COALITION OF

Wound Care Manufacturers

September 27, 2019

Via Electronic Delivery at http://www.regulations.gov

Ms. Seema Verma
Administrator
Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-1713-P,
P.O. Box 8010
Baltimore, MD 21244-8010

Re: Proposed Rule CMS-1713-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) Fee Schedule Amounts, DMEPOS Competitive Bidding (CBP) Proposed Amendments, Standard Elements for a DMEPOS Order, and Master List of DMEPOS Items Potentially Subject to a Face-to-Face Encounter and Written Order Prior to Delivery and/or Prior Authorization Requirements

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). The focus of our comments is in the following section: **V. Establishing Payment Amounts for New Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Items and Services (Gap-filling)**

We acknowledge the importance of this proposed rule especially the elements regarding pricing of DMEPOS. We have been on the record when CMS requested comments on gap-filling both in 2018 (Proposed Rule CMS-1691-P) and in 2006 (Proposed Rule CMS-1270-P). Our key comments then about our concerns with gap-filling unfortunately are just as relevant to this current proposed rule.

CMS has placed fostering innovation as one of its 16 strategic initiatives in its 2020 strategic plan in order to transform the health care system to deliver better value and results for patients and specifically stating that the Agency will:

- Ensure beneficiaries have access to the latest medical innovations and remove barriers to support unleashing innovation across our healthcare system
- Optimize coverage coding, coding and payment policy for new medical technologies

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The Coalition supports the need to establish a more appropriate methodology to determine payment for new HCPCS codes including those created for new technology. Unfortunately, CMS's recommendations in this proposed rule are in direct contrast to the Agency initiative of fostering innovation. Therefore, we recommend that the Agency should not move forward with a final rule on payment methodologies for DMEPOS until further work is completed. CMS should work with stakeholder groups related to various technologies (including manufacturers) as well as engaging experts outside of CMS in developing and evaluating payment methodologies to ensure that the agency has a sufficient understanding of all costs associated with the provision of the various types of technology classified under the DMEPOS benefit. We want to ensure that whatever proposals CMS puts in place will allow a fee schedule that will allow access of wound care products to Medicare beneficiaries and allow for innovation by manufacturers.

Finally, anyone with experience with Medicare's DMEPOS coding, coverage and payment processes knows the frustrations with the current system. Coding applications—let alone, approvals—for new wound care products along with other DMEPOS are at an all-time low. The trend is for innovators and manufacturers to create new technologies to fit existing HCPCS coding descriptors—instead of thinking more creatively—so they can avoid the unpredictable HCPCS coding, coverage and payment process. Clinical researchers, manufacturers, and innovators must have the ability to forecast and realize a reasonable return on investment or they will simply move to other areas of medicine, health care, or other fields to apply their talents. As a result, Medicare beneficiaries will not be able to benefit in having these innovative technologies and unfortunately, this DMEPOS rule does little to improve this trend.

We are providing both our concerns and recommendations below.

EXECUTIVE SUMMARY

The following is a summary listing of our primary issues and comments. Further below in the letter we provide additional details and proposed solutions:

- *CMS should not move forward with a final rule on payment methodologies for DMEPOS until further work is completed.*
- *CMS should work with stakeholder groups related to various technologies as well as experts outside of CMS to ensure that the agency has a sufficient understanding of all costs associated with the provision of wound care products and other various types of technology classified under the DMEPOS benefit.*
- *The Medicare "gap filling" payment determination methodology must be replaced as it is archaic, and does not result in reimbursement rates that allow access to medically necessary technology.*
- *Fee schedules developed through comparable technology or technology assessments should be transparent and should include manufacturer's input to ensure a thorough understanding of all associated costs.*
- *CMS should institute an efficient and expeditious appeals process for manufacturers to challenge reimbursement levels established by this new pricing methodology and gap filling.*
- *The HCPCS public meeting should be limited to input on HCPCS codes, which are universal and, as such, should be focused on the needs of all payers.*

SPECIFIC COMMENTS

Calculating Fee Schedule Amounts for DMEPOS Items and Services.

