Preliminary Review Team Findings on

Bundled Payment for All Inclusive Outpatient Wound Care Services in Non Hospital Based Setting

Submitted by Seha Medical and Wound Care,
Ikram Farooqi, MD, CWS-P

Bruce Steinwald, MBA (Lead Reviewer)
Angelo Sinopoli, MD
Grace Terrell, MD, MMM

March 11, 2019
Presentation Overview

• Preliminary Review Team (PRT) Composition and Role
• Proposal Overview
• Background
• Summary of the PRT Review
• PRT Evaluation Using the Secretary’s Criteria
• For Broader Discussion
Preliminary Review Team Composition and Role

• The PTAC Chair/Vice Chair assigned three PTAC members (Steinwald, Sinopoli, and Terrell), including two physicians (Sinopoli and Terrell), to serve as the PRT. Steinwald was designated to serve as the Lead Reviewer.

• The PRT identifies additional information needed from the submitter and determines to what extent any additional resources and/or analyses are needed for the review. ASPE staff and contractors support the PRT in obtaining these additional materials.

• The PRT determines, at its discretion, whether to provide initial feedback on a proposal.

• After reviewing the proposal, additional materials gathered, and public comments received, the PRT prepares a report of its findings to the full PTAC. The report is posted to the PTAC website at least three weeks prior to public deliberation by the full Committee.

• The PRT report is not binding on PTAC; PTAC may reach different conclusions from those contained in the PRT report.
Proposal Overview

**Background** – Proposal is based on the submitter’s experience as a board-certified geriatrician and certified wound specialist physician (CWS-P) who has been operating a freestanding, office-based wound care clinic in the western suburbs of Boston, Massachusetts since 2004.

**Goals** – Seha seeks to develop a fixed-price bundled payment model for office-based wound care services to provide an efficient substitute for hospital-based/outpatient facility-based wound care.

**APM Entity** – An office-based wound care provider or clinic would serve as the APM entity.

**Provider Eligibility** – Independent office-based wound care providers and clinics; required to have at least two years of experience in providing wound care.

**Beneficiary Eligibility** – Any Medicare beneficiary seeking or requiring specialty care in a wound clinic with an acute or chronic wound (including long-term residents of nursing homes that do not employ the services of wound care specialists to provide consultations in-house).

**Enrollment Process** – Patients will be referred by their providers, hospital or emergency department, or by family members or self-referral. Upon referral, patients will be registered, referrals will be logged, and patients will receive a one-paragraph statement indicating that all care provided is included in the per-visit bundled payment.

**Care Delivery Model** – The submitter believes that allowing for flexibility relating to the care model will allow participating providers to find what works best for their patients.
Payment – A $400 flat fee bundled payment per-visit for all wound care services typically provided to patients who are enrolled in the participating wound clinic. The payments would NOT be risk-stratified based on patient acuity.

<table>
<thead>
<tr>
<th>Payment includes the cost of:</th>
<th>Proposed Quality Measures</th>
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<tbody>
<tr>
<td>• Evaluation and management (E&amp;M)</td>
<td>Six quality measures, most of which were adapted from the U. S. Wound Registry:</td>
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<tr>
<td>• Patient education</td>
<td>• Improvement in quality of life</td>
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<td>• Skin care by the staff</td>
<td>• Improvement in pain scale/control</td>
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<td>• Procedures <em>(such as wound debridements, unna boot applications, offloading total contact cast)</em></td>
<td>• Number of visits to heal different wounds such as diabetic and venous leg ulcers (compared with nationally reported data)</td>
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<tr>
<td>• Advanced tissue products/skin substitutes</td>
<td>• Number of prescriptions filled for proper offloading devices and footwear (e.g., diabetic footwear) and prescriptions for compression garments for patients with venous ulcers</td>
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<td>• Dressings done at the clinic</td>
<td>• Blood monitoring of A1C for patients with diabetic ulcers</td>
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<td>• Other supplies, such as medications</td>
<td>• A venous leg outcome measure</td>
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<th>Payment DOES NOT include the cost of:</th>
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<tr>
<td>• Hyperbaric oxygen treatments</td>
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<td>• Any service provided outside of the office-based wound clinic <em>(such as physical therapy, visiting nurse services, the need for hospitalization, laboratory, x-ray, ultrasound, CT Scans, and MRIs)</em></td>
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• In 2016, ~350,000 Medicare Fee-for-Service (FFS) beneficiaries with wound diagnoses received non-emergent wound care in **office-based** settings or **outpatient facilities**
  – Three quarters of their wound care claims were for services provided in **office-based** settings

