

**Questions on “Bundled Payment for All Inclusive Outpatient Wound Care Services in Non Hospital Based Setting” PFFM Proposal Submitted by Seha Medical and Wound Care  
December 13, 2018**

**Target Patient Population and Enrollment Process**

1. On page 2, the proposal says that “nearly 15% of Medicare beneficiaries (8.2 million) had at least one type of wound.” Approximately what proportion of the Medicare patients who have a wound would be eligible for inclusion in the proposed model (e.g., based on diagnoses, levels of severity, comorbidities, etc.)

The above data was drawn from a study of retrospective analysis of the Medicare 5% Limited Data Set for calendar year 2014 which included beneficiaries who experienced episode of care for one or more wounds meaning that medicare paid for care of these beneficiaries with a wound diagnosis.

Any medicare beneficiary who seeks or requires care in a wound clinic with an acute or chronic wound will be eligible to participate in the model.

Patients first try to take care of simple wounds by themselves. Patients seek attention from care providers when the wounds are not healing, get infected or are unable to care for themselves.

Majority of patients are referred to the wound clinics by primary care providers or emergency rooms, have multiple comorbidities and various levels of severity.

The precise diagnosis as to the cause (diabetic, venous ulcers etc.) is most of the times made after evaluation in the wound clinic.

Would the model include patients who are in nursing homes? Would there be any other inclusion or exclusion criteria for patients participating in this model?

Long term residents of nursing homes will be included in the model if they require care in

a wound clinic. However some nursing homes employ the services of wound care specialists to provide consultations in house.

Short term patients are under a different payment model and will have to be excluded.

The inclusion criteria is simple. As mentioned above any patient who is referred to the wound clinic or requires a specialty care in the wound clinic will be included. This is the current system of practice for patients seen in the wound clinic.

Exclusion Criteria:

1. Patients who require immediate intervention in a hospital setting for example amputations, flap procedures or extensive debridements in hospital operating room or intravenous antibiotics to control infection or stabilize other comorbid conditions like congestive heart failure etc. However once discharged from the hospital they can be included in the program for ongoing care of the wound/s as is the current prevailing practice.
  2. Patients who have been previously seen and fail or refuse to comply with the care plan.
  3. Patients who require palliative wound care at the end of life.
2. How does the proposed model address potential variation in patient risk and complexity?

Complex wounds do require more time and resources in the beginning until an optimum regimen is established and they start to progress and heal.

There are always some outliers but majority of the non-healing wounds require standard regimens and time to heal. This spreads the cost across the spectrum and will

mitigate the potential variations in risk and complexity.

This provider has previously worked in a Program of All-inclusive Care for Elderly (PACE), one of the oldest medicare managed programs for the elderly and is well aware of cost management issues in the bundled care models.

How does the model prevent providers from "cherry picking" patients who have relatively less complex medical needs?

For majority of the patients the real complexity of wounds is ascertained only *after* a patient is evaluated by a wound care specialist.

For further safeguard all referrals will need to be logged in a data set. Refusal to accept a patient will have to be documented.

In this providers 15 years of wound care practice the only patients who cannot be seen are the ones who's insurance does not cover the visit.

3. Please explain what patients would need to do in order to formally choose to be enrolled in the model so that the participating non-hospital-based providers could receive the episode-based payments for their wound care.

Patients are either referred from their providers, hospital or emergency room. Some

patients are self-referral, patients or family members calling to seek help.

Once the wound care provider receives the call patients are registered in the wound program.

4. What kinds of information would patients be provided about how participating providers are being paid, and what services the patients should expect to receive prior to enrollment? What if patient preferences or clinical needs suggest that the patient needs to exit the model and get his or her care somewhere else?

Information about the method of payment will be provided to the patients in a simple one

paragraph statement just like advanced beneficiary notice. This will also include the information that all care provided in the wound clinic is inclusive of the bundled payment.

Just like any other area of medical care, patients are on occasion not satisfied with care at

a particular wound clinic or with the provider and seek second opinions.

Most of the patients seen in the wound clinics are elderly. A complex process to transfer care from the model will be cumbersome. Therefore patients can simply, as they currently do, inform the participating provider about their wishes to transfer care to another provider or clinic. This will be documented in the medical records.

### **Services**

5. On page 2, you propose “a bundled payment model in which Medicare will pay a *flat fee* per visit inclusive of all services provided to independent office-based wound care provider/clinic.” Additionally, page 8 states that the bundled payment would be “inclusive of all services i.e. evaluation and management, patient education, skin care by the staff, wound debridements, unna boot applications for compression, offloading total contact cast, advanced tissue products and dressing done at the clinic.” Are there any wound care-related services and/or costs that would not be included in the bundled payment (for example, would hyperbaric oxygen treatments be included)?

Hyperbaric Oxygen Treatments will not be included.

On the average under 5% of total number patients seen in the wound clinics require HBO.

Including the cost of HBO will increase the per-visit cost of care for every patient seen in the model thereby increasing the total cost of care.

The HBO chamber is expensive and requires specially built room and several fire safety

codes for installation. The cost may be prohibitive for some providers.

HBO treatments will have to be billed separately for patients who require this modality.

As stated in the proposal all services provided within the wound clinic will be covered in the proposed payment model.

Any services provided outside of the wound clinic like physical therapy, visiting nurse services for any reason or the need for hospitalization will not be included.

6. Pages 3-4 state that “under the proposed model testing and procedure are done strictly based on individual patient need based on direct physician evaluation on a patient by patient and visit by visit assessment.” Additionally, page 8 states that “unnecessary excesses . . . judicious use of procedures and products to reduce risk of side effects, close monitoring of progress and comorbidity impact with integral physician-patient contact during each episode will add to the quality and value of the model.” Will participating providers be required to implement a specific care model in order to be eligible to receive the proposed bundled payments?

Any provider desiring to participate in the model should have at least of two years of experience in wound care either in his/her own office or in a formal wound clinic.

One of the aims of the proposed model is to keep it simple to participate for the providers

with practice in wound care. Flexibility will allow the providers to find what works best for their patients.

