

Physician-Focused Payment Model Technical Advisory Committee

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May 17, 2019

Alex M. Azar II, Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Secretary Azar:

On behalf of the Physician-Focused Payment Model Technical Advisory Committee (PTAC), I am pleased to submit PTAC's comments and recommendations to you on two physician-focused payment models (PFPMs). These comments and recommendations are required by section 1868(c) of the Social Security Act, which directs PTAC to: 1) review PFPM models submitted to PTAC by individuals and stakeholder entities, 2) prepare comments and recommendations regarding whether such models meet criteria established by the Secretary of Health and Human Services (HHS), and 3) submit these comments and recommendations to the Secretary.

The two proposals—the *Bundled Payment for All Inclusive Outpatient Wound Care Services in Non Hospital Based Setting* proposal submitted by Seha Medical and Wound Care and 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* proposal submitted by Upstream Rehabilitation—are both aimed at improving how Medicare pays for wound care services delivered by independent outpatient providers/clinics. For this reason, PTAC has combined its comments and recommendations on these proposals into a single report. We hope this will better assist HHS in implementing improved approaches to payment for wound care services.

With the assistance of HHS' Office of the Assistant Secretary for Planning and Evaluation (ASPE), PTAC carefully reviewed the proposals, additional information on the proposed models provided by the submitters in response to questions from PTAC Preliminary Review Teams and PTAC as a whole, and public comments on the proposals. At a public meeting of PTAC held on March 11, 2019, the Committee deliberated on the extent to which each of the proposed

models meets the criteria established by the Secretary in regulations at 42 CFR § 414.1465 and whether each should be recommended.

The Committee does not recommend either proposal to the Secretary for implementation as a physician-focused payment model (PFPM). However, we believe the proposals have raised important issues that need to be addressed regarding the delivery of wound care services and payment for those services. In reviewing the proposals from Seha Medical and Wound Care and Upstream Rehabilitation, PTAC concludes that mechanisms for supporting a more comprehensive, multidisciplinary approach to wound care are needed, given the varying and often complicated causes of wounds and the breadth of specialties involved. PTAC believes the submitters and broader stakeholder community should first identify a more comprehensive approach to wound care delivery. Then, a payment model can be designed to support that model of care. Members note that the submitters and other stakeholders may not have access to the necessary data to develop such models themselves, and the Committee is hopeful that the Secretary would consider options for providing these resources. In the interim, the Committee believes that changes to the physician fee schedule could be made that would better support efficient and effective delivery of wound care and improve access to wound care in rural areas.

The members of PTAC appreciate your support of our shared goal of improving the Medicare program for both beneficiaries and the physicians who care for them. The Committee looks forward to your detailed response.

Sincerely,

//Jeffrey Bailet//

Jeffrey Bailet, MD

Chair

Attachments

REPORT TO THE SECRETARY OF HEALTH AND HUMAN SERVICES

Comments and Recommendations on

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

and

*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*

May 17, 2019

About This Report

The Physician-Focused Payment Model Technical Advisory Committee (PTAC) was established by the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) to: 1) review physician-focused payment models (PFPMs) submitted by individuals and stakeholder entities, 2) prepare comments and recommendations regarding whether such models meet criteria established by the Secretary of Health and Human Services (HHS), and 3) submit these comments and recommendations to the Secretary. PTAC reviews submitted proposals using criteria established by the Secretary in regulations at 42 CFR § 414.1465.

This report contains PTAC's comments and recommendations on the *Bundled Payment for All Inclusive Outpatient Wound Care Services in Non Hospital Based Setting* proposal submitted by Seha Medical and Wound Care and 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* proposal submitted by Upstream Rehabilitation. This report also includes: 1) a summary of the proposed models, 2) PTAC's comments on the proposed models and its recommendations to the Secretary; and 3) PTAC's evaluation of the proposed models against each of the Secretary's criteria for PFPMs. The appendices to this report include a record of the voting by PTAC on these proposals and additional information on the proposals submitted subsequent to the proposal submissions.

SUMMARY STATEMENT

Prevention and management of wounds, especially chronic wounds, are important to patients, providers, and payers. Wounds can severely impact patients' lives, can be complex to treat, and are a source of significant spending. However, both the delivery of wound care services and payment for wound care services in traditional Medicare are suboptimal.

The Physician-Focused Payment Model Technical Advisory Committee (PTAC) received two proposals aimed at improving how Medicare pays for wound care services delivered by independent outpatient (i.e., office-based) providers/clinics—the *Bundled Payment for All Inclusive Outpatient Wound Care Services in Non Hospital Based Setting* proposal submitted by Seha Medical and Wound Care and 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* proposal submitted by Upstream Rehabilitation. The Committee does not recommend either proposal to the Secretary for implementation as a physician-focused payment model (PFP). However, the Committee believes the proposals have raised important issues that need to be addressed regarding the delivery of wound care services and payment for those services, including but not limited to, site-of-service differentials in payment for similar services, variation in local coverage determinations for wound care services, insufficient payments for evolving standards of wound care (including preventive care as well as palliative care), and limitations on the types of providers that can bill for wound care services.