• Mean Medicare-allowed charges for wound-related visits:
  – Office-based: $95
  – Outpatient facility: $413 (mean facility charge: $355; mean provider charge: $27)

• Podiatrists provided the majority (75%) of **office-based** wound care visits

• Wound-care providers in **outpatient facilities** were varied (e.g., general surgeons, podiatrists, family practice physicians, internists, emergency medicine specialists)
### Summary of the PRT Review

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<th>Criteria Specified by the Secretary (at 42 CFR §414.1465)</th>
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<td>Does Not Meet Criterion</td>
<td>Majority</td>
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<td>7. Integration and Care Coordination</td>
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<td>10. Health Information Technology</td>
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Criterion 1. Scope (High Priority)

Criterion Description
Aim to either directly address an issue in payment policy that broadens and expands the CMS APM portfolio or include APM Entities whose opportunities to participate in APMs have been limited.

PRT Conclusion
Meets Criterion

Unanimous or Majority Conclusion
Unanimous

- Medicare FFS reimbursement discourages provision of wound care services in some office-based settings and encourages provision of these services in hospital-based/outpatient facility-based settings where patients may be getting care that is more expensive.

- Currently no CMS Innovation Center APM addresses chronic outpatient wound care services for office-based providers.

- The extent to which the proposed model would encourage a significant number of office-based wound care providers to participate is uncertain.

- However, the proposed model could still have an impact on some Medicare beneficiaries who may be able to receive wound care services in lower cost office-based settings.
Criterion 2. Quality and Cost (High Priority)

Criterion Description
Are anticipated to improve health care quality at no additional cost, maintain health care quality while decreasing cost, or both improve health care quality and decrease cost.

PRT Conclusion
Does Not Meet Criterion

Unanimous or Majority Conclusion
Unanimous

• The submitter proposes that a 20% reduction in costs could be achieved by providing a $400 bundled payment per visit and shifting some wound care patients to the less costly office-based setting.

• However, the proposal does not provide sufficient assurances that the quality of wound care services provided by the participating office-based providers/clinics would be better under the proposed model.
  – For example, the proposal does not provide sufficient information about how the proposed quality metrics would be measured, and payment would not be tied to quality.

• The proposal does not provide sufficient assurances that participating providers will not engage in “cherry picking,” or provide excessive care in the form of additional visits that could result in additional costs to the Medicare program.
Criterion 3. Payment Methodology (High Priority)

**Criterion Description**
Pay APM Entities with a payment methodology designed to achieve the goals of the PFPM criteria. Addresses in detail through this methodology how Medicare and other payers, if applicable, pay APM Entities, how the payment methodology differs from current payment methodologies, and why the PFPM cannot be tested under current payment methodologies.

**PRT Conclusion**
Does Not Meet Criterion

**Unanimous or Majority Conclusion**
Unanimous

- The proposed model would permit payment of substantially more than what the current system permits in the office-based setting for wound care services without building in any mechanisms to ensure that the corresponding number of visits does not extend beyond what is appropriate and necessary.
  - It is not clear that the proposed $400 per-visit all-inclusive bundled amount (compared with the current mean Medicare allowed charge of $95 for wound care for providers in office-based settings) is necessary for office-based providers to be able to deliver high-quality wound care services.

- Under the proposed model, there does not appear to be any negative consequence for the participating office-based wound care provider if an enrolled patient is hospitalized after receiving low-quality wound care services.
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<td>Provide incentives to practitioners to deliver high-quality health care.</td>
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- The proposed $400 per-visit bundled payment would potentially provide an incentive for office-based providers to increase the volume of wound care visits in order to maximize revenue.
Criterion 5. Flexibility

- The proposed model would potentially provide additional options and resources that could provide additional flexibility to office-based wound care providers for providing wound care services in additional areas, and delivering higher-quality care.
  
  - For example, some office-based providers might be able to schedule fewer patient visits for medically necessary treatments, or hire additional staff.
Criterion 6. Ability to Be Evaluated

- The proposal mentioned some goals and metrics that could potentially be evaluated (e.g., pain scale, number of visits to heal different kinds of wounds, time to healing).

- However, the proposal does not articulate a methodology for conducting the evaluations.

- The proposal also seeks to compare participating office-based providers’ “total cost of care per wound care episode” with the national average for hospital-based outpatient wound care facilities without comparing cost and quality under the proposed model with the status quo.
Criterion 7. Integration and Care Coordination

- The proposed model could provide an opportunity to improve care coordination between office-based wound care providers and other health care providers for a group of Medicare patients that are clinically complex and typically have multiple comorbidities.

