

Physician-Focused Payment Model Technical Advisory Committee

Preliminary Review Team Report to the Physician-Focused Payment Model Technical Advisory Committee (PTAC) on the *Bundled Payment for All Inclusive Outpatient Wound Care Services in Non Hospital Based Setting* Payment Model

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February 8, 2019

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 [website](#)), 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

- 1. Proposal Name:** Bundled Payment for All Inclusive Outpatient Wound Care Services in Non Hospital Based Setting
- 2. Submitting Organization or Individual:** Seha Medical and Wound Care
- 3. Submitter's Abstract:**

"Effects of aging are most visible on skin. As people grow older all layers of skin become thinner and more fragile. This in addition to a host of co-morbidities can result in delayed or nonhealing of wounds. Non-healing wounds affect all aspects of quality of life, become a source of infection and even hospitalizations.

"According to a retrospective analysis nearly 15% of Medicare beneficiaries (8.2 million) had at least one type of wound. Medicare expenditure for wound care is expected to increase with the aging of the population. The same article concludes a need for more appropriate reimbursement models for smarter spending and better outcomes.

"A significant portion of the cost of chronic wound care is due to hospital facility charges. On the other hand various Medicare guidelines, global period restrictions and

LCDs [local coverage determinations] prevent non-hospital based providers to get reimbursed for all the same services provided during a patient visit.

“Majority of the patients first seek help from their primary care physicians for non-healing and minor trauma wounds. However due to poor reimbursement and the cost of care required in terms of time and supplies to provide wound care in an office setting the current system promotes referral or transfer of care to higher cost settings. It is also noted that many patients have seen 2-3 specialists like vascular surgeons, dermatologists and plastic surgeons before they finally find someone who knows how to treat non-healing wounds. The delay in getting the required treatment prolongs the suffering and adds to the total cost of care.

“We propose a bundled payment model in which Medicare will pay a *flat fee* per visit inclusive of all services provided to independent office-based wound care provider/clinic. This means [Medicare] will not be paying for expensive procedures and advanced tissue products separately resulting in significant savings in total wound care expenditures.”

B. Summary of the PRT Review

The Seha Medical and Wound Care proposal (available on the ASPE PTAC [website](#)) was received by PTAC on October 15, 2018. The PRT met between November 26, 2018, and January 30, 2019, on the proposal. A summary of the PRT’s findings is provided in the table below.

PRT Rating of 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	Does Not Meet Criterion	Unanimous
5. Flexibility	Meets Criterion	Unanimous
6. Ability to Be Evaluated	Does Not Meet Criterion	Majority
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 Seha Medical and Wound Care proposal was received by PTAC on October 15, 2018. The proposal did not receive any letters of public support. The PRT met between November 26, 2018, and January 30, 2019, on the proposal. The PRT reviewed the *Bundled Payment for All Inclusive Outpatient Wound Care Services in Non Hospital Based Setting (OWCS-APM)* proposal and submitted a list of detailed questions to the submitter on December 14, 2018. The submitter provided written responses to the PRT's questions on January 4, 2019. The PRT reviewed the written responses, and it held a one-hour teleconference with the submitter on January 16, 2019, in which the submitter provided additional information regarding the PRT's initial questions and also responded to additional PRT questions. The proposal, questions and answers, and call transcript are available on the ASPE PTAC [website](#).

1. Proposal Summary

The submitter is proposing to develop a fixed-price bundled payment model for office-based outpatient wound care services that 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 OWCS-APM. 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). 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 OWCS-APM, 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”—paying for 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 debridements, unna boot applications, offloading total contact cast; advanced tissue products/skin substitutes; dressings done at the clinic; and other supplies, such as medications).
- 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 all-inclusive 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's 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," other participating providers would not be required to replicate this care model. The submitter believes that allowing for flexibility relating to 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, at which point the wound clinic services would 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 if they desire so 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 in a wound clinic with an acute or chronic wound 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 has 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 debridements in a hospital operating room, or intravenous antibiotics to control infection or 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 OWCS-APM 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, they 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
- A venous leg outcome measure

