ALLIANCE OF
WOUND CARE
STAKEHOLDERS
POWER THROUGH COLLECTIVE ADVOCACY

December 19, 2016

Andrew M. Slavitt
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-5517-FC
P.O. Box 8013
Baltimore, MD 21244-8013

Re: File Code-CMS-5517-FC; Medicare Program; Merit Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) Incentive under the Physician Fee Schedule; and Criteria for Physician-Focused Payment Models

Dear Acting Administrator Slavitt:

The Alliance of Wound Care Stakeholders ("Alliance") appreciates the opportunity to provide comments on the Centers for Medicare and Medicaid Services (CMS) Final Rule with comment period on Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) Incentive Under the Physician Fee Schedule, and Criteria for Physician-Focused Payment Models published in the November 4, 2016 Federal Register. 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 chronic wounds (diabetic foot ulcers, venous stasis ulcers, pressure ulcers and arterial ulcers) 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 whose members include wound care physicians and clinicians described below who possess expert knowledge in complex chronic wounds and in wound care research. A list of our members can be found at www.woundcarestakeholders.org.

Chronic wounds are devastating clinically and have an extraordinary impact on Medicare beneficiaries. In our June 2017 MACRA 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 billion to $96.8 billion with the most expensive category being dehisced and/or infected surgical wounds. Importantly, the majority of wound care costs occur in the outpatient setting.**

We appreciate that CMS staff now have a better understanding of the importance of wound care within the Medicare population as evidenced by our conversations with Amy Bassano and Matthew Press of CMMI, Sean Cavanaugh and Dr. Kate Goodrich of CMS at the recent Health Care Payment Learning and Action Network

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(HCPLAN). In fact during one of the sessions, Dr. Patrick Conway publicly acknowledged that wound care is a "hugh issue for Medicare beneficiaries" and he was willing to work with the Alliance on these issues.

COMMENTS

QCDRs

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. Our commitment includes our staff and members attending both meetings of the Health Care Payment Learning and Action Network this year, becoming a LAN Committed Partner and educating our members on MACRA implementation and APM adoption. In terms of quality, we partnered over the past few years with the US Wound Registry to establish 21 wound care quality measures under its QCDR.

Therefore, our most pressing and important concern in the MACRA final rule, is that it fails to encourage the use of QCDRs since:

- **QCDR measures cannot be used as part of the MIPS quality score**. Although standard quality measures can be reported *through* a QCDR, QCDR *developed* measures can't be *used* as part of the MIPS quality score whereas under PQRS, they could.
- **QCDR measures can't be used for the MIPS quality bonus points**: Although we have many high priority measures which CMS acknowledges that it lacks (e.g. risk stratified outcome, appropriate use, patient reported quality of life, etc.), none can be used for MIPS bonus points.

We understand the need for administrative efficiency, and we understand the pressure CMS was under to simplify MIPS as the program was implemented with a very short lead time. However, we heard Dr. Goodrich verbally reaffirm CMS' commitment to QCDRs at the LAN meeting, so we do not think that the Agency fully understands the negative impact that the final rule will have on QCDRs, or in the way in which QCDRs could work to alleviate the burden of MIPS implementation on EPs if given the freedom to do so.

We ask that the Agency pay attention to the comments submitted by Dr. Caroline Fife of the US Wound Registry who addresses the ways that QCDRs could help CMS in its implementation of MACRA.

Recommendation: We request CMS reconsider the use of QCDRs and allow the quality measures to be used as part of the MIPS quality score and for MIPS quality bonus points.

Virtual Groups

It is our understanding that CMS is interested in comments on the factors that the Agency would consider regarding overall implementation of virtual groups such as establishing minimum standards for members of virtual groups and the use of a group identifier for virtual groups.

We are in agreement with the AMA's recent comment on this issue when it stated:

- We strongly urge CMS to act on forming these groups as soon as possible. Without this assistance, we believe small practices may face even greater challenges when attempting to move into the MIPs program.
- There should be no requirement that all clinicians within a virtual group be within the same specialty.
- MACRA outlined a requirement for virtual groups that would allow small practices to join together and be judged on aggregate data rather than individually under MIPs. CMS has signaled that these groups will not be available for the proposed first performance year. Without this and other key assistance, we urge CMS to expand the low-volume threshold to avoid inadvertently penalizing small practices.

