Physician-Focused Payment Model Technical Advisory Committee

Preliminary Review Team Report to the Physician-Focused Payment Model Technical Advisory Committee (PTAC) on the 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 Payment Model

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In accordance with the Physician-Focused Payment Model Technical Advisory Committee's (PTAC's) Proposal Review Process described in *Physician-Focused Payment Models: PTAC Proposal Submission Instructions* (available on the ASPE PTAC <u>website</u>), physician-focused payment models (PFPMs) that contain the information requested by PTAC's Proposal Submission Instructions will be assigned to a Preliminary Review Team (PRT). The PRT will draft a report containing findings regarding the proposal for discussion by the full PTAC. This PRT report is preparatory work for the full PTAC and is not binding on PTAC. This report is provided by the PRT to the full Committee for the proposal identified below.

A. Proposal Information

- Proposal Name: 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
- 2. Submitting Organization or Individual: Upstream Rehabilitation

3. Submitter's Abstract:

"This proposal will demonstrate how investment and support of outpatient therapy clinics to provide chronic wound care services to Medicare recipients will result in better communication between members of a patient's healthcare team, lower cost to provide care, and greater functional outcomes for the patient that extend beyond simple healing of the wound.

"Upstream Rehabilitation understands the powerful effect that physical and occupational therapists have in patients' lives. They have the skills, training, and knowledge necessary to return patients to full and independent functioning, which includes having the ability to manage chronic wounds, keep in constant contact with physicians as their patient's healing progresses, and aid the patient in regaining skills necessary for compensation during the active wound healing phase as well as restoration of skills once healing is complete.

"Our goal in establishing and managing this program is to gather data for a two-year time period that will:

- Measure the effectiveness of physical and occupational therapy in the healing of chronic wounds
- 2) Measure the overall increase in functional outcomes experienced by patients with chronic wounds who are being primarily managed by physical and occupational therapists
- Measure the cost savings of utilizing physical and occupational therapists in outpatient, private settings versus traditional outpatient hospital-based wound care centers.

"Data to measure these parameters is not currently available because the ability to effectively treat these patients in outpatient facilities is not financially feasible. This proposal seeks to incentivize physical and occupational therapists to treat these patients while measuring specific data points to gauge the cost effectiveness and comparison of functional outcomes to hospital-based outpatient wound care centers."

B. Summary of the PRT Review

The Upstream Rehabilitation proposal, "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," was received by PTAC on November 20, 2018. (The proposal was a revision of an earlier submission with the same title from the same submitter—previously known as BenchMark Rehab Partners, a division of Upstream Rehabilitation—which was received by PTAC on November 6, 2017.) The PRT met on January 15, 2019, to discuss the revised proposal. A summary of the PRT's findings is provided in the table below.

PRT Rating of Revised Proposal by Secretarial Criteria

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

C. PRT Process

The revised proposal, "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," was received by PTAC on November 20, 2018. The proposal was a revision of an earlier submission with the same title from the same submitter—previously known as BenchMark Rehab Partners, a division of Upstream Rehabilitation – which was received by PTAC on November 6, 2017. The PRT sent questions to the submitter on the initial proposal and received detailed written responses to its questions on February 7, 2018, and February 20, 2018, respectively. The PRT also reviewed six public comments that were received on the initial proposal. The PRT provided initial feedback on the initial proposal to the submitter on April 19, 2018 and conducted a conference call on the initial proposal with the submitter on April 30, 2018. After this conversation, the submitter notified PTAC of its intent to revise and resubmit the initial proposal on May 4, 2018.