In reviewing the two proposals (which for brevity will be referred to as the Seha and Upstream proposals), PTAC concludes that mechanisms for supporting a more comprehensive, multidisciplinary approach to wound care are needed, given the varying and often complicated causes of wounds and the breadth of specialties involved. In that context, members believe that each of the proposals the Committee received are too narrowly focused. The Committee also identified other aspects of the proposals in need of refinement. PTAC encourages the submitters and broader stakeholder community to first identify a more comprehensive approach to wound care delivery. Then, a payment model can be designed to support that model of care.

Members note that the submitters and other stakeholders may not have access to the necessary data to design such care and payment models, and PTAC has been advised that it may not provide technical assistance. Therefore, the Committee is hopeful that the Secretary would consider options for providing these resources. Furthermore, until a more comprehensive, multidisciplinary approach to wound care is developed, the Committee

believes that changes to the physician fee schedule could better support efficient and effective delivery of wound care and improve access to wound care in rural areas.

OVERVIEW OF SEHA AND UPSTREAM PROPOSALS

The table below provides a brief side-by-side overview of the two proposals. More detailed descriptions are available later in the document.

Dimension	Seha Proposal	Upstream Proposal
Model Overview	Provide a flat-fee bundled payment per visit for wound care provided in office-based settings	Provide additional payments for PTs/OTs to provide wound care services and products, and require return of payment if functional outcomes are not achieved
Model Objectives	<ul style="list-style-type: none"> • Reduce costs to the health care system and to patients • Encourage more treatment of wounds in lower-cost office-based settings • Provide more access and convenience to patients, especially in rural areas 	<ul style="list-style-type: none"> • Clarify and expand the ability of PTs/OTs to manage chronic wounds • Increase the functional outcomes of rehabilitation clinic patients with wounds • Increase access and provide more convenience to patients, especially in rural areas
Provider Eligibility	Independent office-based wound care providers/clinics; required to have at least two years of experience in providing wound care	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
APM Entity	Office-based wound care providers or clinics	PTs/OTs in independent outpatient therapy clinics; corporations could participate by group application
Beneficiary Eligibility	Medicare beneficiaries with an acute or chronic wound seeking services from an office-based provider/clinic (including long-term residents of nursing homes that do not employ the services of wound care specialist to provide consultations in house)	Medicare beneficiaries identified for participation by an ICD-10 code requiring wound care and a referral from a primary care provider for therapy to address a related functional loss

Dimension	Seha Proposal	Upstream Proposal
Payment Overview	<ul style="list-style-type: none"> • A \$400 bundled payment per visit for all wound care services typically provided to patients who are enrolled in the participating wound clinic • Payment includes the cost of: <ul style="list-style-type: none"> ○ Evaluation and management (E&M) ○ Patient education ○ Skin care by the staff ○ Procedures ○ Advanced tissue products ○ Dressings done at the clinic ○ Other supplies, such as medications • Payment does not include the cost of: <ul style="list-style-type: none"> ○ Hyperbaric oxygen treatments ○ Services not provided in office-based settings (e.g., imaging) 	<ul style="list-style-type: none"> • 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) • Exemption from the Medicare threshold exceptions/review process for outpatient therapy services
Risk Adjustment	None	PTs/OTs would be placed on probation if average PT/OT average 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 less than 80 percent
Quality and Cost	<ul style="list-style-type: none"> • Participating providers would be required to report quality metrics, but performance does not impact payment • Submitter is open to potentially limiting the number of visits 	<ul style="list-style-type: none"> • PTs/OTs would repay CMS if patients do not demonstrate minimal clinically significant improvement • Performance bonus of 3 percent of savings if average Medicare payments for PT/OT services per episode are below the risk-stratified cap over the two-year study period • PTs/OTs would be terminated from the program if the cap is exceeded or patient satisfaction is less than 80 percent during two quarters

COMMON STRENGTHS OF BOTH PROPOSALS

PTAC felt that the proposals had several strengths in common. Both proposals 1) raise attention to important issues in wound care and payment for wound care services; 2) seek to improve access to wound care and patient choice, particularly in rural areas; and 3) would provide increased flexibility for outpatient providers to perform wound care.

Raise attention to important issues in wound care and payment for wound care services

Approximately 15 percent of Medicare beneficiaries are estimated to have had at least one type of wound or wound-related infection in a given year. Chronic wounds can severely affect a

patient's quality of life and are associated with adverse outcomes such as limb amputation or premature death. Estimates of total Medicare (fee for service and Medicare Advantage) spending on wound care per year range from \$28.1 billion to \$96.8 billion. The proposals raise several important issues in the ways Medicare pays for the management of chronic wounds and wound care more broadly.