7. Under the proposed model, please explain what would happen if other resources beyond the services that are included in the bundled payment are warranted, or if care in another setting (such as a hospital-based setting) or from another provider (such as a specialist) would be preferable for the patient.

Typically the services needed beyond resources of wound clinics are hospital admissions for infection requiring IV antibiotics, surgical procedures in hospital operating rooms or admission to a rehabilitation facility. In these cases the wound clinic services are put on hold until the patient is discharged from an inpatient facility at which point the wound clinic services are resumed if the patient still requires them.

Other services done outside of the wound clinic and not included in the wound clinic payments are investigative services like laboratory, x-ray, ultrasound, CT Scan and MRIs etc.

This will continue to be the same in the proposed model.

Patients will have the choice to transfer care to any place of service they wish if they

desire so with a simple notification.

### Care Coordination

8. Page 8 states that “under the proposed model the patient is seen as a whole patient, examining pertinent co-morbidities, and the potential benefits versus costs of possible procedures.” What types of care coordination are implied in the “whole person” approach in the model? What types of care coordination activities will be covered (for example, page 11 mentions “inviting home care nurses to visit with their patients during scheduled office visits to observe care, procedures and patient teaching for more effective follow up and prevention”), and will the bundled payment reimburse providers directly for these activities? With which other providers will patient care be coordinated?

Here is the example I use in my teaching rounds; An 84 year old man was referred to me for second opinion for a non-healing diabetic foot. He had been going to a hospital based

outpatient wound clinic for two years. The son who approached me cautioned me that his

father has been labeled non-compliant so it may be a challenge.

At the time of consultation I asked the gentleman what has been done so far. He said he had been going to the wound clinic for two years. The surgeon would walk in debrided the wound and tell me “stay off of your foot” then walk out. The nurse would come and put some dressing and repeat what the surgeon had instructed. Same thing happened week after week.

ALL 84 year old men have BPH or benign prostatic hypertrophy. Majority of women also have issues with bladder dysfunction necessitating multiple trips to toilet.

On further enquiry the person stated he barely sleeps at night and has to go to bathroom

6-7 times a night. In addition to this he has to do the activities of daily living (ADLs) like going to the kitchen for meals.

An 84 year old man or a woman cannot be expected to hop on one foot less falling and creating another problem for hip fractures or stay in bed 24/7.

We explored his daily routines and brainstormed possible interventions. The answer was simple.

He would use a urinal at night on the bed side and keep a bedside commode just in case.

This way he will not have to “walk on his foot” 6 times a night.

He would use crutches to go to the kitchen. We modified his off loading shoe.

We created/modified dressings on the wound for further protection.

His wound closed in about 5 months.

This is what is meant by 'seeing the whole person and not just the hole in the person'.

Inviting visiting nurses for learning in the care of the patient or coordinating care with all services providers is not separately payable. It is simply a good practice.

Other providers who may be involved in non-healing wounds based on it's etiology are physical therapists, vascular surgeons, infectious disease specialists, cardiologists, nephrologists, endocrinologists, rheumatologists and orthopedic surgeons.

Coordinating care with other providers involved is the standard of care – not separately payable.

9. How does the proposed model promote the ability of participating providers to access relevant information about patients with chronic wounds, particularly those with comorbid conditions, from other providers?

This is made easier with the use EMR systems especially when patient are seen with in the same system.

The main incentive will be cost management. Getting all medical information about a patient will help treat the patient efficiently. For example a patient with congestive heart

failure and venous ulcer from peripheral venous disease may not respond to compression

therapy alone. The heart medications like diuretics need to be increased for a short time until the edema is stabilized. This is only possible with care coordination with other providers.

10. How would the proposed model reduce the burden of documentation, and potentially incorporate the use of telemedicine, as discussed on page 12 of the proposal?

Currently CMS contractors scrutinize every single word in the documentation.

EMRs come with templates for exams and procedures. These templates are used to put in

pertinent patient information. Some of the procedures are done similarly every time with

some modifications according to patient needs. An example would be compression/unna

boot application. So the wording is more or less the same. But CMS contractors deny reimbursement for using 'similar wording' in same patient at different visits and in

different patients (personal experience).

Additionally CMS requires detailed explanation of documentation for procedures like debridements as to the depth, type of necrotic tissue debrided, type of instrument used etc. All of this consumes a lot of time and effort for simple sake of getting payed without any effect on patient care or outcome.

In between patient visits if there is a change a picture is sent to the provider by a VNA or family member. Then a simple call is made to discuss the situation and reach a decision. A secure audio-visual application on the smart phone can be used as well.

### **Quality Measurement and Evaluation**

11. What quality measures would be included in the proposed model, and how would they be measured? Please address whether you considered nationally recognized quality measures, such as Qualified Clinical Data Registry (QCDR) and Merit-Based Incentive Payment System (MIPS) measures that are part of the U.S. Wound Registry, and whether these measures would be appropriate for the model.

Measures in US wound registry were considered and 2-6 are adapted from it. Several of the US wound registry measures pertain to HBOT and therefore not applicable to this model.

The following measures will be included for quality reporting;

- 1- Measurement of a patient's improvement in quality of life
- 2- Improvement in pain scale/control
- 3- Number of visits to heal different wounds like diabetic and venous leg ulcers can be compared with nationally reported data.
- 4- Number of prescriptions filled for proper offloading devices and footwear (for example diabetic footwear), prescriptions for compression garments for patients with venous ulcers.
- 5- Blood monitoring of A1c is a good quality measure for diabetic ulcers, because the value drops with constant education and re-enforcement by the time wound is closing and improving.
- 6- Venous leg outcome measure

12. From a quality perspective, please explain why "reducing the requirement of home health visits" and instead performing compression and other care measures in the office setting (as discussed on page 7) would be an improvement over current care protocols.

There is a wide variation in the technique and proficiency of nurses in providing care at home. It is also a common complaint from the patients that they often do not get the same nurse every time. The inconsistent technique or degree of compression can lead to delayed healing or new complications for example new ulcers on bony prominences if the compression is done too tight. Nursing staff in the wound care clinic perform multiple compressions daily under supervision of a provider thereby improving the quality and consistency.

