for the wound itself.** If they can choose different measures for different patients, how would that choice be made, and how could the patient and CMS be confident that the right measure was being used? **The choice would correspond to the diagnosis, which is common practice currently. For instance, the DASH (Disability of the Shoulder and Hand) is used for upper extremity-based diagnoses, whereas the LEFS (Lower Extremity Functional Scale) is used for lower-extremity based diagnoses.**
38. Please explain how the minimal clinically-important difference (MCID) will be calculated for each of the outcome measures you are proposing to use. **The MCIDs are pre-determined.**
39. How would CMS be able to verify that the outcome measures were being assessed accurately and consistently by participants? **These are self-reported measures. We currently use onset training and annual retraining to enforce the principles of data gathering.**
40. Please give examples of the kinds of patients who would *not* have achieved a “minimal clinically-important difference in outcomes” but who *would* have achieved a “demonstrable increase in functional independence” or a “demonstrable, progressive improvement in at least two objective measurements.” **Patients can improve functional independence (mobility, ROM, strength, increased independence in task performance [often through education in adaptations or environmental modifications]) while a wound is not healed to achieve an MCID. Additionally, patients can achieve a litany of functional increases that allow them to live their lives independently that may not be picked up by outcomes measures. An example of this would be a patient who is able to brush their teeth independently or perform toilet hygiene independently would have a significant improvement in their functional independence, but because these individual items are not asked on the DASH, they might not achieve MCID on that measure.**
41. Please explain how a “demonstrable increase in functional independence” or a “demonstrable, progressive improvement in at least two objective measurements” would be determined and verified. **A demonstrable increase in functional independence can be measured and documented through FIM (Functional Independence Measure) scores and improvement of objective measurements would be assessed through documented increases in strength, ROM, coordination tests, etc.**
42. Is it correct that Patient Satisfaction would be an optional measure? Why would it not be required? Why would a practice voluntarily choose to collect the information if it is not

required and if it cannot be used as an outcome to justify payment? **Many practices utilize this measure to make adjustments in their customer services (ours does). We can certainly make this a required measure and part of the calculations.**

43. What actions, if any, would the APM participants need to take to protect patients who are receiving only PT/OT services from increased exposure to infections because there are more wound care patients receiving services in the practice? **APM participants should have a designated area for wound care patient treatment and should follow all universal precautions for care. Rooms and wound care furniture (treatment chairs, etc.) should be thoroughly cleaned prior to and post each treatment session with an approved cleaning solutions. Tools for wound care should be cleaned with an autoclave or disposable, per-patient tools should be utilized for each patient session. Patients receiving treatment should be educated never to enter the practice with exposed wounds.**

Evaluation

44. Please provide more detail about how you believe the savings achieved through the model could be estimated and how spending could be compared to what Medicare would have spent for these patients. **Savings could be estimated by pulling the average visit rates for hospital-based chronic wound treatment and hospital outpatient-based chronic wound treatment (both of these can be searched by ICD10) and the average per-visit cost for those patients and comparing them directly to the per-visit cost multiplied by the average number of treatments of patients in this program and comparing the two.**

Care Coordination and Integration

45. What assurance would there be that the APM participant would communicate appropriately with the primary care provider or other referring physician? Could an APM participant be paid for all of the services they delivered even if they did not communicate appropriately with the referring physician? **Medicare requires PT/OT communication with referring physicians at evaluation, every 10th visit, and at discharge, so mandated communication is built in to this program.**
46. Would some patients need wound care services that the APM participants could not provide, such as surgical debridement? Who would be responsible for coordinating all of the wound care services these patients needed? **If services are beyond the scope of practice for the PT/OT, the clinician refers the patient to the referring physician; the PT/OT can suggest surgical intervention as a recommendation to the referring physician, but the ultimate decision is the physician's.**
47. What would ensure that the patient is referred to higher level care when needed? **This is mandated by the national practice acts (APTA/AOTA) and each state practice act.**

Health Information Technology

48. Do you participate in any qualified clinical data registries that collect medical and/or clinical data for the purpose of patient and disease tracking? Would it be possible to use a registry as the mechanism for submitting data? If not, why not? **We participate in our**

own database (not mandated by any governing body) and PQRS (voluntarily now). Yes, a registry could be utilized to track, monitor, and analyze the data.

- 49. What kinds of HIT tools are PT/OT practices currently using? What capabilities do those tools have that would assist with success in this APM? What tools are you using in your practice? The large practices utilize Raintree and NextGen typically; a few have an in-house system they have developed. Medium and small practices also use Raintree, but WebPT is a very popular choice for those size practices as well. For outcomes tracking, practices use tracking built into their EMR or easily accessible via the EMR integration, including WebOutcomes (owned by WebPT/Strive Labs) or FOTO. These systems allow for tracking of frequency and duration of treatments per diagnosis, clinician, facility, region, territory, and company-wide; outcomes per diagnosis, clinician, facility, region, territory, and company-wide; and patient satisfaction and pain ratings diagnosis, clinician, facility, region, territory, and company-wide; it also compares those values to national databases of information (all customers providing data int their system). We utilize a WebOutcomes integration into Raintree.**

PHYSICIAN-FOCUSED PAYMENT MODEL
TECHNICAL ADVISORY COMMITTEE (PTAC)

PRELIMINARY REVIEW TEAM (PRT)

CONFERENCE CALL WITH
BENCHMARK REHAB PARTNERS

Monday, April 30, 2018

10:00 a.m.

PRESENT:

HAROLD MILLER, Lead, PTAC Committee Member
BRUCE STEINWALD, PTAC Committee Member
KAVITA PATEL, MD, PTAC Committee Member

STAFF:

AUDREY McDOWELL, Assistant Secretary for Planning and
Evaluation (ASPE)
MARY ELLEN STAHLMAN, ASPE
ANJALI JAIN, MD, Social & Scientific Systems, Inc. (SSS)
ADELE SHARTZER, PhD, PRT Staff Lead, Urban Institute

SUBMITTER:

KRISI A. PROBERT, MD
Senior Vice President of Clinical Services, BenchMark
Rehab Partners

P R O C E E D I N G S

[10:02 a.m.]

1
2
3 MR. MILLER: Krisi, maybe while we're waiting for
4 Kavita, I can just start by giving you a little bit of
5 background. We can introduce ourselves after Kavita joins.

6 But I'm Harold Miller. I'm a member of the PTAC
7 and the lead for what we call the Preliminary Review Team.
8 So I'll just give you a little bit of background to make
9 sure you understand what we're up to and what sort of we're
10 trying to accomplish today --

11 DR. PROBERT: Sure.

12 MR. MILLER: -- and then you can ask any
13 questions, since Kavita will know all this.

14 But, first of all, I just wanted to thank you for
15 submitting a proposal and going through the process. The
16 whole thing is based on people being willing to develop
17 these concepts.

18 We understand, probably better than most, how
19 difficult it is to develop payment models. It's not
20 necessarily the expertise of people delivering services in
21 the community to know how to pay for things. So we're
22 trying to do the best we can to help people through the
23 process, given the limitations that we have under the
24 statute.

1 All of us as PTAC members -- myself, Bruce
2 Steinwald who is also on the call, and Kavita Patel who are
3 joining -- we are all volunteers. We are not compensated
4 for any of this work, et cetera, and we get staff support
5 from ASPE.