The PRT conducted its review of the *revised* proposal between December 10, 2018, and January 15, 2019. During this time, the PRT reviewed the revised proposal, sent questions on the revised proposal to the submitter on December 17, 2018, and received detailed responses to its questions in writing from the submitter on January 12, 2019. The PRT met on January 15, 2019 to review written responses to questions from the submitter and all public comment letters received on the revised proposal, and to prepare its report. The PRT's summary of the revised proposal and evaluation of the revised proposal compared to the Secretary's criteria for PFPMs are below.¹

¹ The revised proposal, questions and answers, and public comments are available on the ASPE PTAC <u>website</u>. Note: the initial proposal, questions and answers, call transcript, and initial feedback relating to the PRT's review of the initial proposal (which took place between January 15, 2018 and April 30, 2018) are also available on the ASPE PTAC website – listed separately under "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

1. Revised Proposal Summary

The revised Upstream Rehabilitation proposal seeks to expand the ability of physical therapists (PTs) and occupational therapists (OTs) to manage chronic wounds occurring in Medicare beneficiaries. The revised proposal is framed as a pilot test among 200 therapists, as part of a long-term payment model that could be expanded nationwide. The revised proposal estimates that 1,500 providers nationwide would be interested in participating in the model following the pilot study. The revised proposal states that expanding the role of PTs/OTs in wound care treatment could reduce Medicare spending; improve access to wound care, particularly in rural settings; and improve quality of care for Medicare beneficiaries with chronic wounds.

The revised proposal cites three major barriers to providing wound care in private outpatient clinics: 1) the requirement to submit a modifier code when billing for services beyond the Medicare-specified threshold on outpatient therapy services, which adds administrative burdens for providers; 2) the inability for free-standing outpatient clinics to be paid for sophisticated dressing products comparable to payment in the hospital outpatient setting; and 3) a lack of clarity and consistency regarding the ability of PTs/OTs to use and be paid for advanced therapeutics.

The submitter proposes to address these barriers by exempting PTs/OTs from the Medicare threshold when treating patients with qualifying wound care diagnoses, identified using the American Physical Therapy Association's list of International Statistical Classification of Diseases and Related Health Problems (ICD)-10 codes for wound care management. In addition, the revised proposal would create a new \$250 one-time billable payment per patient for wound care supplies. The revised proposal would also explicitly allow PTs/OTs to bill for advanced therapeutics such as skin substitutes and bioengineered dressings (Current Procedural Terminology—CPT—codes C5271-C5278 and Q4100-4172) for participating patients.

Medicare beneficiaries would be identified for inclusion in the model if they have a medical diagnosis for wound care as well as an accompanying therapy diagnosis indicating a functional loss requiring PT/OT services. Eligible beneficiaries would be informed about the use of their de-identified data, notified of risks and benefits of participation, and provided the opportunity to opt-out of data collection. Once participation is confirmed, patients would be seen for a normal course of PT/OT therapy, with goals specific to wound healing and functional outcomes.

Participation in the program would require PTs/OTs to attest they meet all program criteria, including professional certification, demonstrated advanced training in wound treatment, and have the data collection capacity for costs and outcome measures, as well as the capacity to bill claims electronically with the Centers for Medicare &

Wounds in Medicare Recipients," which was submitted by BenchMark Rehab Partners (a division of Upstream Rehabilitation) with a comment closing date of November 30, 2017).

Medicaid Services (CMS). Currently, PTs/OTs are required to provide progress notes to referring physicians every tenth visit or 30 days. The revised proposal maintains this requirement. Participating PTs/OTs would be reimbursed using the Medicare physician fee schedule for the wound care and therapy services provided to participating patients and would not be required to submit code modifiers when therapy billings exceed the Medicare threshold. Participating PTs/OTs could also be paid a one-time \$250 wound care supply credit for participating patients to cover dressings and other supplies (excluding cellular and tissue-based products) and could be paid for use of advanced therapeutics. Clinicians would track supplies used for participating Medicare patients, treatment costs for patients, total time in treatment, patient satisfaction, and quality measures and would report this data quarterly to CMS.

