

September 27, 2019

Ms. Seema Verma  
Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1717-P  
Mail Stop C4-26-05  
7500 Security Boulevard  
Baltimore, MD 21244-1850

Comments Submitted Electronically to <http://www.regulations.gov>

Re: Medicare Program: Proposed Changes to the Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Price Transparency of Hospital Standard Charges; etc.

Dear Administrator Verma:

On behalf of the Association for the Advancement of Wound Care [AAWC] we welcome the opportunity to provide feedback on the proposed CY 2020 Hospital Outpatient Prospective Payment System. AAWC has some concerns within the draft policy which we believe will affect patients with wounds that need to be corrected.

AAWC is a non-profit organization of multi-professional clinical and research specialists in wound care. AAWC's nearly 2,000 members that represent physicians (general, family practice, dermatology, endocrinology, cardiology, infection specialists), surgeons (vascular, orthopedic, plastic, general), podiatrists and podiatric surgeons, nurse practitioners, clinical nurse specialists, physical therapists, physician assistants and researchers all dedicated to the delivery of evidence-based wound care treatment for beneficiaries that suffer with wounds. AAWC promotes the improved management of wounds through evidence-based clinical practice, education, public policy and research initiatives.

AAWC respectfully submits our comments that support our request regarding the supervision of therapeutic services in the draft policy for your consideration. We are available to provide the CMS expert input to support our position on the recommended enhancements and would welcome the opportunity to do so.

### **Background**

Wounds impact a significant number of Medicare beneficiaries each year and many live with chronic wounds that are often associated with other major medical conditions and comorbidities. Nearly 15% of Medicare beneficiaries (8.2 million patients) suffer with a chronic wound<sup>1</sup>, many due to systemic disease.

Research conducted by Driver and de Leon<sup>2</sup> on the health economic implications of diabetic foot ulcers shows the cost to the health system is significant... “Every diabetic foot that becomes infected or requires amputation is a huge cost to the health care system. An uncomplicated diabetic foot ulcer is estimated to cost \$8,000 to treat. If the ulcer becomes infected, the costs increase to \$17,000. If an amputation is required to resolve the ulcer, the costs soar to \$45,000.”

Nussbaum et al.<sup>1</sup> identified through claims data research for CY 2014 on Medicare and Medicaid patients with wounds (arterial ulcers, chronic ulcers, diabetic foot ulcers, diabetic infections, pressure ulcers, skin disorders, skin infections, surgical wounds, surgical infections, traumatic wounds, venous ulcers, or venous infections) that CMS spends more than \$37.1B for care when the wound was a primary diagnosis and cost of care reached up to care reached \$96.8 billion when including wounds as a secondary diagnosis. The hospital outpatient settings drove the greatest proportion of costs, demonstrating a major shift in costs from hospital inpatient to outpatient settings.

Eaglstein, Kirsner and Robson<sup>3</sup> showed that in addition to rising health costs, wounds have been related to increased mortality. Studies suggest that common chronic cutaneous ulcers, especially pressure ulcers and diabetic foot ulcers, are serious and often fatal. The 5-year mortality data showed that diabetic ischemic ulcers are more lethal than many cancers with 52% lethality for patients with diabetic ulcers compared with 48% for colon cancer, 47% for Hodgkin’s disease, 15% for breast cancer, and 15% for prostate cancer patients. Additionally, patients with unhealed neuropathic diabetic ulcers, even without ischemia, also have a 5-year mortality that exceeds that of patients with Hodgkin’s disease and breast and prostate cancer. A high mortality (28% in 2 years) was also documented in non-diabetic patients with chronic lower extremity wounds.

Fife et al.<sup>4</sup> utilized registries to extract a 5-year slice of de-identified data from electronic health records originating from 59 hospital-based outpatient wound centers in 18 states. In the prepared dataset of 5,240 patients with 7,099 wounds, the majority of patients were Medicare beneficiaries (52.6%). These 5,240 patients accrued a total “cost to the system” of \$29,249,500 for their outpatient care alone in 2012 dollars. The average number of serious comorbid conditions per patient was 1.8 (range 0–9) with the most common being diabetes, present in 46.8% of patients. A surprising 71.3% of patients were classified as obese or overweight (BMI > 25), and 51.3% had diagnoses indicating cardiovascular or peripheral vascular disease. Of note, 7.5% of patients were on dialysis or had undergone renal transplantation, and 8.5% of patients were taking prednisone, a drug likely to inhibit normal healing processes.