6 And the 3 PTAC members that are on the call
7 today, the members of what we call the PRT, are just 3 of
8 the total 11 PTAC members, and what we do, these PRTs do,
9 is we basically data gathering about the proposal and pre-
10 thinking about the proposal for the full PTAC.

11 We do not as a subgroup make any decisions on
12 behalf of the whole PTAC. The whole PTAC, 11 members, all
13 make their decisions based on deliberations that they do at
14 a public meeting, and so a lot of people are confused about
15 that. There is literally no discussion of any of these
16 proposals that goes on amongst the full PTAC membership
17 before that public meeting. So it's only the three of us
18 that have talked about this so far, and so you're basically
19 just simply talking to this preliminary review process.

20 Now, our role, statutorily, is evaluating
21 proposals against the 10 criteria that the Secretary
22 established. We don't sort of just independently decide
23 whether we like something or not. We have to evaluate
24 against the 10 criteria. So what the PRT essentially does

1 is try to gather data and information relevant to those 10
2 criteria, so that we can make good judgments about all
3 that. And so we appreciate all the answers that you have
4 already provided to the written questions.

5 Now, today is actually somewhat different than in
6 the past, so this is a little bit new for us as well as new
7 for you. In the past, what we have done with applicants is
8 after we got responses to written questions, we had a call
9 so that we could ask any final questions that we had before
10 we actually prepared our report to the PTAC.

11 And the law just changed recently that enables us
12 to provide feedback to the applicant.

13 Is that Kavita?

14 DR. PATEL: Hi, Harold.

15 MR. MILLER: Hi, Kavita. I'm just giving some --
16 a brief background -- and then we can introduce ourselves --
17 - while we were waiting.

18 So the new law that passed enables us to provide
19 feedback. So this is actually the first time that we've
20 done anything where we've actually provided something to
21 the -- some preliminary indications of how we felt about a
22 proposal to an applicant before the formal meeting
23 occurred, so this is a new process for us.

24 And so what we gave you was a draft of the report

1 that we would ultimately submit to the full PTAC
2 membership, and it's just a draft. It is not done. So
3 rather than essentially asking you questions today to
4 enable us to complete that report, we gave you a draft to
5 be able to get your reactions and feedback on that. So
6 we're giving you our feedback, but we need to get your
7 feedback in terms of what we came up with to tell us where
8 we're wrong, things that we may be missing, as well as to
9 ask us any questions about what we put in there.

10 As you probably saw in the material that was sent
11 out, we're not, though, technically allowed to provide
12 technical assistance. We can tell you where we think there
13 are weaknesses. We are not to tell you what you should do
14 about those things.

15 DR. PROBERT: Okay.

16 MR. MILLER: So you might say, "I don't know how
17 to solve that," and we'd say we sympathize with that, but,
18 you know, it's not our role to tell you specifically what
19 to do about that.

20 So that's kind of the outline of all of that.
21 Let me just introduce briefly everybody, now that we've
22 gotten through all that and now that Kavita is on the call,
23 and then I'll ask if you have any questions about any of
24 that.

1 So I'm Harold Miller. I'm from the Center of
2 Healthcare Quality and Payment Reform. I am one of the
3 members of the PTAC and chairing this.

4 Bruce?

5 MR. STEINWALD: My name is Bruce Steinwald. I'm
6 a health economist. I live in Northwest Washington, D.C.

7 MR. MILLER: Kavita?

8 [No response.]

9 MR. MILLER: Hello, Kavita?

10 [No response.]

11 MR. MILLER: She may be on mute, or she may have
12 -- we have -- Kavita is a physician and is probably doing
13 this on top of a clinic or something like that.

14 And Mary Ellen and Audrey introduced themselves.
15 Adele has introduced herself. We have a reporter, a court
16 reporter on the phone who will be recording and
17 transcribing this. There will be a written transcript of
18 this, and so we should all remember if it's not clear to
19 introduce -- to say who is speaking for the benefit of the
20 court reporter.

21 And, Krisi, do you want to introduce yourself?

22 DR. PROBERT: Sure. I'm Krisi Probert. I am
23 basically a simple clinician by background. I'm an
24 occupational therapist and a certified hand therapist by

1 background. Now I serve as the senior vice president of
2 Clinical Services for the third largest outpatient
3 rehabilitation provider in the nation, and so I'm just
4 happy to be here.

5 MR. MILLER: Well, congratulations for that.

6 DR. PROBERT: Well, thank you. Thank you. Happy
7 to be here and honored that you guys would give me this
8 opportunity, so thank you for your audience today.

9 MR. MILLER: So, first, let me ask you if you
10 have any just questions about the process before we get
11 into the substance of the material that we sent.

12 DR. PROBERT: Yeah. So you answered a few of my
13 questions. My thoughts were the "What happens next at this
14 point?"

15 So, Harold, will I have an opportunity after
16 today's call to go back and do some written suggestions?
17 Because some of the things I feel like I could address, but
18 I would love to get clarification from you guys, and some
19 of it's going to take just some thinking, processing, and
20 developing on my end how will we accomplish that. Will
21 there be an opportunity for that after this call?

22 MR. MILLER: Yes. If you feel that additional
23 information would be helpful to us that you can't provide
24 on the call, I think you should just tell us that, and then

1 we will factor that into our process.

2 What we try to do is not to impose any arbitrary
3 deadlines in terms of applicants, in terms of providing
4 information. The only effect would be that if you need
5 more time to respond, we may not be able to finalize our
6 work in time to be able to do this at, for example, the
7 June meeting that's coming up because -- so I think the
8 issue would be in terms of how quickly you would need to
9 respond.

10 Now, there's no sort of penalty for you other
11 than a delay. So if you say, "I really think it would be
12 helpful for me to get you some additional information, but
13 it's going to take me a month to do that" -- I'm just
14 making that up -- we might say, "That's perfectly fine, and
15 we'll wait to get that." But we'll basically put your
16 proposal on hold until we get that information, and then we
17 will complete the process. So that's the only issue, would
18 be the potential delay, and we can talk more. After we get
19 through the call, we can talk more about what the timetable
20 might be for that.

21 DR. PROBERT: Okay. Sounds great.

22 MR. MILLER: Any other questions about the
23 process?

24 DR. PROBERT: I think that's it so far, so thank

1 you.

2 MR. MILLER: Okay. So maybe what would make
3 sense to do would be to -- so we've sort of, as I said,
4 laid out this -- these draft reactions in terms of
5 strengths and weaknesses, and we saw, as you can tell from
6 the report, lots of strengths in terms of the kinds of
7 issue that you're trying to deal with. And you had some, I
8 thought, very creative components to the payment model that
9 many other people have not had in terms of sort of an
10 episode maximum and a refund for failure to perform, et
11 cetera, but also a variety of weaknesses.

12 So I guess we can proceed, whatever would be
13 useful for you. We can either go through point by point,
14 or if you have specific things you want to focus on, to
15 give us feedback on, or identify areas where there are
16 errors, maybe you could start with those. And then we can
17 ask questions along the way.

18 DR. PROBERT: Okay. Great.

19 What I'd love to do first, if you guys are okay
20 with this, is to start with the points that did not meet
21 and go through those weaknesses, and maybe I can give some
22 clarification or we can problem-solve about what
23 information you guys need --

24 MR. MILLER: Sure.

1 DR. PROBERT: -- to move forward. Does that
2 work?

3 MR. MILLER: Yeah, that's fine.

4 DR. PROBERT: Okay. Great.

5 So the first one I'm looking at is -- and, again,
6 for my court reporter, this is, of course, Krisi. So I'm
7 the only one with a strong Southern accent on the call, so
8 --

9 MR. MILLER: You are recognizable in that regard.

10 DR. PROBERT: Exactly, exactly.

11 So on point two -- and I saw this comment several
12 times about increased therapy use, and if you guys will
13 just elaborate on that for me a little bit, your concern on
14 increased therapy use and high utilization. I guess my
15 question there would be as opposed to what.