The Seha and Upstream proposals are aimed at improving how Medicare pays for care of wounds, especially chronic wounds, treated by independent outpatient (i.e., office-based) providers/clinics. There is currently no comprehensive alternative payment model (APM) available to support improvements in wound care services.

Both proposals highlight the potential for achieving savings in Medicare by delivering wound care treatment outside of hospital-based settings. For example, in 2018, the national payment rate for debridement of up to 20 square centimeters of subcutaneous tissue (CPT code 11042)¹ was approximately \$375 if provided in a hospital outpatient department but approximately \$121 if provided in an office-based setting. Payment for some wound care services and products is not available in office-based settings, making it necessary for these services to be delivered in more expensive hospital-based settings. Additionally, local coverage determinations can vary by Medicare Administrative Contractor, so the extent to which wound care services can be delivered in office-based settings varies across the country. Such site-of-service differentials for similar services are also a challenge in Medicare payment more broadly.

The Seha and Upstream proposals and the public comments received by PTAC indicate that current payments may be insufficient to support current and evolving standards of care in the treatment of wounds. The Medicare Physician Fee Schedule (PFS) assigns global periods to many wound care procedures. The Seha proposal shows that payments based on global periods, which are intended to reflect care typically provided before, during, and after a given procedure, can prevent providers from billing for multiple wound care procedures within the global period while providing payments that may not be sufficient to cover the cost associated with providing optimal care. A specific example raised by the Seha proposal is that providers are unable to bill for compression on the same day as debridement due to an applicable 0-day global period. In such situations, providers are faced with absorbing the additional cost or asking the patient to come back the next day. PTAC also understands that payment for more costly cellular and tissue-based products (CTPs) can be insufficient or altogether lacking.

The Upstream proposal attempts to make changes in Medicare payment policy to address barriers to physical therapists (PTs) and occupational therapists (OTs) delivering wound care services. The proposal explains that PTs and OTs who have training in wound care are

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well positioned to provide these services, and that patients who are receiving therapy service frequently also have wounds. However, barriers described in the proposal include a lack of clarity and consistency regarding the ability of PTs/OTs to receive payment for advanced therapeutics such as CTPs and that the provision of wound care services could cause PTs/OTs to exceed outpatient therapy thresholds. Even though PTs/OTs can bill for medically necessary services that exceed the threshold, doing so involves additional administrative burdens.

These payment issues may result in referral or transfer of patients to higher cost settings and reduce the ability for more accessible providers to deliver (and beneficiaries to receive) appropriate care at a lower cost. Therefore, PTAC commends the submitters for bringing attention to these areas. The Committee is interested in a more comprehensive, multidisciplinary approach to wound care. However, members believe that changes to the PFS should also be considered to better reflect current and evolving standards of care.

Improving access to wound care and patient choice, particularly in rural areas

The Seha and Upstream proposals seek changes in Medicare payment policy that would make it more feasible for office-based providers to deliver wound care services. Office-based providers would be more likely to supply evidence-based wound care services if they have sufficient resources to cover the costs of those services. Higher payments for office-based services has the potential to reduce the number of patients referred to more expensive hospital-based clinics, and to provide better access to wound care services in rural areas. The Seha and Upstream proposals indicate that patients in rural communities often must drive long distances to access the nearest hospital-based wound clinic. Increasing options for patients to be treated locally could also result in more timely care.

Furthermore, addressing obstacles in Medicare payment policy to PTs/OTs delivering wound care, which the Upstream proposal aims to achieve, could give patients the option to receive wound care services and therapy services during the same appointment. Rehabilitation and wound care may each require treatment over multiple visits. Therefore, such consolidation could enable these patients to have significantly fewer appointments.

Increased flexibility for office-based providers in the delivery of wound care

Both proposals contain features that attempt to offer providers greater flexibility in the delivery of wound care. As described above, payment for some wound care services is not available in an office-based setting or does not adequately account for evolving standards of care. The Seha

proposal describes a flat-fee bundled payment that is intended to make it more feasible for office-based providers to deliver comprehensive wound care services within a visit.

The Upstream proposal describes a way to improve the ability of PTs/OTs to deliver certain wound care services, including a one-time payment per patient for wound care supplies, authorization to bill for certain advanced wound care materials, and removal of the outpatient therapy threshold (and the accompanying coding burden when the threshold is exceeded). These additional resources and reduction in burden would provide PTs/OTs greater flexibility to offer more services to patients.

ADDITIONAL STRENGTHS OF THE SEHA AND UPSTREAM PROPOSALS

In addition to common strengths, PTAC also notes individual strengths unique to each proposal.

