COALITION OF

Wound
Care
Manufacturers

September 9, 2018

Ms. Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1691-P
7500 Security Boulevard
Baltimore, MD 21244-1850

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

**Re: Comments on CMS-1691-P, "Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Competitive Bidding Program (CBP) and Fee Schedule Amounts, and Technical Amendments to Correct Existing Regulations Related to the CBP for Certain DMEPOS**

Dear Administrator Verma:

The Coalition of Wound Care Manufacturers ("Coalition") is submitting the following comments on the Centers for Medicare and Medicaid Services' (CMS') above captioned proposed rule. The Coalition represents leading manufacturers of wound care products used by Medicare beneficiaries for the treatment of chronic wounds including but not limited to surgical dressings, pneumatic compression devices and Negative Pressure Wound Therapy (NPWT).

We appreciate the opportunity to submit public comments on this important proposed rule and are providing our concerns, recommendations and a request to collaborate with the Agency on these issues. Our comments are organized under two of the headings of the proposed rule:

1. Section V. "Changes to the Durable Medical Equipment , Prosthetics, Orthotics and Supplies (DMEPOS) Competitive Bidding Program (CBP)"

2. Section X- "Request for Information on the Gap-filling Process for Establishing Fees for New DMEPOS"

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## Section V. "Changes to the Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Competitive Bidding Program (CBP)"

CMS believes that two proposed reforms to the DMEPOS CBP would simplify the program, eliminate the possibility for price inversions, and ensure the long-term sustainability of the program:

1. Lead Item Pricing for all Product Categories under the DMEPOS CBP, and
2. Calculation of single payment amounts (SPAs) using maximum winning bids for lead items.

The Coalition agrees that these proposals will eliminate the risk of price inversions that exist in some product categories. However, we do not believe the calculation of SPAs as a percentage of the maximum winning bid for the lead item based on 2015 fee schedule ratios is appropriate for all categories, and may result in some unintended risks, including reimbursement for non-lead item supplies well below product acquisition cost.

The net results could be:

- Disincentive for small suppliers to participate where their accessory/disposable acquisition cost is highest
- Disincentive for appropriate use of accessories/supplies where reimbursement falls below SPA.
- Loss of quality products in the market where cost may be slightly higher
- Disincentive for product improvements and innovation within a category

To mitigate this risk, we urge CMS to work with industry on the appropriate definition of product categories and development of safeguards to prevent extreme price distortions of non-lead items.

In addition, we believe that product categories must be constructed to ensure beneficiary access by grouping together related products that are generally provide together to address a beneficiary's needs. We would add that negative pressure wound therapy (NPWT) items and services deserve their own attention. In particular, it will be important for CMS to work closely with NPWT manufacturers and providers to ensure that the NPWT category fee schedule ratios do not result in irrational relative pricing for the respective HCPCS codes within this category.

Furthermore, we do not support breaking large CBAs into additional CBAs due to the burden placed on discharge planners to determine provider by patient zip code. It is a challenge for discharge planners to ensure they have equipment from a contracted supplier on hand and ready to go at time of discharge. In the largest CBAs, many hospitals will have patients from across the city/MSA, and dealing with multiple suppliers based on contract awards by patient zip code is an unnecessary burden.

The Coalition also recommends that CMS should ensure full transparency and tactics to mitigate risk in the program by doing the following:

- Ensure bona fide bidders through evaluation of historical claims data (Medicare and/or Commercial claims within the CBA state)
- Provide a capacity limitation of 20% on all bona fide bidder capacity to ensure enough suppliers as is in place today

## Section X- "Request for Information on the Gap-filling Process for Establishing Fees for New DMEPOS"

### *Concerns with Current Gap-Filling Methodology*

The proposed rule addresses the gap-filling pricing methodology, which applies when new technologies receive a new Healthcare Common Procedure Coding System (HCPCS) code by the HCPCS Coding Committee and CMS must establish a fee schedule amount for these new items or devices. The gap-filling process is designed to fill the gap in the data due to the lack of historic reasonable charge payments from the statutorily-prescribed base year of 1986-1987 (or 1992 for surgical dressings) by estimating what the historic reasonable charge payments would have been for the new technology under consideration.