16 I see this as a lens of these folks need care.
17 It's therapy here versus therapy in a higher environment as
18 sort of a choice we're looking at. So if you can clarify
19 that for me, that would be great.

20 MR. MILLER: Well, I think the issue was a
21 patient has a wound. They need care for the wound. What
22 you said in some of your responses -- one of your responses
23 was essentially that that would be part of the physical
24 therapy service that you deliver and that you would not be

1 delivering wound care in the absence of physical therapy.

2 So that raises a concern that if I'm a patient, I
3 have a wound, I need wound care, the physical therapist is
4 offering wound care, but in order to get the wound care
5 from the physical therapist, I have to get physical
6 therapy. Then I might be getting physical therapy that I
7 wouldn't have otherwise gotten in order to get the wound
8 care closer to home.

9 DR. PROBERT: So I guess my answer to that would
10 be is that the two are not mutually exclusive, under our
11 practice act -- and this is nationally, I'm speaking, not
12 just statewide, but in order to perform treatment on a
13 patient, they need physical therapy. So the end game is
14 not the healing of the wound in any case of therapy
15 intervention, no matter what environment it takes place in,
16 whether it's the hospital or outpatient setting. But you
17 would never have a wound and go see a physical therapist
18 with the end game being the healing of that wound, period.
19 The way we philosophically look at the treatment of a
20 patient is, how is this affecting their function? That is
21 the end game across the board.

22 So the assumption here always is if a patient has
23 a wound, there is going to be an effect on function, so
24 that's what I mean by that, is that the wound is

1 encapsulated in the overall patient's function.

2 So if you have a wound, the therapy that you have
3 is not like, okay, I'm going to do these shoulder range-of-
4 motion exercises, separate from this foot wound I have.
5 It's not about that at all.

6 What it is, is that we look at it from a lens of
7 how is this wound decreasing your overall independence,
8 right? So if it disables you to move around like you would
9 before, it prevents you from going into certain
10 environments, right? You can't focus. You can't perform
11 your normal daily life activities because of this wound.
12 So that's what I mean by that, is that the end game of the
13 physical or occupational therapist is not just the healing
14 of the wound. It's healing of the wound in order to allow
15 them to participate fully in their functions of life.

16 MR. MILLER: So if I have a wound that is not
17 impairing my function in any fashion -- I have a cut on my
18 arm. I can still do everything perfectly appropriately.
19 It's just a wound, and it need to heal. It might hurt a
20 little bit, but it doesn't stop me from doing anything.
21 Does that mean that I could not get wound care for that
22 from the physical therapist?

23 DR. PROBERT: Well, if you had some other kind of
24 underlying -- I think I would probably argue that it's hard

1 to find that patient, that that's a pretty rare patient,
2 that, "Hey, I've just got this wound. It's affecting
3 nothing else," because normally those of us that are
4 suffering from acute wounds, they're going to heal, anyway.
5 You don't need a wound care specialist to take care of
6 that.

7 If somebody has a wound that they would need
8 treatment, that they would need to get it healed, has a
9 chronic wound, which means there's something underlying
10 going on with you to prevent you from healing on a normal
11 basis. We just don't normally see those patients that have
12 the wound and it heals because you're looking at 10 to 14
13 days normally when they move through that first
14 inflammatory phase into proliferative.

15 MR. MILLER: Yes.

16 DR. PROBERT: And they can treat it over the
17 counter. So this --

18 MR. MILLER: So I have a 97-year-old father-in-
19 law right now who has a very serious skin tear on his
20 wrist, which is having some difficulty healing and has got
21 some special bandage on it, et cetera, but it's not
22 impeding him in any fashion from doing anything.

23 DR. PROBERT: So, in that case, I would say, "Is
24 he caring for the wound independently? Is he doing his

1 wound care independently?" That's part of his life right
2 now. So is he moving through all of his daily functions?
3 Right now, his function includes caring for that wound.
4 Even though it's prolonged and protracted, for him he's 97.
5 The underlying thing for him is his advanced age. So
6 because of that, we have a wound that's slowing down, for
7 whatever reason, and directing and caring for that wound is
8 part of his normal daily routine. So if he needs
9 assistance with that to get that healed, then that's the
10 lens under which the therapist would be treating him.

11 Does that make sense?

12 MR. MILLER: Well, I guess so, but, I mean, he is
13 getting assistance. He's in an assisted living facility,
14 but he's not getting anything that you would call physical
15 therapy.

16 So I guess the question is if he came to your
17 physical therapy practice, because there was no one else to
18 care for his wound, would you simply care for the wound, or
19 would you then also add -- I guess the concern is would you
20 then also add 15 minutes of strengthening exercises on top
21 of that just because he happened to be there, but if he
22 went to a primary care physician to get his wound -- his
23 bandage changed, et cetera, there would be no such service?

24 DR. PROBERT: Yeah, I hear what you're saying,

1 and we would see if that's appropriate. You do an
2 evaluation, and you would see, hey, he actually has a
3 strength loss due to his wound or he actually has a range
4 loss due to his wound. That would be certainly something
5 that we assess.

6 But with the ICD-10 code that is only a wound
7 itself, I don't know that that would fit very appropriately
8 under the scope of physical therapy care.

9 MR. MILLER: Okay.

10 DR. PROBERT: So when we look at that in the
11 proposal, does it mean then that we identify ICD-10 codes
12 and they have to be paired with something else, like it has
13 to be a range loss or a strength loss or some kind of
14 function loss paired with the ICD-10 code? That could be a
15 possible solution to that --

16 MR. MILLER: Okay.

17 DR. PROBERT: -- if that's the concern.

18 MR. MILLER: Yeah.

19 So let me see if Bruce or if Kavita is back on,
20 if they have any questions about that.

21 MR. STEINWALD: This is Bruce.

22 I would say in general when we see models that
23 expand the scope of services that certain providers can
24 perform, this is a concern that often arises. It's not

1 unique to your proposal.

2 MR. MILLER: Yeah. But I think it comes back to
3 one of the overriding questions we had in here, was it
4 wasn't quite clear in the proposal exactly what subset of
5 patients were being addressed by this, and whether or not
6 they were patients who -- I mean, this may be a case where
7 they need wound care and they need physical therapy and
8 weren't getting either thing, but whether or not this was
9 sort of drawing an extra service along with it that would
10 not have otherwise come if they had gone somewhere else
11 with the service.

12 So why don't we move on to other points you
13 wanted to address.

14 DR. PROBERT: Sure, sure. Absolutely. And I
15 think I can give you guys more information on that piece,
16 so I've got some work to do on my end on that.

17 MR. MILLER: Okay.

18 DR. PROBERT: So the third criteria with the
19 payment methodology, no incentive to provide the cost at
20 less than \$3,500 and doesn't include adequate
21 substantiation for the \$250 supply credit. Can you guys
22 kind of talk to me more about that?