In a randomized controlled trial for patients with venous leg ulcers<sup>5</sup>, the researchers identified significant comorbidities in the study participants, all of which complicate the care decisions in the management of these types of patients. For this study group, the average BMI was 36.5 and 56% had a recurrent ulcer. 83% had four or more comorbidities:

- 67% Hypertension
- 61% Edema
- 35% Diabetes
- 25% Arthritis
- 14% Anemia
- 7% Cardiovascular arterial disease
- 6% Pulmonary disease

- 6% Autoimmune disease
- 5% Kidney disease

Patients with chronic wounds heal differently than patients with acute post-operative or traumatic wound and require treatment(s) that is individualized. Variations in wound characteristics, such as depth, location, size, presence of ischemia or infection, malnutrition, autoimmune disease, etc., dictate the specific care and treatment modalities necessary to heal a specific patient's wound(s). These patients have high rates of readmission, total cost of care, longer length of stay, and greater antibiotic utilization. As documented in the literature, patients with chronic wounds often have multiple comorbidities such as diabetes, heart failure, chronic kidney and vascular disease, and their bodies respond differently at various times to various wound healing components.

The age of the wound, severity of the underlying venous or arterial disease and other comorbid conditions, the need and frequency of debridement of necrotic tissue, patient follow-up intervals, and receipt of and compliance with supportive measures such as effective compression therapy (e.g. venous leg ulcers), pressure off-loading (e.g. diabetic foot ulcers, pressure ulcers), are all contributing factors that impact the progression of wound healing.

Because of all these complicating issues, the AAWC does not agree with the CMS that the therapeutic services provided to wound care patients as identified in the draft policy should be under 'general' versus 'direct' supervision.

### **General Supervision for Hospital Outpatient Therapeutic Services**

AAWC disagrees with CMS to move all therapeutic services from direct to general supervision. The definition of general supervision [42 CFR 410.32(b)(3)(i)] indicates the procedure is furnished under the physician's overall direction and control, but the physician's presence is not required during the performance of the procedure. As we have indicated, the management of patients with a wound cannot be simplified and parsed into individual therapies provided to the surface of the wound. Selection of topical therapy is based on the provider's knowledge of and assessment of the complex condition of the patient and their comorbidities as these are known to impact the response of the wound to topical treatment. While many caregivers can be instructed on the application of the wound treatment to the wound, in the outpatient clinic setting where patients have multiple comorbidities, it requires detailed patient assessment prior to implementation to assure the appropriateness and safety of the interventions. Wound management is complex and requires involvement of many specialists and multidisciplinary teams to manage the full patient condition. AAWC appreciates that the CMS is trying to ensure that patients have access and receive required care, especially in rural areas, by proposing to lower the level of supervision required for therapeutic services in the hospital outpatient setting from 'direct' to 'general'. However, this could result in detrimental consequences for patients with wounds, especially those with chronic wounds.

The Hospital Outpatient PPS (HOPPS) was developed to manage patients too sick to be cared for in a doctor's office, but not sick enough to be admitted to an acute care setting. As confirmation that the HOPPS is fulfilling this mission, Dr. Caroline Fife recently published<sup>6</sup> the CMS analysis of her 2017 Hierarchical Condition Classification (HCC) score, calculated by CMS based on the average HCC score of all

the patients treated in the CHI SLHS Woodlands Wound clinic (Woodland, TX) in which she practices. Her HCC score was 3.29, which is higher than the typical cardiologist or infectious disease doctor.

The average age of her wound clinic patients is 75 years, with 19.6% older than 84. The prevalence rates of a few major comorbid conditions include: chronic kidney disease 60%, diabetes 56%, ischemic heart disease 54%, rheumatoid arthritis and osteoarthritis 50%, asthma/COPD 48%, atrial fibrillation 24%, and Alzheimer's 23%. We care for patients with approximately the acuity level of a dialysis center.

The job of Dr. Fife and other wound care clinicians is to try to keep these patients progressing toward healing, while not having to utilize hospitals and outpatient clinics so frequently. When patients as complicated as those with wounds are managed appropriately under the direct supervision of a wound care specialist, outcomes improve and ultimately the cost of overall care is reduced. Moving therapeutic services to 'general' supervision for this group of patients will jeopardize this balance and can increase risk to this vulnerable patient population.

AAWC is willing and available to meet with CMS to discuss the unintended consequence of changing supervision for therapeutic services from 'direct' to 'general' supervision and the negative impact this will have on quality of care and patient access to care.

Respectfully,



Tomas Serena, MD, FACS  
President, AAWC

#### References

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3. Eaglstein WH, Kirsner RS, Robson MC. Food and Drug Administration (FDA) drug approval endpoints for chronic cutaneous ulcer studies. *Wound Rep Regen* 2012;20:793-796.
4. Fife CE, Carter MJ, Walker D, Thomson B. Wound Care Outcomes and Associated Cost Among Patients Treated in US Outpatient Wound Centers: Data From the US Wound Registry. *WOUNDS* 2012;24(1):10-17.
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