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

Initial Feedback from the Preliminary Review Team

Disclaimer Regarding Initial Feedback:

- *Initial feedback is preliminary feedback from a Preliminary Review Team (PRT) subcommittee of the PTAC and does not represent the consensus or position of the full PTAC;*
- *Initial feedback is not binding on the full Committee. PTAC may reach different conclusions from that communicated from the PRT as initial feedback; and*
- *Provision of initial feedback will not limit the PRT or PTAC from identifying additional weaknesses in a submitted proposal after the feedback is provided.*
- *Revising a proposal to respond to the initial feedback from a PRT does not guarantee a favorable recommendation from the full PTAC to the Secretary of Health and Human Services (HHS).*

Summary of PRT Assessment Relative to Criteria:

Criteria Specified by the Secretary (at 42 CFR§414.1465)	PRT Rating	Unanimous or Majority Conclusion
1. Scope (High Priority)	Meets	Unanimous
2. Quality and Cost (High Priority)	Does not meet	Unanimous
3. Payment Methodology (High Priority)	Does not meet	Unanimous
4. Value over Volume	Meets	Unanimous
5. Flexibility	Meets	Unanimous
6. Ability to be Evaluated	Meets	Unanimous
7. Integration and Care Coordination	Does not meet	Unanimous
8. Patient Choice	Meets	Unanimous
9. Patient Safety	Does not meet	Unanimous
10. Health Information Technology	Does not meet	Unanimous

Criterion 1: Scope (High Priority)
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 Rating: Meets, Unanimous

Strengths:

- The proposed model addresses a patient population with significant health needs; chronic non-healing wounds are estimated to affect nearly 15 percent of Medicare beneficiaries. Chronic wounds can severely impact a patient's quality of life and are associated with adverse outcomes such as limb amputation or premature death.
- There currently is no alternative payment model (APM) focused on wound care, nor have there been HCIA awards or other Medicare demonstration projects focused on wound care.
- The model addresses providers (Physical Therapists and Occupational Therapists, hereafter PTs/OTs) who have limited opportunities to participate in an APM.
- Medicare annually spends about $28 billion on wound care, presenting an opportunity for savings and more efficient delivery of services.

Weaknesses:

- The model does not explicitly focus on patients who would be appropriate candidates for treatment of their wounds by PTs/OTs.
- The short-term goal of the proposal is data collection on cost and effectiveness of the concept in a pilot phase, so the scope as proposed is minimal (200 PTs/OTs). The model does have the potential to have a wider reach if implemented as an APM.
- The APM is designed to support only the specific types of wound care that can be delivered by PT/OTs, not the full spectrum of wound care that a patient may need.

Criterion 2: Quality and Cost (High Priority)
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 Rating: Does not meet, unanimous

Strengths:

- The model could generate savings by shifting wound care from hospital outpatient departments and wound therapy clinics to a lower cost setting (private therapy clinics).
- PTs/OTs would be required to assess wound healing on a regular basis using a detailed, validated scale and report the results to CMS.
- The requirement to refund payments for individuals who do not demonstrate improvement on wound healing and functional outcome measures could encourage improved outcomes for patients.

Weaknesses:

- The model has the potential to lead to increased therapy use. The receipt of wound care services is linked to therapy services, so some patients with chronic wounds might receive therapy services in this APM who otherwise would not need therapy.
- In addition, the removal of the therapy cap could lead to higher therapy charges that are unrelated to wound care. There is no incentive for participating PTs/OTs to achieve outcomes

with fewer services than the $3,500 per episode cap nor is It clear how the suggested model could explicitly identify opportunities to offer services that are lower in cost compared to current care.
- The model raises potential significant concerns related to quality of care. Evidence suggests that the best and highest quality care for chronic wounds is multidisciplinary, yet the proposal does not include adequate safeguards or processes to ensure that the most appropriate provider is delivering services commensurate with the needed level of care.
- The PRT found the approach to performance measurement in the model unclear. The actual standard of performance (minimum clinically important difference, or MCID) on the four possible outcome measures is not described within the proposal. The proposal also does not include existing validated measures of wound care quality that could help ensure the care meets recognized standards of quality.
- The PRT is concerned about the credentials of PTs/OTs to perform services for all patients, particularly because sharp debridement by PTs/OTs is not within the scope of practice in many states; again reinforcing concerns about how the payment model would ensure that only appropriate patients would participate.
- Skin substitutes are generally viewed to be effective when used as part of a multidisciplinary approach for managing chronic wounds that do not respond to more conservative or first-line therapies, but the evidence on cost-effectiveness is limited. The expansion of use of expensive wound care products by PTs/OTs could lead to additional spending without improvements in quality.