23 MR. MILLER: Well, so you have an upper bound,
24 the \$3,500, which is good, right? It's not unlimited

1 particularly whenever you're talking about removing the
2 therapy cap, but there's a lot of experience in Medicare
3 and other payment systems that whenever there is a cap,
4 people go right up to the cap. They stop right there.

5 So the issue now that it isn't necessarily
6 anything that stops that today, but the question was here
7 does that mean that everybody would get \$3,500 worth of
8 care.

9 And I'll just do both of these, and then you can
10 respond.

11 The \$250 supply credit seemed to be that there
12 was clearly supplies weren't being paid for separately, but
13 it wasn't clear where the \$250 number came from, and it
14 wasn't clear whether or not that would mean that in a sense
15 there would be a bias towards patients who needed less than
16 \$250 worth of services rather than saying there might be
17 something based on the type of wound care products that
18 they needed, and there might be some different amount of
19 money for those. The fact that it was a flat amount, which
20 might be better than what exists today, but would suggest
21 that it would be focused on patients who needed less than
22 that.

23 So we didn't know where the number came from, and
24 it wasn't clear whether all patients would have less than

1 \$250 of need or whether there was a much broader range of
2 costs associated with the patients.

3 DR. PROBERT: So I got to tell you, you guys know
4 when I mentioned it in my proposal that I have a database
5 where I'm pulling a lot of my information from, my own
6 personal stuff, because there's just a dearth of literature
7 in pulling, you know, what these things actually cost. So
8 that's sort of my personal, looking at my clinicians and my
9 clinics as far as their average spend. So that's where the
10 \$250 came from.

11 Again, I think this is something that I could tie
12 to ICD-10s and maybe do some tiered ICD-10s to look at
13 those credits, but my thought wasn't --

14 MR. MILLER: Well, that was based on your -- an
15 average spending from your own data?

16 DR. PROBERT: Yes, yes.

17 MR. MILLER: So what kind of a range did you see
18 whenever you looked at that, or don't you recall?

19 DR. PROBERT: The range was pretty wide. I mean,
20 the range was anywhere from \$25 up to \$500-plus, but that
21 was the average spend. \$250 seemed to be the average spend
22 for most of those, and like I say, as a balance, just a
23 non-reimbursed supply for the clinics.

24 MR. MILLER: Mm-hmm.

1 DR. PROBERT: And the thought was not to say,
2 "Okay. Here's your \$250 credit." The thought was for a
3 reimbursement-type system for any of those. So I think
4 that's something that I need to clarify, that it would be a
5 reimbursement up to \$250, but not just a \$250 credit.

6 MR. MILLER: Oh, you're envisioning it as a cost-
7 based reimbursement?

8 DR. PROBERT: Exactly. Yes.

9 MR. MILLER: Oh, okay.

10 DR. PATEL: And cost -- sorry, Harold. Just to
11 clarify, cost-based reimbursement at full cost for using
12 that average as, like, potential ceiling? I'm just asking.

13 DR. PROBERT: Kavita, could you clarify what
14 you're asking?

15 DR. PATEL: Sorry. And I'm trying to get some
16 quiet area, so I apologize for the background noise.

17 DR. PROBERT: No problem.

18 DR. PATEL: The \$250, you had mentioned that that
19 was your average, but if it's a cost basis, would the max
20 be \$250, or it would actually be a true cost? Meaning
21 let's say it cost \$275, then it would still be reimbursed
22 at cost?

23 DR. PROBERT: I was thinking it as a cost-based
24 reimbursement with a ceiling of \$250.

1 DR. PATEL: Okay, okay.

2 DR. PROBERT: So CMS would know they would, yeah,
3 not pay more than \$250, so --

4 DR. PATEL: And then just to get back to your
5 original question about that kind of criterion -- and this
6 conversation about the cost-based reimbursement is helpful,
7 but it goes back to the question of how to kind of prevent
8 what looks like almost -- whenever there is like an
9 opportunity to have a payment up to a certain dollar amount
10 -- think about DRGs, for example, or other instances.

11 DR. PROBERT: Mm-hmm.

12 DR. PATEL: Institutions, whether they be one
13 doctor or one physical therapist, one individual clinician,
14 or thousands, like the organization I work in, they tend to
15 try to do what they can to achieve the maximum. I'm not
16 talking about committing fraud, not at all, but, I mean,
17 people want to try to maximize reimbursement.

18 Did you have, just based on -- it sounds like you
19 did your own internal kind of review of dollars. Did you
20 have a sense of what -- you talked about the average, \$250,
21 for cost that's not -- a cost of goods that's not -- that's
22 not -- but in general -- in general -- I guess I would ask
23 -- and, Harold, I don't know if this is overreaching --
24 kind of if you had a sense of what the range was for --

1 like if you brought all of this in, what the lower part of
2 that range would be.

3 If \$3,500 was kind of the upper limit, do you
4 have a sense of what that lower number might be?

5 DR. PROBERT: Well, I base this on not only my
6 internal research but also looking at what was the average
7 number of treatments needed for these patients, so that's
8 kind of where that number, \$3,500, came from.

9 And just so you guys know my math a little bit,
10 it's \$3,500 would be in the neighborhood of 30 to 35
11 visits. That's what I was looking at as sort of the upper
12 limit of spend, if you would, 30 to 35 visits on these
13 patients on average.

14 And as far as the range goes, you can have wounds
15 that will heal in as quickly as four weeks, right? So if
16 you look at four weeks, if you're seeing them five days a
17 week, which many times some of these nastier wounds we get
18 sometimes can be five days a week, so you'd be looking at
19 about 20 visits there, which would be \$2,100- to \$2,200 in
20 reimbursement, up to -- you have some that are in the
21 neighborhood of 50 visits, or if they've got underlying
22 stuff that goes on, that can even stretch out farther and
23 farther. And those kind of pull your averages up, of
24 course, and you'd want to manage those appropriately.

1 But that's sort of the range that I saw, but I
2 hear what you're saying. I mean, it happens in industry,
3 and I don't think it means to be fraud, but I was -- back
4 in the day when everything was fee-based, right, you seem
5 to see patients more than you do when that gets capped.

6 DR. PATEL: Right.

7 DR. PROBERT: And that's why the whole \$3,500,
8 you know, payback situation was intended to help control
9 people because if you lift the cap altogether, "Oh, let's
10 see them forever and ever."

11 DR. PATEL: Right.

12 DR. PROBERT: So --

13 MR. MILLER: That's true.

14 DR. PATEL: And I think -- and I guess the
15 feedback is around having -- we didn't see in the proposal
16 any sort of floor. Just to your point about like a ceiling
17 --

18 DR. PROBERT: Mm-hmm.

19 DR. PATEL: -- on the same flip side, there was
20 no --

21 MR. MILLER: Well, there was no incentive to do
22 it lower and a reward. So, in other words, if you were
23 better at getting -- and you have an outcome measure in
24 here, but if you were better at getting the wounds to heal

1 and achieve that outcome measure for \$2,500, there would be
2 nothing to reward you for doing that. That's kind of --

3 DR. PROBERT: I like that. I like it a lot,
4 Harold.

5 MR. MILLER: Well, but, I mean, you'd have to
6 think about how you want to deal with that.

7 The other, I would just make the observation and
8 leave it at that, that cost-based payment is much more
9 complicated administratively for everyone.

10 DR. PROBERT: Mm-hmm.

11 MR. MILLER: And the kind of what are you
12 achieving by doing that, if it's a small amount, I think
13 the question really with the \$250 was, A, where did it come
14 from, right? So the fact that you said you have data and
15 can provide data showing that that is in fact the average
16 and that there is a fairly narrow range would be useful to
17 have.