To assess quality, the revised proposal would require that participating PTs/OTs measure participating patients' functional status using the Bates-Jensen Wound Assessment Tool (BWAT) during the initial evaluation, at each progress note, and at discharge. PTs/OTs would also assess functional status with one of the following measures at the same intervals: QuickDASH (Disabilities of the Arm, Shoulder, and Hand Questionnaire); the LEFS (Lower Extremity Functional Scale); a pain scale; or the Oswestry Disability Index. Participating PTs/OTs who do not demonstrate a minimal clinically important difference (MCID) on the quality measure would be required to refund the full payment for that patient to CMS. There would be an appeals process for refunds; if the provider documents improvement in a functional independence measure or a demonstrable, progressive improvement in at least two objective measures (such as range of motion, strength, or edema), the provider would not be required to refund the payment to CMS. Participating providers would also face another potential penalty based on poor patient satisfaction: a provider who does not achieve 80 percent patient satisfaction scores would be placed on probation; if patient satisfaction does not improve above 80 percent in the subsequent quarter, the PT/OT would be dismissed from the program.

Participating PTs/OTs would classify chronic wound care patients into three risk categories using the CPT codes for PT/OT evaluation (97161/2/3 and 97165/6/7). The revised proposal includes a payment target for average Medicare payments for PT/OT visits for each of these three risk categories: \$3,500 for low-complexity patients, \$4,500 for moderate complexity, and \$5,500 for high complexity patients. Although the language in the revised proposal describes the payment target as "average total Medicare reimbursed cost per treatment episode across all patients treated", in response to additional questions, the submitter clarified that the payment target only involves Medicare payments for PT/OT visits, not payments for wound care supplies or other wound care-related services the patient receives. At the end of the two-year pilot period, there would be a 3 percent savings bonus ("performance bonus") for providers who achieve average payments below the threshold for the risk category. On the other hand, providers with average payments above the thresholds in the quarterly reports to

CMS would be placed on probation for one quarter and dismissed if high spending is continued in a subsequent quarter.

2. Additional Information Reviewed by the PRT

a. Literature Review and Environmental Scan

ASPE, through its PTAC support contractor, conducted an environmental scan that included a review of peer-reviewed literature as well as a search for relevant grey literature, such as research reports, white papers, conference proceedings, and government documents to support the PRT's review of the initial proposal. The search and the identified documents were not intended to be comprehensive and were limited to documents that met predetermined research parameters, including a five-year look back period, a primary focus on United States-based literature and documents, and relevancy to the letter of intent. Results of the environmental scan are located on the ASPE PTAC website (in the section relating to the PRT's review of the initial proposal, which was submitted by BenchMark Rehab Partners, a division of Upstream Rehabilitation).²

b. Data Analyses

The PRT did not request any additional data analyses for the initial proposal or the revised proposal.

c. Public Comments

The PRT reviewed three public comments on the revised proposal. The public comment letters are available on the ASPE PTAC <u>website</u>. Note: Six additional public comments that were considered as part of the PRT's review of the initial proposal are also located on the ASPE PTAC <u>website</u> (in the section relating to the PRT's review of the initial proposal, which was submitted by BenchMark Rehab Partners, a division of Upstream Rehabilitation).

d. Other Information

The PRT did not review other additional information on the revised proposal. However, the PRT did review additional information compiled by the ASPE PTAC support contractor during its assessment of the initial proposal. This information

² As discussed earlier, information relating to the PRT's review of the initial proposal is listed separately on the ASPE PTAC <u>website</u> under "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," which was submitted by BenchMark Rehab Partners (a division of Upstream Rehabilitation) with a comment period closing November 30, 2017.

included a supplemental literature review assessing the evidence relating to the use and effectiveness of different skin substitutes in chronic wound care; and targeted inquiries focused on local coverage determinations related to physical and occupational therapists billing for the application of skin substitutes, scope of practice, and debridement. This analysis is available on the ASPE PTAC website (in the section relating to the PRT's review of the initial proposal, which was submitted by BenchMark Rehab Partners, a division of Upstream Rehabilitation).

