



March 1, 2016

Dear CMS staff with responsibility for CMS Episode Groups

On behalf of the Alliance of Wound Care Stakeholders (“Alliance”), we are pleased to submit the following comments in response to the methodology CMS is using to create Episode Groups under MACRA. This request for comments was included in CMS’s link:

<https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/Episode-groups-summary.pdf>.

The Alliance is a nonprofit multidisciplinary trade association of physician medical specialty societies and clinical associations 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. A list of our members can be found at www.woundcarestakeholders.org.

Over the years the Alliance has been a member of the National Quality Forum and we have recently worked with the Chronic Disease Registry (d/b/a the U.S. Wound Registry or USWR), a CMS recognized Qualified Clinical Data Registry, to create wound care quality measures. The U.S. Wound Registry website can be found here: <https://www.uswoundregistry.com/> The specifications for the 20 wound related electronic clinical quality measures (eCQMs) can be found here: <https://www.uswoundregistry.com/specifications.aspx>

Comments

Chronic wounds and ulcers are reaching epidemic proportions in the United States. A rough prevalence rate for chronic non-healing wounds in the USA is 2% of the general population, which is similar to that of chronic heart failure. Despite their prevalence, this problem remains off the CMS radar screen even though **Medicare will devote at least \$30 billion dollars to their treatment this year (and by some estimates, twice that amount)**. This surprising statistic is due to the additive effects of age and obesity which increase the likelihood of pressure ulcers, diabetic foot ulcers, and venous stasis leg ulcers. In fact, the national epidemic of diabetes continues to ensure that diabetic foot ulcers are the number one cause of non-traumatic amputations in the USA. Sadly, the 5 year survival rate of a diabetic patient after a major amputation is only 30%, which is worse than most cancers. Non-healing wounds occurring among patients with peripheral vascular disease (nearly as common as coronary artery disease and stroke), or as a result of unique medical problems (e.g., sickle cell anemia, vasculitis), or in association with immunosuppression (e.g., AIDS, steroid use or transplantation medications), are all increasing as the life expectancy of these patients increases. Yet, of the 255 measures available in the 2015 PQRS – including 63 outcomes based measures and 19 cross cutting measures – there are

no measures in the 2015 PQRS relevant to wound care which is why the QCDR option for quality reporting is vital to these practitioners.

It appears that CMS has also failed to recognize the cost of care associated with non-healing wounds when it created episode groups. Here are some important points to consider with regard to these expensive healthcare problems:

- 1) A large percentage of care provided to patients with non-healing wounds is provided in hospital based outpatient clinics (site of service 19 or 22). Patients with non-healing wounds may be seen for weeks or months as *outpatients*. In fact, the majority of the costs for the care of non-healing wounds occur not on the inpatient but the **outpatient setting where many resource intensive therapies are utilized** (e.g. cellular and/or tissue based products, hyperbaric oxygen therapy, debridements, negative pressure wound therapy, and home nursing services). We realize that creating episodes of care for these conditions will be difficult. However, the implementation of ICD-10 makes it easier to identify some types of wounds. For example, it is surprising to consider that until the implementation of ICD-10, there was no diagnosis code for a diabetic foot ulcer.
- 2) The average patient with a non-healing wound has 8 co-morbid conditions and is more likely to be hospitalized for one of these co-morbid diseases than for his/her wound (e.g. for his/her heart failure but not for his/her leg ulcer).
- 3) There currently are no PQRS measures targeting conditions such as diabetic foot ulcers, venous stasis ulcers, pressure ulcers, or peripheral vascular disease despite the prevalence of these problems in the population and their contribution to the Medicare budget. **Wound care clinicians can now utilize QCDR quality measures to satisfy PQRS requirements using wound care specific quality measures available as eQMs. They can report both process and risk stratified outcome measures.**
- 4) The current CMS episode grouping somewhat defeats the hard work of the QCDR process because none of the methods for creating episodes of care capture the conditions or the patients in whom physicians report their quality metrics. After hundreds of thousands of dollars were spent creating eQMs for conditions like diabetic foot ulcers, we see that physician resource use is based on episodes of care around COPD and heart failure. This seems to defeat the purpose of attempting to align quality and value when quality is reported on one group of patients and resource use on an entirely different group of patients.

Recommendations

1. We urge CMS to create episodes of care around the following high resource use conditions:
 - a. Diabetic foot ulcers
 - b. Venous stasis ulcers
 - c. Stage 3 and 4 pressure ulcers

To validate this recommendation, we remind the Agency that due to Medicare expenditures and prevalence of pressure ulcers over the years, it has included them in 2008 as one of the hospital acquired conditions. In its fact sheet:

<https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2008-Fact-sheets-items/2008-08-045.html>

it states:

Since 2008, Medicare has selected conditions that are reasonably preventable by following evidence-based guidelines and that are either costly or common. These conditions include severe pressure ulcers - deterioration of the skin, due to the patient staying in one position too long, that has progressed to the point that tissue under the skin is affected (Stage III), or that has become so deep that there is damage to the muscle and bone, and sometimes tendons and joints (Stage IV). Hospitals are required to report back quarterly on this and other hospital acquired conditions and reimbursements are dependent upon these specific scores per hospital.

2. When CMS develops its episodes of care regarding wound care, we would request that the Agency includes clinicians who have knowledge of wound care and/or treat patients with wounds within the workgroup.
3. We urge CMS to investigate whether it is possible to use patient groups identified through QCDRs as the basis for resource use calculations since QCDRs would seem to be an excellent opportunity to evaluate novel approaches to resource use methodology since clinicians with unique practices must develop risk stratification methods specific to their unique patient populations.

The Alliance of Wound Care Stakeholders and the Chronic Disease Registry (d/b/a the US Wound Registry) would welcome the opportunity to discuss how QCDR data could be used to identify episodes of care among patients within the QCDR.

The Alliance appreciates the opportunity to comment on the CMS Episode Groups and would be pleased to serve as a resource to the Agency as it continues to develop this important initiative.

Sincerely,



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Executive Director