COALITION OF
Wound
Care
Manufacturers

March 28, 2014

Marilyn Tavenner
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1460-ANPRM
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Submitted Electronically

RE: **CMS-1460-ANPRM:** Medicare Program; Methodology for Adjusting Payment Amounts for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) using Information from Competitive Bidding Programs

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 Proposed Methodology for Adjusting Payment Amounts for Certain Durable Medical Equipment Prosthetics Orthotics and Supplies using Information from Competitive Bidding Programs. 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 an impact analysis be conducted prior to any changes being made.

Impact Analysis

The Coalition is concerned that CMS has not 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

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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.

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

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.

Specific Comments

While there were several questions posed by CMS for comment, the Coalition will only be commenting on the following questions:

Do the costs of furnishing various DMEPOS items and services vary based on the geographic area in which they are furnished?

The Coalition suggests that the costs of furnishing DMEPOS and services do in fact vary based on the geographic area in which they are furnished. CMS has already recognized this fact as all other Medicare provider payments are adjusted to reflect differences in costs that occur as a result of specific geographic location, urban/rural designation, and wages/salaries of those involved in providing service.

Wounds requiring NPWT are complex and are located in different areas of the body. The provision of NPWT is extremely labor intensive. Providers need to be trained on the appropriate way to prepare the skin, apply the dressing to maintain an appropriate seal for the negative pressure and attach and set the device. This labor needs to be factored in as well as the costs of the delivery, maintenance of the device, training etc. As labor and fuel costs have increased the costs of serving patients in less densely populated areas, as well as remote geographic areas, is higher than in urban areas due to increased travel time, higher reliance on third party support and fewer centralized training/educational opportunities.

As stated above, CMS already knows that the costs of furnishing items and services vary based on geographic areas in which they are furnished and as such any DMEPOS payments need to reflect these variations.

Should an interim or different methodology be used to adjust payment amounts for items that have not yet been included competitive bidding? For example, items such as transcutaneous electrical nerve stimulation (TENS) devices have only been phased into the nine Round 1 areas thus far.

The Coalition urges CMS not to create an interim or different methodology to adjust payment amounts 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

The Coalition 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.

Would there be any negative impacts associated with continuous 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.

It would be difficult to bundle payments for DMEPOS and this type of proposal could not – and 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.

In addition, this type of bundling would be so complex that it would not be realistic to expect 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.

Finally, 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.

Conclusion

The Coalition is opposed to both proposals. CMS should conduct an appropriate impact analysis before moving forward with any of the proposals set forth in this advanced notice of proposal rulemaking. 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.

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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