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

2. Current Reimbursement for Wound Care Services

Although nearly 15 percent of all Medicare beneficiaries (8.2 million) were estimated to have had at least one type of wound or wound-related infection in 2014,¹ the estimated number of Medicare fee-for-service (FFS) beneficiaries with chronic, non-healing wounds that were treated in outpatient settings is much smaller. According to analyses conducted at the request of the PRT, approximately 350,000 Medicare FFS beneficiaries in 2016 had at least one visit with a provider in an ambulatory setting for non-emergent treatment of a wound (i.e., excluding emergency room visits). Four-fifths of these beneficiaries saw a provider in an office-based setting,² and the remainder went to a provider in an outpatient facility.³

In 2016, Medicare FFS beneficiaries had nearly 900,000 visits for non-emergent wound care. Approximately three-quarters of these visits were with office-based providers, where the mean Medicare-allowed charge was \$95. The remaining quarter were with providers in outpatient facilities, where the mean Medicare-allowed charge was \$413 (of which \$355 was the mean facility charge, and \$27 was the mean provider charge).

¹ This figure represents an estimate of the overall prevalence of wound-related infections in the Medicare population based on an analysis of all Medicare claims data for inpatient and outpatient hospital, skilled nursing facility, home health agency, and hospice services.

² Including all places of care except those paid under the Medicare Physician Fee Schedule as facility-based: Off Campus-Outpatient Hospital, Inpatient Hospital, On Campus Outpatient Hospital, Emergency Room—Hospital, Ambulatory Surgical Center, Inpatient Psychiatric Facility, Comprehensive Inpatient Rehabilitation Facility, Skilled Nursing Facility, Community Mental Health Center, Military Treatment Facility, Ambulance (Land, Air, or Water), Hospice, Psychiatric Facility—Partial Hospitalization, Psychiatric Residential Treatment Center.

³ Including hospital outpatient departments/clinics, as well as Rural Health Centers, Federally Qualified Health Centers, and Critical Access Hospitals.

In office-based settings, Podiatrists provided 75 percent of Medicare FFS non-emergent wound care services in 2016. Meanwhile, in outpatient facilities, various types of specialists provided the majority of non-emergent wound care services to Medicare FFS beneficiaries that year, including: General Surgeons (19 percent), Podiatrists (19 percent), Family Practice physicians (13 percent), Internal Medicine physicians (10 percent), and Emergency Medicine physicians (10 percent).

The submitter has expressed a concern that it is currently more difficult for office-based wound care providers to receive Medicare reimbursement for the same services that wound care providers in hospital/outpatient facilities are reimbursed for during a patient visit. The proposal cites three major barriers to providing wound care services in office-based provider settings: 1) global period restrictions, 2) local coverage determinations, and 3) poor reimbursement relative to the cost of providing care.

The following is a summary of the PRT's understanding of these Medicare FFS reimbursement issues, based on information in a supplemental literature review that is available on the ASPE PTAC [website](#).

- In total, Medicare payments for wound care services provided in hospital outpatient departments can be higher than payments for services provided in physician offices: Medicare makes two payments in the first case (one under the Medicare Outpatient Prospective Payment System [OPPS] and one under the Medicare Physician Fee Schedule [PFS]), but just one payment under the PFS for wound care services in physician offices.⁴ For example, the 2018 total National Medicare Payment Amount for Healthcare Common Procedure Coding System (HCPCS) code 11042 (Debridement of Subcutaneous Tissue 20 sq cm/<) was:
 - \$374.88 for HOPDs—including \$310.80 for the HOPD APC Facility Fee under the OPPS and \$64.08 for the Professional Fee (which represents the Facility Payment under the PFS)
 - \$120.60 for physician office-based providers (based on the total PFS payment in a Freestanding Office-Based Setting).⁵

⁴ The PFS payment is developed from relative value units (RVUs) for physician work, practice expense (PE), and malpractice (MP). PE includes the direct costs (clinical labor, medical supplies, medical equipment) associated with providing the service as well as indirect costs based on work and direct costs. For services provided in facilities that are eligible to bill Medicare (e.g., hospital outpatient), the PFS amount is lower since the physician does not incur the direct costs of providing the service. For these facility-based services, the physician is paid for work, some indirect costs, and MP, but since the facility incurs the direct costs (and related indirect costs), Medicare's payment to the facility covers those costs.

⁵ Caution should be used when making direct comparisons between PFS and OPPS payment rates, due to underlying differences between the specific billing and reporting requirements in the two payment systems.