CMS Proposal:

CMS is proposing that if a new code is added, CMS or contractors would determine the fee schedule in one of the following ways:

1) Cross-walking from an old code to a new code: If there is a fee schedule pricing history, the previous fee schedule amounts for the old code(s) would be associated with, or cross walked to the new code(s), to ensure continuity of pricing.

2) When the code for an item is divided into several codes for the components of that item, the total of the separate fee schedule amounts established for the components would not be higher than the fee schedule amount for the original item.

3) When there is a single code that describes two or more distinct complete items (for example, two different but related or similar items), and separate codes are subsequently established for each item, the fee schedule amounts the fee schedule amounts for the new code would be established by adding the fee schedule amounts used for the components

4) When the codes for several different items are combined into a single code, the fee schedule amounts for the new code would be established using the average (arithmetic mean), weighted by allowed services, of the fee schedule amounts for the formerly separate code.

Concerns and Recommendations:

DMEPOS manufacturers have made numerous attempts to obtain HCPCS codes that reflect homogeneous technologies. The proposals submitted to CMS have delineated products based on features and function of the technology as well as the clinical indicators for use and intended patient populations. To date, CMS has responded that the current coding structures are working by changing the descriptor of an existing code to include "any type". Unfortunately by doing so, it groups heterogeneous technologies without recalculating the fee schedule to reflect the inclusion of higher featured technologies. The focus has been to group products based on the lowest common denominator. The failure to recognize the additional features and functions or the cost to provide those, results in a barrier to access.

If the need to create a new HCPCS code is due to the mix of disparate products in the original code, CMS should initially analyze MSRP for the items being moved out of the existing code to determine whether merely cross-walking an existing code will allow appropriate access. CMS should consider factors that impact the costs to provide a product within the new code such as:

a) Feature and function differences
b) Clinical application and intended user population- in order to directly cross walk payment the items should have similar clinical indicators and should essentially be interchangeable.
c) In addition, CMS needs to take into consideration the service/delivery costs. For items to be grouped together for pricing, they should be the same or similar in terms of service/delivery costs.

d) Determine whether the pricing for the products being moved out of the original code were used to establish the original fee schedule. In many cases, the CMS workgroup has modified code descriptors to allow new technology to be grouped into existing HCPCS codes. The fee schedule is not routinely adjusted when definitions, descriptors or code requirements change.

As stated above, CMS should complete an initial analysis of the MSRP for each item before applying historic fee schedule information that may be flawed**. Most importantly, we recommend that CMS contact the manufacturer to give input and provide information to the Agency if the Agency does not believe that the new HCPCS code should not be paid at the fee schedule amount of the older HCPCS code.**

Gap-Filling Provisions

Summary of CMS proposal in this section:

- CMS proposes that if a HCPCS code is new and describes items and services that do not have a fee schedule pricing history:
    - the fee schedule amounts for the new code would be established whenever possible using fees for comparable items with existing fee schedule amounts. The Agency proposes that items with existing fee schedule amounts are determined to be comparable to the new items and services based on a comparison of: physical components; mechanical components; electrical components; function and intended use; and additional attributes and features.
- If there are no items with existing fee schedule amounts that are comparable to the items and services under the new code, the fee schedule amounts for the new code would be established using supplier or commercial price lists or technology assessments if supplier or commercial price lists are not available or verifiable or do not appear to represent a reasonable relative difference in supplier costs of furnishing the new DMEPOS item relative to the supplier costs of furnishing DMEPOS items from the fee schedule base period.

Coalition Concerns and Recommendations for each proposal:

The Coalition has been on the record that the current statutory and regulatory framework for gap-filling is out of date, wholly flawed and must be reformed from top to bottom. We submit that CMS must replace, not build upon, the current gap filling methodology it uses to calculate the payment rate for new and updated HCPCS codes.