- However, the proposed per-visit payment model does not incentivize care coordination, and the proposal does not include any other details regarding how the model would ensure that increased care coordination occurs.

PRT Conclusion
Does Not Meet Criterion

Unanimous or Majority Conclusion
Unanimous
Criterion 8. Patient Choice

**Criterion Description**
Encourage greater attention to the health of the population served while also supporting the unique needs and preferences of individual patients.

**PRT Conclusion**
Meets Criterion

**Unanimous or Majority Conclusion**
Unanimous

- The proposed model would increase patient choices for Medicare beneficiaries by potentially increasing the number of lower-cost office-based wound care service providers.

- The proposed model does not discuss how patients would become aware of information about differences in costs and outcomes across settings, which would enable them to make an informed choice regarding where to receive their care.
Criterion 9. Patient Safety

- The proposal has the potential to improve patient safety by reducing the incentives to provide excessive care through the provision of a $400 fixed price, per-visit bundled payment for wound care services.

- However, there is no assurance that individual patients would receive the care they need from participating providers during each wound care visit under the proposed model.
  - The proposal would not require participating providers to implement a specific care model in order to achieve the desired results.
  - The $400 fixed price, per-visit bundled payment could result in risks related to stinting on care or increasing the number of visits.
Criterion 10. Health Information Technology

Criterion Description
Encourage use of health information technology to inform care.

PRT Conclusion
Does Not Meet Criterion

Unanimous or Majority Conclusion
Unanimous

- The proposal does not include provisions that would encourage participating providers to use health information technology to inform the provision of wound care services to their patients.

- The proposal also does not include provisions to facilitate information exchange with other providers.
For Broader Discussion

• The submitter has identified that Medicare payments for wound care services are not site neutral.

• The proposal as written has a number of structural flaws and elements that are not sufficiently developed.
  – Most notably, the proposed payment model—a $400 per-visit flat fee payment for wound care services—
    raises concerns about the potential impact that not limiting the number of visits per wound care episode
    could have on utilization and total cost of care.
  – The model also does not include a severity or complexity component to account for comorbidities and
    other factors; would not require participating providers/clinics to bear any financial risk; and does not
    include sufficient features to prevent the potential for “cherry-picking” and stinting on care.
  – The proposal is also under-developed with respect to several other important dimensions, such as quality
    assurance, coordination of care, evaluation methodology, and health information technology.

• It is not clear the extent to which some of the reimbursement-related concerns that have been raised by the submitter could be potentially addressed by making modifications to the Medicare Physician Fee Schedule.
Preliminary Review Team Findings 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 Upstream Rehabilitation

Harold D. Miller (Lead Reviewer)
Kavita Patel, MD, MSHS
Bruce Steinwald, MBA

March 11, 2019
Presentation Overview

• Preliminary Review Team (PRT) Composition and Role
• Proposal Overview
• Summary of the PRT Review
• Key Issues Identified by the PRT
• PRT Evaluation Using the Secretary’s Criteria
The PTAC Chair/Vice Chair assigned three PTAC members (Miller, Patel, and Steinwald), including one physician (Patel), to serve as the Preliminary Review Team (PRT). Miller was designated to serve as the Lead Reviewer.

The PRT identified additional information needed from the submitter on the original proposal. ASPE staff and contractors supported the PRT in obtaining these additional materials and also conducted a literature review on wound care.

The PRT provided initial feedback to the submitter on the original proposal and held a conference call with the submitter. The submitter withdrew the original proposal and submitted a revised proposal.

The PRT requested additional information from the submitter on the revised proposal.

After reviewing the revised proposal, additional information provided by the submitter, and public comments received, the PRT prepared a report of its findings to the full PTAC. The report and additional materials were posted to the PTAC website prior to public deliberation by the full Committee.

The PRT report is not binding on PTAC; PTAC may reach different conclusions from those contained in the PRT report.
**Proposal Overview**

**Background** – The submitter, a network of private outpatient therapy clinics, is proposing a two-year pilot study with 200 therapists to evaluate the effects of the proposed model, with the potential for expansion to a long-term payment model.

**Goals** – The submitter seeks to expand the ability of physical therapists (PTs) and occupational therapists (OTs) to manage chronic wounds in Medicare beneficiaries.

**APM Entity** – PTs/OTs in free-standing, private outpatient therapy clinics would serve as the APM entity. Corporations could participate by group application.