13. Page 11 states that “we follow national protocols for infection prevention and safety in the outpatient wound clinic.” Does the proposed model reference any national guidelines or established protocols that participating providers will be required to follow in order to ensure that Medicare pays for the standard care for wounds under the proposed model? If so, please specify these national guidelines and protocols.

This refers to published guidelines for operating wound clinics by several wound healing societies. They are very similar and any one of them can be adapted. These serve as a reference.

<https://www.apwca.org/Resources/Documents/APWCA-Wound-Cntr-Principles-061508%5B1%5D.pdf>  
[http://woundheal.org/files/2017/final\\_pocket\\_guide\\_treatment.pdf](http://woundheal.org/files/2017/final_pocket_guide_treatment.pdf)

14. How does the model propose to measure patient outcomes and costs under the model as compared to what would have been expected under conventional care?

Quality measure #3 in the proposed model deals with number of visits to heal a wound. Since the model is paid a flat fee each visit total cost can be deduced from the total number of visits. This will be measured against total cost of care incurred by CMS in traditional hospital based wound departments for individual wounds like diabetic ulcers and venous ulcers.

### **Payment**

15. How was the \$400 payment for the bundle of services derived? Could you provide a calculation based on your wound care clinic or for a hypothetical non-hospital-based wound care clinic showing how the proposed visit-based bundled payment amount relates to the costs of delivering high-quality wound care services? Please show as explicitly as possible how the proposed higher revenue compares with current fee-for-service payments and the average cost per visit and length of stay in the practice per patient (including the degree of variability in cost for different kinds of wounds).

In the Quality and Cost section of the proposal the various figures from literature about the average cost of wound care to Medicare in the hospital based wound clinics are explained.

Medicare cost to hospital based outpatient wound clinics is \$586 per visit (without Hyperbaric Oxygen therapy) (2).

Physician payments amount to 15% of the cost (\$88).

Hospitals are paid \$100 for hospital out-patient clinic visit under the prospective payment system for overhead and staffing.

This leaves \$398 paid to the hospitals for procedures, dressing supplies, advanced tissue products like artificial skin grafts and for part 'A' billing for procedures like unna boots for compression. But some of the included payment is redundant as both physicians (under part 'B') and hospital (under part 'A') are paid for same procedures like debridements.

Hence a bundled payment of \$400 per visit as proposed in the model. The total cost to heal the wound in 12 weeks will be \$4800.

Based on the figure cited above (\$586/visit) the total cost of wound care in a hospital based wound clinic will be \$7032 in 12 weeks.

Majority of the wounds heal in 16 weeks. (US wound Registry data).

In this provider's 15 ½ years of running a wound clinic the average time to heal a wound is 12 weeks.

The current fee-for-service system for non-hospital based physicians doing wound care is based on primary care office visit reimbursements. The average per visit payment is about 30% more than what physicians are paid (\$88) for their services in a hospital based wound clinic. This severely limits the ability to hire more staff and equipment and meet all patient's need in a visit.

16. Does the proposed model include a remedy if a participating provider's actual costs exceed expected costs?

The proposed model incentivizes efficient cost management sufficiently covers typical expenses in wound care.

17. Would the participating providers bear any risk for achieving quality objectives under the proposed model?

No

18. On page 5, the proposal states that “when a debridement is done an unna boot (compression bandage) cannot be charged at the same time though it is a necessary component of the healing process in many cases. . . . This means either the physician has to absorb the cost of supplies and application of unna boot done when a debridement is needed or simply send the patient to a hospital based clinic.” Please provide additional information clarifying why a physician in a non-hospital-based freestanding wound care clinic would have to absorb this cost.

Physicians in non-hospital based wound clinic are paid as if seeing patients in a primary care office. Furthermore physicians are paid *either* for E/M or procedure. If multiple procedures are done like debridement and unna boot application then according to medicare rules only one procedure can be charged which leaves the physician to provide the other free of charge. Both debridements and unna boots require their own set of supplies and staff time and often have to be done together to prevent the wound from getting worse first and then to help it heal. This leaves the physician to absorb the cost of the second procedure at a significant disadvantage compared to hospital based wound clinics which are paid for both procedures.

#### **Impact on Utilization and Spending**

19. Why do you believe that providers participating in the proposed model will be able to achieve more savings than under the current system? How would an episode of care be defined under the proposed model? How many visits are typically included in an episode, and to what extent does this vary by type of wound? How will the proposed model ensure that providers do not increase the volume of visits in response to receiving a visit-based bundled payment?

Hospitals are paid in multiples of what non-hospital based providers are paid.

Under the current system a patient could be going to a hospital based wound clinic for years without resolution. Under the proposed model quality data will have to be reported

including the number of visits to heal making it important for the providers to heal the wounds in a timely manner.

An episode of care will be defined as when a patient presents with a wound for the first time.

Based on various studies it takes on the average about 16 weeks for a wound to heal.

Venous and diabetic ulcers take longer to heal.

20. Page 8 states that the model “will create incentive to heal most of the wounds with in [sic] a minimum number of visits to maintain the quality of the program.” How will the proposed model ensure that participating providers do not avoid providing medically appropriate, more expensive services or materials whose cost may exceed the amount of the \$400 bundled payment?

As mentioned in the model, sometimes an autologous partial thickness skin graft is more feasible than the artificial grafts. The artificial grafts are much more expensive but the procedure to do a small ‘punch graft’ carries a 90 day global period. This means all care provided in the next 90 days is covered in the payment for the procedure.

This is a high risk for non-hospital based provider as care has to be provided and other procedures may have to be done until wound is fully closed. The cost of subsequent care exceeds what medicare pays for globally restricted procedure. Similarly alternate options can be found for other circumstances as they arise.

21. Page 11 states that “consistency of specially trained medical staff, safe care without unnecessary excesses procedures [sic] based on individual physician-assessed needs, extensive patient education during care provided by the actual clinician rather than ancillary staff, judicious use of procedures and products to reduce risk of side effects, close monitoring of progress and comorbidity impact with integral patient contact during each episode, and continuous vigilance to reduce time to healing motivated by appropriate tracking of each patient’s healing trajectory are some of safety measure which can get enhanced attention under the new model.” Are any of these services currently being provided in your wound clinic, and if so, to what extent and what impact have they had on utilization and cost of care?