D. Evaluation of Revised Proposal Against Criteria

Criterion 1. Scope (High-Priority Criterion). The proposal aims 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 Qualitative Rating: Meets Criterion

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 comprehensive Medicare alternative payment model (APM)
 focused on wound care, though CMS has been testing a Medicare Prior Authorization
 Model for Non-Emergent Hyperbaric Oxygen (HBO) to assess whether requiring prior
 authorization for HBO can reduce costs without adversely affecting quality of care for
 beneficiaries requiring this specific wound care service. No multipayer models for
 wound care currently exist.
- The model addresses providers (PTs/OTs) who have limited opportunities to participate in an APM.
- Medicare annually spends about \$28 billion on wound care, presenting a potential 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 revised proposal is data collection on the cost and
 effectiveness of the concept in a pilot phase, so the scope as proposed is minimal (200
 PTs/OTs). However, the model does have the potential to have a wider reach if
 implemented as an APM.
- The proposed 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.

Summary of Rating:

The proposed PFPM meets the criterion. The revised proposal addresses a Medicare patient population with significant health needs where an opportunity to improve access and quality and reduce spending exists. The revised proposal also targets health care providers who have had a limited opportunity to participate in APMs.

Criterion 2. Quality and Cost (High-Priority Criterion). The proposal is anticipated to (1) improve health care quality at no additional cost, (2) maintain health care quality while decreasing cost, or (3) both improve health care quality and decrease cost.

PRT Qualitative Rating: Does Not Meet Criterion

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. The revised proposal does specify that a referral for therapy services is necessary for beneficiary participation in the model, but patients may still be referred for therapy who otherwise would not have received it.
- The revised proposal's proposed 3 percent performance bonus for providers who achieve average Medicare payments below the thresholds for each risk tier is a modest financial incentive. In response to questions, the submitter clarified that the proposed methodology for risk classification is based on approaches currently in use. The performance targets for each risk tier are based on a data analysis of complexity and average length of stay for a sample of 200 patients in the submitter's own practice, but no details on the methodology or data were provided. In addition, the revised proposal does not describe the methods providers could use to reduce payments below the caps without jeopardizing patient outcomes.
- 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 revised 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 revised proposal. The
 revised 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. The revised proposal specifies that the program would not supersede any state practice acts for PTs/OTs. However, the PRT remains concerned that there are not sufficient safeguards in the model design to ensure that patients are appropriately matched to providers with the skill sets to treat their particular wounds.
- 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.

Summary of Rating:

The proposed PFPM does not meet the criterion. Although savings would potentially be achieved by having PTs/OTs deliver wound care services to patients who would otherwise have been treated in a hospital outpatient department, spending could increase if the patients treated by PTs/OTs would otherwise have been treated by a primary care physician (PCP) or if they receive physical or occupational therapy services they did not need. The PRT is concerned that the proposed model does not include specific eligibility criteria to ensure that only patients whose wounds are appropriate for treatment by PTs/OTs participate in the model. The PRT is also concerned that there are not adequate safeguards for quality of care.

Criterion 3. Payment Methodology (High-Priority Criterion). Pay APM Entities with a payment methodology 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 Qualitative Rating: Does Not Meet Criterion

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 a demonstrable, progressive improvement in at least two objective measurements (the criteria for PT/OT appeal of refunds).

- The proposed model would cap payments for PT/OT visits per episode (\$3,500 for low-complexity patients, \$4,500 for moderate complexity patients, and \$5,500 for high complexity patients), which creates a strong incentive to limit the number of visits, although the effectiveness in controlling the total cost of wound care services is uncertain.
- The revised proposal includes a three-tiered approach to risk adjustment, classifying
 patients as having low, moderate, or high risk. The revised proposal would set a
 spending performance target for average Medicare payments for PT/OT visits to reflect
 differences in wound care services needed by patients in these three categories.

