ALLIANCE OF
WOUND CARE
STAKEHOLDERS
POWER THROUGH COLLECTIVE ADVOCACY

August 21, 2017

Ms. Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-5522-P
Mail Stop C4-26-05
7500 Security Boulevard,
Baltimore, MD 21244-1850

Submitted electronically to www.regulations.gov

Re: [CMS-5522-P] CY 2018 Updates to the Quality Payment Program

Dear Administrator Verma:

On behalf of the Alliance of Wound Care Stakeholders ("Alliance"), we are pleased to submit the following comments in response to the proposed updates to the CY 2018 Quality Payment Program (QPP). 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. As such, we have a vested interest in this policy. A list of our members can be found at www.woundcarestakeholders.org.

Our specific comments follow.

QUALITY MEASURES

The Alliance is concerned that CMS has no quality measures that address the needs of wound care clinicians. Chronic wounds are devastating clinically and have an extraordinary impact on Medicare beneficiaries. In our June 2017 comments, we presented the results of a comprehensive Medicare claims analysis with the most current assessment of chronic wound care expenditures for Medicare patients (based on 2014 Medicare data). We found that chronic wounds impact nearly 15% of Medicare beneficiaries and the expenditures range from $28.1 to $96.8 billion with the most expensive category being dehisced and/or infected surgical wounds. (Nussbaum, Samuel R. MD, Carter, Marissa J. PhD MA, Fife Caroline E.MD, "*An Economic Evaluation of the Impact, Cost, and*

5225 Pooks Hill Rd | Suite 627S | Bethesda, MD 20814
T 301.530.7846 | C 301.802.1410 | F 301.530.7946
marcia@woundcarestakeholders.org

Medicare Policy Implications of Chronic Nonhealing Wounds" Value in Health 2017 in press) Importantly, the majority of wound care costs occur in the outpatient setting.

The Alliance has long been a supporter of quality care, as it is our mission to promote quality care and access to products and services for people with wounds. Yet, despite providing information to CMS on the cost of care to treat patients with wounds and the necessity to create and accept quality measures for wound care clinicians to report under the QPP, CMS has ignored chronic wounds in the measure development process.

Wound care is multidisciplinary which does not allow for the American Board of Medical Specialties to recognize it as a medical specialty. The Alliance is fully supportive of the CMS' efforts to direct physicians to suites of measures that are relevant to their specialty so that the quality reporting process can at last become meaningful. Practitioners of many specialties now practice wound care full time. We are concerned that quality measures which might once have been relevant to them by virtue of their specialty board certification (e.g. Family Practice, General Surgery, Physical Medicine, etc.) are no longer applicable. Furthermore, there are no MIPS measures for them to report as Wound Care specialists.

The Alliance attempted for 7 years to get quality measures relevant to wound care into PQRS but was unsuccessful due to barriers with NQF endorsement, in part because wound care was not a CMS priority for measure endorsement. When Qualified Clinical Data Registries (QCDR) were created, the Alliance had high hopes for this as a mechanism to address serious gaps in practice which had been identified and documented in peer reviewed literature (e.g. peripheral arterial screening among patients with leg ulcers, diabetic foot ulcer off-loading). We were pleased to partner with the US Wound Registry (USWR) to develop 14 wound care relevant measures in the first year, many of them targeting proven gaps in practice, as well as some being high value measures including risk stratified outcomes.

However, the biggest obstacle to the widespread use of QCDR quality measures as a way to improve wound care quality and practice standards are CMS policies. The following reasons highlight our claim:

- Despite the absence of a specialty society to support our efforts, we made considerable headway getting wound care clinicians to participate in the US Wound Registry QCDR, as long as participation in a specialty registry was *mandatory* under Meaningful Use (MU).
- Under the QPP, registry participation is not mandatory under the ACI component. As such, wound care practitioners are not likely to commit to registry reporting when the value of a "bonus point" is in a sub-category that is weighted at only 25% of their final score.
- The result is that the QPP ended our ability to drive participation in the QCDR through CMS mandates.
- Current CMS policy links high quality scores to reimbursement. It is understandable that when CMS allows doctors to pick any measures they wish, doctors will report their HIGHEST scoring measures in order to maximize reimbursement.
    - The result is that practitioners may be reporting on measures that are not relevant to their practice.
    - This makes the entire quality process a sham.

- With respect to measure reporting:
    - Under PQRS, practitioners had to sacrifice the opportunity for a higher PQRS score in order to submit data on new QCDR measures since new, unbenchmarked measures did not count towards their quality score.
    - The same is true for the first year of new QCDR measures in a MIPS registry. New measures are worth only 3 out of a possible 10 points, which means no clinician has an incentive to report un-benchmarked new QCDR measures.
    - As long as clinicians can report any quality measures they wish, through any QCDR they chose, it will not be possible for CMS to determine if a gap in practice exists, because the doctors with a gap in practice did not report that measure in the first place.
    - The result is that the QCDR measures which ARE reported, all have very high rates of passing since anyone scoring poorly would not report that measure.
    - CMS then rejects high scoring QCDR measures under the logic that there is no gap in practice when, in fact, there might be if more practitioners report the measure.