- This payment differential can also have an impact on beneficiaries because under Medicare Part B, beneficiaries are responsible for paying 20 percent coinsurance after the annual deductible has been satisfied.
- Global surgical periods can affect Medicare reimbursement for wound care services, regardless of setting. Under the PFS, payment rates for some wound care are set to include services that are normally furnished by a provider before, during, and after a given procedure.⁶ This means that the provider may not receive separate payment for care related to the wound if it falls in the global period for the index service, since the payment rate was established to reflect the typical level of such care during the global period. However, the provider can bill for E&M visits or other services that are *not* related to the index service during the global period.
- Additionally, differences in Local Coverage Determinations (LCDs) by Medicare Administrative Contractors (MAC) regarding whether a particular item or service is “reasonable and necessary” in a given area affects whether wound care providers in different geographic areas can be reimbursed for certain kinds of wound care dressings and advanced therapies.⁷

3. Additional Information Reviewed by the PRT

a. Literature Review and Environmental Scan

The Office of the Assistant Secretary for Planning and Evaluation (ASPE), through its contractor, conducted a targeted environmental scan that included a review of peer-reviewed and non-peer-reviewed publications and a formal search of major medical, health services research, and general academic databases, as well as a search for relevant grey literature, such as research reports, white papers, conference proceedings, and government documents and a review of websites of professional associations/societies and CMS for relevant evaluation reports and program documentation. Key words guiding the environmental scan and literature review were directly identified from the Proposal. The search and the identified documents were not intended to be comprehensive and were limited to documents that met predetermined research parameters, generally including a five-year look-back period, a primary focus on United States-based literature and documents, and relevancy to the Proposal. These materials are available on the ASPE PTAC [website](#).

⁶ CMS views global periods as being somewhat similar to packaged or bundled services, in that services are valued based on being furnished together, rather than being furnished individually.

⁷ CMS recently updated the LCD process (effective on January 1, 2019) to improve transparency and facilitate stakeholder engagement. The process also requires MACs to use clinical guidelines, consensus documents, and consultation; public notice and comment periods; and open Contractor Advisory Committee meetings.

b. Data Analyses

The PRT sought additional information regarding the current number of Medicare FFS beneficiaries with wound care claims by place of service; the number of wound care services by provider specialty, place of service, and type of wound; the distribution of wound care charges by place of service; and out-of-pocket costs for Medicare beneficiaries for wound care services in outpatient facilities versus office-based settings. ASPE, through its contractor, produced data tables that are available on the ASPE PTAC [website](#).

c. Public Comments

There were no public comments submitted for this proposal.

d. Other Information

The PRT sought additional information regarding local coverage determinations and global periods in the context of wound care reimbursement; differences in wound care reimbursement in physician offices and hospital outpatient departments; and international standards for wound care. ASPE, through its contractor, summarized this information, which is available on the ASPE PTAC [website](#). ASPE also communicated with staff in the Centers for Medicare & Medicaid Services (CMS) Center for Medicare (CM) and Center for Clinical Standards and Quality (CCSQ) to gain a fuller understanding of Medicare payment for wound care services in office-based settings and outpatient facilities.

D. Evaluation of 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 submitter has identified a genuine problem—noting that current Medicare FFS reimbursement requirements make it financially difficult for certain kinds of office-based providers to provide wound care services. The submitter also states that the current system promotes referral or transfer of patients to higher-cost settings for wound care services. Additionally, some hospital-based/outpatient facility-based wound care centers can be more expensive when compared with office-based wound care

providers—which can affect the cost of care for both patients (in the form of deductibles, coinsurance, and/or copayments) and payers.

- The proposal seeks to address this issue with a payment model that is specifically designed to provide additional resources that would make it possible for more patients to receive wound care services in potentially lower-cost office-based settings.
- There are currently no alternative payment models (APMs) available through the CMS Center for Medicare and Medicaid Innovation that address chronic outpatient wound care services for office-based providers. However, CMS has been testing a Medicare Prior Authorization Model for Non-Emergent Hyperbaric Oxygen (HBO) to test whether requiring prior authorization for HBO can reduce costs without adversely affecting quality of care for beneficiaries requiring this wound care service.
- Although most Medicare FFS beneficiaries currently receive outpatient treatment for chronic (non-emergent) wound care services from office-based providers (more than 80 percent), there may still be some Medicare FFS patients who are currently receiving wound care services in hospital-based outpatient facilities who could potentially benefit from this type of proposal—which could increase their access to the ability to receive wound care services in lower-cost office-based settings.

