COALITION OF

# Wound Care Manufacturers

August 29, 2014

Marilyn Tavenner
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–1614–P
Mail Stop C4–26–05
7500 Security Boulevard
Baltimore, MD 21244–1850

RE: CMS-1614-P: CY 2015 End-Stage Renal Disease (ESRD) Prospective Payment System (PPS) and Durable Medical Equipment Prosthetics, Orthotics, and Supplies (DMEPOS) Proposed Rule.

Dear Administrator Tavenner:

On behalf of the Coalition of Wound Care Manufacturers ("Coalition"), I am pleased to submit the following comments in response to the methodology for adjusting Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) fee schedule payment amounts using information from the Medicare DMEPOS Competitive Bidding Program (CBP); The Coalition represents leading manufacturers of wound care products used by Medicare beneficiaries for the treatment of wounds including those products that are subject to the competitive bidding program. Since our members have a vested interest in the provision of quality, coverage and payment of Negative Pressure Wound Therapy, this regulation is of interest and concern to us. The Coalition appreciates the opportunity to offer our comments.

## General Comments

The Coalition is completely opposed to both CMS adjusting payment amounts based on information obtained from the competitive bidding program and to bundling payments for DMEPOS. The current system is flawed and the payment amounts used in the current competitive bidding program cannot and should not be used in any other way as they are skewed and inaccurate. The Coalition also questions whether CMS has the statutory authority to implement such a proposal and would recommend that a legitimate impact analysis be conducted prior to any changes being made. Making broad statements about the impact does not give the type of attention that this issue deserves. The flaws in the competitive bidding program have been widely acknowledged by experts. Their findings have unanimously found that the system is flawed and more specifically, that key design features systemically skew bid pricing downward and as a result the SPAs are inaccurate and unreliable.

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## ***Impact Analysis***

The Coalition is concerned that CMS has not seriously analyzed the impact of the competitive bidding program. There continues to be significant issues with that program, including but not limited to unintended consequences in rural areas, beneficiaries' inability to easily change providers, and increased time in the hospital due to delays in discharge in order for appropriate equipment to be secured by multiple vendors. In addition, CMS has not been doing an adequate job vetting the vendors that are chosen in the competitive bidding program, or taking steps to ensure quality standards are implemented or quality products are delivered. The Agency also does not have a mechanism in place to ensure that vendors are providing quality service or maintenance, adequately monitoring access to products with the current existing program as well as how the program is disrupting patient care. It is not a transparent system and it is flawed; yet, CMS seems to be blinded to the success of the program, often ignoring such aspects as beneficiary access and quality of patient care.

Competitive bidding has already impacted discharge planning from acute care facilities. In these settings, discharge planners have to contact upwards of 3-4 suppliers per beneficiary prior to discharge to ensure that the beneficiary has appropriate DMEPOS. Often times, this process delays the discharge up to 48 hours with some vendors refusing to provide product to the beneficiary unless ALL products are being provided by that vendor. However, that vendor may not have been vetted appropriately by CMS and is unable to provide all the maintenance and service that the beneficiary may need. Sometimes the beneficiary wants to use a particular vendor that does not always provide all of the products that the beneficiary requires. There are multiple layers that often need to be considered before a vendor is chosen for a particular beneficiary. Yet, this all delays the discharge of that patient, and CMS has not provided any oversight or investigations into these types of scenarios.

The Coalition urges CMS to listen to beneficiaries and clinicians as they describe the problem that competitive bidding has created for them, conduct a proper impact analysis and then fix the flaws in the current system before moving forward with any type of bundled payment in the DMEPOS arena.

## ***Statutory Authority***

To our knowledge, CMS does not have the authority to develop a new bundled payment system for DMEPOS competitive bidding. CMS states that section 1847 of the Medicare law provides the agency "with flexibility and discretion with regard to the payment rules for items furnished under competitive bidding programs." Yet, Section 1847 refers only to "items and services," or "particular" items and services, not bundles of such items and services. CMS's authority under 1847 is limited to establishing payment amounts for DME or enteral nutrition using competitive bidding – not bundling.

Furthermore, Section 1834 of the Medicare law is the basis of payment for the items and services described in Section 1847. That section states that the use of the single payment amount derived through competitive bidding in a competitive bidding area is the payment basis for the item or service in

that competitive bidding area. In neither section does Congress intend for the products to be bundled or have pricing extend outside of the competitive bid area.

In reviewing section 1847 as well as 1843, the Coalition sees no evidence that Congress authorized or intended CMS to apply a bundled payment arrangement under the DMEPOS competitive bidding program. While CMS has clear authority to **select** among items and services for various competitive bidding purposes, we see no explicit authority to **bundle** those items and services on a monthly or other basis and are opposed to CMS doing so. The Coalition is opposed to the bundling of items and services under the competitive bidding program and in reviewing the statutes does not believe that CMS has the authority to move forward with the bundling of items and services under the competitive bidding program.