The only way to compare will be to obtain cost data from medicare for surrounding hospital based wound clinics by PTAC.

This providers is providing wound care at a fraction of cost (15-20%) compared to nearest hospital based wound clinic. This is based on review of actual hospital bills provided by a patient who had been going there for almost 2 years without resolution until she came for second opinion to us. This patient had weekly visits and medicare paid \$750-\$1446 for each visit. Medicare has paid this provider average of \$97 for a visit for same amount of care. Patient’s son was trained to do the dressings so she comes only once a month – that is 3 less visits a month. The wound is 95% closed in 4 months.

This is an elderly patient who had multiple comorbidities and physical limitations. We worked extensively with patient and her son to achieve the goal of closing the wound.

Similarly we use expensive skin graft only when a patient is not healing instead of just expediting the time as encouraged by manufacturers.

We do not order venous vascular studies routinely on every patient with lower extremity ulcer. Majority of my elderly patients have poor hand dexterity, back pain and arthritis of hips and knees which makes it impossible for them to bend and pull compression stockings to wear. Doing extensive venous testing in these patients becomes irrelevant and wasted effort. We work with family members or simpler versions of compression garments to make it work under the circumstances.

These are just a few examples.

### **Level of Practice Interest in the Payment Model**

22. There were no letters of support from other providers included with your proposal and we did not receive any public comments supporting it. How many, and what types of providers do you believe would be interested in participating in this model if it were made available by CMS?

Due to the cost constraints from current system of reimbursement not many physicians want to deal with wound care.

Physicians already providing wound care out of their offices with passion for wound care will be delighted to join the model if CMS makes it available.

23. Page 4 states that “the proposed model will provide opportunity for more providers to join the model and provide care to patients in convenient less costly settings.” What, if any, requirements would be necessary for other providers to be eligible to participate in this model?

Providers should have provided wound care for at least 2 years.

This is the requirement for certification by American Academy of Wound Management.

24. Please describe the characteristics of your practice site (e.g., number and types of staff, equipment, and any other distinguishing characteristics). Are there any reasons why some other freestanding providers might not be able to implement the proposed model as it is currently being implemented at your site?

I am a Board Certified Geriatrician. I am also a certified wound care specialist physician (CWS-P), certified by American Academy of Wound Management. I started one of the first wound centers in Boston’s western suburbs in 2004.

I operate the only free standing wound clinic in Massachusetts.

This wound clinic has one licensed practical nurse, two medical assistants and an

office manager. The office is equipped with specially designed wound exam chairs, dressing supplies and instruments similar to any hospital based outpatient wound department. About 45% of patients are referred by other care providers, Urgent Cares, ERs and hospitals. 55% of the patients come through word of mouth. I have been cited as one of Boston's top doctors in various Boston area magazines Every year since 2015.

Not many physicians are interested in wound care. It is seen as something at the Bottom of food chain as I was once told by a medical director. Any physician with passion for wound care will be able to replicate my services. There are few but some physicians across the country who provide wound care out of their offices.

<https://www.woundsource.com/blog/comparing-private-and-hospital-based-wound-care-centers>

25. Do you believe that other providers would prefer to participate in your proposed model, or would they prefer that CMS address the concerns that you have raised that affect Medicare wound care payments to non-hospital-based wound care providers and clinics (for example, related to global period restrictions and local coverage determinations)?

I believe physicians interested in wound care will prefer the proposed model. The proposed model not only allows adequate reimbursement for physician services but adequate revenue for better staffing, equipment and supplies. The cost of hiring a full time staff in metropolitan areas like Boston is very high. If medicare removes some of the global restriction it will definitely relieve some financial constraints but the effect will still be limited. Hospitals are paid in multiples of what non hospital based wound providers get for providing same or better quality of care. Commercial insurances pay almost twice as much as medicare.

26. Do you currently have any similar reimbursement arrangements with other non-Medicare payers that are similar to what is being proposed in this model for non-hospital-based wound care? If so, please provide additional details regarding these arrangements, and what impact they have had on cost, quality of care, and outcomes.

No. Majority of patients seen in my wound clinic are elderly and have medicare. Commercial insurances pay twice or more compared to medicare. Unlike medicare they also reimburse for all the services provided without restrictions of global periods.

PHYSICIAN-FOCUSED PAYMENT MODEL TECHNICAL  
ADVISORY COMMITTEE (PTAC)

PRELIMINARY REVIEW TEAM (PRT)

CONFERENCE CALL WITH IKRAM FAROOQI, MD, CWS-P,  
SEHA MEDICAL AND WOUND CARE  
SUBMITTER

TUESDAY, JANUARY 16, 2019

3:00 p.m.

PRESENT:

BRUCE STEINWALD, MBA, Lead, PTAC Committee  
Member

ANGELO SINOPOLI, MD, PTAC Committee Member

GRACE TERRELL, MD, MMM, PTAC Committee Member

AUDREY McDOWELL, Assistant Secretary for  
Planning and Evaluation (ASPE)

GRETCHEN TORRES, NORC at the University of  
Chicago

ADELE SHARTZER, PhD, Urban Institute

KELLY DEVERS, PhD, NORC at the University of  
Chicago

AMY AMERSON, NORC at the University of Chicago

LAUREN ISAACS, NORC at the University of Chicago

ALLEGRA CHILSTROM, Neal R. Gross & Co.

Transcription

IKRAM FAROOQI, MD, CWS-P, Seha Medical and Wound  
Care

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

3:02 p.m.

MS. MCDOWELL: Thank you, everyone, for joining us. As we know, Dr. Ikram Farooqi submitted a proposal to the Physician-Focused Payment Model Technical Advisory Committee, also known as PTAC, regarding "Bundled Payment For All-Inclusive Outpatient Wound Care Services In Non-Hospital Based Settings."

And this is a meeting that has been called by the Preliminary Review Team, also known as the PRT, that is reviewing this proposal in order to ask some additional follow up questions to Dr. Farooqi regarding this proposal.

My name is Audrey McDowell. I'm on the ASPE staff and that's the Office of the Assistant Secretary for Planning and Evaluation within the Department of Health and Human Services.