These issues also apply for wound care physicians and clinicians in the following manners:

- Wound care is multidisciplinary and therefore, the American Board of Medical Specialties does not recognize it as a single medical specialty. Practitioners of many specialties are in the full time practice of wound care so that the 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 so.

  However, these diverse specialists now have a mechanism by which to identify themselves to CMS as wound care practitioners by using the USWR QCDR.
  <u>Recommendation:</u> We suggest that CMS use this as a group identifier for virtual groups.

  - Additionally, there are many currently non-eligible providers who are vital components of the team such as Physical Therapists and nutritionists.
  - These non-eligible clinicians could agree to submit wound care quality data and the USWR would be able to identify them.
  - The US Wound Registry has crafted QCDR measures to capture the broad range of interdisciplinary activities which include nutritional screening, functional assessment and many other activities that require the participation of these valuable providers.

- **<u>Recommendation:</u> In addition, the Alliance recommends that a minimum standard for a virtual group be defined as clinicians (such as EPs certified in Wound Care), who agree to report a designated "Specialty Measure Set" through a QCDR such as the USWR QCDR, and through CPIA projects promoted through the QCDR as set forth above.**
  - The Specialty Measure Set must be allowed to include QCDR measures, particularly if they are high value measures such as patient reported measures and risk stratified outcome measures that are not otherwise available in MIPS.
  - It is our understanding that the USWR would like to designate a group of measures as a Wound Care Specialty Measure set.
    - The EPs who choose to report this measure set via the USWR QCDR by contractual agreement at the beginning of the year would meet the minimum standard for the group.
  - The USWR QCDR has the ability to aggregate their quality data and report it as a group to CMS.

- The low-volume threshold issue is very important for wound care providers. There are many wound care providers who will be blow the low-volume threshold because they work part time in several facilities. We believe that they should be able to report whatever volume they have because in many cases, their other sites of care may not be wound care. For example, a podiatrist may practicing in his private office 70% of the time and in the wound care center 30% of the time. As a result, he is below the low volume threshold and can't report wound care quality measures even though he may want to do it.

Quality Performance Category

"Cross-cutting measures" are defined as "any measures that are broadly applicable across multiple clinical settings and eligible clinicians, both individually and in a group, within a variety of specialties". This definition describes every wound care measure in the USWR QCDR. However, it will be difficult to break down silos of care as long as quality measure development is conceived in relation to various clinical "settings" (otherwise known as "silos"). Because nearly every possible medical specialist participates in wound care, it is the ideal model to conceptualize the new way of thinking about healthcare that CMS has identified as a national priority—specifically, Patient Centered Healthcare." ***We submit that quality development should be "patient centric***," or at the very least, problem centric rather than "setting based." In other words, the measures should follow the patient and not the site of care if patient centered care is going to exist.

The Alliance analysis of the Medicare claims dataset revealed that wound care occurs in every possible setting covered by Medicare. For example, it identified that the most expensive wound type for Medicare are complicated surgical wounds (e.g. dehiscence, infection). This problem transitions across all care settings from the acute care hospital to home. Many of our QCDR measures are broadly applicable to this problem (e.g. debridement of necrotic tissue, nutritional screening).

The factors we think CMS should consider for "cross-cutting" measures are:
- That they are patient centered
- That the term "patient- centered" be used instead of "cross-cutting" measures
- That they target areas with gaps in care
- That they target issues patients care about

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The Alliance thanks CMS for understanding the importance of wound care in the Medicare population. Wound care physicians and clinicians are a unique group of individuals—they are committed to continuously monitoring patients with chronic wounds, providing ambulatory services which decrease amputation and keeping them out of the hospitals. We request that the Agency advance patient care by collaborating with us on this joint journey. We request a reconsideration of QCDRs in the joint domain which would allow the quality measures to be used as part of the MIPS quality score and for MIPS quality bonus points. In addition, we recommend that CMS use the US Wound Registry QCDR as a group identifier for virtual groups which could report a designated "wound care special measure set" through it. Finally, we suggest that quality development

be “patient centric” and the measures should follow the patient and not the site of care if patient centered care is going to exist.

We look forward to working with CMS to revise this final rule so that it meets its intended purpose to ensure Medicare beneficiaries have access to timely, quality care provided by wound care practitioners.

Sincerely,

Marcia Nusgart R.Ph.
Executive Director