ALLIANCE OF
WOUND CARE
STAKEHOLDERS
POWER THROUGH COLLECTIVE ADVOCACY

September 2, 2015

Mr. Andrew Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1631-P
7500 Security Boulevard
Baltimore, MD 21244-1850

Comments Submitted Electronically to **http://www.regulations.gov**

Re: CMS -1631-P: Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2016

Dear Acting Administrator Slavitt:

On behalf of the Alliance of Wound Care Stakeholders ("Alliance"), I am pleased to submit the following comments in response to the proposed CY 2016 Physician Fee Schedule. 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 the Alliance member clinical specialty societies and organizations who 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. There are several provisions included in this proposed rule that impact wound care and therefore we have a vested interest in ensuring that our comments are taken into account by your staff as they write the final rule. Our specific comments follow.

POTENTIALLY MISVALUED SERVICES UNDER THE FEE SCHEDULE

Congress, with the passage of the Affordable Care Act, required CMS to identify and review potentially misvalued codes and make appropriate adjustments to the relative values of those services identified as being misvalued. In addition to the 7 categories that already existed, the Protecting Access to Medicare Act of 2014 amended the law to expand the categories of services that CMS is directed to examine for the purpose of identifying potentially misvalued codes to an additional 9 categories.

In this proposed rule, CMS includes a list of 118 CPT codes for the RUC to review that fall into the category of "High Expenditure across Specialties with Medicare Allowed Charges of $10,000,000 or more." The Alliance does not understand CMS's belief that charges greater than $10 million means that the code is misvalued. As such, we urge CMS to provide the RUC with any data used that would explain why charges of greater than $10 million would potentially translate into misvalued codes

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REFINEMENT PANEL

CMS has proposed to eliminate the Refinement Panel process currently in effect that has been used by CMS to consider comments on interim relative value units. The Alliance is very concerned with the elimination of the Refinement Panel because this would mean that CMS would no longer solicit the views of contractor medical directors, practicing physicians and others to determine if there is a need to modify proposed values. While we support the proposed change to include proposed RVUs in the fee schedule proposed rulemaking each year, we do not agree that this new process eliminates the need for a Refinement Panel. These two processes are distinct from each other and together would allow for multiple avenues to appeal. As such, the process affords an important opportunity for outside stakeholders to appeal CMS decisions, and provides an additional layer of accountability for these decisions. The Alliance urges CMS to continue to retain the refinement panel process as this is an important mechanism in ensuring the accuracy of the valuation of physician services.

LACK OF TRANSPARENCY AND PREDICTABILITY REGARDING NEGATIVE PRESSURE WOUND THERAPY PAYMENT RATES

Over the past few years, our clinical members advocated at the CPT and RUC meetings for the establishment of new CPT codes and payment for single-use NPWT services. The codes were implemented on January 1, 2015. However, since that time, there has been, and continues to be, significant confusion among physicians regarding the payment rates for the new CPT codes. In contrast, many of the MACs published payment rates on their websites for the predecessor G-codes, creating transparency and certainty.

By way of background, CMS implemented HCPCS codes G0456 and G0457 on January 1, 2013, to describe the service of furnishing NPWT using a disposable device.[1] *See* Table 1. CMS later clarified, on February 19, 2013, that these codes were not limited to the use of any one-particular NPWT technology, but that the code could be used by providers for all NPWT product types.

TABLE 1: HCPCS Codes implemented January 1, 2013 to describe NPWT

HCPCS Codes	Descriptor
G0456	Negative pressure wound therapy. (e.g. vacuum assisted drainage collection) using a mechanically-powered device, not durable medical equipment, including provision of cartridge and dressing(s), topical application(s), wound assessment, and instructions for ongoing care, per session; total wound(s) surface area less than or equal to 50 square centimeters.
G0457	Negative pressure wound therapy. (e.g. vacuum assisted drainage collection) using a mechanically-powered device, not durable medical equipment, including provision of cartridge and dressing(s), topical application(s), wound

[1] CMS, Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, DME Face-to-Face Encounters, Elimination of the Requirement for Termination of Non-Random Prepayment Complex Medical Review and Other Revisions to Part B for CY 2013; Final Rule, CMS-1590-FC, 77 Fed. Reg. 69069 (Nov. 16, 2012), *available at* http://www.gpo.gov/fdsys/pkg/FR-2012-11-16/pdf/2012-26900.pdf.

	assessment, and instructions for ongoing care, per session; total wound(s) surface area greater than 50 sq. cm

Since their implementation, these HCPCS codes always have been carrier priced as indicated by their status code of "C."[2] Several MACs had published payment rates for these codes on their websites, creating transparency and predictability for physicians providing these services.