And, I am supporting this particular PRT and, later on, the members of the PRT will be introducing themselves. But, we want to just

1 reiterate that this call is being recorded and  
2 transcribed.

3 And so, for purposes of the  
4 transcription, please try to remember to state  
5 your name as you speak so that it will be easier  
6 for the transcriptionist to be aware of who's  
7 speaking as we are going through the discussion.

8 So, I'm now going to turn it over to  
9 Bruce to do some additional housekeeping.

10 MR. STEINWALD: Okay. I think Dr.  
11 Farooqi should know who's on the call in addition  
12 to the PRT.

13 Grace, is that you by any chance?

14 DR. TERRELL: Yes, I'm sorry I was in  
15 another meeting, I'm a little bit late. I  
16 apologize everybody.

17 MR. STEINWALD: Not a problem, we were  
18 just doing the housekeeping.

19 But, why don't we -- so, the three  
20 members of the PRT are myself, I'm Bruce  
21 Steinwald and I'm lead reviewer. I'm an  
22 economist.

1                   But the other team members are  
2 physicians.       And I'll let them introduce  
3 themselves.

4                   Go ahead.

5                   DR. TERRELL: Okay, I'm Grace Terrell.  
6 I'm a general internist and have -- and the CEO  
7 of a company called Envision Genomics which is a  
8 company focused on rare, undiagnosed and  
9 misdiagnosed diseases.

10                  But, I've got a background in  
11 value-based healthcare through roles I had as the  
12 CEO of a medical group called Cornerstone and as  
13 the CEO of a population health management  
14 company.

15                  So, nice to meet you.

16                  DR. SINOPOLI: Angelo Sinopoli and I'm  
17 a pulmonary critical care physician and the Chief  
18 Clinical Officer for Prisma Health in South  
19 Carolina and the CEO of the Care Coordination  
20 Institute which is an integrated network  
21 enablement company.

22                  MR. STEINWALD: And there are some

1 people from the National Opinion Research Center,  
2 that's one of the contractors who work with ASPE  
3 to help support the PTAC.

4 Why don't you identify yourselves?

5 MS. TORRES: This is Gretchen Torres.

6 DR. SHARTZER: This is Adele Shartzter.

7 MR. STEINWALD: And, anyone else from  
8 ASPE?

9 (No response)

10 MR. STEINWALD: No?

11 And anyone else on the call who hasn't  
12 been identified yet?

13 MS. AMERSON: Hi, Amy Amerson from  
14 NORC and also our transcriptionist, Allegra  
15 Chilstrom.

16 MR. STEINWALD: Okay. And --

17 DR. DEVERS: Kelly Devers, NORC.

18 MR. STEINWALD: Okay.

19 MS. ISAACS: I'm Lauren Isaacs, NORC.

20 MR. STEINWALD: All right, so we  
21 requested the call, Dr. Farooqi, and am I  
22 pronouncing your name correctly?

1 DR. FAROOQI: Yes, perfect.

2 MR. STEINWALD: All right, thanks.

3 But to get a couple of additional  
4 clarifications.

5 Thank you for all your hard work in  
6 preparing your proposal and for responding to our  
7 questions. We know that's not a simple matter  
8 for someone with a busy clinical practice to set  
9 time aside for.

10 So, we do certainly appreciate your  
11 effort and also your willingness to take the time  
12 to talk to us today.

13 I'll start with a question or two and  
14 I'll let Dr. Terrell and Dr. Sinopoli ask their  
15 own.

16 I notice in your response to our  
17 questions that you run the only freestanding  
18 wound care clinic in the State of Massachusetts,  
19 is that true?

20 DR. FAROOQI: That is correct.

21 MR. STEINWALD: Yes. I know you had  
22 said that you thought that if the payment system

1 that you proposed were to be put in the field,  
2 that you think there'd be a lot of physicians who  
3 would be interested in participating. But we  
4 would also want to know why you believe that  
5 there would be a number of providers who would  
6 also be interested in participating in a -- in  
7 your model, assuming that it was implemented as a  
8 model, not as a change in the Medicare payment  
9 system.

10 Do you -- are you really confident  
11 that there would be other doctors who provide  
12 wound care services in a freestanding office  
13 setting, be willing to participate in the  
14 initiation of a model of this kind?

15 DR. FAROOQI: Yes, I have been to  
16 wound conferences and there are definitely, I  
17 have run into people who are in the other part of  
18 the country who do wound care out of their  
19 offices. Actually, I added one of the links in  
20 the responses of a physician who had -- was sort  
21 of similar feelings that I have and frustrations  
22 about the reimbursement system and trying to care

1 -- take care of the patients.

2 And she had written a blog on it. So,  
3 I'm sure there are people around the country that  
4 this would be not only attractive to them, but it  
5 would be very helpful.

6 MR. STEINWALD: Okay. And one of --  
7 either of you, Angelo or Grace like to follow up  
8 on that question before I change the subject a  
9 little bit?

10 DR. TERRELL: Not right now, no.

11 MR. STEINWALD: Okay.

12 So, one of our interests is also in  
13 you're getting a good sense of how the wound care  
14 that would be performed in your office would  
15 continue in an episode.

16 The payment system you're proposing is  
17 not a per visit payment. I noticed you said that  
18 most -- that your average time of healing was 12  
19 weeks I believe you said at one visit per week.

20 Elsewhere, you said --

21 DR. FAROOQI: That is correct, that is  
22 correct.

1           MR. STEINWALD: And that's a bit below  
2 the national average, is that also correct?

3           DR. FAROOQI: It is a bit below, so  
4 then it's a little bit of a tricky situation,  
5 yes.

6           The national average is about 14 weeks  
7 and so we are able to do it in about 12 weeks.  
8 And then other data goes anywhere from -- some  
9 data goes anywhere from 10 to 16 weeks, so it  
10 really depends.

11           So, that's what I was comparing  
12 myself, with U.S. wound registry. And, there is  
13 a critique for that, too.

14           So, but by and large, it's anywhere  
15 from 12 to 16 weeks for all our wound care and  
16 the individual wounds can take longer like  
17 diabetic and venous ulcers. Simple wounds are a  
18 little bit shorter. So, overall, it comes to  
19 about 12 weeks, yes.