## Specific Comments

CMS has proposed to make two significant changes: 1. Applying Competitive Bid pricing to the national fee schedule and 2. Bundling of enteral nutrition and other items of DMEPOS. The Coalition is opposed to both provisions for the reasons stated below.

### *Applying Competitive Bid Pricing to the National Fee Schedule*

The Coalition urges CMS not to apply the competitive bid amounts for the national fee schedule for items that have not yet been included in competitive bidding. There is simply not enough data to support this type of adjustment and what it would do to beneficiary access to these items. CMS only has authority to apply competitive bidding pricing from the competitive bid areas to other areas of the country. It cannot make payment adjustments based on competitive bidding for items that were not competitively bid. Any items that were excluded from competitive bidding must be excluded from payment adjustments based on competitive bidding pricing. Furthermore, data from the competitive bid program is unreliable and cannot be applied to areas outside of the competitive bid area.

However, if CMS was to use single payment amounts from competitive bidding to adjust current Medicare payment amounts for beneficiaries outside of an existing CBA, we request that the Agency carefully consider the following:

- The bulk of operating costs in the provision of NPWT to home beneficiaries are labor-related (Training/Education, Administration and Service), often increasing for hard to reach patients and/or healthcare practitioners.
- Administrative costs have increased since the time of bid submission due to the rise in pre-payment audits and medical necessity documentation requirements for NPWT
- Sales and service labor and fuel costs have increased since the time of bid submission
- The cost to serve patients in less dense and remote geographic areas is higher than their urban counterparts, due to increased travel time, higher reliance on third party support, and fewer centralized training/education opportunities

- Vendors from the competitive bid programs may have been chosen and then withdrew from the competitive bid program. Their bids skewed the program as they were often low-ball bids. CMS has never taken this into consideration

CMS recognizes operational cost differences between rural and urban areas under other payment systems which include add on payments to reconcile the factors that contribute to the differences in costs. As such, the Coalition recommends that should CMS move forward with this proposal – they do so in a responsible way and ensure that these operational cost differences (and add ons) are established prior to this rule becoming final. The Coalition further urges CMS to refrain from using the payment amounts for items that have only recently been subjected to competitive bidding or are limited in the competitive bid areas in which they are provided as CMS does not have enough data to support the impact with barely 90 days experience with these items under competitive bidding.

## ***Bundled Payments for Enteral Nutrients, Supplies and Equipment or for Certain DME***

The methodology CMS has used for determining single payment amounts in the first few rounds of bidding to date has resulted in unreasonably low rates, largely because bidders have not had to submit binding bids and because single payment amounts have been set at the median of winning bids. This methodology also has led to bidders with little or no experience in providing a product to become winning bidders, particularly crucial for patients as the program has incorporated advanced technologies such as negative pressure wound therapy into competitive bidding. CMS has not implemented any quality standards and their oversight to ensure vendors are providing what they said they would provide has been haphazard at best.

The Coalition is opposed to CMS's proposal to bundle payments for DMEPOS and recommends that this type of proposal should not be implemented without a comprehensive analysis of the costs to furnish the equipment to chronically ill patients with progressive conditions. Patients' needs are different and they are treated differently depending on their co-morbidities. As such, in addition to different equipment needs, each beneficiary will have a different level of utilization and require higher – or lower – service intensity depending on their condition. In other Medicare programs, CMS ties payments together by bundling services and certain equipment and supplies that a beneficiary might use during an episode of care – and the payment is based on the assessment of the beneficiary's condition. However, CMS lacks any data which identify the factors that influence an individual's length of need for a specific type of equipment or aligns an individual's medical necessity for this equipment or service to the Medicare payment for those items and services or what factors may trigger their progression to the next level of equipment. In addition, the historical data that CMS might have does not factor in quality or value of the product or procedure and take into account clinical practice guidelines. CMS would need to take into account the services associated with the products to be bundled to treat the beneficiary for the specific conditions.

Moreover, this type of bundling is so complex that it is not realistic to expect CMS to implement this methodology under the DMEPOS benefit without a comprehensive analysis of the costs to furnish equipment to a chronically ill patient with a progressive condition. CMS would need to provide a

mechanism for which the suppliers could include the accessories associated with providing NPWT that currently are not covered at this point in time.

Unlike the home health or the skilled nursing facility (SNF) prospective payment systems (PPS), this proposal lacks any mechanism to tie the medical needs of the patient to the payment for the items and services he or she needs. The PPS methodology relies on a comprehensive patient assessment to determine the care and intensity of the services a beneficiary will use. The home health and SNF PPS also include factors for adjusting payment amounts to account for individuals who require more or less care than typical patients with similar conditions. Finally, the PPS methodology takes into account geographic variations in the costs relevant to a SNF or home health agency and adjusts the episodic payment accordingly.

