October 11, 2018

Physician-Focused Payment Model Technical Advisory Committee
c/o US DHHS Asst. Secretary of Planning and Evaluation Office of Health Policy
200 Independence Ave., SW
Washington DC 20201
PTAC@hhs.gov

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

To: Physician Focused Payment Model Advisory Committee

Dear Committee Members,

Seha Medical and Wound Care is pleased to present an innovative model for out-patient wound care services in non-hospital based setting. The proposed model of bundled payments per visit will result in significant savings to medicare and shift focus from procedure oriented care to a patient focused model.

Sincerely,

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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 non-healing 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(2). Medicare expenditure for wound care is expected to increase with the aging of the population(1). The same article (2) 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 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.

Background and Model Overview

Medicare expenditure for wound care is estimated to be between $28 to $96 billion. It is also believed to be much larger than known. With the aging of the population it will continue to grow further(1).
Over the last 15 to 20 years the wound care industry has grown rapidly. Hundreds of outpatient hospital based wound clinics have opened around the country. These are run by a few national management companies with major focus on revenue generation.
A significant portion of the cost of chronic wound care is due to hospital facility charges. Hospitals often utilize over 200 elements of staff work for acuity scoring to drive optimal facility reimbursement.

A recent review of cost in a hospital based outpatient wound clinic shows facility charges of as much as $23,450 and medicare payments ranging from $750 to $1446 for **each** visit leaving the patient liable for up to $369 for her unique visits. This did not include the physician (part B)bill or the cost of advanced tissue products.

Review of various articles in the literature show that average Medicare cost to hospital based outpatient wound clinics ranges from $586 (without Hyperbaric Oxygen therapy) (2) to $850 (when the cost of HBO is included) (3) ***every time*** a medicare beneficiary visits a hospital based out -patient wound clinic. Mean total cost of healing a wound (per episode) can be upwards of $15732 (6) for venous ulcers and up to $52,000 for diabetic ulcers(4). This does not include the cost to patients for the hospital and physician charges.

We propose, for the same visit, instead of separate Part A payments for facility charges to hospital based wound centers and Part B payment to their providers i.e. physicians, one bundled payment to a provider/clinic will lower overall cost of care. A bundled payment will shift focus from separate procedures, and facility acuity score-based charges to streamlined, patient oriented episodic care. The cost to Medicare per episode with an independent outpatient provider would thus be decreased by at least 20% or more based on lower overhead cost to provide direct, personalized wound care outside of a hospital setting.

A simple google search shows hundreds of articles illustrating the prevalence of old age poverty. A lot of senior citizens simply cannot afford a secondary insurance and struggle to qualify for state insurance. The financial burden of their portion (20%) of hospital facility charges can become an impediment for seeking care. This can sometimes lead to complications like cellulitis or even near catastrophic events like sepsis from non-healing wounds landing the patients in hospitals and eventually costing both the patients and medicare many times more.

Episodic care and testing driven by strict hospital algorithms can mean increased cost of care regardless of whether the individual patient actually needs said procedures and tests. Under

the proposed model testing and procedure are done strictly based on individual patient need based on direct physician evaluation on a patient by patient and visit by visit assessment.

The patient is seen as a whole patient, examining pertinent co-morbidities, and the potential benefits versus costs of possible procedures i.e. venous testing on patient who cannot tolerate compression - reducing the validity of performing the test in the first place.

There will be reduced requirement of home health by providing compression and other care measures during office visits.

We strongly believe the opportunities to improve the quality of care and reduce expenditures associated with this model will benefit all parties involved.

The proposed model provides more choice and convenience to patients. Many of our elderly patients do not drive. They are dependent on family members, friends or ride services to come to the appointments. Most of the hospitals are located in urban areas which makes it even more challenging to keep up with weekly wound appointments especially if the time and cost of travel is also included. This does not include navigating the long hallways with painful wounds. In certain cases hospital copays can be financial deterrent for continuation of care thereby leading to larger complications. The proposed model will provide opportunity for more providers to join the model and provide care to patients in convenient less costly settings.

Changing re-imbursement environment is putting more emphasis on managed care to control the health care cost. This includes a variety of plans from commercial insurances as well as quality improvement and value based incentive programs from medicare. One such example is ACOs in which a hospital and it's affiliated group of physicians share the profit or loss. The other example is medicare advantage plans in which medicare pays fixed monthly amount to the plan for all the care provided to its beneficiaries. These plans have to operate in very carefully managed budget and contract with a select group of providers and hospitals for this purpose. Not all hospitals have hospital based wound care out-patient departments. This means if the patient ends up in a different or out of network hospital system the primary physician and hospital lose all control over the cost management. The proposed model will be an incentive for the primary care physicians, hospitals, their affiliated rehabilitation departments and managed care medicare plans to participate in this model for cost containment and further improvement in quality of care.