20           MR. STEINWALD: Did you consider  
21 adding a severity or complexity component to your  
22 proposal where -- what you called simple wounds

1 might be -- have a different standard for time  
2 for healing than the more complex wounds and the  
3 way that would be reflected in the payment  
4 system? Did you consider that?

5 DR. FAROOQI: No, I did not consider  
6 it. It becomes difficult to do, part of the  
7 reason is, again, as I said, most of the people I  
8 see are elderly people. So, sometimes they can  
9 come with what looks like a simple wound and it's  
10 recorded as a simple wound.

11 But then, if it doesn't heal, it can  
12 go on like it gets infected in between or  
13 something happens then it can turn into  
14 complications.

15 So, for simplification of the model,  
16 I thought if we just keep it sort of one standard  
17 evaluation that would make it easier.

18 MR. STEINWALD: Okay. In the system  
19 where you're proposing the payment in the -- for  
20 a visit would be substantially more than what the  
21 current system permits in the office setting.

22 What kind of -- now, reflecting here

1 is a number of sites participating, not just your  
2 own, what kind of controls do you think need to  
3 be put in place to make sure that the number of  
4 visits doesn't extend beyond what is appropriate  
5 or necessary?

6 DR. FAROOQI: I think one of the ways  
7 would be to have a total cost as the limit. So,  
8 then you know the data is all over the place,  
9 depending on articles and who did the study and  
10 where the study was done.

11 But, by and large, the average amount  
12 that is spent for treating the wound is around  
13 for all costs I would say is about \$7,000,  
14 ranging anywhere from \$6,500 two or three  
15 thousands, so it roughly comes to about \$7,000  
16 from there.

17 So, if we stick to 12 weeks and if we  
18 stick to \$400 per visit, I think that would be  
19 reasonable.

20 MR. STEINWALD: And so, you're, again,  
21 you're saying 12 weeks, so you think that others  
22 could achieve the 12-week standard in addition to

1       yourself    from    other    adopters    who    would  
2       participate in the model like this could set the  
3       standard of 12 weeks on average for healing?

4                   DR. FAROOQI:    Yes, yes.

5                   MR. STEINWALD:    Okay, okay, that's  
6       interesting, thank you.

7                   So, I think that at this time I'd like  
8       to ask Dr. Terrell and Dr. Sinopoli if they'd  
9       like to ask you any questions and please go right  
10      ahead.

11                   DR. SINOPOLI:       So, this is Dr.  
12      Sinopoli.

13                   If you're in the middle of a course of  
14      treatment and a patient becomes ill for whatever  
15      reason and has to be hospitalized and received  
16      wound care in the hospital and then is discharged  
17      back, do you envision picking that patient back  
18      up where you left off?

19                   And would -- how would the payment  
20      model fit into that scenario?

21                   DR. FAROOQI:    So, if the patient was  
22      there in between, once he or she comes back, we

1 pick up from there.

2 Typically, once they are in the  
3 hospital, you would assume that, you know,  
4 keeping the legs up or feet up, the wound would  
5 be better. So, we can simply pick up from where  
6 we left off unless, you know, there is a new  
7 wound or there is a new issue.

8 But for that particular wound, we'll  
9 have to just pick up from where we left off.

10 DR. SINOPOLI: Okay.

11 MR. STEINWALD: Go ahead.

12 DR. TERRELL: So, my question for you  
13 is related to -- it's often a claim by hospitals  
14 that physicians will cherry pick the simpler  
15 stuff to do in the office setting and leave the  
16 more difficult cases for them.

17 And, that's one of the ways that they  
18 sometimes justify the higher fees that they get  
19 for hospital outpatient services.

20 I don't necessarily agree with that,  
21 but my -- I guess my question for you is related  
22 to the fact that your wound healing time is fewer

1 weeks than theirs.

2 How can we -- number one is, do you  
3 send -- what types of cases do you not do in the  
4 setting that you have now? Or would not be  
5 appropriate from your model and ought to go  
6 elsewhere?

7 And the second one is, what types of  
8 things would be put in place to reassure that  
9 there's not cherry picking going on?

10 Why is your healing rate faster? Is  
11 it because you're doing better care or because  
12 the incentives are different?

13 I just need to kind of understand it  
14 because that argument is what's typically made by  
15 the facility people, as you well know.

16 DR. FAROOQI: Yes, so I don't agree  
17 with that argument either.

18 So, number one, until the patient  
19 comes in, we, you know, we do the diagnosis most  
20 of the time when we get the phone call, it's a  
21 leg wound or an arm wound or a foot wound. So,  
22 until you see it, you don't know the details.

1 So, that's one thing.

2 But definitely people can ask more  
3 questions about it.

4 But I'm not sure, I mean, if there is  
5 any hundred percent way of preventing cherry  
6 picking if somebody wants to do that, but the  
7 hospital themselves, to be honest, do that, too.

8 And the hospitals are paid -- the  
9 thing is, most of the hospitals have management  
10 companies which come in and run the practice for  
11 them and do all this investment.

12 So, there are -- obviously the  
13 interest is revenue more than anything else.

14 I think so to answer the first  
15 question on why my healing rate is a little bit  
16 better than that? Is, and I feel -- I don't  
17 think I'm the only one, I'm sure there are many  
18 other people who have interest in wound care who  
19 really take time to do the things in an orderly  
20 fashion. They probably all have the same rates.  
21 So, that's one thing.

22 I did put an example there of a person

1 who was going to another hospital-based wound  
2 clinic where somebody worked that's filling in  
3 and that makes the difference.

4 So, back to cherry picking, to be  
5 honest, I -- you know, the only way to prevent it  
6 or to keep track of it would be to have every  
7 call from the patient logged in and have, if  
8 somebody wants or somebody says I cannot take  
9 care of this patient, then there should be a  
10 detailed -- or at least some explanation of why  
11 not.

12 For example, if somebody comes to me  
13 who needs surgery in a hospital which does happen  
14 like foot ulcers or a large hematoma that I  
15 cannot handle, I do have to send them to a  
16 surgeon who can do it in the hospital.