18 DR. PROBERT: Okay.

19 MR. MILLER: And then the other question would be
20 are there really different strata of patients that have
21 really different costs, and should you try to distinguish
22 them in some fashion or not?

23 So the concern here was if in fact there was a
24 very wide range and there were two very different strata --

1 and again, I don't know, but, I mean -- so, hypothetically,
2 if you told me, "Well, we have a bunch of patients that
3 cost \$100. Now we have a bunch of patients that cost
4 \$1,000," then saying \$250 would suggest that there would be
5 a strong bias towards focusing on the patients who cost
6 \$100. But if it's really hard to predict and there's an
7 average, then we would not have as much concern about it, I
8 don't think.

9 DR. PROBERT: Right. Well, that's a great
10 suggestion.

11 DR. PATEL: And, Harold, just one more point --

12 MR. MILLER: I did not make any suggestion.

13 Please don't interpret anything I made as a suggestion. I
14 merely made an -- I made an observation, and what I was
15 saying was the information, how we interpret the proposal,
16 would be based on the kind of data that you provide.

17 DR. PROBERT: Exactly. Gotcha.

18 DR. PATEL: Harold, just to -- I think this will
19 cover some other criterion, but I think it's just adjacent
20 or related to what you were saying. Just clinically
21 speaking, because you have such a strong background and
22 you're obviously a leader -- you wouldn't be submitting a
23 proposal unless you were a leader -- I wonder if you could
24 also think about, in line with kind of payments and

1 appropriateness, kind of as Harold mentions -- I didn't say
2 suggested -- I would also think about how you would think -
3 - the reason I brought up the word, like kind of "ceiling"
4 and "floor" is also thinking about clinical appropriateness
5 because anytime you're doing something new, you worry about
6 unintended consequences with people doing too much or too
7 little of something.

8 And especially in programs like Medicare, you
9 want to make sure that one of the unintended consequences
10 is avoided, which is that people don't actually receive the
11 standard of care in a field where the quality metrics are
12 not that robust, which I think you alluded to in your
13 proposal as well.

14 DR. PROBERT: Right, right. Okay. I like that
15 observation as well.

16 MR. MILLER: Okay. Why don't we keep going?

17 I would just observe from our perspective, any
18 data that you have that you could share that would be
19 relevant to this would be helpful because sometimes lack of
20 data inherently leads people to believe the worst --

21 DR. PROBERT: Sure.

22 MR. MILLER: -- because if you have no data --
23 and we all struggle with lack of data. So if you happen to
24 have data, which good for you for having data, it would be

1 useful to know what that says. Even though we understand,
2 it would simply be your practice, and it wouldn't
3 necessarily be representative --

4 DR. PROBERT: Right.

5 MR. MILLER: -- of everything else.

6 DR. PROBERT: Okay. Fantastic. I'll include
7 that. I didn't know if it was appropriate to include my
8 internal data, so I'll certainly do that as well.
9 Absolutely. Great.

10 MR. MILLER: Okay. Other questions or concerns
11 or feedback or errors that we made?

12 DR. PROBERT: Well, so the care coordination, I
13 think there was some concern about the care coordination.

14 MR. MILLER: Yes.

15 DR. PROBERT: And I guess my thoughts are, as
16 therapists, we have to have referrals from the primary care
17 physician, and then every tenth visit, we have to
18 communicate with that physician. And then every 90 days,
19 they have to go back and get recertified. So we're sort of
20 naturally tied into a care communication that has to
21 happen, and that any other referral sources that are
22 brought into the care cycle, we have to communicate with
23 them.

24 It sounds like you guys thought perhaps that if

1 there were a more robust way to increase communication on
2 patients that are in this program that it would be more
3 often than that or a certification that happened every 30
4 days versus every 90 days. Is that the clarification you
5 wanted on that piece?

6 MR. MILLER: I think the concern was -- and
7 Kavita can weigh in on this too -- is that those current
8 communications may be perfunctory in many circumstances,
9 and the concern was if that's simply the perfunctory
10 concern -- I won't speak about physical therapy, but one of
11 the big concerns with home health nationally has been that
12 there's supposed to be certification from physicians. And
13 it becomes kind of just a mill of them signing a form.

14 So the question here is, how do you know that
15 this is really coordination going on as opposed to just a
16 check the box, drop something in the fax machine?

17 MR. STEINWALD: Also -- this is Bruce -- it's not
18 just care coordination with the primary care physician.
19 It's care coordination with others that might be involved
20 in wound care as well.

21 MR. MILLER: Right. So why don't we in fact
22 separate those things.

23 So, first of all, what makes the communication
24 with the PCP more than something showing up on the fax

1 machine, and then what is it that you see doing with others
2 if in fact you need to have a surgeon involved or you need
3 to have a nutritionist involved or whoever else in terms of
4 the patient?

5 DR. PROBERT: Okay. I'm going to need to think
6 about that and flesh that out a little bit more because I
7 agree with you. Is it just signing the box and moving
8 forward, or is it a real sense of communication that truly
9 happens feeding into assessment pieces that actually feed
10 into the note from others involved in care? So I'm going
11 to need --

12 DR. PATEL: And that's what I was -- that's what
13 I -- since I receive many of those PCP -- like the forms we
14 use and the forms that most therapists use, most of our
15 offices and most primary care doctors like myself have kind
16 of gotten immune to them. We just sign, quickly review it
17 to see if anyone has flagged anything.

18 What we were trying to do is understand how these
19 communications could signal that, yes, there's something
20 that's more active that's happening with this patient than
21 standard of -- you know, kind of the routine.

22 DR. PROBERT: Okay.

23 What I can do is model something up. We have a
24 very robust, sophisticated EMR that we utilize, and we can

1 customize different note types and information and feed
2 that together.

3 So I would love to mock up something that would
4 indicate that. Would that be helpful to actually have a
5 model of what it might look like?

6 MR. MILLER: Well, I think -- potentially. I
7 think that the issue is this is a proposal for a payment
8 model that would be implemented by you and/or others,
9 whoever it is that gets solicited to participate.

10 So think about it in the perspective of not kind
11 of what just you would do, but what in fact could be put
12 into a payment model that Medicare, CMS would implement,
13 right?

14 DR. PROBERT: Sure.

15 MR. MILLER: So if you would say this should be
16 the standard form that we would think would need to be
17 implemented with all of this, okay. So, I mean, because
18 then you'd say this is the thing that would be required for
19 somebody to participate in this, in this particular model,
20 whoever they are, wherever they are.

21 And it couldn't -- it shouldn't be something that
22 only you could do or that is somehow particularly
23 customized to the way you do things. It would have to be
24 something that would be -- that would be workable across

1 all participants because we don't approve payment models
2 for individual practices.

3 DR. PROBERT: Sure. So a template for that sort
4 of thing. Okay. I can do that.

5 MR. MILLER: And then you would have to also --
6 we would be asking -- we should -- we would be asking
7 whether or not there was a way to in fact verify that
8 something was actually happening or not, so that's the
9 other kind of issue with all this, is how do we, how does
10 Medicare know that something is happening here.