Recommendations:

1. **Practitioners should not be permitted to report measures which are irrelevant to their practice in order to achieve high scores – which is exactly what is taking place under this system. This concept goes against the very foundation of the QPP. This can be remedied by mandating that clinicians report on the quality measures which impact their area of practice.**

2. **Additionally, the Alliance recommends that while there were 14 measures created and are currently accessible for reporting under the QPP, that additional wound care quality measures are necessary to ensure that wound care practitioners are and continue to provide quality care.**

3. **Finally, if CMS wants to drive practice improvement, the Alliance recommends that CMS increase the value of the Clinical Practice Improvement Activities (CPIA) sub-score when the activity is improving performance in a suite of practice relevant quality measures. This will allow a different area of MIPS to compensate for the loss of points in Quality.**

QCDR

The Alliance supports the use of QCDRs and the ability of all eligible clinicians to use the QCDR option for reporting. However, the Alliance encourages CMS to permit clinicians to receive the full score or provide some incentive to clinicians when they report via a QDCR using QCDR measure sets.

The Alliance further supports the proposal in which CMS has simplified the process in which existing QCDRs or qualified registries in good standing may continue their participation in MIPS by attesting that their approved data validation plan, cost, approved QCDR measures (applicable to QCDRs only), MIPS quality measures, activities, services, and performance categories offered in the previous year's performance period of MIPS have no changes.

Finally, the Alliance also supports the term "QCDR measures" replacing the term "non-MIPS measures," as we believe that will lead to less confusion with practitioners who otherwise have been under the impression that QCDR measures were/are not reportable for their composite score under the QPP.

GAPS IN PRACTICE/TOPPED OUT MEASURES

We have grave concerns that CMS has eliminated certain wound care measures from the QCDR because the Agency erroneously believes that high performance rates mean no gap in practice continues to exist. Yet, CMS has created a system in which high quality scores are linked to possible monetary rewards and therefore, by design, practitioners report the measures for which they score the highest. As long as clinicians can report any quality measures they wish, it is not possible for the QCDR to mandate any particular suite of measures. As such, wound care practitioners can choose to report on measures specifically identified in the QPP – which have nothing to do with their practice. When reporting through a QCDR they will not be able to obtain more than 3 points when reporting new unbenchmarked measures. Clinicians *who have a gap* in practice will not report on measures that show any gap in practice – especially when there are other measures that they can report. Clinicians who *do not have a gap in practice will report on those measures and* score well (otherwise they would not report it).

The Alliance has significant issues with how CMS rejects measures when the measure tops out. The system CMS has created is designed to produce measures with only high scores since practitioners can cherry pick the measures they report and thus will report the measures in which they score well. The result is that QCDR measures developed at much expense to small organizations are promptly rejected by CMS under the logic that there is not a gap in practice, when in fact, the system is designed to produce measures with only high scores. Yet, CMS continues to support measures in MIPS which have long since been topped out, presumably because it feels they are important (e.g. medication reconciliation). This is a double standard and one which should not persist under this program. Some processes ARE important. We know that failure to perform things such as off-loading of diabetic foot ulcers or compression of venous ulcers results in higher spending, and worse outcomes, and that a gap in practice does continue to exist in process measures that WE KNOW ARE IMPORTANT. Yet, these measures will almost surely be rejected.

The only way to determine whether a gap in practice really exists, is to mandate a suite of measures that is relevant to a specific group or specialty, and provide some incentive for practitioners to participate in a QCDR for the purpose of improving quality rather than simply maximizing their quality performance score. This cannot happen as long as quality is 60% of the sub-score and practice improvement is only 15%.

Recommendation:

As such, the Alliance recommends that CMS develop a more comprehensive approach to determining which measures should be topped out. Currently, practitioners choose which measures they report and how they report them. This voluntary reporting leads to cherry picking - reporting only measures on

which they perform best or only on a sample of the relevant population. An accurate picture of topped out measures requires more universal data collection with mandatory reporting on a clinicians entire population – even for practitioners who are not part of a specialty – such as wound care practitioners.

LOW VOLUME THRESHOLD

The Alliance supports the CMS proposal to increase the low-volume threshold beginning in 2018 as well as its proposal to permit individual MIPS eligible clinicians and groups to opt in to MIPS participation in 2019 if they might otherwise be excluded from the low volume threshold because they only meet one of the threshold determinations. There are many wound care providers who currently are not permitted to participate in MIPS as they are not defined as eligible clinicians under MIPS.

Recommendation:

The Alliance recommends that CMS open MIPS participation to *any* eligible professional who wishes to opt-in to the program.

SUMMARY OF COMMENTS

1. There are very few MIPS measures even indirectly relevant to wound care for those practitioners who practice wound care to report under the QPP.
2. All the wound care specific quality measures that practitioners can report are located in QCDRs.
3. Since practitioners can cherry pick the measures they wish to report, regardless of whether the measures are relevant to what they actually do, the current quality measure system does not meet the intent of the program with regards to evaluating the quality of actual practice for any specialist, and wound care in particular.
4. Because clinicians report the measures with the highest score, it can appear as though there is no gap in practice when in fact, CMS only sees the data from the providers who do NOT have a gap in practice. Those who do have a gap in practice do not report a related measure.
5. This results in CMS eliminating process measures that are linked to clinical outcome even though they are still very much needed (e.g. DFU off-loading and VLU compression).
6. The only remedy for this is if CMS mandates a particular measure suite for wound care practitioners so that all practitioners report measures regardless of whether they have achieved a high score. This is the only way that CMS will know if a real gap in practice exists.

Therefore, the Alliance recommends that CMS mandate a measure set for wound care practitioners so that it will be possible to actually evaluate gaps in practice with process measures that are linked to outcome. We submit that additional wound care quality measures should be developed and utilized as well.

CONCLUSION

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,

Marcia Nusgart R.Ph.
Executive Director