**Provider Eligibility** – Registered PTs/OTs would be eligible if they have: 1) demonstrated advanced training in the treatment of wounds; 2) the ability to collect required outcomes measures and track the frequency, duration, and supplies utilized for participating patients; and 3) the ability to bill CMS electronically.

**Beneficiary Eligibility** – Medicare beneficiaries will be identified for participation by an ICD-10 diagnosis code requiring wound care and a referral from a primary care provider (PCP) for therapy to address a related functional loss.

**Enrollment Process** – Patients will be referred by their PCPs and evaluated by the participating therapist. Eligible patients would be informed about the program, and be given the opportunity to opt out of collection of de-identified data.

**Care Delivery Model** – PTs/OTs would take primary responsibility for the treatment of the wounds, with a focus on functional improvement. Standard communication with PCPs would occur every 10th visit or every 30 days via progress notes.
Payment Methodology
- PTs/OTs would receive standard payments under the Medicare Physician Fee Schedule for PT/OT visits, but PTs/OTs would repay CMS if patients do not demonstrate minimal clinically significant improvement.
- New one-time payment of $250 per patient for wound care supplies *(except cellular and tissue-based products)*.
- PT/OT ability to bill for use of advanced therapeutics (C5271-C5278 and Q4100-Q4172).
- PTs/OTs would be placed on probation if average PT/OT costs per episode exceed a risk-stratified cap ($3,500 for low risk, $4,500 for moderate risk, and $5,500 for high risk beneficiaries) in a quarter or if patient satisfaction is below 80%. PTs/OTs would be terminated from the program if the cap is exceeded or patient satisfaction is below 80% during two quarters.
- Performance bonus of 3% of savings if average Medicare payments for PT/OT services per episode are below the risk-stratified cap over the 2-year study period.
- Exemption from the Medicare threshold exceptions/review process for outpatient therapy services.

Proposed Outcome Measures
- Functional outcomes using the Bates-Jensen Wound Assessment Tool, plus one of the following:
  - QuickDASH (Disabilities of the Arm, Shoulder, and Hand Questionnaire)
  - Lower Extremity Functional Scale (LEFS)
  - Pain Scale
  - Oswestry Disability Index
- Patient Satisfaction
## Summary of the PRT Review

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The revised proposal focuses on an area where there are significant opportunities to improve access to care for patients, to improve outcomes, and to achieve savings for Medicare.

The proposed approach to care delivery has the potential to improve patient access to wound care, reduce spending and patient cost sharing, and promote more rapid healing and reductions in complications. However, the PRT is concerned the proposal is focused only on services that can be delivered by PTs/OTs, and this will not include all of the services many patients with chronic wounds need.

Also, the model would only apply to patients who also need physical or occupational therapy, which could limit access to wound care services to patients who also needed physical/occupational therapy or encourage patients with wounds to be referred for therapy who otherwise would not receive it.

The payment model has several desirable and novel features. It is outcome-based, i.e., the PT/OT would not be paid unless the patient achieved a minimum level of improvement, and there would be a cap on average payments per patient.

However, the PRT has several major concerns about the proposed payment model. The cap on average payments only applies to the PT/OT services, not the total cost of wound care; the incentive to reduce spending below the cap is very weak; there is no requirement to continue delivering services when the cap has been reached or a desirable outcome is not being achieved, nor is there a requirement to accept all patients who need services; and the outcome measures are based on function and pain rather than wound healing.
Criterion Description
Aim to either directly address an issue in payment policy that broadens and expands the CMS APM portfolio or include APM Entities whose opportunities to participate in APMs have been limited.

PRT Conclusion
Meets Criterion

Unanimous or Majority Conclusion
Unanimous

• The proposed model addresses a patient population with significant health needs; wounds are estimated to affect nearly 15% of Medicare beneficiaries.

• There is no comprehensive Medicare APM focused on wound care.

• PTs and OTs have limited opportunities to participate in APMs.

• Though the number of participating providers is small in the short term (200), the proposed model has the potential to be expanded.

• However, the model is only designed to support the specific types of wound care that can be delivered by PTs/OTs. The model design does not explicitly define which patients would be appropriate candidates for treatment of their wounds by PTs/OTs.
Criterion 2. Quality and Cost (High Priority)

**Criterion Description**
Are anticipated to improve health care quality at no additional cost, maintain health care quality while decreasing cost, or both improve health care quality and decrease cost.