Weaknesses:

- It is not clear that at least some of the reimbursement-related concerns that have been raised by the submitter could not be addressed by making modifications to the Medicare PFS.
- When examining proposed APMs, it is important to think beyond implementing the proposed model at a single site and to also consider opportunities for broad implementation. It is unclear how many office-based providers would be interested in participating in the proposed OWCS-APM model, or how many would prefer it over other approaches. No letters of support were included with the proposal, and no public comments (positive or negative) were received.
- It is also not clear to what extent the proposed model would be able to encourage office-based providers who are not already providing wound care services to begin providing this service—particularly given that the OWCS-APM model would require at least two years of wound care experience in order to participate.
- Moreover, given that the submitter has estimated that it would be necessary to have approximately 10 patients per day in order to operate a full-scale freestanding office-based wound clinic, it is not clear whether there would be sufficient patient volume to make this kind of model attractive for office-based providers in more rural areas.

Summary of Rating:

The proposed PFFM meets the criterion. Although there is not evidence that the OWCS-APM would encourage a significant number of office-based wound care providers to participate, the proposed model could still have an important impact on some individual

Medicare beneficiaries who may be able to receive wound care services in lower cost office-based settings.

Criterion 2. Quality and Cost (High-Priority Criterion). 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 proposed model's \$400 all-inclusive bundled payment to office-based providers for wound care services has the potential to reduce costs if some patients can be shifted from more costly hospital-based/outpatient facility settings while maintaining quality and avoiding increases in utilization.

Weaknesses:

- Participating office-based providers would be paid the same \$400 fixed bundled payment amount per visit, regardless of the patient's level of severity, and regardless of how many wound care services were provided during a given visit. Therefore, it is possible that a participating provider could receive the full per-visit payment even if a patient is receiving poor-quality care—for example, due to stinting on necessary care or due to providing excessive care in the form of additional visits (which could result in additional costs to the Medicare program).
- The proposed OWCS-APM model does not include provisions that would address potential concerns related to the risk of participating providers "cherry-picking" the simpler wounds to do in the office-based setting while leaving the more difficult cases for the outpatient facility-based setting—except for potentially requiring participating providers to log all of their referrals and document why a particular patient was not accepted.
- Since the majority of chronic (non-emergent) outpatient wound care services are already being provided in office-based settings, it is unclear how many wound care visits could potentially be shifted from more expensive hospital-based/outpatient facility-based settings to less expensive office-based settings under this proposal. Additionally, it is not clear that other participating providers would be able to achieve the submitter's 12-week (1 visit per week) average time of healing per wound (which is lower than the U.S. Wound Care Registry's national average of 14 weeks, which varies depending on the type and severity of the wound). Therefore, there is a risk that the higher proposed reimbursement rates for office-based wound care providers could actually result in a higher total cost of care.

- The proposal does not provide sufficient assurances that the quality of wound care services provided by the office-based providers/clinics participating in the OWCS-APM model would be at least as good as or better than the services provided to other patients who are not in the model.
- The submitter states that the proposed payment model will create the incentive to heal most of the patients' wounds within a minimum number of visits in order to maintain the quality of the program. While the proposal would require participating providers to have at least two years of wound care experience, it would not require them to adhere to a particular care model or follow a particular set of national guidelines or established protocols in order to achieve the desired cost and utilization objectives.
- Additionally, the submitter's reference to lack of adherence to algorithms and protocols is potentially problematic because patient care should be based on best practices.
- The proposal does not provide sufficient information about how the proposed quality metrics would be measured and does not include other potentially useful quality metrics, such as the rate of wound healing and the number of amputations. The proposal also does not discuss whether risk stratification will be used in calculating the various quality metrics.
- The proposed use of the monitoring of A1C levels for patients with diabetic ulcers does not appear to be an appropriate measure for quality in the context of the proposed model for a number of reasons. First, it is a process measure, not an outcome measure. Second, there is no obvious indication that a wound care specialist would be responsible for management of an inappropriate A1C level, and a wound care specialist who is monitoring A1C levels could potentially submit lab work that is more appropriately being done by the patient's primary care physicians or endocrinologists (which would be duplicative). Additionally, recent guidelines from the American Diabetes Association (ADA) have been loosening strict control of A1C levels in elderly patients for a number of legitimate reasons.
- It is not clear if participating providers/clinics in the OWCS-APM model would be required to submit encounter forms to Medicare describing the services that are delivered as part of each wound care visit that is provided under the model, which could affect Medicare's ability to collect patients' coinsurance and monitor quality of care.