11 And how about what -- talk about the
12 interdisciplinary care aspect of this.

13 DR. PROBERT: So I think that if we did this
14 template, the model of communication, if there were other
15 disciplines that need to be involved, we many times -- from
16 the primary care physician, they'll then go to a plastic
17 surgeon. There are other folks of participating care. So
18 I think if we have a template model for this kind of
19 communication, we could fold in those other participants in
20 care and ensure that we indicate other participants in care
21 with any kind -- within any kind of certification period.

22 So let's say if we do a 30-day certification
23 period, we would need notes and references from anybody
24 involved within that, that care cycle, so --

1 MR. MILLER: Could you give just an example or
2 two of how you deal with this with your patients? Maybe it
3 doesn't come up very often, but what happens with patients,
4 the sharp debridement issue, et cetera? What if they need
5 something that is outside of scope of practice? How do you
6 handle that?

7 DR. PROBERT: We refer along. It's part of our
8 practice and part of what we're educated to do, is if
9 something is beyond our scope, we refer.

10 So what we do is we always coordinate with the
11 primary care because the primary care, the person that
12 referred it to you, is ultimately responsible for that
13 care. So what happens in practice is if I'm treating
14 someone and I see an injury and I think, okay, this is
15 going to need a graft or this is going to need intense
16 sharp debridement, then I would speak to that primary care
17 and say I would love to refer this person to Dr. Such-and-
18 Such who handles -- you know, who is a plastic surgeon or
19 who can handle this, "Is that okay with you?" And, of
20 course, they say, "Yes, that's fine," or they might say,
21 "No. I want to refer them to somebody that I know that
22 does that work."

23 So that's kind of how it happens in practice, is
24 that we know when it's beyond our scope, and we go back to

1 the primary care and say, "This is our suggestion." And
2 they sign off or do something different.

3 MR. MILLER: So do you typically have kind of a
4 team with a surgeon or whatever that you tend to work with
5 as the default?

6 DR. PROBERT: Yes. Yeah, we do. We do,
7 especially when it's in different body parts.

8 Like, for instance, being a hand therapist by
9 background, I know the surgeons that I typically work with
10 are the ones that handle wounds. There are some that
11 handle -- if I'm getting a keloid scar that's happening,
12 there are certain surgeons that handle those.

13 So it's not necessarily one, but we do have a
14 cadre of folks that we sort of know, and we can make those
15 suggestions to the primary care. And like I say, they
16 might say, "No. I would rather them go to this person or
17 this specialist," but we tend to in practice gather that
18 cadre of who we know specializes in different areas.

19 MR. MILLER: Mm-hmm. So, in a sense, you're
20 saying that you -- you don't have a formalized team that
21 you offer for wound care, but you have sort of an informal
22 team that would be the default, unless it's overridden by
23 the primary care physician?

24 DR. PROBERT: Exactly. We tend to -- when we're

1 seeing these patients every day, on a daily basis, we tend
2 to take a little more of the -- of the vice quarterback, if
3 you will, to the primary care because we're seeing it all
4 the time and able to report on that status, so it becomes
5 an informal team approach accomplishing the final goal.

6 MR. MILLER: And do you perceive any barriers
7 elsewhere in the Medicare payment system to getting the
8 right people involved in this?

9 DR. PROBERT: I mean, there are certainly payment
10 considerations. You have to ensure that the person to whom
11 you're referring many times financially makes sense for the
12 patient. That's why we keep a cadre, more than just one,
13 that we sort of work through, but those would be the main
14 barriers, are basically the financial situation, the
15 payment, working around the insurance, making sure
16 everything gets coordinated, so --

17 MR. MILLER: So you don't have -- you don't
18 experience a surgeon saying, "I don't want a case like this
19 unless I can manage the overall care," that they're happy
20 to do the periodic procedure that you need as the
21 complement to what you can do?

22 DR. PROBERT: Right. We have great cooperation
23 with that. We really have great working relationships with
24 folks and folks that are willing to come in secondary to

1 take on a case and look at it or do some sort of
2 specialized procedure and then release them back to the
3 primary care at that point. We've had a lot of success
4 with that, and I don't know if that's going to be unique to
5 us or if that's a barrier for this, but we've been very
6 successful.

7 MR. MILLER: Okay. So the question was merely
8 just really trying to get at whether there are broader
9 barriers in the Medicare payment system to getting good
10 wound care to patients that you're addressing one silo of,
11 and there may be others then that will appear later on.
12 But if you're not seeing that problem, then maybe it
13 doesn't exist. But that's the only reason why I was asking
14 that.

15 DR. PROBERT: Sure, sure.

16 If we want to move forward, Bruce, the --

17 MR. MILLER: Yep. Go ahead.

18 DR. PROBERT: Okay. So the last one was about
19 the health information technology. Now, probably, again,
20 this is probably my fault because I have it in my brain in
21 how we utilize it, but what are your -- what are your
22 thoughts on that? Do you think we should move toward a
23 national wound care registry as a proposal as part of this,
24 or is that what you were expecting to see or -- if you

1 could just clarify that piece for me.

2 MR. MILLER: Well, first of all, this criterion
3 is a somewhat strange criterion. It simply says does the
4 proposal or does the action encourage the use of health
5 information technology to inform care.

6 So part of the evaluation of that ends up being
7 driven by whether there is a gap of some kind that needs to
8 be filled.

9 So what wasn't quite clear here was where the
10 data are coming from, where any benchmarks would be coming
11 from when you're talking about the minimum clinically --
12 and for improvement, and we didn't -- that was a question
13 that you didn't really quite answer very specifically was -
14 - so what is that, and where does that come from? And an
15 obvious question is, well, it depends on what people could
16 expect to achieve, and it wasn't clear where that was
17 coming from.

18 So is there a need to try to support that by
19 having some place that data is submitted to? It clearly
20 also relates to the earlier discussion about the
21 integration of care coordination, is how does that
22 communication occur effectively right now? If it's
23 dropping faxes into the fax machines, that isn't as
24 effective as using some better way to communicate with all

1 the members of the team, PCP, surgeon, et cetera.

2 DR. PROBERT: Sure. I think one of the
3 limitations here is -- you guys probably know that we don't
4 use a lot of national registries as therapists, but what we
5 do are our own outcomes. And there are a couple of
6 companies out there that have sort of formed not only some
7 recognized outcomes, but they sort of have done their own
8 internal [unintelligible].

9 [Unintelligible] is one that comes to mind, and
10 they do sort of a clinical effectiveness registry, which
11 doesn't have a lot of -- I mean, they've got data behind
12 it. I shouldn't say that, but what is clinical
13 effectiveness? What does that mean? It's not an accepted
14 thing like DASH and LEFS and that sort of thing, so --

15 MR. MILLER: Well, there is a national wound care
16 registry of some kind.

17 DR. PROBERT: There's a wound care registry,
18 right. Exactly.

19 MR. MILLER: And do you participate in that?

20 DR. PROBERT: We do not. We do not. We --

21 MR. MILLER: Why is that?

22 DR. PROBERT: Well, again, it's because it's --
23 wound care is not something that you're going to see of the
24 top even 50 diagnoses in physical therapy, so they focus

1 mainly on what therapists are going to see. So it has not
2 been something that we've done in the past, but I do think
3 for the purpose of this that we should definitely use that
4 national registry, you know, for the outcomes so that would
5 allow us to measure and then feed back into the whole
6 capping situation and the communication, the functional
7 measuring of this as well.

8 MR. MILLER: Okay. So I think right now, the
9 rating that we gave was more based on lack of any real
10 information in the proposal about what would be done. It's
11 up to you to decide what it is that you would want to
12 provide in terms of additional information on that.