To accomplish this, as stated in the 2018 instructions in Chapter 23, Section 60.3 of the CMS Claims Processing Manual:

> The DME MACs and A/B MACs Part B must gap-fill the DMEPOS fee schedule for items for which charge data were unavailable during the fee schedule data base year using the **fee schedule amounts for comparable equipment, using properly calculated fee schedule amounts from a neighboring DME MAC or A/B MAC Part B area, or using supplier price lists with prices in effect during the fee schedule data base year.**

The DME MACs and A/B MACs then deflate that amount back to 1986-1987 (or 1992 for surgical dressings) based on the annual percentage adjustment to the Consumer Price Index for Urban Consumers (CPI-U) and then re-inflate that number back to present day using the annual CPI-U "covered item update" adjustments enacted by Congress over the past thirty-one-year period. Due to several freezes and reductions in the CPI-U adjustments during this time period, the resulting fee schedule amount constitutes a significant reduction off the starting reimbursement value. In the vast majority of instances, this pricing methodology results in reimbursement levels that are woefully inadequate and do not reflect the value of the technological innovation the CMS HCPCS Workgroup has already determined functions significantly differently or provides patients with a significant therapeutic distinction from existing technology.

CMS previously sought stakeholder input on this issue in Proposed Rule CMS-1270-P in 2006. The Coalition also submitted comments at that time.

Currently, the Coalition has these concerns and recommendations regarding the above criteria that CMS and its contractors use in gap filling:

- The current reasonable price methodology and gap-filling process is a "black box" that lacks transparency, validity, reliability, and has insufficient mechanisms to obtain public input, gather appropriate data, and allow participants to appeal decisions when necessary.

- None of the methodologies used for gap-filling as stated above "**fee schedule amounts for comparable equipment, using properly calculated fee schedule amounts from a neighboring DME MAC or A/B MAC Part B area, or using supplier price lists with prices in effect during the fee schedule data base year"** are viable for many new technologies simply because the innovation is beyond anything that is contemplated in current fee schedules, other contractor fee schedules or a supplier price list from 30 years ago.

- "Comparable items"- New items that have been priced using fee schedules for comparable items have produced insufficient fee schedule amounts that deny access to important technologies. In fact, recent payment decisions by the Agency have used items CMS determined as "comparable" when in fact the items have little or no relationship in terms of cost to manufacture, technological components, or clinical application.

  This process is incongruent in that on the one hand, as noted above, the HCPCS Workgroup determines a product is significantly different from other available products (i.e. **not** comparable to products with an existing HCPCS code) thereby assigning a new code, but then looks for "comparable" products to begin the pricing/gap-fill process. The Coalition questions CMS's use of "comparable items" to establish a fee schedule for new items and believes that CMS should establish a stakeholder work group to collaborate with and provide a forum for more detailed discussion on alternatives within this very complex topic as suggested in our recommendations.

- However, if CMS believes it needs to look to "comparable items" to help establish a fee schedule for new items, then it needs to establish definitions and guidelines for using it. The Coalition believes in order for an item to be comparable to another item, both should: (1) have similar features and function, (2) be intended for the same patient population and for the same clinical indicators, and (3) be intended to fill the same medical need. For surgical dressings, they should have the same components. In other words, the items should be effectively interchangeable in order to be considered "comparable." In addition, transparency in this process is critical. Stakeholders, including providers who recommend technology, should be included in determining appropriate comparability.

- "Internet and catalog pricing"- When creating fee schedules for new HCPCS codes, CMS and its contractors have used internet pricing and catalog pricing in gap-filling fee schedules. We believe that these sources should not be included when the full array of activities and services are not included. Internet and catalog prices do not reflect the costs of the many Medicare requirements such as supplier accreditation, in-the-home assessment, beneficiary training, and documentation.

### *Statutory Constraints on Pricing Methodology*

The proposed rule seeks additional data sources and methods that could be used to estimate historic allowed charges for new technologies in the framework of the statutory requirements. However, in order to improve the pricing methodology for new technologies, the statute needs to be amended to update the reference year and make this process more reflective of today's technological environment. The current statutory and regulatory framework for gap-filling is wholly flawed and must be reformed from top to bottom. The Coalition recommends that CMS, in its Fiscal Year 2020 budget proposal, include provisions to amend the statute to update and improve CMS's pricing methodology for new DMEPOS technologies that receive a new HCPCS code.