Summary of Rating:

The proposed PFFM does not meet the criterion. The proposal does not provide sufficient assurances that the quality of wound care services provided by the participating office-based providers/clinics would be better under the OWCS-APM model and that providers will not provide excessive care in the form of additional visits that could result in additional costs to the Medicare program.

Criterion 3. Payment Methodology (High-Priority Criterion). 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:

- By creating a bundled all-inclusive payment for office-based wound care services, the proposed model would potentially provide an incentive for more office-based providers to offer wound care services and provide opportunities for additional cost containment and quality improvement.

Weaknesses:

- The proposal does not provide sufficient justification for the OWCS-APM’s proposed \$400 per visit all-inclusive payment for office-based wound care providers. It is not clear that the OWCS-APM’s proposed \$400 per visit amount (compared with the current mean Medicare allowed charge of \$95 for wound care for providers in office-based settings) is necessary for the submitter and other office-based providers to be able to deliver high-quality wound care services.
- The submitter does not explain the basis for recommending an all-inclusive payment on a per-visit basis instead of recommending a bundled payment for an episode of wound care. The proposed payment model does not include any limits on the number of visit-based payments for wound care services in order to manage utilization and cost. Therefore, there is a risk that the submitter’s estimate of a 20 percent reduction in cost associated with shifting to the less expensive setting could be negated by increases in the number of visits. Additionally, there is nothing to prevent participating providers from skimping on providing medically necessary wound care services to patients while collecting the \$400 per visit amount.
- The submitter stated that the average time of healing per wound for its wound clinic was 12 weeks (based on one visit per week), compared with a national average of about 14 weeks (based on comparisons with the U.S. Wound Care Registry). However, while the average healing times for individual wounds can vary—ranging from 10 to 16 weeks because simple wounds can take a shorter time to heal, while diabetic and venous ulcers can take a longer time to heal—the proposed payment model does not include a severity or complexity component.
- It is unclear what the phrase “all-inclusive risk model” means. Under the proposed model, 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. For example, if a patient became ill for any reason during the course of treatment and had to be hospitalized, the participating provider would be able

to pick the patient up where they left off after the patient has been discharged from the hospital with no impact on the OWCS-APM payment model, even though the wound would presumably be better.

- The proposal also does not acknowledge that the current facility-based rates may also reflect compensation for additional surgery center standards and other costs that office-based providers are not required to meet (such as providing uncompensated care).

Summary of Rating:

The proposed PFPM does not meet the criterion. The proposed model would permit payment of substantially more than what the current system permits in the office-based setting without building in any mechanisms to ensure that the corresponding number of visits does not extend beyond what is appropriate and necessary.

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

PRT Qualitative Rating: Does Not Meet Criterion

Strengths:

- Although Medicare FFS payment is already partially bundled for some office-based wound care services, the proposal would create an all-inclusive \$400 per-visit bundled payment for most outpatient wound care services that are provided in an office-based setting—thereby reducing what the submitter views as a focus on maximizing revenue rather than providing the best value for the dollars spent under the current system.

Weaknesses:

- The proposed \$400 per visit bundled payment for wound care services that are provided in an office-based setting under the OWCS-APM would still be tied to the number of services being delivered—in this case, visits.
- Bundled payments that are paid on a per-visit basis do not necessarily address concerns related to value over volume because it is not clear how to ensure that participating providers are not increasing value over volume under such a payment model.

Summary of Rating:

The proposed PFPM does not meet the criterion. The proposed \$400 per-visit bundled payment would still potentially provide an incentive for office-based providers to increase the volume of visits in order to maximize revenue.