For CY 2015, CMS replaced G0456 and G0457 with permanent, Category I CPT codes for disposable NPWT. *See* Table 2.

TABLE 2: CPT Codes implemented January 1, 2015 to describe NPWT and replacing previously implemented HCPCS codes

CPT Codes	Descriptor
97607	Negative pressure wound therapy less than or equal to 50 square cm
97608	Negative pressure wound therapy greater than 50 square cm

Similar to the predecessor HCPCS codes, CMS has given the new CPT codes a status indicator of "C." Additionally, the descriptors for the codes are very similar to the predecessor codes. As a result, physicians expected an otherwise uneventful transition from the G-codes to the new CPT codes. However, concurrent with the implementation of the new CPT codes, the MACs ceased publication of the payment rates for these codes. This has and continues to create significant confusion among physicians with respect to how the continued provision of these services will be regarded by the MACs, obscuring the previous well-functioning transparency and predictability.

Accordingly, we ask CMS to urge the MACs to publically post payment rates for CPT codes that are contractor priced under the PFS, specifically the new codes for single-use NPWT. This will restore the previous transparency and predictability with respect to claims adjudications for these therapies.

GLOBAL PERIOD

The Alliance did not support CMS's proposals to eliminate the 10 and 90 day global surgical periods. We support Congressional efforts to prohibit the elimination of the 10- and 90-day Global Surgical Packages, which was included in the Medicare Access and CHIP Reauthorization Act (MACRA). The Alliance believes this proposal would have created undue burdens for all, including physicians, CMS and Medicare beneficiaries.

If CMS has remaining concerns with the post-operative visits in specific codes, it should nominate those particular codes and have specialty societies work them through the RUC process. We support CMS gathering information needed to value surgical services from a sample of physicians and that beginning the data collection by January 1, 2017 is reasonable. The Alliance strongly recommends that CMS begins this process with a small pilot program using the input of surgical societies to determine how best to collect data

[2] Status indicator C is described as "Carriers price the code. Carriers will establish RVUs and payment amounts for these services, generally on an individual case basis following review of documentation such as an operative report."

(i.e. limited demonstration project, prospective study, etc.). We also submit that requiring all providers to report this information is unreasonable and will be an insurmountable burden. This unfunded mandate would require physicians to hire additional staff to handle the claims/data.

The Alliance is also concerned about the impact the implementation of ICD-10 beginning October 1 will have on global period data. ICD-10 will further complicate the gathering of this global period/surgical data. The structural changes throughout the entire coding system and the increased level of complexity, with an increase in 55,000 codes, are very significant and will require time for surgeons and coders to adapt to the changes.

Moreover, CMS will need to go beyond claims data to determine all the services provided in the post-operative period. Many post-operative services performed in a global surgical period in the days immediately following surgery do not have CPT codes to bill separately, such as a change of surgical dressings or post operative surgical procedures to decrease post operative wound infection rates. The Alliance recommends that if there is a post operative infection or the potential or threat of dehiscence that this should be addressed outside of the global period.

Finally, the Alliance strongly opposes any delay of up to 5 percent of the PFS payment for services in which a physician is required to report information on until the required information is reported. We believe that this action is too punitive, particularly for private practitioners

PHYSICIAN COMPARE INTERNET WEBSITE

The Affordable Care Act requires that CMS, by no later than January 1, 2011, develop a Physician Compare Internet website with information on physicians enrolled in the Medicare program as well as information on other eligible professionals who participate in the Physician Quality Reporting System and also requires that, CMS implement a plan for making information on physician performance publicly available through the Physician Compare Website. In this proposed rule, CMS has continued to make improvements to the physician compare website. While we appreciate some of the improvements we have concerns with others.

Our biggest concern is there is too much data on the website that patients do not understand. In the proposed rule, CMS states "consumer testing has shown profile pages with too much information and measures that are not well understood by consumers can negatively impact a consumer's ability to make informed decisions". We agree with this statement. Most consumers are not familiar with PQRS, registry and EHR measures, so using these measures with just a green check mark continues to be problematic.