Straightforward payment methodology

The Seha proposal includes a straightforward payment methodology. Under the proposal, office-based providers would receive a flat-fee bundled payment for the wound care services delivered during a visit. Evaluation and management, patient education, skin care by staff, procedures, dressings (including CTPs), and other supplies would be included in the flat-fee bundle. Only hyperbaric oxygen treatment and services not provided in office-based settings would be excluded. Medicare payments for some office-based wound care services are already partially bundled. This model would further simplify payment. However, PTAC had concerns (described later) with the lack of risk adjustment in the bundled payment, particularly given the variation in acuity in the patient population with wounds and the wide distribution of costs.

Payment tied to accountability for outcomes

PTAC members felt the outcome-based payment in the Upstream proposal was unique and desirable. Under the proposed model, PTs/OTs delivering wound care services in office-based settings would be accountable for an outcome measure related to functional status. Failure to demonstrate a minimal clinically important difference on the measure could result in the provider having to repay amounts it had already received for services delivered to the patient. In addition, PTs/OTs that failed to maintain high patient satisfaction scores could be dismissed from the program.

The Committee expressed concern that the outcome measures were not based on wound-related outcomes. However, during the public meeting, the submitter clarified that the proposed model is intended to focus on patients who have wounds that interfere with PTs'/OTs' ability to help restore functional status to patients.

FEATURES OF ONE OR BOTH PROPOSALS IN NEED OF REFINEMENT

PTAC finds that a more comprehensive, multidisciplinary approach to wound care is needed, given the varying and often complicated causes of wounds and the breadth of specialties that may need to be involved in a specific patient's care. In that context, members believe that, overall, the proposals are too narrow. In addition, the Committee also identifies other aspects of the proposals in need of refinement.

Relatively narrow focus

The Seha and Upstream proposals are aimed at improving how Medicare pays for care of wounds, especially chronic wounds, treated by office-based providers/clinics. However, PTAC notes that treatment for wounds can be complex. Wounds can be acute or chronic, with chronic wounds having varying and often complicated causes, such as diabetic neuropathy, arterial or venous insufficiency, heart or renal failure, and infectious disease. This variation causes variation in the treatments needed and variation in costs when multiple or differing specialties and settings are involved in the provision of wound care for a given patient. Therefore, the Committee believes that a more comprehensive, multidisciplinary approach to wound care is needed.

In this context, PTAC finds the Seha proposal—which focuses only on the wound care that would be provided by a physician in an office-based setting—and the Upstream proposal—which focuses only on the wound care that would be provided by a physical or occupational therapist—are both too narrow. PTAC believes the submitters and broader stakeholder community should first identify a more comprehensive approach to wound care delivery. Then, a payment model can be designed to support that model of care. In the interim, the Committee believes that changes to the PFS could be made that would better support efficient and effective delivery of wound care and improve access to wound care in rural areas.

Insufficient incentives for cost containment or reduction in volume of services

PTAC finds that neither proposal has sufficient provisions to avoid the delivery of unnecessary services and unnecessarily expensive services. The Seha proposal as written does not include any limits or incentives to control the number of visit-based payments that a provider could receive for delivering wound care services to a patient. During the meeting, the submitter acknowledged some limit could be useful but did not specify a mechanism for determining appropriate limits or consequences from exceeding those limits. The Upstream proposal sets risk-adjusted limits on the average amounts billed for PT/OT services to an individual patient, but it includes only a modest financial incentive (a bonus equal to 3 percent of the savings) for participating providers to hold spending on PT/OT services below those limits. Moreover, 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.

Lack of mechanisms to ensure patients receive the services they need

PTAC had concerns about whether the proposals would ensure patients receive the right services from the right providers at the right time.

Under the Seha proposal, office-based providers would receive a flat-fee bundled payment of \$400 for each visit for wound care services. Since this payment would not be adjusted for patient severity or complexity, it could create incentives to “cherry-pick” less complex wound care patients if the payment was not enough to cover the cost of more expensive treatments needed by more complex patients. The flat-fee bundled payment in the Seha proposal also does not preclude delivering services to patients with more complex needs but stinting on services. The Seha proposal submitter noted that an office-based wound care provider often may not know if a patient is appropriate for office-based care or needs hospital-based care until the assessment during the initial visit.

The Upstream proposal does not require that all patients who need services must be accepted into the model. While the spending targets would be risk adjusted, participating providers could target patients with less complex wounds who are likely to achieve good outcomes quickly at a lower cost, including patients who could have achieved good results at lower cost with services from their primary care physician. In addition, the Upstream model does not require the providers to continue to serve the patients once the dollar cap is reached or if a desirable functional outcome is not achieved.