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 potentially provide more options for office-based providers in non-urban and/or rural areas to provide wound care services to Medicare beneficiaries, in addition to outpatient hospital-based facilities.
- The submitter states that providing a \$400 bundled payment for all-inclusive outpatient wound care services in non-hospital-based settings would provide more flexibility for office-based providers regarding how office-based providers treat certain wounds—for example, instead of having to schedule two visits in order to be able to bill separately for certain medically necessary treatments due to concerns regarding global surgical periods.
- Additionally, the submitter states that the bundled payment would provide additional resources that an office-based wound care provider could use to enhance their practices by hiring additional staff, such as a lymphedema therapist, registered nurse, and nurse practitioner.

Weaknesses:

- The fact that the majority of chronic (non-emergent) Medicare FFS outpatient wound care services are provided in office-based settings suggests that many office-based providers are currently receiving sufficient Medicare FFS reimbursement to cover their costs.
- It is unclear how many additional office-based providers would potentially begin providing wound care services as a result of this proposal, particularly in rural areas, given that the submitter has estimated that it would be necessary to have approximately 10 patients per day in order to operate a full-scale freestanding office-based wound clinic.

Summary of Rating:

The proposed PFPM meets the criterion. The proposed OWCS-APM would potentially provide additional options and resources that could provide additional flexibility to office-based wound care providers for providing wound care services in additional areas and delivering higher-quality care.

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

PRT Qualitative Rating: Does Not Meet Criterion

Strengths:

- The submitter identifies a small number of metrics and goals that could potentially be evaluated for the OWCS-APM.

Weaknesses:

- The submitter does not propose a methodology for comparing the participating office-based providers' cost and quality under the proposed model with the status quo in order to ensure that Medicare beneficiaries are continuing to receive needed care and that utilization has not increased under the proposed model. Instead, the submitter proposes to compare participating providers' "total cost of care per wound care episode" with the national average for hospital-based outpatient wound care facilities, which would not be an "apples to apples" comparison.
- Although the proposal mentions some other goals that could potentially be evaluated (e.g., pain scale, number of visits to heal different kinds of wounds, time to healing), it does not propose a methodology for conducting these potential evaluations.
- Although the proposal states that the OWCS-APM can be evaluated at prescribed intervals, the proposed primary reliance on comparing Medicare claims data with national averages would make it difficult to evaluate participating providers in a timely manner due to the lag time associated with obtaining complete national data. Additionally, it is not clear whether comparisons with regional or local data might be relevant.

Summary of Rating:

The majority of the PRT concluded that the proposed PFPM does not meet the criterion. Although the proposal mentioned some goals and metrics that could potentially be evaluated, it does not articulate a proposed methodology for conducting the evaluations.

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

Strengths:

- Because Medicare patients with chronic, non-healing wounds are clinically complex and typically have multiple comorbidities, the proposed model could provide an opportunity

to improve care coordination between office-based wound care providers and other health care providers who are involved in the participating patients' care. For example, Medicare FFS beneficiaries with several of the most common chronic, non-healing wound types that are seen in non-urgent outpatient settings⁸ were more likely to be older (75+) and to have diabetes, hypertension, heart failure, peripheral vascular disease, rheumatoid arthritis/osteoarthritis, obesity, and mobility impairments when compared with Medicare Part B FFS beneficiaries as a whole.

Weaknesses:

- Although the proposal discusses the potential for increased care coordination, it does not provide details regarding how a freestanding office-based wound care provider would be able to achieve a “whole patient concept” care coordination approach for patients under the proposed model—such as how and where coordination would occur, which providers would be coordinated with, and how costs associated with care coordination will be reimbursed.
- Although the proposal states that the OWCS-APM model would “provide sufficient funds to hire more staff and be able to assign dedicated time to staff members for coordinating care with different providers,” there is no guarantee that this would occur.
- Moreover, the proposed payment model does not incentivize increased care coordination because when providers get paid on a per-visit basis, there is typically less incentive for them to coordinate care. For example, the submitter states that patients who are enrolled in the OWCS-APM model who have to be hospitalized for whatever reason would be disenrolled from the model but could be reenrolled in the model after being discharged from the hospital. It is not clear what, if any, care coordination participating providers would provide for these patients.

