ALLIANCE OF
WOUND CARE
STAKEHOLDERS
POWER THROUGH COLLECTIVE ADVOCACY

August 12, 2016

Mr. Andy Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Baltimore, MD 21244

Submitted electronically to patientrelationshipcodes@cms.hhs.gov

RE: CMS Patient Relationship Categories and Codes

Dear Administrator Slavitt:

On behalf of the Alliance of Wound Care Stakeholders ("Alliance"), we are pleased to submit our comments in response to the Request For Information (RFI) on the *CMS Patient Relationship Categories and Codes*. The Alliance is a nonprofit multidisciplinary trade association of health care professional societies and organizations whose mission is to promote quality care and access to products and services for people with wounds through effective advocacy and educational outreach in the regulatory, legislative, and public arenas. These comments were written with the advice of Alliance clinical specialty societies and organizations that not only possess expert knowledge in complex chronic wounds, but also in wound care research. As a multidisciplinary association, we have a vested interest in this policy. A list of our members can be found at www.woundcarestakeholders.org.

GENERAL COMMENTS

The Patient Relationship Categories and Codes were created in order to assist CMS in the implementation of the payment and resource use measurement provisions required by the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA). In attempting to create its payment systems that better reflect the value of care (i.e. Merit Based Incentive Payment System (MIPS) and Alternative Payment Models (APMs), CMS strives to better measure resource use. The Alliance is pleased that CMS is trying to create mechanisms to ensure that the costs of care allocated to a physician are truly those over those which that physician can influence utilization.

However, the way in which CMS has crafted resource use measures has the perverse effect for wound care physicians of measuring resource use in one group of patients while the physician reports quality measures in an entirely separate group of patients. Surely the intent of a Quality Payment System is to actually CONNECT quality and resource use. Particularly within wound care, the only way to do that is to report resource use among the patient population in whom quality measures were reported. Only in this way will it be possible to demonstrate that improved quality reduces COST. As long as cost and quality are entirely

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unrelated to each other in the area of wound care, the goals of MACRA cannot be achieved for patients with chronic wounds and ulcers. Moreover, the quality reporting under MIPS and APMs are developed for general physicians and certain specialties (i.e. cardiology, oncology) and do not take into consideration the physician specialists and subspecialists who practice wound care. Thus, the obligatory reporting of quality, resource use and clinical performance measures may not truly be indicative of the wound care work nor of the resources that wound care practitioners use to treat patients. Until these practitioners have the ability to report measures based on the work they do and not generalized measures that do not, the comments that we offer here are marginalized.

That said, we believe that the creation of Patient Relationship Categories and Codes has the potential to help develop better mechanisms to allocate resource use if done properly and quality measures are reflective of the care being provided

Our specific comments are provided below.

SPECIFIC COMMENTS

CMS believes that one approach to developing Patient Relationship Categories and Codes is to distinguish patient-clinician relationships where items and services are furnished on an acute and non-acute or continuing basis. CMS has proposed the following definition of an acute episode:

> *Acute episodes may encompass a disease exacerbation for a given clinical issue, a new time-limited disease (e.g. acute bronchitis), a time-limited treatment (e.g., surgery, either inpatient or outpatient) or any defined portion of care (e.g., post-acute care) so long as it is limited, usually by time, but also potentially by site of service or another parameter of healthcare. It may occur or span inpatient and outpatient settings.*

However, The Alliance is concerned that CMS does not separately define non-acute episodes. CMS has merely stated "continuing care occurs when an episode is not acute, and requires the ongoing care of a clinician." The Alliance recommends that CMS further define non-acute episodes of care prior to any Patient Relationship Category and Codes document becoming final. By further defining non-acute episodes of care, there will be less confusion in terms of what relationship category will be appropriate.