Weaknesses:

- The outcomes would be based on functional progress rather than success in wound healing.
- The current physician fee schedule payment amounts, the supply credit, 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 per-episode spending limits would apply only to services delivered by the PT/OT, not to services delivered by all providers involved in the patient's wound care.
- The proposed payment methodology does not provide a strong incentive to achieve quality outcomes at a cost less than the risk category's per episode cap. The payment methodology would also create an incentive for providers to over-classify patients into higher risk categories.
- The revised 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 proposed payment methodology only involves PTs/OTs.

Summary of Rating:

The proposed PFPM does not meet the criterion. The proposed payment model has several innovative and desirable features, including an outcome-based payment structure, risk stratification based on clinical factors, and episode spending limits. However, the proposed outcomes are not based on wound healing, the criteria for the proposed risk categories are not explicitly tied to wound severity, and the incentives to control spending are focused only on the number of PT/OT visits rather the total cost of wound care.

Criterion 4. Value over Volume. The proposal is anticipated to provide incentives to practitioners to deliver high-quality health care.

PRT Qualitative Rating: Meets Criterion

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 strong mechanism for encouraging efficient service delivery. It could also encourage PTs/OTs to avoid patients who would need higher amounts of services.

Summary of Rating:

The proposed PFPM meets the criterion. The potential for the model to shift care from a higher-cost to a lower-cost setting and the use of an outcome-based payment supports the delivery of high-value care rather than a high volume of care.

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

PRT Qualitative Rating: Meets Criterion

Strengths:

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

Weaknesses:

 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.

Summary of Rating:

The proposed PFPM meets the criterion. The revised proposal would expand the ability of PTs/OTs to deliver wound care, enhancing their flexibility.

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

PRT Qualitative Rating: Meets Criterion

Strength:

• The model could be evaluated. For example, it should be possible to determine the total amount spent on wound care and treatment duration for participating patients and compare this information with other nonparticipating chronic wound care 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 nonparticipants.
- 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.

Summary of Rating:

The proposed PFPM meets the criterion. Though the PRT identified some challenges in evaluating the model, in general the collection of cost and quality measures in the model would facilitate its evaluation.

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 Qualitative Rating: Does Not Meet Criterion

Strength:

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

Weaknesses:

• The proposed model relies on the current limited methods of coordination between PTs/OTs and PCPs (consisting of progress notes sent every tenth visit).

- There is no provision for coordination with other practitioners that might be necessary to quickly and successfully treat chronic 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 access barriers in current care, it is not clear how the proposed model would promote coordination of care particularly with the spectrum of providers that also deal with the clinical causes and conditions that either led to development of the wound or complicate the care of the wound.

Summary of Rating:

The proposed PFPM does not meet the criterion. Despite the desirability of multidisciplinary wound care, the revised proposal only requires current approaches to care coordination between PTs/OTs and referring providers.

Criterion 8. Patient Choice. Encourage greater attention to the health of the population served while also supporting the unique needs and preference of individual patients.

PRT Qualitative Rating: Meets Criterion

Strengths:

- 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.

Weakness:

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

Summary of Rating:

The proposed PFPM meets the criterion. The revised proposal would expand the options for wound care treatment that are available to Medicare beneficiaries.

Criterion 9. Patient Safety. How well does the proposal aim to maintain or improve standards of patient safety?

PRT Qualitative Rating: Does Not Meet Criterion

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

Summary of Rating:

The proposed PFPM does not meet the criterion. The PRT is concerned that the proposed model raises significant patient safety issues.

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

PRT Qualitative Rating: Does Not Meet Criterion

Strength:

• The proposed model could encourage or require the use of health information technology (HIT) to measure and analyze outcomes.

Weaknesses:

- 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 improve care coordination with the patient's other providers, including other providers involved with wound care.

Summary of Rating:

The proposed PFPM does not meet the criterion. Though participating providers would be required to track expenditures and quality measures in the model, the proposed model does not use HIT to enhance care coordination or otherwise inform care.

