



March 1, 2016

Eric Gilbertson, CMS MACRA Team  
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Phoenix, Arizona 85016-4545

Dear Mr. Gilbertson,

On behalf of the Alliance of Wound Care Stakeholders (“Alliance”), we are pleased to submit the following comments in response to the CMS Quality Measure Development Plan: Supporting the Transition to the Merit-based Incentive Payment System (MIPS) and Alternative Payment Models (APMs). 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](http://www.woundcarestakeholders.org).

### **General Comments**

The Alliance is supportive of the Quality Measure Development Plan. However, we request that wound care quality measures be represented in this plan and that physicians who treat patients with wounds be part of the Technical Expert Panel as CMS continues to develop this plan. We ask that CMS take the following into consideration as the Agency continues to develop this plan:

1. Wound care is multidisciplinary and currently there is not solely one specialty designated by the American Board of Medical Specialties for wound care. Instead, a whole interdisciplinary team treats patients with wounds- venous stasis ulcers, diabetic foot ulcers, pressure ulcers, arterial ulcers. These practitioners include but are not limited to the following: surgeons (vascular surgeons, foot and ankle surgeons) vascular medicine physicians, podiatrists, dermatologists, nurse practitioners, wound, ostomy and incontinence nurses, physical therapists and dieticians.
2. While Medicare and other payer expenditures for wound care are not as much as cardiology and other episode groups, we would like to point out that venous leg ulcers (VLU), diabetic foot ulcers (DFU) , pressure ulcers and arterial ulcers are prevalent and morbid diseases which consume considerable health care resources. For example, VLU has been estimated to affect 500,000 to 600,000 people in the United States costing 1.5 to 3 billion dollars annually. <sup>1</sup> From 1980 to 2008, the number of diabetic Medicare beneficiaries aged 65 or older increased from 2.3 million to 7.4 million. Among Medicare FFS beneficiaries who had a prevalent DFU, the mean reimbursement for all Medicare services was \$31.6 in

2006, \$33.1 in 2007 and \$35.1 in 2008 in thousands of dollars.<sup>ii</sup> A 2014 study suggests that DFU imposes substantial burden on private and public payers, ranging from \$9-13 billion in addition to the costs associated with diabetes itself.<sup>iii</sup> While we address more details on the expenditures further in our comments, with numbers of diabetic and pre-diabetic Medicare beneficiaries increasing along with the aging of the population and better life expectancy, DFU, VLU, pressure ulcers and arterial ulcers will continue to have a significant impact on health care costs in general and the Medicare beneficiaries specifically.

3. We encourage CMS to also adopt those measures that are used in Qualified Clinical Data Registries (QCDR) at the same time as the Agency utilizes those under PQRS. In 2014, the Alliance of Wound Care Stakeholders worked with the U.S. Wound Registry (USWR) as the QCDR to develop 12 wound care related quality measures which were accepted for the 2015 reporting period. CMS deemed the Alliance to serve as the “de facto” wound care association in order to create these measures.

The USWR currently has 20 wound related quality measures available for reporting, all of which have been developed as electronic clinical quality measures (eCQMs) and thus may be used in any certified electronic health record. There are measures within this QCDR that should be rolled into CMS’s initial measure release for patients since clinicians who treat these patients are not part of a clinical specialty and therefore do not have appropriate measures to report under PQRS that is representative of the patients they treat. The Alliance requests that since those physicians who treat patients with wounds use QCDRs, that these measures should be able to be reported under MIPS.

### **Specific Comments**

1. **Chronic wound care represents a significant economic burden to Medicare and other health care payers**

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 that the additive effects of age and obesity will 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 #1 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.

The cost to treat patients with these wounds differs by wound type but is not insignificant in any of these wound types. For example:

As stated above, diabetic foot ulcers (DFU) imposes a substantial burden on public and private payers in the U.S. doubling the cost of care per patient compared with diabetic patients without foot ulcers. Ulcer care adds \$9 - \$13 billion annually to the direct yearly costs associated with diabetes. In a 2014 study, data for 27,878 matched pairs of Medicare and 4,536 matched pairs of privately insured patients were analyzed. During the 12-month follow-up period, DFU patients had more days hospitalized (+138.2% Medicare, +173.5% private), days requiring home health care (+85.4% Medicare, +230.0% private), emergency department visits (+40.6% Medicare, +109.0% private), and outpatient/physician office visits (+35.1% Medicare, +42.5% private) than matched controls. Among matched patients, 3.8% of Medicare and 5.0% of privately insured DFU patients received lower limb amputations. Increased utilization resulted in DFU patients having \$11,710 in incremental annual health care costs for Medicare, and \$16,883 for private insurance, compared with matched controls. Privately insured matched DFU patients incurred excess work-loss costs of \$3,259.<sup>iv</sup>

Also in our general comments, we stated the cost of treating venous leg ulcers; however, such estimates are related to the direct treatment of VLU and do not include the significant indirect financial loss related to the patient's immobility, loss of work, and disability which leads to two million work days lost annually. The high recurrence rate of VLU further adds to the prevalence of VLU and compounds the cost of treating VLU over time.<sup>v</sup>