**PRT Conclusion**
Does Not Meet Criterion

**Unanimous or Majority Conclusion**
Unanimous

- The model has the potential to shift wound care services to a lower-cost setting. However, it could also lead to increased physical/occupational therapy use for patients who otherwise would not receive such therapy.
- The proposed model does not describe what methods providers would use to reduce payments below the caps without jeopardizing patient outcomes.
- The model does not include adequate safeguards for quality of care to ensure that patients are appropriately matched to providers with the skill sets and services to treat their particular wounds.
- The standards of performance on the outcome measures are not clearly defined.
- The use of expensive wound care products by PTs/OTs could lead to increased spending without improvements in quality.
Criterion 3. Payment Methodology (High Priority)

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- The proposed model would link payment to outcomes by refunding CMS for services delivered to patients who do not demonstrate improvement, but outcomes would be based on functional progress rather than wound healing.

- The payment cap for each of the three risk categories creates a strong incentive to limit visits, but the limits would apply only to PT/OT services, so the effectiveness in controlling total wound care spending is uncertain.

- The proposed 3% performance bonus does not provide a strong incentive to achieve quality outcomes at a cost below the risk category’s per-episode cap.

- Visit payments, the supply credit, and outcome measures in the proposed model are not adjusted based on patient severity or other relevant factors.

- There is insufficient substantiation for the proposed $250 supply credit.

- The payment methodology only involves PTs/OTs despite evidence that suggests multidisciplinary approaches are most effective for chronic, non-healing wounds.
Criterion 4. Value over Volume

- The model includes incentives for providers to deliver high-quality health care, including the requirement that providers repay CMS for services delivered to patients who do not demonstrate a minimal clinically important difference in outcomes.

- The model has the potential to shift care delivery from a higher-cost setting to a lower-cost setting.

- However, the model does not include a minimum wound severity threshold for patient participation, or a strong mechanism for encouraging efficient service delivery.
Criterion 5. Flexibility

**Criterion Description**
Provide the flexibility needed for practitioners to deliver high-quality health care.

**PRT Conclusion**
Meets Criterion

**Unanimous or Majority Conclusion**
Unanimous

- The proposed model would give PTs/OTs greater flexibility to perform wound care. The model provides a supply credit to cover the cost of wound care supplies, and it expands the range of products that PTs/OTs can use to aid in wound healing.

- The model removes the therapy cap (including the exceptions process).
Criterion 6. Ability to Be Evaluated

- In general, the collection of cost and quality measures in the model – such as the total amount spent on wound care and treatment duration for participating patients – would facilitate its evaluation.

- However, the PRT also identified some potential challenges in evaluating the proposed model:
  - Not all patient characteristics that affect wound care spending are captured in diagnosis and claims data, making it difficult to establish a valid comparison group.
  - Other wound care providers do not report wound healing outcomes, which would make it difficult to compare performance of participating and non-participating providers.
  - Participating providers would be able to choose among different functional outcome measures, which could make it difficult to assess overall performance.
Criterion 7. Integration and Care Coordination

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

PRT Conclusion
Does Not Meet Criterion

Unanimous or Majority Conclusion
Unanimous

• The proposed model relies on current limited methods of communication and coordination between PTs/OTs and PCPs.

• Despite the desirability of multidisciplinary wound care, there is no provision for coordination with other practitioners that might be necessary to quickly and successfully treat chronic wounds or comorbidities that led to the development of, or complicate the care of, the wound.

• The model also does not describe when or how cases will be referred to other providers for higher-level care if necessary.
Criterion 8. Patient Choice

Criterion Description
Encourage greater attention to the health of the population served while also supporting the unique needs and preferences of individual patients.

PRT Conclusion
Meets Criterion

Unanimous or Majority Conclusion
Unanimous

- The proposed model would enhance patient choice by increasing Medicare beneficiaries’ ability to get wound care in private outpatient therapy clinics rather than traveling to hospital outpatient departments.
- The model could benefit areas with limited access to wound care services, such as rural communities.
- However, the model does not describe how providers would ensure that patients understand which providers are the most appropriate for their wound care needs.
Criterion 9. Patient Safety

- Better, more frequent access to wound care could improve patient safety by promoting healing of wounds and avoiding adverse outcomes.
- However, the proposed model raises significant patient safety issues.
  - It does not include clear eligibility criteria to ensure participating patients are appropriately matched to the necessary PT/OT skill set.
  - It also does not address what would happen to patients who do not show improvement, particularly since PTs/OTs would be required to refund payments to CMS if outcomes are not achieved, and their payments per episode are capped.
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- The proposed model could encourage or require the use of health information technology (HIT) to measure and analyze outcomes.
- However, the model does not describe how HIT would be used to enhance care coordination or otherwise inform care.