Potential barriers to appropriate referral

Given that wound care is a complex disease requiring a multidisciplinary team approach, it is important to ensure that payment models address potential barriers to appropriate referrals. PTAC has concerns that providers could hold onto patients for extended periods of time due to the financial incentives associated with the respective models. The potential risks associated with delaying appropriate referrals are relevant for both care coordination and patient safety.

The Seha proposal does not include any specific requirement that the primary wound care provider make appropriate referrals to specialists or to coordinate those services. Since the proposal’s per-visit bundled payment does not include the cost of seeing a specialist, there would not be a direct financial penalty for the primary wound care provider if a patient received a service from a specialist. However, the wound care provider might be reluctant to make a referral if there is no assurance the patient will return to the original provider for continued services.

PTAC had similar concerns about whether PT/OT practices would make appropriate referrals to specialists under the Upstream proposal. PTAC noted that many states place restrictions on PTs'/OTs' scope of practice related to wound care. The submitter stated that the proposed model would not supersede any state practice requirements and further stated that it is the provider's professional obligation to refer when appropriate and that a PT/OT would put their licensure at risk by not providing appropriate referrals.

Committee members believe that both proposals could be strengthened by including clear language and definitions regarding standards of practice that all providers have to adhere to within their training and licensure relating to determining when a patient should be referred to a specialist.

Performance measurement and evaluation concerns

Committee members were concerned that both the Seha and Upstream models lack clarity relating to their cost and quality metrics, and their ability to be evaluated. Although the Seha proposal mentions some goals and metrics that could potentially be evaluated, it does not articulate a proposed methodology for conducting the evaluation. The proposal also does not provide sufficient information about how the proposed quality metrics would be measured, or whether risk stratification would be used in calculating the various quality metrics. Additionally, the Seha proposal does not require accountability by the participating providers for outcomes based on the quality measures. There does not appear to be any negative consequence for the office-based wound care provider if an enrolled patient is hospitalized after receiving low-quality wound care services.

In the Upstream proposal, the providers participating would be able to choose among different functional outcome measures on which to be evaluated. This provision would make it difficult to compare performance between different participants.

Limited use of health information technology

Since both proposals are focused on office-based providers, and wound care is a specialty that requires a multidisciplinary team approach, it would be particularly important to ensure that health information technology (HIT) is being appropriately used to improve care coordination with the patient's other providers. However, neither the Seha proposal nor Upstream proposal

describes how HIT would be used to ensure care coordination with the patient's other providers.

SUMMARIES OF SEHA AND UPSTREAM PROPOSALS

Seha Proposal: Bundled Payment For All Inclusive Outpatient Wound Care Services In Non Hospital Based Setting

The Seha Medical and Wound Care proposal was received by PTAC on October 15, 2018. The submitter is proposing to develop a flat-fee bundled payment model for office-based outpatient wound care services, which would potentially provide a more efficient substitute for hospital-based/outpatient facility-based wound care providers.

Provider Eligibility: Independent office-based wound care providers and clinics would be eligible to participate in the proposed model. Additionally, the submitter states that any provider desiring to participate in the model should have at least two years of experience in providing wound care either in his or her own office or in a formal wound clinic (which is a requirement for certification by the American Academy of Wound Management). During the public meeting, the submitter stated that a number of family practice and internal medicine physicians who provide wound care in their office-based settings would be included in this proposal. The office-based wound care provider or clinic would likely serve as the APM Entity. While there are no practice size or geographic restrictions, the proposed model is designed specifically for office-based wound care providers.

Payment Model: Under the proposed model, office-based wound care providers/clinics would be paid in the following way:

- The provider or clinic would receive a \$400 flat-fee bundled payment per visit that would be “all-inclusive” and would cover all wound care services that are typically provided to a patient during a visit to an office-based or freestanding outpatient wound clinic (including the cost of evaluation and management visits, or E&M; patient education; skin care by the staff; procedures, such as wound debridement, Unna boot application, offloading total contact cast; advanced tissue products/skin substitutes; dressings done at the clinic; and other supplies, such as medications).¹

¹ While the submitter stated during the public meeting that if CMS is told that the average number of visits is supposed to be, say 12 or 14, this could potentially be used to trigger that the beneficiary is going to the participating provider too much, the submitter did not provide any details regarding how this would actually work in practice (i.e., what, if any, consequences there would be for exceeding the average number of visits).