17 But, yes, cherry picking is, to be  
18 honest, it's difficult.

19 DR. TERRELL: Thank you.

20 MR. STEINWALD: Dr. Farooqi, I noticed  
21 that you said that your team, in addition to  
22 yourself, one licensed practical nurse, two

1 medical assistants and an office manager.

2 Do you regard that as an ideal  
3 composition of a team? What constitutes a good  
4 team from your standpoint and how might it be the  
5 same or different from what you have yourself?

6 DR. FAROOQI: So, one -- a couple of  
7 people I would like to have is maybe one full RN  
8 and then somebody who is a lymphedema therapist  
9 who can come in and have some work with us.

10 So, we used to have a lymphedema  
11 therapist 15 years ago when we started the wound  
12 clinic, but because of the reimbursement issues,  
13 we just could not keep her.

14 Again, this is bare bones because this  
15 is all I can afford, but if there is better  
16 investments, yes, I would prefer to have at least  
17 one RN and NP onboard, too.

18 And then, depending on the volume of  
19 the patients, you know, you have more medical  
20 assistants.

21 MR. STEINWALD: What training do the  
22 medical assistants receive?

1 DR. FAROOQI: So, medical assistants,  
2 we train them ourselves. So, when they come in,  
3 one of my medical assistants has been with me for  
4 many years. The other was -- had worked in one  
5 of the large hospitals in plastic surgery before  
6 she came to us.

7 But the specific wound care, then I  
8 and the LPN that I have for many years, we train  
9 them in how to take the dressings off, take the  
10 picture, measure the wound, how to wash the leg  
11 and the foot.

12 So, there is a whole -- we have a  
13 step-wise protocol for everything and we go over  
14 it and it takes a few weeks to train them. But  
15 we do it -- I do it myself.

16 MR. STEINWALD: Okay, that's it.

17 So, in a more -- in a different and  
18 more generous reimbursement regime, you would  
19 like to expand your staff to include more highly  
20 trained participants?

21 DR. FAROOQI: That is correct.

22 MR. STEINWALD: Okay.

1 DR. SINOPOLI: This is Angelo.

2 I'm just curious, did you think that  
3 there's a minimum number of patients or volume  
4 needed to or a center to actually see to be  
5 successful with -- from a quality standpoint and  
6 financially?

7 DR. FAROOQI: You are looking for a  
8 minimum number?

9 DR. SINOPOLI: Yes, the practice does  
10 one of these patients a month are there quality  
11 indicators that would say what the centers needed  
12 to be concentrated or specialized in this area?

13 If added practice doctors started  
14 billing and seeing patients with these problems?

15 DR. FAROOQI: I believe for -- to have  
16 a dedicated wound clinic outpatient independent,  
17 about 10 patients a day would be I think  
18 sufficient to run a, you know, a full scale  
19 clinic.

20 DR. SINOPOLI: Okay.

21 MR. STEINWALD: Dr. Farooqi, I'm sure  
22 many of your patients have multiple chronic

1 illnesses, you said they're all elderly.

2 Your example was very interesting  
3 because it was a case of a patient of yours who  
4 had a chronic illness who -- was difficult for  
5 that patient to stay off of his wounded foot, if  
6 I remember correctly.

7 DR. FAROOQI: That's correct.

8 MR. STEINWALD: Yes, how, in general,  
9 how do you manage to treat patients with multiple  
10 chronic illnesses and what do you need to know  
11 about these patients in order to treat their  
12 wounds effectively if there are other chronic  
13 illnesses and they somehow affect the success of  
14 that treatment?

15 DR. FAROOQI: Yes, so we have a whole  
16 range of chronic illnesses. I think the average  
17 age of patients I see is about 80 years old, they  
18 go as high as 106.

19 They have -- the most common,  
20 obviously, by that age is peripheral vascular  
21 disease and a lot of times, they may have a  
22 borderline peripheral vascular disease. They are

1 able to do the compression stockings, but once  
2 they like hit a leg or they suffer a small trauma  
3 and there is a skin tear, it does not heal  
4 because of that.

5 So, that's the very common scenario.  
6 We have people with rheumatoid arthritis. We  
7 have people who have congestive heart failure.

8 So, in those cases, I have to work  
9 with their primary care or with their  
10 cardiologist and, in the case of CHF causing all  
11 -- making the edema of the leg with the  
12 peripheral vascular disease even more  
13 complicated, more worse or worse, then we have to  
14 work with them, increase the Lasix, being an  
15 internist sometimes I can do it myself and then  
16 collaborate with the internist or the  
17 cardiologist.

18 Rheumatoid arthritis, we have had  
19 cases where we had to hold off their medications.  
20 There's about a two week window before their  
21 symptoms will start to get worse.

22 So, we have to really do everything

1 within that two weeks if we withhold somebody's  
2 rheumatoid medication.

3 So, it really varies from case to  
4 case.

5 I think maybe it's a little bit easier  
6 for me because my background is geriatrics and  
7 internal medicine. So, but some of the people  
8 that I have looked online where the -- they will  
9 have the general approach.

10 So, that's how I, you know, I'm able  
11 to put things in.

12 One of the things we do is, as soon as  
13 the patient comes in for whatever reason, a  
14 venous ulcer or a diabetic ulcer, we start the  
15 education from day one that, and I tell them, you  
16 know, easy -- the healing is not the most  
17 difficult part, the most difficult part is to  
18 prevent it from coming back.

19 I usually tell a joke with them about  
20 that, you know, if you don't want to see me  
21 again, you have to do this, this, this, this.

22 So, there's a whole variety of things

1 that we work with people to achieve the goal.

2 MR. STEINWALD: Do you consider  
3 function and activities of daily living or things  
4 of that nature in addition to wound healing as  
5 one of the services that you're providing for  
6 these patients?

7 DR. FAROOQI: That is actually  
8 correct, sir. The -- I think I always tell  
9 people, you use it or lose it. So, I, you know,  
10 unless absolutely necessary will be that could be  
11 hardly error.

12 I always encourage them to get up and  
13 walk as much as they can instead of just telling  
14 them that, you know, keep your legs up or keep  
15 your feet up.

