ALLIANCE OF
WOUND CARE
STAKEHOLDERS
POWER THROUGH COLLECTIVE ADVOCACY

September 6, 2016

Mr. Andrew Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H Humphrey Building
200 Independence Avenue, SW
Washington DC 20201

Submitted by courier to the Hubert Humphrey Building

Re: [CMS-1656-P] Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Organ Procurement Organization Reporting and Communication; Transplant Outcome Measures and Documentation Requirements; Electronic Health Record (EHR) Incentive Programs; Payment to Certain Off-Campus Outpatient Departments of a Provider; Hospital Value-Based Purchasing (VBP) Program

Dear Acting Administrator Slavitt:

On behalf of the Alliance of Wound Care Stakeholders ("Alliance"), we are pleased to submit the following comments in response to the proposed changes to the Hospital Outpatient Prospective Payment and Ambulatory Surgical Payment Systems and Quality Reporting Programs. 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 Reporting

ECQM and Future Measures for Consideration

Chronic wounds are devastating clinically and have an extraordinary impact on Medicare beneficiaries. The Alliance recently commissioned a comprehensive Medicare claims analysis to obtain the most current assessment of choric wound care expenditures for Medicare claims patients (based on 2014 Medicare data). The results are staggering. *Chronic wounds impact nearly 20% of Medicare beneficiaries (over 11 million) and cause as much as 35 billion dollars in Medicare*

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expenditures (including both fee-for-service and Medicare advantage). [1]A large percentage (36%) 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 in the inpatient but the **outpatient setting where many resource intensive therapies are utilized** (e.g. cellular and/or tissue based products for skin wounds, hyperbaric oxygen therapy, debridements, negative pressure wound therapy, and home nursing services). [2]Yet, there are **no measures in the Hospital Outpatient Quality Reporting (OQR) program that are specific to wound care**.

The list of the current measures available for reporting is not sufficient for wound care practitioners. Currently there **are 3 quality measures that a wound center could report** (since nearly all of them are designed for the ER, outpatient surgery center, or imaging center): They include:

OP -12:The ability for providers to receive lab data electronically into the EHR system as discreet searchable data
OP-17: Tracking clinical results between visits
OP- 27: Influenza vaccination coverage among healthcare personnel

However, with the exception of OP-17, the measures are not specific to a wound care clinician and the services that they perform. Furthermore, CMS has proposed 7 new measures two claims based and five OAS CAHPS measures. These measure include the following:

Claim based measures

(1) OP – 35: Admissions and Emergency Department Visits for Patients Receiving Outpatient Chemotherapy
(2) OP – 36: Hospital Visits after Hospital Outpatient Surgery (NQF #2687)

Survey based measures

(1) OP – 37a: OAS CAHPS – About Facilities and Staff;
(2) OP – 37b: OAS CAHPS – Communication about Procedure;
(3) OP – 37c: OAS – CAHPS – Preparation for Discharge and Recovery
(4) OP – 37d: OAS CAHPS – Overall Rating of Facility;
(5) OP – 37e: OAS CAHPS – Recommendation of Facility.

Again, there are only two measures that an outpatient wound center could use – the patient surveys of the facilities and staff and whether the patient would recommend the facility (OP-37d and OP-37e). While it is nice that wound care centers can use these two measures, neither are claim based and there

[1] In June 2016, the Alliance of Wound Care Stakeholders commissioned Dobson DaVanzo & Associates, LLC (Dobson | DaVanzo) to perform an analysis of the prevalence and cost of wound care in the Medicare population titled "Prevalence and Spending for Wound Care in the Medicare Population --An Analysis of Medicare Claims Data.
[2] DaVanzo & Associates, LLC (Dobson | DaVanzo), "Prevalence and Spending for Wound Care in the Medicare Population --An Analysis of Medicare Claims Data. June 2016

are no quality measures specific to the care clinicians provide to their wound care patients despite the large percentage of patients that receive care to treat their chronic wounds.