Scope

We propose one bundled payment per visit to an independent outpatient wound provider/clinic will create significant savings.

Providing wound care is expensive. It requires specially trained staff and advanced dressings which are costly. When patients are seen in hospital based outpatient wound clinics they are reimbursed through separate part 'A' billing to the hospitals for material and nursing care and part 'B' billing to the providers.

Because of current CMS payment policies working in a non-hospital based free standing wound clinic is challenging and puts the physicians at a significant financial disadvantage. This is because of limited physician only (part B) reimbursement. Additionally based on various Medicare guidelines, global period restrictions and LCDs (33631, 33614 etc.) non-hospital based providers cannot get reimbursed for all the services provided in a single visit. This means billing either for evaluation and management or one item/procedure at a time due to conflict with medicare assigned global periods. For example when a debridement is done an unna boot(compression bandage) cannot be charged at the same time though it is a necessary component of the healing process in many cases. It is necessary for controlling edema which prevents the wounds from healing in venous leg ulcers (in hospital based wound clinics they are done and reimbursed at the same time through part 'A' billing). This raises the cost of doing care in private setting. This means either the physician has to absorb the cost of supplies and application of unna boot done when a debridement is needed or simply send the patient to a hospital based clinic.

Majority of wound patients are older individuals and have a host of co-morbidities which need to be addressed often on an ongoing basis. But none of it can be billed under the E&M code if it is not a *uniquely* new issue when a procedure is done in the same visit. All of this makes it difficult to provide and get reimbursed for all the time spent and care needed in one visit. For example venous leg ulcers arise from peripheral venous disease and edema of the leg. But a number of patients also have concurrent cardiac disease and congestive heart failure. Or they may be taking medications for hypertension with the side effect of swelling of the legs. This can make edema difficult to manage thereby slowing the wound healing. These patients need constant education and intervention to make sure they are taking right combination of medications, watch salt in the diet and their fluid intake and output balance is to promote improvement of fluid status which will help to reduce edema. Delayed healing becomes a potential for infection and even hospitalization.

The current system of reimbursement creates an unfair advantage for the hospital based wound clinics and it is the main reason there are few practitioners working independently as wound care providers in low cost settings.

A new model which brings the per episode payments to independent wound care provider closer to total (combined) average amount paid by CMS to the hospitals and providers when a patient is seen in a hospital based wound clinic will be a great incentive. More physicians will be willing to learn treating non-healing wounds, take the risk, work independently and help control the bludgeoning cost of wound care.

Quality and Cost

As mentioned above with aging of the population the number of people with chronic non-healing wounds is also increasing. According a recent article (1) Medicare expenditure related to wound care is much larger than previously recognized. This and several other literature reviews show that nearly 15% of medicare beneficiaries (8.2 million) have at least one chronic wound. The total medicare spending on wound care range between $28.1 billion to $96.8 billion. The data also shows a larger portion spent on out-patient care.

According to an Agency for Healthcare and Quality article (4) the cost of care for a medicare beneficiary with diabetic foot ulcer is substantial at $33000 per year and about $52000 for those who require lower extremity amputations.

Another study by Diabetes Care (5) shows $28031 in costs for treating foot ulcers for beneficiaries with diabetes vs $16320 for beneficiaries without diabetes.

Similarly the total mean cost of care for Venous Leg Ulcers is $15732 when healed(6). It is as high as $33907 when the venous leg ulcers do not heal. According to the same study a significant portion of the cost ($10,332) is for hospital based outpatient facility.

Though it is difficult to get exact figures from medicare review of various articles in the literature show that Medicare cost to hospital based outpatient wound clinics is $586 (without Hyperbaric Oxygen therapy) (2) and $850 (when the cost of HBO is included) (3) *every time* a medicare beneficiary visits a hospital based out -patient wound clinic.

Based on these figures this provider at SMWC already has a stablished track record for saving cost.