### *Summary of Recommendations for Changes to Gap Filling Pricing Methodology*

The Coalition is in agreement with other trade associations such as NCART with the following recommendations:

- CMS should increase transparency with regards to fee schedule development.

- CMS should establish a stakeholder work group to collaborate with and provide a forum for more detailed discussion on alternatives within this very complex topic.

- Adequate payment can only be established through the gap-filling process if the past CPI freezes and cuts to the DMEPOS fee schedule are not applied when establishing fee schedules for new HCPCS codes.

- CMS include, in its Fiscal Year 2020 budget proposal, provisions to amend the statute at 42 U.S.C. §1395m to update and improve CMS's pricing methodology for new DMEPOS technologies that receive a new HCPCS code. This may include eliminating or modifying the 1987 base year requirement for payment for DMEPOS and 1992 for surgical dressings and explore alternatives within the stakeholder work group mentioned above.

- CMS should develop guidelines and definitions for determining whether an item is comparable for the purpose of assigning a fee schedule amount to a new item.

- CMS should not include internet or catalog pricing in the gap-filling process unless there is evidence that the price is being offered through a supplier that meets all Medicare criteria, and the price includes all Medicare-required services.

- To more fairly identify an appropriate median deflated price, a weighting method should be created and implemented within the gap-filling process that would factor in the existing market utilization of each product being used for pricing development.

- CMS should collaborate with stakeholders to identify information that applicants could submit with their HCPCS code application that would support their established MSRP. This information would require a confidential mechanism for it to be shared with the agency.

- CMS should develop an appeals process in situations where the manufacturer or supplier disagrees with the recommendation of a contractor or a final payment decision by CMS.

- When establishing the Medicare payment for new items, CMS must recognize all manufacturer and supplier costs that must be covered. Manufacturer costs include: Materials, Direct labor (such as manufacturing labor, engineering, and quality control), Indirect Labor (such as customer service, technical support, and human resources) and Overhead (such as building, equipment, vehicles and much more). Supplier costs include: Direct Labor, Indirect Labor (such as order intake staff, repair staff, billing staff and more), and Overhead (building, vehicles and much more).

***HCPCS Coding Decisions and New Fee Schedules Impact Patient Access to New Wound Care Technology***

- The Coalition would also notes its continuing concerns with the HCPCS coding process as applied to DMEPOS items. Before reasonable pricing methodology or gap-filling is even considered, the CMS HCPCS Workgroup decides whether a new technology performs a significantly different function, operates differently, and provides a significant therapeutic distinction compared to existing coded treatments or products. If a new technology meets this standard, then a new HCPCS code is issued and the reasonable pricing methodology or gap-filling process begins.

  However, too often, new technologies that arguably meet this standard are forced into existing HCPCS codes, or assigned to a code that is slightly revised to broaden its scope to encompass the new technology (e.g., xxxxxx, any type). In the vast majority of instances, this results in an insufficient reimbursement level that does not appropriately recognize advancements in technology and, therefore, curtails access to new innovations. This also has the effect of creating HCPCS codes that are so broad that CMS does not really know what it is paying for, which has significant implications on CMS' ability to identify overutilization and monitor and compare the outcomes of one technology verses another. This also impacts Medicare beneficiaries who may be denied access to needed DMEPOS technology.

- The Coalition is a member of the Alliance for HCPCS Coding Reform, a broad stakeholder group consisting of patient organizations, clinical specialty societies, medical device associations and companies, key law firms, lobbying firms, coalitions, and reimbursement consulting companies committed to seek improvements to the HCPCS coding process so that it is fair, transparent, predictable, accurate, understandable, timely and accountable. We urge CMS to continue to focus on this important area and improve the coding and payment processes for wound care technologies as well as the broader Medicare DMEPOS benefit.

## Conclusion

The Coalition appreciates the Agency's consideration of these comments and requests to collaborate with CMS on these important issues. We would be pleased to work with the Agency also as stated in our recommendations as part of a stakeholder work group to collaborate with and provide a forum for more detailed discussion on alternatives within this very complex topic.

Sincerely,

Marcia Nusgart R.Ph.

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Executive Director