Although it is required by Medicare statute, the 1986-87 base year for DMEPOS and 1992 as the base year for surgical dressings is outdated and must be corrected since using these base years have resulted in reimbursement levels that are terribly inadequate. While this methodology may have made sense during that time frame, it makes little sense today. By CMS using this statutory base year, it provides a double hit on reimbursement on providers and manufacturers. When CMS uses both reimbursement levels of comparable products that existed in 1986-'87 (or 1992) and then deflates the selected price for a new code back to 1986-'87, (or 1992) that serves as a double whammy on providers and manufacturers. The deflation/re-inflation aspect of the gap-filling process is outdated and unreliable as a mechanism for innovators of, and investors in, new DMEPOS and specifically wound care technologies to forecast the anticipated reimbursement level for their new items and technologies. As a result, investment in DMEPOS research and development suffers, to the detriment of patients in need of wound care products as well as other DMEPOS.

We recommend that in order for the Agency to develop a more robust reimbursement calculation procedure, CMS should collaborate with stakeholders to develop an alternative to this current methodology.

Until CMS takes this step, the Agency should gap-fill as the primary methodology and only use "comparable" products or technology assessments to establish payment where there is reliable and justifiable evidence that applying the gap-fill method would result in grossly inappropriate fee schedule rates.

If and when the Agency does decide to create a fee schedule using comparable technology or technology assessments, the process should be transparent and should include input from the manufacturer to ensure a thorough understanding of all associated costs and also to explain why there are similarities or differences to existing codes. In addition, the Agency should also institute an efficient and expeditious appeals process for manufacturers to challenge the reimbursement levels established by the new pricing methodology and gap-filling process.

While we believe these proposals are a first step by the Agency in addressing this issue, the Coalition has the following concerns and recommendations for each of the CMS proposals:

1. **Assigning fee schedule from comparable products**- CMS has proposed to establish a set framework and basis for identifying comparable items in regulation. In the proposed rule, CMS identified five main categories upon which new DMEPOS items can be compared to older DMEPOS items: physical components; mechanical components; electrical components (if applicable); function and intended use; and additional attributes and features.

   Coalition concerns:

   While CMS means to provide clarity to describe comparable items, the Coalition has concerns that these categories are so broad and comprehensive that these factors could have been used to tie a new technology to an item or product that was available years ago and give a new technology a payment amount that effectively denies Medicare beneficiaries access to it. With such a broad set of factors that CMS will take into consideration, it will have authority to do whatever it wishes to do, without any recourse or appeal for manufacturers of that new technology.

   In addition, we are concerned that simply because a new device has "same or similar" attributes does not mean the product or its costs is equivalent to another product. We submit that for the products to be deemed "comparable**" they need to be comparable in all five categories not just one.** Moreover, as we stated in our 2018 comments on this same issue:

   > *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.*

In addition, while CMS has identified key attributes in five categories, we have concerns that there may be no predictability in terms of how these attributes will be assessed.

While CMS does list out function and intended use as part of the assessment, the Agency has not demonstrated that there is a willingness to create new codes in order to develop payment that will ensure that Medicare beneficiaries can obtain the technology they require. This is a fundamental flaw in Medicare payment today and the provisions within this proposed rule further expands this problem.

2. **Supplier or commercial price lists will be used to establish fee schedule** amounts for items and services without a fee schedule pricing history described by new HCPCS codes that are not comparable to items and services with existing fee schedule amounts. CMS states that it will use supplier price lists, including catalogs and other retail price lists (such as internet retail prices) that provide information on commercial pricing for the item. Potential appropriate sources for such commercial pricing information can also include payments made by Medicare Advantage plans, as well as verifiable information from supplier invoices and non-Medicare payer data. In 2015, CMS clarified to the DMEMACs that manufacturer's suggested retail prices (MSRP) should not be used for gap-filling due to CMS's concerns that MSRPs may not represent routinely available supplies price lists, which are incorporated for supplier charges in calculating fee schedule amounts that the statute mandates be based on historic reasonable charges. (pg. 149).