In 2017 a total of 3066 medicare out-patient visits were logged at SMWC. SMWC does provide hyperbaric oxygen treatments when patients meet the clinical criteria for this adjunct treatment. Based on the estimate cited above ($850/visit including HBO) medicare would have spent over $2 million extra in addition to what was paid to SMWC if these same visits were

done in a hospital based out-patient wound clinic. And this is only a one year estimate. At SMWC this provider has been providing high quality wound care in an office setting for the last 14 years which means SMWC has so far saved medicare over $20 million using the same estimate. This does not include the savings from prevented ER visits, judicious use of ancillary services and counseling patients before undergoing surgical procedures which may have limited benefit given their age and co-morbidities.

Episodic care and testing driven by strict hospital algorithms can mean increased cost of care regardless of whether the individual patient actually needs said procedures and tests.

Under the proposed model the patient is seen as a whole patient, examining pertinent co-morbidities, and the potential benefits versus costs of possible procedures i.e. venous testing on patient who cannot tolerate compression - reducing the validity of performing the test in the first place.

Expected reduced requirement of home health by providing compression and other care measures during office visits.

Under the proposed model Medicare will pay a *flat fee* per visit inclusive of all the services provided to an independent office-based wound care provider or a Free Standing Outpatient Wound clinic. This means medicare will not be paying separately for expensive skin substitute/advanced tissue products, total contact casting for off loading and other procedures usually provided in the hospital based outpatient clinic or a physician office during the care.

Value over volume

The current system of reimbursement with a number of nonsensical global periods and LCDs actually fosters a system of *volume over value,* especially for non-hospital based providers.

The proposed model will cut waste and encourage physicians to adopt a model with best value to patients and medicare. It will replace the fee for service model focused on maximizing revenue rather than providing the best value for the dollars spent.

Hospitals utilize hundreds of elements to maximize facility reimbursement. The current system also encourages the utilization of ancillary services and use of expensive products for same reasons.

For example some of the skin substitutes/graft cost over $1500. The total cost with wound bed preparation and application can exceed $2000 per application. Some of these grafts are allowed and used for 6 applications per patient adding significantly to total cost of care. But often all applications may not be necessary.

Unnecessary excesses (such as hospital debridement in surgically sterile operating rooms with pre-op preparation and post-op recovery costs adding prolonged exposure to pressure ulcers from procedure tables, versus debridement performance in a safe, aseptic office based environment), judicious use of procedures and products to reduce risk of side effects, close monitoring of progress and comorbidity impact with integral physician-patient contact during each episode will add to the quality and value of the model.

Similarly expensive workup may not always be prudent for common ulcers in elderly who make the majority of chronic wound care patients. This is because the utility of these tests may be of limited value to them in terms of ultimate outcome and long term management.

This provider has a 14 year track record of utilizing expensive products and medications very judiciously, only when necessary.

A bundled system of payment will shift focus from procedures and facility scoring to patient oriented care.

It will also create incentive to heal most of the wounds with in a minimum number of visits to maintain the quality of the program.

Payment methodology

An equitable payment mechanism will be very helpful to continue to provide care in an outpatient non-hospital based setting to Medicare clients in a cost efficient manner to the communities served.

We propose a $400 per visit bundled payment inclusive of all services i.e. evaluation and management, patient education, skin care by the staff, wound debridements, unna boot applications for compression, offloading total contact cast, advanced tissue products and dressings done at the clinic (Hospital based wound clinics itemize all these services to maximize reimbursement).

The proposed payment of $400 per visit will bring at least 32% savings to medicare based on the cost estimate of $586 per visit as cited above. The per episode total

cost of outpatient care will be much less if all the other variables like the separately charged cost of adjunct services and products is included.

The proposed model is a fully shared risk program because of *all-inclusive care* to be provided during the duration of the program.

Flexibility

Current system of payment puts a lot of burden on documentation to justify not only the actual visit but each and every aspect of care and counseling provided yet reimbursement is limited due to various conflicting rules and global periods. The current system also makes it difficult to provide all the necessary care in the most efficient way which may require multiple procedures at the same visit due to various LCD restrictions.

This program will also help prevent waste. For example some of the advanced tissue products come in a particular minimum size. If a wound being treated is small, the rest of the graft has to be discarded. For certain very small wounds an autologous pinch graft is a better option but the 90 day global periods becomes a strong deterrent to utilize this option.

A fixed bundled system of payment will free the provider from revenue focused care. It will also ease the burden of excessive documentation required. The bundled payment system will instead enable the provider to implement a fully patient focused high quality plan of care to heal the wounds in the most efficient time and manner and minimize patient suffering.

Ability to be evaluated

Once approved the proposed model can be evaluated at prescribed intervals.