In 2014, the Alliance worked with CMS and the U.S. Wound Registry to form a Qualified Clinical Data Registry (QCDR) that allowed us to create quality measures essential for wound care practitioners to use to show the work that they do to treat patients with chronic wounds. CMS approved the measures when the QCDR was approved. These measures were designed for physicians to report under the PQRS. While these are measures for clinicians to report, they are not specific to any setting as they are specific to the work/services that wound care clinicians perform. There are 21 quality measures specific to the practice of wound care, **fully programmed as electronic clinical quality measures (eCQMs) available within the U.S. Wound Registry Qualified Clinical Data Registry (QCDR**), As such, hospitals can utilize these measures in their OQR since they are formatted to be installed into the hospital EHR. The Alliance requests that CMS consider utilizing the Alliance's QCDR measures to satisfy the quality reporting requirements under the hospital OQR program.

Skin Substitutes (Cellular and/or Tissue Based Products for Skin Wounds)

Since 2014, CMS has issued regulations to package skin substitutes – now widely referred to as cellular and/or tissue based products for skin wounds (CTPs).[3] From the inception of the packaging of CTPs, CMS did not utilize the correct cost information because the number of square centimeters applied were not coded and charged correctly. The Alliance actually presented CMS with actual invoices to prove that the product costs built into the packaged payment were not accurate. As a result, packaged payment complicated an already complex coding and billing situation for hospital outpatient departments.

For the past several years, the Alliance has consistently recommended to CMS that in order to accurately set the packaged payment rates for CTPs, correct coding and billing of these products is essential. The Alliance continues to maintain that it is the responsibility of CMS to ensure that these products are coded and billed appropriately so that the APC Group assignments are assigned correctly. The Alliance submits that these products are not being coded and billed correctly: the claims data are inaccurate and the APC Group assignments are negatively impacted. It is the responsibility of CMS to ensure that hospitals are not only reporting the correct CPT application code, but also that the number of units applied align with the number of units reported with the CPT code. For example, claims should never show a unit of 1 attached to the product code when the physician applies a CTP to a 20 sq. cm wound. Moreover, if the procedure code is reported for 100 sq. cm, a minimum of 100 sq. cm should be reported on the claim for the product. In addition CMS should verify that the correct revenue code for the products is reported on the claims: revenue code

[3] Cellular and or Tissue Based Products for Skin Wounds (CTP) is a more appropriate descriptor for these products as they do not function as substitutes for skin. The clinical community and scientific journals utilize the CTP nomenclature, and has been approved by the ASTM (the international standard setting organization). Published in February 2016, the new standard is devoted to the nomenclature for these products and is titled "Standard Guide for Classification of Cellular and/or Tissue-Based Products for Skin Wounds."

636, not 278, should be reported on the claim.

Unless CMS establishes edits to accurately reflect the number of square centimeters that have been applied, the APC Group assignment will continue to be inaccurate. APCs are evaluated every year. It is the Alliance's recommendation - and has been for the past two years - that CMS educate facilities on the correct coding and billing of CTPs. This will ensure that appropriate APC Group assignments are made which reflect the true costs of the CTPs. In addition, the Alliance recommends that CMS mandates its Medicare Administrative Contractors to establish edits that reject claims whose CTP codes reflect one wound size and whose products codes do not reflect a similar size. If only one unit is coded and billed for wounds that are 20 sq.cm, or if less than 100 sq. cm of product is reported when the procedure is reported at 100 or more sq. cm, then the claim should kick it out of the system. In addition, CMS should also edit for facilities who do not purchase CTPs to adequately cover the base of the entire wound and the wound margins which are not large enough to allow for the surgeon's choice of the fixation. The contractor should request that the facility purchase the right size product to cover the entire wound and correctly code the correct number of sq. cm applied. The Alliance urges CMS to issue a MedLearn Matters (MLM) article to describe the proper coding and reporting of units. This will ensure that accurate, appropriate claims are submitted – which in turn will ensure accurate, appropriate APC Group assignments for CTP products. Accurate claims reporting is absolutely necessary – it is up to CMS to ensure that it is.

Furthermore, it is disconcerting that CMS believes that the reimbursement should be different when applying a CTP to a wound that is over 100 sq. cm on the foot versus applying the exact same size CTP to a wound that is over 100 sq. cm on the leg. Regardless of whether the CTP is designated as "high cost" or "low cost", the same amount of product is needed for the same size wound no matter what anatomic location receives the CTP. Yet CMS pays significantly less when a CTP is applied to the smaller anatomic locations such as the foot than it pays for the larger anatomic locations such as the leg. As such, the Alliance recommends that CMS align the payment of applying a 100 sq.cm wound on the foot to the payment of applying the same 100 sq.cm on the leg.