Criterion 3: Payment Methodology (High Priority)
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 Physician-Focused Payment Model cannot be tested under current payment methodologies.
PRT Rating: Does not meet, unanimous

Strengths:
- There would be a direct tie between outcomes and payment, since PTs/OTs would be required to refund CMS for services delivered to patients who do not achieve a minimum clinically important difference on an outcome measure or who do not achieve a demonstrable increase in functional independence or achieve a demonstrable, progressive improvement in at least two objective measurements (the criteria for PT/OT appeal of refunds).
- The model caps spending per episode at $3,500, creating a strong incentive to ensure the cost of services does not exceed the per episode limit.

Weaknesses:
- The current fee schedule payment amounts, the supply credit, the spending cap, and the outcome measures are not adjusted based the severity of patients' wounds or other factors that could make wound healing more difficult. This could result in overpayment for some patients and underpayment for others.
- The payment methodology does not provide any incentive to achieve quality outcomes at a cost less than the $3,500 per episode cap.
- The proposal does not include adequate substantiation for the $250 supply credit.
- Though evidence suggests that multidisciplinary approaches are most effective at addressing chronic, non-healing wounds, the payment methodology only involves PTs/OTs.

Criterion 4: Value over Volume
Provide incentives to practitioners to deliver high-quality health care.

PRT Rating: Meets, unanimous

Strengths:

- The model includes incentives for providers to deliver high-quality health care, including a 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.

Weaknesses:

- There is no minimum threshold on wound severity needed to participate in the model, which could encourage treatment of patients by PTs/OTs who could be adequately treated by a PCP.
- The model does not include a mechanism for encouraging efficient service delivery, so it could encourage higher spending on patients for whom the same outcomes could be achieved with fewer services. It could also encourage PTs/OTs to avoid patients who would need higher amounts of services.
- The model removes the therapy cap, which could lead to the utilization of additional therapy services that may not be necessary.

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

PRT Rating: Meets, unanimous

Strength:

- The model gives 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 PTs/OTs can apply (such as skin substitutes) to aid in wound healing. The model also removes the therapy cap (including the exceptions process).

Weakness:

- All currently billable services would continue to be billed using the same codes at the same rates, which would not provide any flexibility to deliver services in different ways.

Criterion 6: Ability to be Evaluated
Have evaluable goals for quality of care, cost, and any other goals of the PFPM.

PRT Rating: Meets, unanimous

Strength:

- The model could be evaluated; it should be possible to determine the total amount spent on wound care and treatment duration for participating patients and compare with other patients.

Weaknesses:

- Not all of the characteristics of patients that affect spending on wound care are captured in diagnosis codes or claims data, so it could be difficult to assess whether differences in costs or outcomes are due to the fact that the patients in the APM are different from patients who are not in the APM.
- Other wound care providers do not report wound healing outcomes, so it would be impossible to compare the performance of the APM participants to non-participants.
- The providers participating in the APM would be able to choose among different functional outcome measures on which to be evaluated, which would make it difficult to compare performance between different participants.

Criterion 7: Integration and Care Coordination

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

PRT Rating: Does not meet, unanimous

Strength:

- The proposal indicates that the referring primary care physician would continue to provide oversight of the care and that the physical/occupational therapy practice would communicate regularly with that physician.

Weaknesses:

- The model relies on the current limited methods of coordination between PTs/OTs and PCPs (consisting of progress notes sent every 10th visit).
- There is no provision for coordination with other practitioners that might be necessary to quickly and successfully treat wounds, including surgeons, home health nurses, nutritionists, etc.
- The model does not describe when or how cases will be referred to other providers or higher-level care if necessary.
- The PRT understands that while there are barriers in access in current care, it is not clear how the proposed model promotes coordination in care particularly with the spectrum of providers that also deal with the index clinical causes and conditions that either led to development of the wound or complicate the care of the wound.

Criterion 8: Patient Choice
Encourage greater attention to the health of the population served while also supporting the unique needs and preferences of individual patients.
PRT Rating: Meets, unanimous

Strengths:

- The model enhances patient choice by increasing their 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.

Weakness:

- The expansion of patient choice is only desirable if it leads to better care for patients. The PRT is concerned the model does not have adequate safeguards to ensure patients understand which providers are the most appropriate for their wound care needs.

Criterion 9: Patient Safety
Aim to maintain or improve standards of patient safety.

PRT Rating: Does not meet, unanimous

Strength:

- Better, more frequent access to wound care could improve patient safety by promoting healing of chronic wounds and avoiding adverse outcomes such as amputations.

Weaknesses:

- The proposal does not include clear eligibility criteria that would ensure participating patients are appropriately matched to the PT/OT skill set. For example, in some states it is not within the scope of practice for PTs/OTs to perform sharp debridement, a task which could be a necessary component of many patients' care.
- The proposal 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.

Criterion 10: Health Information Technology
Encourage use of health information technology to inform care.

PRT Rating: Does not meet, unanimous

Strength:

- The model could encourage or require the use of HIT to measure and analyze outcomes.

Weakness:

- The model does not explicitly describe how HIT would be used, such as the use of registries or other systematic reporting systems to track outcomes and support comparison across practices.
- The model does not describe how HIT would be used to coordinate with the patient's other providers, including other providers involved with wound care.