16 And then, we a lot of times, we go  
17 around, you know, what's the limitation of the  
18 wound is to so that they can do at least some  
19 exercise.

20 Sometimes they can just, you know, do  
21 the -- what's called the "sittercise," they can  
22 sit and do some exercises. They can get up and

1 walk.

2 So, this is very important for the  
3 ADLs, yes.

4 And then, as I have cited the example  
5 in the questions when I was answering, this was  
6 one of the issues is activities of daily living  
7 that if you give a person an instruction that  
8 interferes with their activities of daily living,  
9 then you are setting up the person for  
10 non-compliance.

11 MR. STEINWALD: How do you manage the  
12 flow of information between you and the other  
13 providers making sure that you have all the  
14 information that you need to do your wound care  
15 treatment successfully and that the primary care  
16 physician and others have the information that  
17 they need from you in order to ensure that with  
18 their services that they're providing don't  
19 undermine the services that you're providing?

20 How do you manage the flow of  
21 information is the question?

22 DR. FAROOQI: So, most of the people

1 I see are within -- about half -- not half, about  
2 60 percent come from the same hospital system  
3 which is the Partners HealthCare in greater  
4 Boston area.

5 And they have the electronic medical  
6 record system which is called Epic. So, it  
7 covers at least five or six hospitals. So a lot  
8 of physicians are on the same system.

9 When people are on a different system,  
10 that's when we have to either call them or fax  
11 them information or have them fax information or  
12 come in and we do it the old fashioned way.

13 MR. STEINWALD: Okay. All right then  
14 --

15 DR. FAROOQI: But most of the patients  
16 being on the Epic, at least in my case, because a  
17 lot of people are in this area have the, you  
18 know, physicians on the same system. So, we can  
19 upload the pictures. I always send them the  
20 pictures and the updates, it's much easy -- it's  
21 very easy, you know, all we have to do is collect  
22 the PCP and send information and it goes there.

1                   MR. STEINWALD: And so, the area from  
2                   which you get your patients sounds like it's  
3                   fairly well contained then within Boston proper,  
4                   is that correct?

5                   DR. FAROOQI: I am in the Boston  
6                   suburbs, the town of Wellesley, so like you said,  
7                   about 60 percent are one or the other, we are  
8                   affiliated partners.

9                   So, the other larger system embedded  
10                  is MetroWest system from where I get patients,  
11                  too. So, I do not have direct information to  
12                  their electronic system, but then, you know, we  
13                  communicate either a simple phone call or a fax.

14                  MR. STEINWALD: Okay, okay, that's  
15                  good information. Thank you.

16                  Grace or Angelo, any additional  
17                  questions?

18                  DR. TERRELL: I'm good, thank you.

19                  DR. SINOPOLI: I'm fine.

20                  MR. STEINWALD: Okay.

21                  All right, I'm at the end of my  
22                  questions, too. But, Dr. Farooqi, it would only

1 be fair if we gave you the opportunity to ask  
2 some questions of us, some of which we maybe  
3 couldn't answer, but is there anything that you  
4 would like to know or any clarification of the  
5 process that PTAC goes through that would be  
6 helpful to you?

7 DR. FAROOQI: Yes. So, I understand  
8 that this is preliminary work to put everything  
9 together and then it goes to PTAC where it will  
10 be discussed, correct?

11 MR. STEINWALD: Correct, yes.

12 DR. FAROOQI: Okay. So, and then  
13 depending what they decide, the, you know,  
14 whether to move forward or not, if they do decide  
15 to make a recommendation that this is something  
16 to be tried on, so then the recommendation goes  
17 to the Secretary of Health?

18 MR. STEINWALD: And Human Services,  
19 yes.

20 DR. FAROOQI: Yes. So, what happens  
21 after that?

22 MR. STEINWALD: That's a good

1 question, we ask that of ourselves.

2 We only have the authority to make  
3 recommendations to the Secretary. And the  
4 Secretary has to respond to our recommendations.

5 But the Secretary's not required to  
6 follow our recommendations.

7 And over the time that we've been in  
8 existence, we've had a lot of back and forth with  
9 the Secretary and staff, especially the Center  
10 for Medicare and Medicaid Services on how they  
11 can take advantage of the work that we do and our  
12 recommendations.

13 It's unlikely that many of our  
14 recommendations are followed to the nth degree.  
15 But there are some that have been at least  
16 partially followed.

17 CMS has to fit in what we're  
18 recommending into their portfolio of projects  
19 that they already are funding.

20 So, it's a long way of saying that  
21 once we make a recommendation, what happens after  
22 that is always a bit uncertain.

1 DR. FAROOQI: Okay, okay, all right.  
2 All right. And I guess that's all I needed to  
3 know.

4 MR. STEINWALD: And there's always a  
5 lot of additional information that gets exchanged  
6 at the full public meeting.

7 As I said, the Preliminary Review Team  
8 is only three of the 11 members and there's  
9 always a richness of discussion among the full  
10 membership of PTAC and very often with the  
11 individuals who are proposing payment changes and  
12 models. That's been over the two years that  
13 we've been doing this, that's been a very  
14 interesting process.

15 DR. FAROOQI: Okay, thank you.

16 MR. STEINWALD: You're welcome.

17 Audrey, is there anything else that we  
18 need to cover?

19 MS. MCDOWELL: No, not at this time  
20 unless there's something else that you want to  
21 discuss.

22 MR. STEINWALD: No, I think we're

1 good.

2 Dr. Farooqi, thank you for taking the  
3 time and again, thank you for all the work that  
4 you've put into your proposal. And, I guess we  
5 might be seeing you again at a meeting.

6 DR. FAROOQI: Sure. Thank you very  
7 much everyone.

8 DR. TERRELL: All right, thank you.

9 DR. FAROOQI: Yes. I appreciate your  
10 time and interest.

11 MR. STEINWALD: We appreciate you,  
12 too. Thank you, bye-bye.

13 (Whereupon, the above-entitled matter  
14 went off the record at 3:35 p.m.)

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C E R T I F I C A T E

This is to certify that the foregoing transcript

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Before: PTAC PRT

Date: 01-16-19

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