Similarly the Alliance is concerned that the level of reimbursement is not adequate when CTP products - whether designated as "high cost" or "low cost" - are used to treat large wounds (wounds equal to and greater than 100 sq.cm in area). As a result, facilities have to make the choice of losing money when treating patients with large wounds or treating the patient with insufficient amounts of CTP products to treat the wound effectively. Case in point, we are aware that a CTP manufacturer is encouraging facilities to use a small amount of a CTP in a large wound in order for the facility to continue to use their product and not lose money in the process. This is not right when a facility has to make the choice to either lose money or not be able to treat their patients effectively. This is a direct result of the issues raised above – the claims data is not accurate and we believe CMS is not doing anything to ensure that the data is correct – either by implementing edits or issuing a MEDLearn Matters article for correct billing of these products. The Alliance urges CMS to review the 2015 claims data to ensure that claims for large wound procedures include 100 or more units of CTP products. We believe that CMS will find that on a majority of the claims the facilities did not accurately report this data and as such the payment rate has been skewed and does not accurately reflect the true cost of the products used in these procedures.

Finally, many of our members would like to utilize "low cost" CTP products assigned to the Level 3

Skin Procedures APC (5053). However, their facilities are losing money on these products. Providers who are using the low cost CTPs (codes C5271, C5275, C5277) within APC 5053 are losing approximately $150-$350 per treatment session. As such, facilities are instructing clinicians to utilize "high cost" products. In 2014, the Alliance's primary objection to packaged pricing was that it would force clinicians to make treatment decisions based on reimbursement rather than on the basis of what product might be the most clinically effective for a given wound in a given patient. The objection raised is currently taking place as CMS has not matched resource expenditures and the true cost of the products with the payment rates established in APC 5053. To remedy this problem, the Alliance recommends that CMS remove the low cost CTPs from APC 5053 and create a new APC for the application of low cost CTPs (codes C5271, C5275, C5277). By creating a new APC for these "low cost" CTPs, CMS will eliminate the financial incentive to utilize "high cost" CTPs which are included in the same APC. This will allow clinicians to make treatment decisions based on the most clinically effective product to treat their patients.

Provider Based Issues

The Bipartisan Budget Act of 2015, and specifically Section 603, changes the payment rules applicable to off-campus, provider-based locations that are new as of November 2, 2015. More specifically, Section 603 specifies that off-campus sites that had not furnished services and submitted to Medicare "provider-based" billings as of November 1, 2015, will be considered "new" and, effective January 1, 2017, will no longer be able to bill Medicare under the Outpatient Prospective Payment System (OPPS). Congress specified that, effective January 1, 2017 Medicare instead will pay these sites for services as though they were free-standing locations under the Medicare physician fee schedule.

The off campus sites that have furnished services and submitted to Medicare "provider based" billings prior to November 1, 2015 are grandfathered (or exempted) according to the proposed rule. Yet CMS has further proposed that off-campus departments and the items and services that they furnish will be considered "new" if that department "moves or relocates from the physical address that was listed on the provider's hospital enrollment form as of November 1, 2015 or if they do not offer the same services. The Alliance questions this definition of new providers as we believe that CMS has once again gone beyond the statutory intent. Congress did not intend for providers to be considered new if they had already furnished services and submitted to Medicare "provider-based" billings prior to November 1, 2015 regardless of whether they changes or relocated.

A straightforward reading of the statute requires that an off-campus provider based department that billed any covered outpatient hospital service prior to November 2015 may continue to bill for any covered outpatient hospital service. CMS does not cite any specific provision of Section 603 that supports its interpretation and even acknowledges that there is no legislative history from which it can determine Congressional intent. The Alliance recommends that CMS restructure this provision so that it is in line with Congressional intent – that is that an off campus provider based department that billed any covered outpatient hospital service prior to November 2015 continues to bill Medicare under the outpatient prospective payment system regardless of whether it has relocated or started to offer new services.