Furthermore, in other program areas, CMS has identified quality standards or measures that were required to be met as part of the payment. This has been an important concern for the Coalition in the area of competitive bidding and in fact we advocated for more stringent guidelines to ensure that suppliers who were awarded bid contracts were qualified to furnish NPWT both in, and out, of competitive bidding. The Coalition and the Alliance of Wound Care Stakeholders presented these guidelines and accreditation checklist to CMS. At that time, CMS officials agreed that contracts would only be awarded to suppliers that met the Medicare quality standards and that are accredited specifically for furnishing covered NPWT items and services under the competitive bidding program. However, vendors that have been chosen as contract suppliers not only did not meet the quality standards – they were not accredited, nor have they ever provided NPWT in the past. These are the types of issues that do not lend themselves well for moving forward with bundled payment.

The Coalition urges CMS that in order for meaningful and efficient bundling to move forward in this space, CMS will need to significantly revise the current HCPCS coding process. The current HCPCS code set includes broadly defined codes that are often ambiguous and imprecise, resulting in dissimilar products and technologies being lumped into the same code. This creates situations where CMS does not really know what it is paying for, which raises serious concerns about program integrity. The use of codes that are not sufficiently granular to describe the items and related services being provided leads to imprecise payments and, perhaps more importantly, barriers to access of medically necessary devices and technologies. Unless HCPCS codes identify homogeneous items and services – it is impossible to measure actual clinical outcomes data at the code level. This creates insurmountable barriers and impedes the ability of Medicare and other payers to effectively use claims data to inform payment decisions, such as the appropriate bundle as suggested in this advanced notice of proposed rulemaking. In short, inaccurate coding that does not adequately describe the product or device results in groupings of heterogeneous products, prevents the ability to evaluate data to develop a meaningful and accurate bundle which in turn increases opportunities for abuse of Medicare and other health care programs.

Unless there are adequate codes developed to distinguish new technologies entering the market, the use of existing product categories' single payment amounts will not reflect the costs of resources needed for these new technologies. Beneficiaries, as a result, will not be able to access such new technologies. Beneficiaries should be able to rely on program policies to provide access otherwise available to patients

with other third party payer coverage, at a minimum.

Finally, it is our opinion that CMS has provided very little specific information regarding the process by which CMS plans to administer this new bundled program and as such afforded the public little opportunity to provide meaningful comments. The Administrative Procedures Act (APA) requires CMS to give public notice and comment on proposed rules. However, providing an outline of the bundling program with little specific information on this new program does not meet the requirements of the APA. Until CMS can provide specific information regarding how bids are evaluated, how bids are selected, how the payment amount is determined and what is included in the bundle, with the appropriate public notice and comment period, the Coalition recommends that CMS not move forward in implementing the bundling proposal.

## ***Selection of CBAs for Bundling Demonstration***

CMS has proposed to implement a bundling demonstration project in 12 CBAs and will roll out another 12 comparator CBAs in order to assess the effect of bundling. However CMS has not provided any information on the 12 CBAs or comparator CBAs in terms of how they will be selected. The Coalition recommends that before CMS moves forward with this demonstration, they identify how the CBAs will be selected and what the criteria are. This information needs to be provided in a fashion that allows for appropriate public notice and comment.

## ***Conclusion***

The Coalition is opposed to both the proposal to establish a fee schedule using the average regional SPA amount for an item subject to national payment ceilings and floors as well as to establish competitive bidding programs using bundling of equipment, services and supplies for enteral products and DME. CMS should conduct an appropriate impact analysis before moving forward with any of the proposals set forth in this proposed rule. Since we believe that the competitive bidding program is flawed, it would be irresponsible for CMS to expand it by using single payment amounts to adjust Medicare reimbursement outside of the competitive bidding areas. CMS should develop a mechanism for obtaining and analyzing crucial data needed for informing bid amounts or bid evaluation before attempting a bundling program.

If CMS decides to pursue the bundling concept, then CMS should implement a limited demonstration project. In addition, CMS must:

1. Review current HCPCS codes for items being considered for a bundling program. The items in any HCPCS code must be homogeneous and the code definition must identify and require the key features of the technology that matches with the coverage policy for that code. In addition, if codes for accessories are being bundled with a HCPCS code, it will be necessary to retain the HCPCS codes for the accessories for billing replacements and repairs.
2. Form a HCPCS Advisory panel, inclusive of all stakeholder groups, to review current high use HCPCS codes and any HCPCS codes being considered for a bundling program to analyze and recommend HCPCS coding changes to ensure appropriate access and payment of technology.

3. Allow for appropriate public notice and comment.

The Coalition appreciates the opportunity to provide our comments. We hope that CMS will work with stakeholders to ensure a more equitable and transparent process should they move forward. If you need more information or have any questions, please do not hesitate to contact me.

Sincerely,

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