Unfortunately wound care is not even recognized as a separate specialty despite increasing segment of population suffering from chronic wounds and bludgeoning costs. The disease focused metric in MIPS do not include any criteria for chronic wounds to begin with and are often criticized for being unrelated to patient's experience or quality of life.

Non healing wounds affect a person's every aspect of life including limitation of physical activities, social isolation, psychological welfare on top of pain and suffering. This does not include the financial cost to the patients and family.

Model evaluation can be done in many ways:

1- Measurement of a patient's improvement in quality of life
2- Improvement in pain scale/control
3- Physical and psychological improvements.
4- Number of visits to heal different wounds like diabetic and venous leg ulcers can be compared with nationally reported data.
5- Number of prescriptions filled for proper offloading devices and footwear (for example diabetic footwear), prescriptions for compression garments for patients with venous ulcers.
6- Blood monitoring of A1c is a good quality measure for diabetic ulcers, because the value drops with constant education and re-enforcement by the time wound is closing and improving.
7- Signing of patient contracts to encourage adherence to the plan of care encourages adherence and also allows the physician to re-educate and re-evaluate the patient's individual needs.

A combination of 3-4 of any of the above criteria will be a good start at the initiation of the program. More criteria can be added in later years for further proof of the quality of the program.

Total cost of care per episode can be compared to national averages for cost savings if medicare makes its data available on payments to hospital based outpatient wound departments and overall wound care expenditures.

Integration and Care coordination

As multiple comorbidities can affect the healing of a wound, coordination of care and integration between different service providers and specialties becomes a key function for smooth delivery of care across the continuum. The model will free up time for the wound care provider to have better communication, coordination and follow up with all health care providers involved in a patient's care. The proposed model will also provide sufficient funds to hire more staff and be able to assign dedicated time to staff members for coordinating care with different providers. The staff will have more time to follow up with patients to assure adherence with care plan and keeping up with their appointments.

Improved coordination of care between patients, home care and or nursing homes, and an office based provider would help prevent untimely complications between visits that often result in hospital admissions.
Possible use of telemedicine between providers and home care for this purpose can be promoted.

Ongoing education in the community health care system is fostered in a small provider based wound practice, by inviting home care nurses to visit with their patients during scheduled office visits to observe care, procedures and patient teaching for more effective follow up and prevention.
The success of the model will be a strong incentive for the provider to coordinate the care among all providers related to wound care.

Patient Choice

A new model which brings the per episode payments closer to the total combined average amount paid by CMS to the hospitals and providers when a patient is seen in a hospital based wound clinic will be a great incentive for eligible providers.
This model will enable and encourage more providers with the knowledge of wound care to be able to provide high quality care on their own instead of depending on hospital based outpatient wound clinics. This will actually expand the choice of wound care providers for the patients.
The new model will be especially helpful for patients who live in suburban, semi-rural and rural communities who often have to drive long distances week after week to seek care and follow ups at hospital based wound clinics as more providers will have a financially viable option to join the model and provide office based wound care closer to home.

Patient Safety

Under the program we seek to maintain and whenever possible improve patient safety. The model will create incentive for best outcomes to make it successful. It will also free up some of the time which can be used for more frequent reviews of safety protocols not only in the office setting but also for patient education.

We follow national protocols for infection prevention and safety in the outpatient wound clinic.

The new model will promote patient safety in many ways.

We start patient education from the very first visit to recognize signs of infection, future recurrences of venous and diabetic ulcers and falls prevention to reduce traumatic events that lead to lower extremity non healing trauma wounds in a lot of elderly population.

Consistency of specially trained medical staff, safe care without unnecessary excesses procedures based on individual physician-assessed needs, extensive patient education during care provided by the actual clinician rather than ancillary staff, judicious use of procedures and products to reduce risk of side effects, close monitoring of progress and comorbidity impact

with integral physician-patient contact during each episode, and continuous vigilance to reduce time to healing motivated by appropriate tracking of each patient's healing trajectory are some of safety measure which can get enhanced attention under the new model.

Health Information Technology

Under the new model use of information technology will be encouraged.

Currently this provider already uses a CEHRT.

Under the new model the burden of documentation will be reduced. This will encourage providers to use CEHRT to focus on improved quality, patient satisfaction and reduced cost. The need to prove better quality of care provided with less cost in it-self require providers to use CEHRT.

Use of telemedicine between providers and home care for this purpose is also a modality which can be incorporated for HIT use.

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