Furthermore, the Alliance has concerns with how CMS has described acute vs. non acute episodes since neither are well defined. Specifically,

- Our members can attest that patients do not fit into a particular mold nor does their treatment. CMS has not defined an acute care episode versus a non acute episode well, yet this is the center point of the patient relationship categories and codes. A patient's episode can, depending on his or her condition, bounce back and forth between acute and non acute care episodes. We ask: How is CMS planning on tracking this movement? It is not clear from the definitions or the patient relationship categories that there is any flexibility to change categories depending on the patient's health status. There are many examples in wound care in which a patient's condition can be both

chronic and acute or bounce between the two. We have provided several examples in order for CMS to understand the complexities of treating a patient with a wound. Examples include:

1. *A 42 y.o.. WF with diabetes and renal insufficiency is disabled due to diabetic retinopathy. She is referred to a hospital based outpatient wound center by her primary doctor for bilateral plantar foot ulcers due to severe neuropathy, both of which have been present for 6 months. She has a severe Charcot deformity on the right and is status post amputation of 3 toes on the left. Non-invasive vascular screening is done with transcutaneous oximetry and the values are normal. The wound care clinician debrides the right plantar ulcer and it probes to the joint space of the third metatarsal head. The left leg is placed in a total contact cast. The patient is followed for 2 months with regular visits to the outpatient wound center for TCC on the right and one application of a cellular product. She is then fitted with a custom orthotic for the right foot. During that time she develops an acute cellulitis of the left leg and is hospitalized for 3 days under the care of a hospitalist. X-rays reveal osteomyelitis of the left 3rd MT head and when the right plantar foot is healed, she is seen by an orthopedic surgeon for debridement of the osteomyelitic bone on the left. The large surgical (now post operative) wound is packed open and she is sent back to the wound center for continued care of the left plantar post operative wound for 3 months with negative pressure wound therapy and a cellular and/or tissue based product until that wound closes. She is then fitted with an orthotic on the left. The total time she has been seen in the hospital based outpatient wound setting is 5 months. When the patient comes to the outpatient wound physician due to her diabetic foot ulcers (DFUs) – this would be a <u>chronic problem</u>. However, she develops cellulitis, which is an <u>acute</u> problem, but the outpatient wound physician does not treat her for the cellulitis – another clinician in the outpatient facility does. She is then referred back the wound care physician with a surgical wound, which might be considered an <u>acute</u> problem.*

2. *A 47 year old female presents to the outpatient wound center for a failing flap after mastectomy and immediate breast reconstruction for breast cancer. She has had multiple sclerosis for years and has had an episode of optic neuritis. She has already had chemotherapy and radiation, and after the surgery, lymph nodes are positive, so further chemotherapy is recommended. However, her breast reconstruction is at risk, and chemotherapy will worsen the situation. Her plastic surgeon recommends urgent hyperbaric oxygen therapy. Optic neuritis is a relative contraindication for hyperbaric oxygen due to limited case reports, so she is referred to a neuro-ophthalmologist for retinal mapping, and every 10 day follow-up during her hyperbaric therapy.*

3. *A 65 y.o. WM has a diabetic foot ulcer (hallux) as well as venous insufficiency. He was treated at the outpatient wound clinic for serial debridements with multilayer compression and then other offloading modalities for 6 months. Due to his social situation, he missed a few wound visits and his foot ulcer eroded into osteomyelitis. He was then admitted into the hospital for surgical debridement and medical management of his ulcer. The wound care clinician also treated him as an inpatient to continue his advanced care. He first underwent a hallux amputation and then a transmetatarsal amputation. Ultimately, he underwent a below the knee amputation due to the severity of his infection. He was treated at an acute rehab unit in the same hospital and then transitioned back to the wound center postoperatively for management of his amputation stump. Total time invested in the patient- 2 years.*

4. *A 39 year old male who suffered a c-spine fracture in a diving accident as a teenage, now is paraplegic. Despite appropriate care, he has developed a Stage 4 pressure injury ulcer on his sacrum. He is seen by his neurologist, who refers him to general surgery. They debride the area and then they order a course of negative pressure wound therapy with home health that is only partially successful in closing the ulcer. Exposed sacral bone becomes infected and he is seen by an infectious disease physician who begins IV antibiotics. After 2 months, re-biopsy of the exposed bone reveals chronic osteomyelitis, and he is referred for another round of IV antibiotics, plastic surgery to attempt a sensate flap, and hyperbaric oxygen because of the refractory osteomyelitis. Part of his outpatient wound care and hyperbaric clinic work up reveals nutritional deficiencies, and he is referred to a nutritionist. After 6 weeks of offloading, IV antibiotics and hyperbaric oxygen, there is no more exposed bone, so the negative pressure wound therapy device is restarted, and he is a candidate for his sensate flap closure.*

As demonstrated in the above scenarios, wound care patients tend to bounce between settings, between acute and non acute episodes and are treated in a multidisciplinary approach. Beside the creation of better definitions and examples for acute versus non acute care episodes, the Alliance recommends that CMS take into account those situations in which a patient has an acute episode while also being treated for a non-acute care episode. Furthermore the Alliance recommends that CMS create a post acute care episode.