Summary of Rating:

The proposed PFSM does not meet the criterion. Although the OWCS-APM model could provide an opportunity to improve care coordination between office-based wound care providers and other health care providers, the proposed per-visit payment model does not incentivize care coordination, and the proposal does not include any other details regarding how the model would ensure that increased care coordination occurs.

⁸ These include chronic ulcers, diabetic foot ulcers, diabetic infections, diabetic skin ulcers, pressure ulcers, and venous ulcers.

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 payment model could encourage more office-based providers to provide wound care services, thereby increasing the number of non-hospital-based/non-outpatient facility-based settings that patients have to choose from, particularly in non-urban areas that may not have a hospital nearby.
- The proposed model could also increase patient choice and improve access by increasing the number of lower-cost office-based providers that are offering wound care services (available data indicate that the average beneficiary liability for wound care services provided by facility-based outpatient providers can be 300 percent higher than for wound care services provided by office-based providers).

Weaknesses:

- The submitter states that patients would be registered for the OWCS-APM program as soon as the participating provider receives the initial referral. However, the proposal does not: 1) discuss how patients would become aware about their other options for receiving wound care services; or 2) define or set standards for the information that would need to be provided to patients to enable them to make an informed choice about whether to receive wound care services from an office-based wound care provider that is being paid in this way (including information that would help them to understand the differences in out-of-pocket costs and services in one type of setting versus another for their care, as well as the potential impact on outcomes).

Summary of Rating:

The proposed PFPM meets the criterion. The proposed model would increase patient choices by potentially increasing the number of lower-cost office-based wound care service providers. However, it will also be important for beneficiaries to have access to information about differences in costs and outcomes across settings, which would enable them to make an informed choice regarding where to receive their care.

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

PRT Qualitative Rating: Does Not Meet Criterion

Strengths:

- The submitter states that the proposed model would help to reduce costs associated with providing wound care services through “judicious use of procedures and products” based on “individual physician-assessed needs” and “close monitoring of progress and comorbidity impact with integral physician-patient-patient contact.” The submitter also describes some of the patient-oriented services that are provided by the submitter’s freestanding office-based wound care clinic (such as following national protocols for infection prevention and safety in outpatient wound clinics, providing extensive patient education, and consistent use of specially trained medical staff).
- There is some evidence suggesting that quality wound care can potentially be provided less expensively for at least some of the Medicare patients who may currently be receiving care in more expensive hospital-based/outpatient facility-based settings. For example, within the international context, a recent United Kingdom National Institute for Health and Care Excellence (NICE) meta-analysis cited a lack of quality evidence on the cost- and clinical-effectiveness of certain advanced dressings that are sometimes used for wound treatment.

Weaknesses:

- The proposal has the potential to improve patient safety by reducing the incentives to provide excessive care through the provision of a \$400 fixed price, per-visit bundled payment for wound care services. However, the proposal would not require participating providers to implement a specific care model in order to achieve the desired results.
- The \$400 fixed-price, per-visit bundled payment could result in risks related to stinting on care. There is nothing in the proposed model that would prevent participating providers from undertreating less complicated cases. The proposal’s discussion about avoiding the use of “strict hospital algorithms” to determine whether an individual patient needs certain wound care procedures and tests in order to reduce the cost of care could also raise potential concerns within this context. An additional concern would relate to determining how best to ensure patient safety if the proposed model was expanded beyond the submitter’s practice to include multiple sites across the nation.
- Additionally, the \$400 per-visit bundled payment could also provide an incentive for some participating providers to increase the number of visits and thereby potentially increase the potential risk of infection and the average amount of time to heal.

Summary of Rating:

The proposed PFPM does not meet the criterion. There is no assurance that individual patients would receive the care they need from participating providers during each wound care visit under the proposed model.

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

PRT Qualitative Rating: Does Not Meet Criterion

Strengths:

- The proposal states that the submitter already uses Certified Electronic Health Records Technology (CEHRT). More specifically, because the submitter has access to the electronic medical record system of the hospital system that is the source of 60 percent of its current patients, the submitter is able to upload pictures and updates that can be seen by other physicians who have access to the same system for those patients.