E. PRT Comments

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

Comments on the Proposed Care Delivery Model

The proposed approach to care delivery has the potential to address all of these opportunities:

- Patient access to wound care could be improved by enabling more patients to receive wound care services closer to home rather than having to travel to a hospital outpatient clinic. This could be particularly helpful for patients in rural areas who live a long distance from a hospital.
- The wound care services would be delivered by independent PTs/OTs, who would be
 paid less for wound care services than what Medicare typically pays for wound care
 services delivered by a hospital outpatient department.
- The combination of easier access to services and the lower cost-sharing for services could encourage more patients to receive wound care sooner and more reliably, thereby promoting more rapid healing and reductions in complications.

However, the PRT is concerned that the revised proposal is designed to support only the services that can be delivered by PTs/OTs, and this will not include all of the services that many patients with chronic wounds need in order to achieve the best outcome at the lowest cost. For example, sharp debridement is an essential part of wound care for many patients, but PTs/OTs are not permitted to perform this service in many states. The revised proposal also does not require or encourage PTs/OTs to form multi-disciplinary teams with surgeons, PCPs, and other providers so that the patient can be assured of receiving the most appropriate and cost-effective services.

In addition, PTs/OTs would only be performing wound care for patients who also received physical therapy or occupational therapy. Although this could result in more coordinated care for patients who needed both types of services, it would either: a) limit access to the wound care services available under the revised proposal to patients who needed physical or occupational therapy, or b) encourage patients to be referred for physical or occupational therapy that they would otherwise not receive it, which could reduce savings or even increase total spending.

Comments on the Proposed Payment Model

The proposed payment model has several desirable features, some of which are not used in any Medicare APMs and/or have not been included in other proposals submitted to PTAC. The payment is literally outcome-based, i.e., the PT/OT would not be paid at all for the wound care services delivered to a patient unless that specific patient achieved an MCID on an outcome measure. In addition, there is a proposed cap on the total amount that the PT/OT can be paid for an individual patient, and this cap is higher for patients who have higher needs.

However, the PRT is concerned about several aspects of the payment model:

- The participating PT/OT would still be paid under the standard fee-for-service system, receiving an additional amount for each visit with the patient and for each service the patient receives, and the PT/OT would also be newly eligible to bill for the use of expensive skin substitutes. This does not provide flexibility to deliver different kinds of services than what is specified in current CPT/HCPCS (Healthcare Common Procedure Coding System) codes. No changes in payment are proposed for providers other than PT/OTs that could facilitate an interdisciplinary approach to wound care treatment.
- Although there would be a stratified cap on average payments per patient to discourage overuse of services, the proposed caps would apply only to visits billed by the PT/OT, not to wound care supplies or to services delivered by other providers that are related to care of the wound. It is also not clear whether the proposed caps would be higher or lower than the amounts currently spent on similar patients. The model includes a very small incentive to spend less than the cap (if the PT/OT spends less on average than the cap, they would receive 3 percent of the savings), but since the payments would represent revenue for the PT/OT practice, the practice would appear to benefit more financially by spending up to the cap for as many patients as possible.
- There is no requirement that a practice continue to deliver services to a patient after the payment cap has been reached or when a good outcome is not being achieved, so it is possible that high-need patients could be dropped when the payment cap is reached or when it is clear that an MCID will not be achieved. There is no minimum threshold on the wound severity needed to qualify for services, nor is there any requirement that a practice accept all patients who need services, so it is possible that a practice could cherry-pick the patients who are likely to achieve good outcomes quickly, including patients who could have achieved good results at much lower cost with services from their PCP.
- Although an outcome-based payment is a very desirable innovation, the outcomes are based on measures of function and pain, not on wound healing per se, so a participating provider could potentially be paid even if a wound fails to heal. Also, the revised proposal does not clearly define what the MCIDs would be for the measures that are proposed.