CMS is proposing to expand data on the website, which include the following: adjustments for the value modifier, Qualified Clinical Data Registry (QCDR) measure reporting, benchmarking and Board certification. The Alliance is concerned with the use of a benchmark allowing consumers to evaluate the information published by providing a point of comparison between groups and between individuals. We also oppose including Open Payments data as part of Physician Compare. This data is already available at http://www.cms.gov/openpayments, but has very little relevance to patient treatment and adds even more data to the website that could be misinterpreted by patients.

The Alliance recommends that CMS provide health care professionals the opportunity to preview data and measures in confidential formats and provide methods for feedback prior to posting the information on the site. We have concerns that CMS may be challenged in getting timely feedback reports to all providers to view prior to the public release of data on Physician Compare with the expansion of public reporting for all EPs and groups across all reporting formats. EPs should be allowed a reasonable period of time for review of reports in order to access and gather supporting information to correct errors, discrepancies, and other concerns.

Additionally, if CMS expects usage of the Physician Compare Website by consumers to compare data for all eligible providers, the name is confusing as it suggests it is only a means to compare data for physicians. In order to be more reflective of the inclusion of other providers, the Alliance strongly encourages CMS to consider an alternative name for the Physician Compare Website.

QUALIFIED CLINICAL DATA REGISTRY (QCDR)

The creation of QCDRs have been very important to wound care and to our Alliance members. But there are gaps in measures for both consumers and stakeholders, particularly in the area of wound care. It is estimated that as much as 5% of the entire budget of CMS is spent on the management of wounds and ulcers. Chronic wounds affect more Medicare beneficiaries than heart failure. Despite the number of patients affected and the cost to the country, we have no patient reported outcome measures in wound care. Healing or closure is not the only outcome of importance to patients. Patients frequently tell us that outcomes of importance to them include the control of odor and drainage and the reduction of pain. The development of improved patient reported outcome measures in the area of wound healing would fill a significant gap in both the measure of patient care and the development of wound treatments.

Yet, since wound care" is not a recognized specialty or subspecialty of the American Board of Medical Specialties, it had been very difficult to create quality measures through the National Quality Forum process. In 2014, the Alliance met with CMS staff and in the absence of a medical specialty society to represent the wound care industry, the CMS staff agreed to allow the Alliance to act as a *de facto* specialty society for the field of wound care in the development of PQRS measures as part of a QCDR program. The Alliance collaborated with the U.S. Wound Registry (USWR), one of the oldest PQRS reporting registries in the USA, to establish wound care measures by the USWR becoming a QCDR. While some measures were developed – none were for patient reported outcome measures. We would like to continue to work with CMS to ensure that wound care practitioners and the patients they serve have adequate measures to report.

With respect to the specific provisions proposed in this regulation, the Alliance supports CMS's proposal to allow group practices use of a QCDR to participate in the PQRS.

Furthermore, the Alliance also appreciates CMS' proposal to have materials for QCDR nomination available as of December 1 of the prior year followed by 60 days for self-nominations to be accepted. However, we are concerned that after the entity submits its validation plan and measure specifications for non-PQRS measures, there would be no opportunity to change any of this information post-submission for the purposes of qualification. CMS has not indicated what information would be considered supplemental. Therefore, the Alliance urges CMS to be more explicit regarding what would be considered supplemental information and we recommend that CMS provide a window of time during March of a given year where supplemental

information or corrections to measure specifications could be submitted, assuming this information is related to information submitted by the January 31 deadline.

In reference to both the QCDR program, as well as the traditional PQRS program, the requirement of reporting 9 measures across 3 National Quality Strategy (NQS) domains and one cross-cutting measure is going to be challenging for CY 2016 reporting. Once CMS analyzes the 2015 reported data, there will likely be many more providers receiving a penalty due to this complex and burdensome reporting requirement for providers. It is important to note that not all of the 6 NQS domains have what a sufficient number of measures for wound care practitioners/clinicians to report. Each domain should contain several diverse, high quality measures to choose from to meet the requirement that reported quality measures cover 3 of the domains. These are elements of the PQRS reporting program that need to be evaluated prior to the program being combined into the MIPS.

Finally, the Alliance has concerns about the lack of transparency provided in regard to the Measures Application Validity process for those EPs who do not meet the 9 measure/3 domain threshold. A more transparent process that is offered at the beginning of the reporting period for physicians to pre-verify the lack of 9 measures would be more appropriate. As such, the Alliance recommends that CMS allow physicians to apply to the Measure Application Validity process at any time during the reporting period to verify that the measures they are reporting will meet the PQRS reporting requirements. This is an important step to assure providers that they can meet the requirements of the PQRS program and not incur unnecessary penalties.

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.

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Executive Director