- Multiple clinicians can be treating the same patient for a variety of different clinical scenarios. How is CMS going to treat a multidisciplinary approach to treatment within the patient relationship categories/codes? How is CMS going to treat a team approach? It does not appear in this document that CMS has considered or addressed these issues, yet it is more than likely in the current health care delivery environment that there will be a team of clinicians treating one patient.

  If CMS is planning on utilizing acute versus non acute episodes of care in order to create patient relationship categories, then a better definition of non-acute episodes should be provided. Furthermore, even within the acute care episode definition, clarity is necessary. For example: in the definition of acute care, CMS states that the episode may encompass, "*a time-limited treatment."* We question, what does time limited mean – months, a year? When CMS states*, "Acute episodes may encompass a disease exacerbation,"* does this mean a person with venous disease who has a venous ulcer would be considered a "disease exacerbation"? The definitions and examples that are provided need to be clear and transparent.

- We recommend that there should also be a preventative care episode created in addition to acute and non-acute episodes. This would be more reflective of patient relationships and the type of care clinicians perform.

- Currently, the patient relationship categories are very physician centric. The wording of the current patient relationship categories is insufficient to represent all physicians and non physician practitioners. It would be helpful to consider adding categories for supportive and/or allied care. The Alliance has reviewed the American Medial Association's (AMA) categorization and support their suggestions that the provider relationship be categorized in to continuous or episodic, and

broad or focused. This categorization, when coupled with the ability of many providers to share the same designation, most adequately defines our practices.

ISSUES REQUIRING CLARIFICATION

The Alliance is seeking clarification in the following areas:

- How are the patient relationship designations going to interact with other requirements within MACRA and specifically the episodic groupings?
- How and where will the codes be reported on the claim form?
- How will cost be attributed to clinicians – especially when multiple clinicians treat one patient?
- How will care delivered by clinicians who provide supportive care but do not directly bill the Medicare program for their professional services. (e.g., dieticians or physical therapists) be considered for reporting purposes?
- Within the Continuing Care Relationship category, CMS used the term "primary care provider". What is CMS's intention on utilizing the term "primary"? The Alliance believes that this term will cause confusion as many physicians are not considered primary care physicians but may be responsible for providing the majority of a patient's care in some circumstances. As such, CMS needs to provide more clarity when defining a primary care provider.
- Within the Continuing Care Relationship category, CMS uses the term "chronic care" for the first time without providing a definition of what is meant by chronic care. CMS needs to provide clarification of this term.

CONCLUSION

Overall, the Alliance believes that designating Patient Relationship Categories and Codes puts another burden on the clinician for tracking, coding and documentation that adds no value to patient care, or treatment outcomes. We submit that to obtain value for tracking resource use and costs, a well defined, easy and clear approach must be employed. For the wound care clinician, the only way to do that is to report resource use among the patient population in whom quality measures were reported.

Currently under MIPS, there are no quality measures that a wound care clinician can report for the actual wound care treatment they perform. As such, the obligatory reporting of quality, resource use and clinical performance measures may not truly be indicative of the wound care work nor of the resources that wound care practitioners use to treat their patients. Thus, resource use for any wound care clinician will be skewed until this issue is resolved. The Patient Relationship Categories and Codes approach needs to be delayed at least unto 2018 or beyond to allow clinicians' time to first adjust to all the other MACRA and MIPS documentation and reporting changes and challenges.

On behalf of the Alliance of Wound Care Stakeholders, we appreciate the opportunity to submit these comments. If you have any questions or would like further information, please do not hesitate to contact me.

Sincerely,

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