Weaknesses:

- Since many patients with chronic, non-healing wounds are also likely to have multiple comorbidities, the ability to exchange information with other providers and provide ready access to relevant patient information is very important. However, the proposal does not include any discussion about facilitating information exchange with other providers or ensuring continuing care after a patient's wound has been healed.
- The submitter suggests that reductions in the burden of documentation under the OWCS-APM model, as well as the need to improve quality and patient satisfaction while reducing cost under the proposed model, will require participating providers to use CEHRT. However, there is no guarantee that expansion of participating providers' CEHRT capabilities will occur if the proposed model is expanded to additional sites.
- The proposal also states that the proposed model will encourage the use of information technology—including the potential to incorporate the use of telemedicine between participating patients' office-based wound care providers and home care providers—but it does not include specific mechanisms for ensuring that these kinds of innovations will occur.

Summary of Rating:

The proposed PFPM does not meet the criterion. The proposal does not include provisions that would encourage participating providers to use health information technology to inform the provision of wound care services to their patients or for the facilitation of information exchange with other providers.

E. PRT Comments

The OWCS-APM proposal raises a real issue in Medicare payment policy. The current Medicare FFS reimbursement system discourages provision of wound care services in some office-based settings and encourages provision of these services in hospital-based/outpatient facility-based settings where patients may be getting care that is more expensive. The proposed payment changes under the model have the potential to reduce aggregate costs for chronic wound care services by shifting some patients from the more expensive hospital-based/outpatient facility-based setting to the less costly office-based setting—assuming that the submitter’s proposed 20 percent reduction in costs can be achieved. The proposed model also has the potential to provide increased flexibility for providers while increasing patient choice by providing more options for office-based providers to provide wound care services—including in non-urban and rural areas (although 77 percent of chronic, non-urgent outpatient wound care services are already being provided in office-based settings).

The PRT believes that the proposal as written has a number of structural flaws and elements that are not sufficiently developed. The centerpiece of the proposal’s payment model is a \$400 per-visit flat-fee payment for wound care services. However, this proposed payment model raises concerns about the potential impact that not limiting the number of visits per wound care episode could potentially have on utilization and total cost of care (as compared with other potential approaches, such as bundling the payment for the diagnosis or for a certain period of time). Although wound healing rates vary by patient and wound characteristics, the proposed payment model does not include a severity or complexity component to account for comorbidities and other factors. Additionally, participating providers/clinics would not bear any financial risk under the proposed payment model; they would continue to receive the same \$400 per-visit bundled payment rate regardless of patient outcomes. Similarly, the proposed model also does not include sufficient features that are designed to prevent the potential for “cherry-picking” and stinting on care.

The OWCS-APM also does not have an evidence-based care model. Although the proposal would require participating providers to have at least two years of wound care experience, it would not require them to adhere to a particular care model or follow a particular set of national guidelines or established protocols in order to achieve the desired cost and utilization objectives.

The proposal also does not have a well-developed evaluation methodology. For example, one of the primary proposed metrics that would be used to evaluate the proposed OWCS-APM model would involve comparing the participating office-based wound care providers’ “total cost of care per wound care episode” with the national average for hospital-based outpatient wound care facilities, which would not be an “apples to apples” comparison and would not allow for comparison with historical cost and utilization data for those providers.

In addition to these structural problems, the proposal is under-developed with respect to several other important dimensions, such as quality assurance, coordination of care, and health information technology. For example, the proposal does not provide sufficient assurances that the quality of wound care services provided by the participating office-based providers/clinics would be better under the proposed model. Additionally, the proposal does not provide sufficient information about how the proposed quality metrics would be measured and does not include several other potentially useful quality metrics. Similarly, the proposed per-visit payment model does not incentivize care coordination, and the proposal does not include any other details regarding how the model would ensure that increased care coordination occurs between office-based wound care providers and other health care practitioners. Moreover, the proposal does not include provisions that would encourage participating providers to use health information technology to inform the provision of wound care services to their patients or for the facilitation of information exchange with other providers. The proposal also does not discuss how it would ensure that patients receive enough information that would enable them to make an informed decision regarding whether they want to enroll in the OWCS-APM model.

Finally, while the PRT evaluated the proposal as a PFPM, it is possible that at least some of the problems identified by the submitter could be addressed as modifications to the Medicare Physician Fee Schedule. Also, the problem identified by the submitter is an example of the “site neutrality” issue in Medicare payment. We anticipate some discussion of these points at the PTAC meeting.