- The \$400 all-inclusive bundled payments per visit for office-based wound care services would not be risk-stratified based on patient acuity. The submitter states that because the majority of complex, non-healing wounds require standard regimens and time to heal—although there are outliers—this helps to spread the cost across the spectrum and will mitigate against the potential variations in risk and complexity.
- The \$400 bundled payment will not include the cost of hyperbaric oxygen treatments. Although the submitter currently offers hyperbaric oxygen treatments, the cost of offering this service on-site may be prohibitive for some office-based providers. Therefore, under the proposed model, hyperbaric oxygen treatments will have to be billed separately for the estimated fewer than 5 percent of all patients seen in wound clinics who require this treatment modality.
- Additionally, the \$400 all-inclusive bundled payment per visit will only cover all services provided to patients in the wound clinic. Any services provided to patients outside of the wound clinic, such as physical therapy, visiting nurse services, or the need for hospitalization, would not be included. Other services that are done outside of the office-based wound clinic that would not be included in the \$400 bundled payment include investigative services such as laboratory, x-ray, ultrasound, computerized tomography (CT) scan, and magnetic resonance imaging (MRIs).
- The proposal does not provide details regarding documentation requirements under the proposed model, such as whether participating providers would be required to submit encounter forms to Medicare describing the services that are delivered during each office-based visit for wound care services.

Care Delivery Model: While participating providers would be required to have at least two years of wound care experience, the submitter states that one of the proposed model’s objectives is to make it easy for providers with experience in wound care to participate. Although the submitter states that its own wound care practice utilizes a comprehensive whole-person approach that focuses on patient-oriented care in which the “patient is seen as a whole patient, examining pertinent co-morbidities, and the potential benefits versus costs of possible procedures,” the proposal does not require providers to replicate this care model in order to participate in the payment model. The submitter states that it believes allowing for flexibility on the care model will allow the providers to find what works best for their patients.

The submitter states that in the event that patients need services that are beyond what is available at the office-based wound care clinic (such as hospital admissions for infection requiring intravenous antibiotics, surgical procedures in hospital operating rooms, or admission

to a rehabilitation facility), the wound care clinic's services would be put on hold until the patient is discharged from the inpatient facility. After discharge, the wound clinic services could be resumed if the patient still requires them.

Additionally, the submitter states that patients will have the choice of transferring their care to any place of service they wish by providing a simple notification to the participating provider, so that this information can be reflected in the patient's medical record.

Beneficiary Eligibility Criteria: The submitter states that any Medicare beneficiary who seeks or requires specialty care with an acute or chronic wound in a wound clinic will be eligible to participate in the model. Medicare beneficiaries who are long-term residents of nursing homes would also be eligible to participate in the model if they require care in a wound care clinic (e.g., if their nursing home does not employ the services of wound care specialists to provide consultations in house). The submitter notes that the majority of patients are referred to wound clinics by primary care providers or emergency rooms with multiple comorbidities and various levels of severity, with the precise diagnosis of the cause of the referral typically being made after evaluation in the wound clinic.

The submitter identified the following exclusion criteria for identifying patients who would not be eligible to participate in the model:

- Patients who require immediate intervention in a hospital setting (e.g., for amputations, flap procedures, or extensive debridement in a hospital operating room, for intravenous antibiotics to control infection, for services to stabilize other comorbid conditions such as congestive heart failure, etc.). However, once discharged from the hospital, these patients would be eligible for inclusion in the proposed model for ongoing wound care, as is the current prevailing practice
- Patients who have been previously seen by the office-based wound care provider/clinic and have failed or refused to comply with the care plan
- Patients who require palliative wound care at the end of life.

Enrollment Process: The submitter anticipates that patients will be referred by their providers, hospital, or emergency room. Additionally, some patients are self-referrals—with the patients or their family members contacting the office-based wound care provider to seek help. Participating providers/clinics in the proposed model will also be required to log all referrals into a data set.

Regarding the process for formally enrolling in the model, the submitter states that once the wound care provider receives the call, patients will be registered in the wound care program.

Patients will receive a simple one-paragraph statement indicating that all care provided in the independent office-based wound care clinic is included in the per visit bundled payment. In the event that a given patient wishes to transfer his or her care to another wound care provider, he or she can notify the participating provider/clinic, and this information will be documented in the patient's medical records.

Quality: The submitter has identified six quality measures that will be used for quality reporting under the proposed model, most of which were adapted from the U. S. Wound Registry:

- Measurement of a patient's improvement in quality of life,
- Improvement in pain scale/control,
- Number of visits to heal different wounds, such as diabetic and venous leg ulcers (compared with nationally reported data),
- Number of prescriptions filled for proper offloading devices and footwear (for example, diabetic footwear) and prescriptions for compression garments for patients with venous ulcers,
- Blood monitoring of A1C for patients with diabetic ulcers, and
- A venous leg outcome measure.

However, the proposal does not include many details regarding how the proposed quality metrics would be measured or evaluated.

Upstream 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

The Upstream proposal 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 revised Upstream Rehabilitation proposal seeks to expand the ability of PTs and 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 inability for free-standing outpatient clinics to be paid for sophisticated dressing products comparable to payment in the hospital outpatient setting; 2) a lack of clarity and consistency regarding the ability of PTs/OTs to use and be paid for advanced therapeutics; and 3) 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.