13 DR. PROBERT: Okay.

14 And then I skipped the one right before that,
15 which was the patient safety.

16 MR. MILLER: Yes.

17 DR. PROBERT: And, well, so we operate under
18 these barriers right now because even though Medicare
19 allows certain procedures or things to happen, not all
20 states do, anyway.

21 So I think for this, we would have to say that
22 this program would involve clinicians that are -- you'd
23 heal the wound based on what you're allowed to do within
24 your state practice act, and that's, I think, just

1 something that we need to acknowledge because we're not
2 going to override the state practice act for a clinician.
3 So that was the first piece of that.

4 And then patients that do not show improvement,
5 we --

6 MR. MILLER: Well, let me just -- let me pause on
7 the previous one. So I guess the question is there is what
8 you're allowed to do, and then there's what you would be
9 the best at doing from the patient's perspective.

10 DR. PROBERT: Right.

11 MR. MILLER: So the question was -- I mean, one
12 issue obviously is that we don't want to create a model
13 that basically pays you to do something you're not allowed
14 to do under a state practice act.

15 DR. PROBERT: Right.

16 MR. MILLER: But the question here was really so
17 if, all of a sudden, there is a financial incentive of some
18 kind for a physical therapist to start doing wound care,
19 what would be the risk to the patients? That a patient who
20 is technically within scope of practice, but would not be
21 the -- you know, the physical therapist would not be the
22 best place for them to be getting their wound care would
23 suddenly start going to physical therapists and ending up
24 having worse outcomes.

1 DR. PROBERT: I agree, and I think that's where
2 the piece -- and again, I apologize for not knowing exactly
3 where it was, but I believe in the proposal that I talked
4 about the advanced certification piece. That is certainly
5 something we could require, like a CWS, the number one
6 established baseline, right? What are you -- are you
7 demonstrating the competence --

8 MR. MILLER: Mm-hmm.

9 DR. PROBERT: -- in order to treat this wound?
10 So that would be one way to handle that.

11 And then the other is you -- under our national
12 practice act, you need to refer. If it's beyond your scope
13 of practice, then you have to --

14 MR. MILLER: Well, the question -- the question
15 we were asking was more not on the eligibility of the
16 practitioner, but the eligibility of the patient. In other
17 words, should there be any limitations for the purpose of
18 this model in terms of which patients could participate in
19 this particular model in order to ensure that it was being
20 targeted at the patients for whom the physical therapist
21 was the best option? And that's just a question again.

22 DR. PROBERT: Yeah. Okay. I got you, and I
23 think that goes back to ICD-10 control. We could do that
24 under excluding certain diagnoses or excluding certain

1 combinations of diagnoses.

2 MR. MILLER: Okay.

3 DR. PROBERT: So I think I need to flesh that out
4 more, so --

5 MR. MILLER: Okay. And then on the second, the
6 second point was this issue of -- it's good that you've got
7 a -- in some way that you've got an outcome-based payment.
8 Hardly anybody has that, but then it raises the question
9 of, well, what happens if you've already essentially failed
10 to deliver -- you know, you spent \$3,500. You didn't
11 achieve the outcome. You had to give the money back, and
12 you say to the patient, "Sorry. We're done."

13 DR. PROBERT: Yeah. That's a good point. I'm
14 writing here -- it down.

15 MR. MILLER: Okay.

16 DR. PROBERT: Okay.

17 And I -- you know, honestly, that's not something
18 that I fleshed out or really put a lot of thought into, but
19 it certainly is something that needs to be addressed. So
20 let me think about that one and come with some proposed
21 solutions or what that would mean for that patient.

22 MR. MILLER: Mm-hmm. Well, it's also a matter
23 of, again, to what extent you even think that there's --
24 that is likely to happen. We obviously want to think about

1 even if it's a small probability, but if in fact -- and it
2 may relate to the previous discussion, is depending on what
3 the eligibility criteria are --

4 DR. PROBERT: Right.

5 MR. MILLER: -- if this is focused on patients
6 who almost always should be able to achieve the outcome for
7 that amount of money, then it would be less of a concern
8 then -- because this is the lack of data issue, is we don't
9 have a clear sense right now of what that distribution
10 would look like when you say \$3,500, for example --

11 DR. PROBERT: Right.

12 MR. MILLER: -- or when you say what the
13 performance criteria would be.

14 If it turns out that a lot of patients take
15 \$10,000 worth of care to be able to achieve the kind of
16 outcome that's necessary, it would be a whole lot bigger
17 concern than if most patients are done -- could be done for
18 \$2,000.

19 DR. PROBERT: Well, I think another way that you
20 could handle it is just putting some stop gaps into the
21 care, and that's -- we talked about shortening that
22 certification period down to 30 days or maybe even a
23 certain smaller number of visits or maybe at that 10-visit
24 point that we have, anyway. Maybe we put some stop gaps in

1 there that they have to achieve a certain level. Like by
2 10 visits, they have to have this much improvement, by 20
3 this much, which would prevent you from going your full 30,
4 35 visits, "Whoops. There's just not getting any better,"
5 right, if you've got those stop gaps first before you get
6 there.

7 MR. MILLER: Mm-hmm. Well, I would say the first
8 question really is, Is it a problem? To what extent do you
9 have any data to help us understand the extent of the
10 problem? And then if your own data suggests that it could
11 be a problem, what is it that you think would be done about
12 it?

13 DR. PROBERT: Right. And I don't think it is,
14 but I'm going to have to dig into my data to answer that
15 question.

16 MR. MILLER: Yeah. Because we come up against
17 this in a lot of -- in a lot of payment models, is that
18 under fee-for-service, in a sense, it's an inherently risk-
19 adjusted system, right? If a patient needs more, you get
20 paid more. Not quite the case because you've got therapy
21 caps, but in most cases, that's it. So there's always the
22 concern in anything that's different, where there's any
23 kind of incentives or penalties or whatever or risk
24 associated with it that some patients might be hurt, so we

1 try to think about what circumstances might arise, and then
2 the question is always, well, we don't know exactly how
3 often that would happen because we don't have data on that
4 because it's never been an issue before, so that's --

5 DR. PROBERT: Right.

6 MR. MILLER: That's partly where that comes from
7 here, and then we have to assess to what extent do we think
8 that the safety risk is a serious safety risk or a minor
9 safety risk, and so, again, that comes back to the issue of
10 what's the nature of the patients who are going into this
11 model and how problematic would it be if they end up with a
12 therapist who does a bad job or cuts them off prematurely
13 or whatever.

14 DR. PROBERT: Yeah. Thank you for that, Bruce
15 [sic].

16 I also think that some of the other weaknesses
17 that you guys talked about was patient choice. I think we
18 can probably handle that through education or required
19 literature that is given to patients to talk about what is
20 a therapist, what is their practice, what is the training
21 of this individual therapist. Perhaps I need to look at
22 some education for that piece as well.

23 But overall, those were kind of my main -- my
24 concerns and questions I had, and I guess at this point for

1 you guys, what else would you like to see from me,
2 information data-wise?

3 MR. MILLER: Yeah. Let me see. Bruce or Kavita,
4 do you have any other questions you want to ask Krisi?

5 MR. STEINWALD: I don't think so. I think when
6 we're done talking about particulars, though, we should
7 also go back to talking about the process.