In addressing the costs of treating patients with VLU, in one study<sup>vi</sup>, the median total cost to treat such as patient is \$10,976. The cost of care for a patient if the ulcer did not heal is \$26,280. This does not include outpatient facility fees (\$4354), home/visiting nurse fees (\$12,600) and Inpatient admission (\$27,487). A patient with these types of ulcers needs off-loading as well. For 10 weeks of outpatient treatment with compression techniques the range is \$1441 – \$2711 (which does not take into consideration venous intervention costs or inpatient care if required). To further illustrate, in a 2014 study<sup>vii</sup>, data for 58,672 matched VLU/non-VLU pairs of Medicare and 22,476 matched pairs of privately-insured patients were analyzed. Relative to matched non-VLU patients, VLU patients used more medical resources and incurred annual incremental medical costs of \$6391 in Medicare (\$18,986 vs \$12,595), and \$7030 (\$13,653 vs \$6623) in private insurance (\$7086 including drug costs). Compared with non-VLU patients, privately-insured VLU patients had more days missed from work (14.0 vs 10.0), resulting in 29% higher work-loss costs (comparisons significant at  $p < 0.0001$ ). The average annual incidence rate of VLU was 2.2% in Medicare and 0.5% in private insurance. These findings suggest an annual U.S payer burden of \$14.9 billion.

Included as one of the areas for focus within the hospital acquired conditions, pressure ulcers are associated with an excess mortality rate of 72 deaths per 1,000 and excess costs of \$17,000/case. The estimated cost per pressure ulcer is based on a report for CMS by RTI international<sup>viii</sup>. RTI estimated that the difference in costs between patients with hospital-acquired Stage III and Stage IV pressure ulcers and matched patients without hospital-acquired Stage III and IV pressure ulcers, based on bivariate descriptive analysis, is \$17,286.

As one can see from the few examples provided, treating patients with wounds is expensive. Establishing and utilizing quality measures under MIPS or any APM should be a priority in ensuring that clinicians who treat patients with wounds are following appropriate quality metrics and are reimbursed accordingly.

**2. The Alliance encourages CMS to also adopt those measures that are used in Qualified Clinical Data Registries (QCDR) at the same time as the Agency utilizes those under PQRS**

For more than a decade, medical specialty societies have been developing quality measures and have facilitated the mechanism by which these measures can be reported to the Centers for Medicare and Medicaid Services (CMS), usually through the creation of qualified patient registries. Since wound care does not fall within any particular medical specialty, and the treatment approach is multidisciplinary, providers who treat chronic wounds are fragmented and do not belong to a particular medical specialty. As such, efforts to develop wound care quality measures have been left to other organizations such as the American Medical Association (AMA)–convened Physician Consortium for Performance Improvement® (PCPI) initiative, other specialty societies, or quality organizations.

The Alliance is a member of the NQF and had wanted to develop PQRS wound care quality measures through the NQF. Unfortunately, none of the “Call for Measures” included wound care and the method to obtain these measures through this process were long and costly. In addition, 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. There are only 3 measures relevant to the examination of the diabetic foot.

However, on January 1, 2014 CMS allowed registries meeting certain criteria to apply for consideration as a qualified clinical data registry (QCDR) and while not officially part of the PQRS Eligible professionals could report measures developed by QCDRs to satisfy PQRS requirements.

The Alliance teaming up with the U.S. Wound Registry (USWR) developed 12 wound care related quality measures which were accepted for the 2015 reporting period. The USWR currently has 20 wound related quality measures available for reporting, all of which have been developed as electronic clinical quality measures (eCQMs) and thus may be used in any certified electronic health record. These can be found at: <https://www.uswoundregistry.com/specifications.aspx>.

This is important under the current draft quality measure development plan. In reviewing the plan, it is still apparent that CMS is still focusing on the PQRS and while QCDRs will become more widely accepted/used, the measures developed under this plan will likely stem from PQRS measures initially. The Alliance recommends that instead of this initial focus, that CMS also view those quality measures within the QCDRs with equal importance as those for PQRS and allow both to be reported under the MIPS.

**3. MACRA authorizes CMS to include measures for MIPS that are not consensus endorsed.**

Measures originating from qualified clinical data registries (QCDRs) are exempted from evidence requirements. As discussed above, the field of wound care has received insufficient funding in comparison to diseases of similar prevalence so we strongly agree with allowing QCDRs additional leeway to develop measures based on the data available.

**4. Issues related to performance gaps.** CMS will collaborate with specialty groups and associations to

develop measures that are important to both patients and providers and that represent important performance gaps in the targeted quality domains. We question how CMS will establish what these performance gaps are? There are significant performance gaps in the field of wound care but to date CMS has expressed no interest in developing quality measures to address costly areas such as pressure ulcers, diabetic foot ulcers or peripheral vascular screening despite the national emphasis on cerebral and cardiovascular disease. When considering measures, CMS will prioritize outcomes, person and caregiver experience, communication and care coordination, and appropriate use/resource use measures that are important to both patients and providers and that represent important performance gaps in the targeted quality domains. We would like to point out that there are no outcome measures for patients with chronic wounds, nor are there measures in any of these other areas.