The submitter proposes to address these barriers by: 1) creating a new \$250 one-time billable payment per patient for wound care supplies, 2) explicitly allowing 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, and 3) 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.

Beneficiary Eligibility Criteria: The revised proposal stated that 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. However, in response to questions during the public meeting, the submitter indicated that although the title of the proposal references “Measuring the Effectiveness of Physical or Occupational Therapy Intervention as the *Primary Means* [emphasis added] of Managing Wounds in Medicare Recipients,” the primary goal of the proposal is to improve wound care for patients who are in need of PT/OT due to significant functional limitations and who also have a wound that would potentially preclude good outcomes and that could support limiting the proposed payment model to those patients.

Eligible beneficiaries would be informed about the use of their de-identified data for performance measurement 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.

Provider Eligibility: Participation in the program would require PTs/OTs to attest that they meet all program criteria, including professional certification, to demonstrate advanced training in wound treatment, and to have the data collection capacity for costs and outcome measures, as well as the capacity to bill claims electronically with the Centers for Medicare & Medicaid Services (CMS). Currently, PTs/OTs are required to provide progress notes to referring

physicians every tenth visit or 30 days, and the proposal would not require any additional communication or coordination beyond this requirement.

Payment Model: Participating PTs/OTs would be paid using the Medicare PFS 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 and could be paid additional amounts for use of CTPs in accordance with the PFS. 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, the provider would receive a performance bonus equal to 3 percent of the amount by which average payments were 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 continues in a subsequent quarter.

APPENDIX 1. COMMITTEE MEMBERS AND TERMS

Jeffrey Bailet, MD, Chair

Grace Terrell, MD, MMM, Vice Chair

Term Expires October 2019

Paul N. Casale, MD, MPH
New York Quality Care
New York-Presbyterian, Columbia University College
of Physicians and Surgeons, Weill Cornell Medicine
New York, NY

Bruce Steinwald, MBA
Independent Consultant
Washington, DC

Tim Ferris, MD, MPH
Massachusetts General Physicians Organization
Boston, MA

Term Expires October 2020

Rhonda M. Medows, MD
Providence St. Joseph Health
Seattle, WA

Len M. Nichols, PhD
Center for Health Policy Research and Ethics
George Mason University
Fairfax, VA

Harold D. Miller
Center for Healthcare Quality and Payment Reform
Pittsburgh, PA

Grace Terrell, MD, MMM
Envision Genomics
Huntsville, AL

Term Expires October 2021

Jeffrey Bailet, MD
Blue Shield of California
San Francisco, CA

Angelo Sinopoli, MD
Prisma Health
Greenville, SC

Kavita Patel, MD, MSHS
Johns Hopkins Health System
Baltimore, MD

Jennifer Wiler, MD, MBA
University of Colorado School of Medicine
Aurora, CO

APPENDIX 2. PFPM CRITERIA ESTABLISHED BY THE SECRETARY

PFPM CRITERIA ESTABLISHED BY THE SECRETARY

- 1. Scope.** 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.
- 2. Quality and Cost.** 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.
- 3. Payment Methodology.** 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.
- 4. Value over Volume.** Provide incentives to practitioners to deliver high-quality health care.
- 5. Flexibility.** Provide the flexibility needed for practitioners to deliver high-quality health care.
- 6. Ability to Be Evaluated.** Have evaluable goals for quality of care, cost, and any other goals of the PFPM.
- 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.
- 8. Patient Choice.** Encourage greater attention to the health of the population served while also supporting the unique needs and preferences of individual patients.
- 9. Patient Safety.** Aim to maintain or improve standards of patient safety.
- 10. Health Information Technology.** Encourage use of health information technology to inform care.

APPENDIX 3a. DISTRIBUTION OF MEMBER VOTES ON EXTENT TO WHICH SEHA PROPOSAL MEETS CRITERIA

Criteria Specified by the Secretary (at 42 CFR §414.1465)	Not Applicable	Does Not Meet Criterion		Meets Criterion		Priority Consideration		Rating
	*	1	2	3	4	5	6	
1. Scope (High Priority) ¹	0	0	2	2	4	1	2	Meets
2. Quality and Cost (High Priority)	0	6	5	0	0	0	0	Does Not Meet
3. Payment Methodology (High Priority)	0	8	3	0	0	0	0	Does Not Meet
4. Value over Volume	0	4	7	0	0	0	0	Does Not Meet
5. Flexibility	0	0	2	8	1	0	0	Meets
6. Ability to Be Evaluated	0	2	7	2	0	0	0	Does Not Meet
7. Integration and Care Coordination	0	7	3	1	0	0	0	Does Not Meet
8. Patient Choice	0	0	2	8	1	0	0	Meets
9. Patient Safety	0	3	7	1	0	0	0	Does Not Meet
10. Health Information Technology	0	4	5	2	0	0	0	Does Not Meet

¹Criteria designated as “high priority” are those PTAC believes are of greatest importance in the overall review of the payment model proposal.