8 MR. MILLER: Right.

9 Kavita, are you still on, or did you -- I heard a
10 beep, and she may have disappeared somewhere along the
11 line.

12 And one of the reasons why we transcribe these
13 also is so that we can all -- even if we weren't able to
14 make the call, we can get the gist of it.

15 DR. PROBERT: Sure.

16 MR. MILLER: Okay. Well, if you have nothing
17 else, I think we covered all the issues that I had
18 questions about because most of them were focused on those
19 areas where we were concerned about whether the criteria
20 were met.

21 So, as Bruce said, why don't we talk about
22 process? You said you wanted to provide some more data and
23 potentially some responses or suggestions here. What kind
24 of timetable do you -- would you need on that?

1 DR. PROBERT: I think I can give you guys all of
2 this information by -- and I apologize; I'm opening up my
3 calendar right now -- by the 11th of May.

4 MR. MILLER: Okay. Well, we'll assess after
5 we're done whether -- what implications that may or may not
6 have for the timetable that we're on. I would just say I
7 think that you should take whatever time you need to do the
8 best job you can.

9 DR. PROBERT: Sure.

10 MR. MILLER: And if that means we have to delay
11 this, I think we're better off doing that.

12 I think the other question that you should
13 address is whether -- if you think that you're making
14 significant changes in terms of the proposal -- so one of
15 the things that -- a question, is there additional
16 information that you can provide that would be helpful?
17 That's one thing. If you say, "Now having read this and
18 thought about it, I really think I ought to change
19 something in the proposal in some significant way," then it
20 may be more appropriate for you to say, "I want to withdraw
21 and resubmit."

22 DR. PROBERT: Okay.

23 MR. MILLER: Because then we have an opportunity,
24 everybody, to basically kind of look at it fresh rather

1 than having to try to -- at the last minute try to assess
2 that, and it's difficult in many cases to determine if it's
3 just one little fix of some kind.

4 DR. PROBERT: Mm-hmm.

5 MR. MILLER: That's a different issue than saying
6 I'm going to change a bunch of things because if everything
7 relates to everything else, then if we essentially have to
8 go back to the beginning and do that, then it's essentially
9 we would have to delay it, anyway.

10 DR. PROBERT: Understood. Sure.

11 MR. MILLER: So I think that's up to you to
12 decide, and you don't have to decide on this call. You
13 just -- it would be helpful, obviously, for you to let us
14 know because the default -- the default process that we
15 will go through at this point, unless you tell us that you
16 want to do something differently -- and Mary Ellen can jump
17 in and correct me if I am wrong on this -- is we will
18 proceed to finalize our report based on what you've said to
19 us today and any information that you give to us in a --
20 within the time frame that we would need to finalize it.
21 And then we would proceed to move forward.

22 Whether this is on the June agenda or not will
23 depend on the overall demand for the time on the June
24 agenda.

1 But if you decide that you want to withdraw or
2 resubmit or if you say, "I really" -- you need a whole
3 bunch of more information and "It's going to take me longer
4 than that to put it together accurately," then we might
5 decide to simply hold off and delay finalizing what we're
6 doing but essentially continue with the same proposal.

7 Mary Ellen, did I get that okay?

8 MS. STAHLMAN: I think that's perfectly accurate.

9 The only other thing I would say to you is that
10 we've -- to the extent that a revise-and-resubmit is
11 something you would like to think about, it helps the PTAC
12 members who are not on this PRT, who will be evaluating
13 this proposal in a public meeting, to see all the
14 information in one place.

15 So to the extent that you have an original
16 proposal and then there's Q's and A's and then there's this
17 transcript and then there's something else that you'll be
18 submitting, when the pieces and parts are in multiple
19 locations, it gets hard for members who are not on the PRT
20 to track any changes in your proposal as it goes through
21 the system. And having one place where it's all together
22 can be a really positive thing.

23 I've heard the Chairman at public meetings say,
24 "You want to put your best foot forward. You want to put

1 your best proposal on the table," and so just think about
2 that. It's not a requirement, but I think it's worth
3 thinking about.

4 DR. PROBERT: I think that makes sense.

5 If you guys don't mind, I would love to put my
6 brain around this, this week, to really make a decision
7 about -- and I'm really leaning toward the revise-and-
8 resubmit, not like rebuilding one from scratch, of course,
9 but having this information and resubmitting it in one go,
10 I think probably would be wise. So if you guys don't mind
11 allowing me to think about that this week and then possibly
12 letting you know at the end of this week which route I want
13 to go, does that work?

14 MR. MILLER: I think that would be fine.

15 Mary Ellen, does that time table -- do you think
16 that makes sense?

17 [No response.]

18 MR. MILLER: I can't tell whether Mary Ellen
19 dropped off or whether she's thinking, but let me just say
20 I think that works fine, Krisi.

21 And by the way, you would not be the first person
22 to have withdrawn and resubmit it. In fact, we had one
23 other proposal in March that we approved that we had --
24 that went the whole way to a public meeting in the fall.

1 The discussion basically ended up with -- almost like this
2 kind of a discussion, but in the public meeting that
3 basically raised so many questions that the applicant said,
4 "We think we'd rather withdraw and resubmit."

5 So the question is really do you want to get to
6 that point before doing it, or if you know that early on
7 enough, then it actually speeds up things if you do it --

8 DR. PROBERT: Sure.

9 MR. MILLER: -- if you do it sooner. As Mary
10 Ellen said, everybody gets something where all the parts
11 are more clearly and compellingly presented.

12 But I think you need to make the judgment about
13 what makes sense. We're not in any fashion pushing you in
14 one direction or the other.

15 MR. STEINWALD: And just to emphasize, it's one
16 thing to present some additional information that explains
17 your existing proposal in greater depth versus another
18 thing that materially changes it, and to the extent that
19 some of the things you're thinking about would constitute
20 changes in your proposal, then that's the kind of thing
21 that should lead you to consider revising and resubmitting.

22 DR. PROBERT: Sure.

23 MR. MILLER: Right. Particularly if those things
24 are -- there are multiple things or they have implications

1 across the board.

2 I mean, we've had situations in which somebody
3 said, "Oh, I forgot to say the following thing." It was --

4 DR. PROBERT: Right.

5 MR. MILLER: So it maybe was a modification, but
6 it was clearly -- it was just filling in a blank that
7 didn't affect anything else.

8 But on the other hand, when people have said,
9 "Oh, we want to change the following six things," and that
10 would all relate to other things, then as Mary Ellen said,
11 it's really hard to figure out what's still there and
12 what's not.

13 So, anyway, that's up to you, and we appreciate
14 it. We'll end here and leave you to think about that.
15 Again, I want to thank you for having done all this work,
16 which is a public service over and above doing your regular
17 patient care and putting up with all the questions that we
18 have asked and doing such a nice job of responding to them
19 and joining us on the call today.

20 DR. PROBERT: No worries. I want to thank you
21 guys too. It's an honor just to be here, to make it to
22 this point, and that you guys are even taking the time to
23 consider and go through this with me, so thank you, guys.
24 I appreciate it.

1 MR. MILLER: Okay. Thanks very much.

2 MR. STEINWALD: You're welcome.

3 MR. MILLER: And to Bruce and Kavita and all,
4 we're going to call back on for a different call.

5 DR. PROBERT: Awesome. Thank you guys. Bye-bye.

6 MR. MILLER: Bye.

7 [Whereupon, at 11:02 a.m., the conference call
8 concluded.]

9

10

11

12

13