5. **CMS will conduct a systematic gap analysis of the existing measures including home care, telehealth, and measures applicable to patients with certain healthcare conditions.** We would like to know what these certain healthcare conditions are and how the systematic gap analysis will be conducted. There is a substantial percentage of home health services provided to patients with chronic wounds which we would be pleased to provide more information on.
6. **Questions on obtaining MACRA money to develop quality measures.** Many of our physician specialty societies and clinical associations have written guidelines and are interested in turning them into quality measures. We are interested to understand the details for them to not only obtain MACRA money from CMS but also who would have control over developing the quality measures and whether they would follow the NQF process.
7. **Need for reduction of barriers or to incentivize the reporting of specialty measures through the QCDRs.** MACRA encourages the use of certified EHR technologies and QCDRs for reporting quality measures. We are in strong support of this process since we have developed 20 eQMs for the reporting of quality measures in the field of wound care and hyperbaric medicine. However, despite the availability of eQMs (including the necessary reference tables), without exception, EHR vendors demand substantial amounts of money to incorporate eQMs into their EHR products. Providers currently have no incentive to pay the high cost of eQM incorporation in order to report specialty specific quality measures. Thus, despite dedicated efforts to address gaps in practice, the USWR has developed “appropriate use” measures in hopes of identifying overuse of expensive interventions, and have developed patient experience of care measures such as wound related quality of life and nutrition. However, little progress has been made due in getting clinicians to report these measures because of the barriers created by the EHR vendors. Unless CMS acts to reduce these barriers or to incentivize the reporting of specialty measures through the QCDRs, eligible providers will continue to report PQRS measures which are not relevant to their practice and which do not address current gaps. The eQMs for our measures can be found here: <https://www.uswoundregistry.com/Specifications.aspx>
8. **CMS promotes the development of measures using hybrid data sources to link information between healthcare settings.** CMS solicited comments and suggestions for development of measures in this domain. We would like to point out that diabetic foot ulcers represent the most common non-traumatic cause of amputation in the USA. The vast majority of the cost and care provided to DFUs occurs in the outpatient setting. Measures directed at the episode of care for DFUs would cut across many care settings. Furthermore, eQMs focused on wound care represent an excellent way to obtain

data from diverse settings since wound care occurs in doctor’s offices, the hospital based outpatient clinic, long term care, nursing homes and home nursing. However, as stated in #6 above, unless CMS acts to incentivize reporting or decrease barriers to the incorporation of eCQMs, it will not be possible to use eCQMs to their best advantage.

**9. CMS will ensure that measure developers continue to include members from clinical specialty societies and other healthcare organizations that create clinical practice guidelines in the Call for Technical Expert Panel process.** We urge CMS to include an expert in wound care and electronic clinical quality documentation, preferably associated with the USWR QCDR on the technical expert panel.

**10. CMS considers measures of overuse and measures of inappropriate care that do not places the patient’s health at risk a high priority.** The USWR has developed appropriate use measures and would like to develop more for reporting via its QCDR. However, as stated in a previous comment, unless CMS acts to incentivize clinicians to report these measures, the QCDR may have no reason to invest in the considerable cost of further “appropriate use” eCQM development.

**11. We believe that submission of appropriate use measures via eCQM might be used as a method of assessing whether clinicians have been compliant with Medicare coverage policy and this might reduce the cost associated with pre-payment review.**

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

Sincerely,



Marcia Nusgart R.Ph.  
Executive Director

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<sup>i</sup> Ma, Henry, O’Donnell Jr. Thomas Francis Jr, Rosen, Noah Andres, Iafrazi, Mark David, “The real cost of treating venous ulcers in a contemporary vascular practice.” Journal of Vascular Surgery, Vol 2. No. 4.2014 355-361  
<sup>ii</sup> Margolis, David, Malay DS, Hoffstad OJ et al, “Economic Burden of diabetic foot ulcers and amputation. Diabetic Foot Ulcers. Data Points #3. Agency for Healthcare Research and Quality January 2011.  
<sup>iii</sup> Rice J.B., et al, Burden of diabetic foot ulcers for Medicare and private insurers. Diabetes Care, 2014;37(3):651-8  
<sup>iv</sup> Rice, J.B. Ibid.  
<sup>v</sup> Ma. Henry Ibid. p.356  
<sup>vi</sup> Ma, Henry Ibid.  
<sup>vii</sup> Rice, J.B., et al Burden of venous leg ulcers in the United States J.Med. Econ 2014 May; 17 (5):347--56

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<sup>viii</sup> Kandilov et al; Analysis report: estimating the incremental costs of hospital-acquired conditions (HACS) (Prepared by RTI International) Baltimore Maryland CMS 2011.