APPENDIX 3b. DISTRIBUTION OF MEMBER VOTES ON RECOMMENDATION ON SEHA PROPOSAL

Recommendation Vote: Part 1 of 2¹

Not Recommended for Implementation as a PFPM	Recommended	Referred for Other Attention by HHS	Result
10	0	1	Not Recommended for Implementation as a PFPM

Recommendation Vote: Part 2 of 2 (if applicable)

Proposal substantially meets Secretary’s criteria for PFPMs. PTAC recommends implementing proposal as a payment model.	PTAC recommends further developing and implementing the proposal as a payment model as specified in PTAC comments.	PTAC recommends testing the proposal as specified in PTAC comments to inform payment model development.	PTAC recommends implementing the proposal as part of an existing or planned CMMI model.	Result
N/A	N/A	N/A	N/A	N/A

Final recommendation to Secretary: PTAC does not recommend this model for implementation as a PFPM.

¹In 2018, PTAC adopted new voting categories, used first at their December 2018 public meeting. First, PTAC votes on the three categories listed above as Part 1 of 2. PTAC must achieve a two-thirds majority for one of these categories. If a two-thirds majority votes to not recommend the proposal for implementation as a PFPM or to refer the proposal for other attention by HHS, that category is the Committee’s final recommendation to the Secretary. If the two-thirds majority votes to recommend the proposal, the Committee proceeds to Part 2 of 2 to determine the final, overall recommendation for the Secretary. The second vote uses the four subcategories listed above. A two-thirds majority must be achieved for one of these four categories.

APPENDIX 4a. DISTRIBUTION OF MEMBER VOTES ON EXTENT TO WHICH UPSTREAM PROPOSAL MEETS CRITERIA¹

Criteria Specified by the Secretary (at 42 CFR §414.1465)	Not Applicable	Does Not Meet Criterion		Meets Criterion		Priority Consideration		Rating
	*	1	2	3	4	5	6	
1. Scope (High Priority) ²	0	0	1	2	4	1	2	Meets
2. Quality and Cost (High Priority)	0	0	9	0	1	0	0	Does Not Meet
3. Payment Methodology (High Priority)	0	0	7	2	1	0	0	Does Not Meet
4. Value over Volume	0	0	0	9	1	0	0	Meets
5. Flexibility	0	0	0	5	5	0	0	Meets
6. Ability to Be Evaluated	0	0	1	5	3	1	0	Meets
7. Integration and Care Coordination	0	0	7	1	1	1	0	Does Not Meet
8. Patient Choice	0	0	0	3	6	1	0	Meets
9. Patient Safety	0	0	4	6	0	0	0	Meets
10. Health Information Technology	0	1	6	3	0	0	0	Does Not Meet

¹PTAC Member Rhonda M. Medows, MD, abstained from voting.

²Criteria designated as “high priority” are those PTAC believes are of greatest importance in the overall review of the payment model proposal.

APPENDIX 4b. DISTRIBUTION OF MEMBER VOTES ON RECOMMENDATION ON UPSTREAM PROPOSAL¹

Recommendation Vote: Part 1 of 2²

Not Recommended for Implementation as a PFPM	Recommended	Referred for Other Attention by HHS	Result
9	1	0	Not Recommended for Implementation as a PFPM

Recommendation Vote: Part 2 of 2 (if applicable)

Proposal substantially meets Secretary's criteria for PFPMs. PTAC recommends implementing proposal as a payment model.	PTAC recommends further developing and implementing the proposal as a payment model as specified in PTAC comments.	PTAC recommends testing the proposal as specified in PTAC comments to inform payment model development.	PTAC recommends implementing the proposal as part of an existing or planned CMMI model.	Result
N/A	N/A	N/A	N/A	N/A

Final recommendation to Secretary: PTAC does not recommend this model for implementation as a PFPM.

¹PTAC member Rhonda M. Medows, MD, abstained from voting.

² In 2018, PTAC adopted new voting categories, used first at their December 2018 public meeting. First, PTAC votes on the three categories listed above as Part 1 of 2. PTAC must achieve a two-thirds majority for one of these categories. If a two-thirds majority votes to not recommend the proposal for implementation as a PFPM or to refer the proposal for other attention by HHS, that category is the Committee's final recommendation to the Secretary. If the two-thirds majority votes to recommend the proposal, the Committee proceeds to Part 2 of 2 to determine the final, overall recommendation for the Secretary. The second vote uses the four subcategories listed above. A two-thirds majority must be achieved for one of these four categories.