Status Indicator Q1

CMS has proposed to assign the Q1 status indicator to many procedures within this proposal. The Alliance will only comment on one of them – Noncontact Low Frequency Ultrasound (NLFU). The Alliance submitted comments last year when CMS assigned this status indicator to this procedure. At that time, and we continue to maintain, that this status indicator is incorrect as it inappropriately characterizes this independent service as an "ancillary service" and bundles payment for this procedure with S, T, and V services. The status indicator for this APC and the CPT code that describes NLFU Therapy, 94610, must revert to the "T" status indicator previously assigned to it. CMS guidance has made clear that Status Indicator Q1 is assigned only to ancillary services, which include "minor diagnostic tests and procedures that are often performed with a primary service."

We submit that the CPT Code 97610 is a primary service, not an ancillary service, per the definitive guidance on this code from the American Medical Association ("AMA"). First of all, the CPT descriptor of the service includes not only the NLFU Therapy itself, but also wound assessment and instructions for ongoing care, encompassing the full scope of required practitioner services related to providing NLFU Therapy. In addition, guidance from the AMA in the June 2014 CPT Assistant clearly describes this service as a standalone procedure. The clinical vignette included therein notes that the service described by 97610 includes "careful wound assessment, measurement, and photography" before cleansing the wound and surrounding tissue. A qualified health care professional must be in "continuous attendance" during the provision of NLFU Therapy, and at its conclusion, performs an additional assessment of the wound bed and surrounding tissue and applies an appropriate dressing. Even more compelling, the AMA states that debridement services and NLFU Therapy "represent different interventions using different medical equipment with distinctly different clinical outcomes," suggesting that one service is not ancillary to another. CMS attributing Status Indicator Q1 to 97610 would directly contradict the guidance from the AMA and the limits on CMS's authority to package services as "ancillary" by associating NLFU Therapy with a "primary" debridement procedure.

In addition to the clear clinical guidance demonstrating that NLFU Therapy is not an ancillary service, the cost data provided by CMS in the Proposed Rule confirms that NLFU Therapy is an independent service. First, as a matter of practice, the CMS data show that providers frequently perform NLFU Therapy as a standalone, independent procedure, with greater than half of the 12,091 procedures coded with CPT 97610 being billed as single claims with no associated service. Second, neither the APC 5051 nor CPT code 97610 meets the Geometric Mean Cost ("GMC") criteria CMS established to define "ancillary services." On the theory that low-cost procedures are more likely to be ancillary than higher-cost procedures, CMS limited APCs containing conditionally packaged services to those APCs with a proposed GMC of less than or equal to $100. GMC cost data shows that the GMC for LCU is $149.78 – which exceeds this $100 threshold. By assigning the Q1 status indicator to this APC, CMS is arbitrarily packaging services like NLFU Therapy that are not ancillary services and do not meet the cost thresholds established by CMS. To avoid the inconsistent and arbitrary application of its definition of "ancillary services," the Alliance recommends that CPT code 97610—an independent clinical procedure that exceeds the cost thresholds for ancillary services—does not receive a Q1 status indicator rather it should be assigned to status indicator T.

Conditional Packaging

The Alliance is concerned that CMS has expanded conditional packaging for all procedures with Q1 and Q2 status indicators without any regard to whether those procedures have any clinical and/or expense overlap. CMS should ensure that the procedures are ancillary, adjunctive, or integral to another service on a case-by-case basis and not categorically expand conditional packaging for all procedures without any regard to whether or how the procedures may overlap. Moreover, it appears that CMS is conditionally packaging all procedures with status indicator Q1 and Q2 based on the services that are billed on the same claim form. The Alliance does not agree with this method. It is not uncommon for a patient to receive treatment at an outpatient wound care center in which multiple weekly visits - which occur during different outpatient stays - are billed by the facility on the same claim form with different dates of service being represented on the claim form. As such, the Alliance requests that CMS provide clarification that with regard to its conditional packaging policy in that procedures/services will only be packaged when they are provided during the same stay and NOT when the procedures/services are billed on the same claim form.

Conclusion

The Alliance appreciates the opportunity to provide you with our comments. If the Agency needs further information or has any questions, please do not hesitate to contact me.

Sincerely,

Marcia Nusgart
Executive Director