Coalition concerns:

Use of internet retail prices

We have concerns with CMS using internet retail prices since the sources are unreliable, the products may not be either the same version for comparison's sake and that the products may be diverted merchandise or fakes. The DMEPOS Quality Standards require providers to verify, authenticate, and document that "products" delivered to the end user have not been "adulterated, counterfeit, suspected of being counterfeit, and have not been obtained by fraud or deceit." (Medicare Final DMEPOS Quality Standards, Section I, F, Effective January 9, 2018.) There is no way to verify, simply by perusing the internet, whether items and products may be comparable to new DMEPOS technologies. If providers and suppliers are required under the quality standards to meet this standard, then CMS itself should not rely on products off the internet to set reimbursement levels for new technologies that very well may fail this same test.

Use of Supplier Invoices and MSRP

We believe that both supplier invoices and MSRP should be used by CMS as viable and important reference points for the Agency to consider when conducting its gap-filling analysis. While we recognize the concern that there may be potential inflation of MSRP when new products are introduced in the marketplace, but we maintain that CMS should still consider MSRP as a data point in its analysis. MSRP is a long-standing manufacturer's convention that is not irrelevant when determining a reimbursement level for a new technology and should continue to be considered and tempered by other data points involving pricing.

Other viable reference points may include invoices across care settings (hospitals, SNFs, OPPS), and manufacturer data on ASP.

3. **Technology Assessment for determining prices**- Finally, when commercial pricing data is not available, unverifiable, or insufficient to determine fee schedule amounts, CMS proposes to

utilize technology assessments (either internally or by contracting with outside companies) analyzing samples of the product(s) as well as older items to determine relative supplier costs of furnishing the item.

Coalition Concerns

The Coalition believes the payment methodology CMS proposes when items are subject to a technology assessment fails to account for significant changes in manufacturing processes, and other indirect costs associated with wound care products. Examples of these higher costs relate to direct labor (manufacturing, labor, engineering and quality control) and indirect labor (customer service, technical support, and human resources), overhead (such as the building, equipment, vehicles) material and equipment, taxes, and shipping costs. Additionally, there have been legislative and regulatory changes that impact the cost of manufacturing medical devices, such as, but not limited to, demonstrating compliance with current and future statutory and regulatory requirements associated with environmental performance. There are also supplier costs which include shipping, repairs, claims processing, administrative, collection, delivery and patient training.

The Coalition also maintains that if CMS uses contractors to conduct these technology assessments, there should be specific requirements to ensure each contractor has particular expertise in the subject matter area under review and that they seek robust public input before rendering decisions or conclusions.

4. **CMS proposes to perform a one-time adjustment by conducting gap-filling a second time if prices drop notably.**
Specifically, if the **supplier or commercial prices** used to establish fee schedule amounts for a new item decrease by *any amount* below 15 percent within 5 years of establishing the initial fee schedule amounts, and the amounts calculated using the new prices would be no more than 15 percent lower than the initial amounts, CMS would conduct a second round of gap-filling. In other words, if the IR process is not triggered by supplier and commercial prices for a particular item or service, **CMS is empowering itself to use a second gap-filling process to reduce prices, as long as the decrease is less than 15%.**

Coalition concerns:

CMS offers no rationale for this assertion and, in fact, it is completely plausible that this new process will result in chronically and unrealistically low reimbursement levels with little due process for providers and manufacturers.

When the prices are deflated to the 1986/87 base period (or 1992 for surgical dressings) and then re-inflated to the current day, the final fee schedule amount is often inadequate to allow access. This is due to a decade or more of fee schedule freezes, reductions in the CPI-U, (such as Productivity Adjustment and sequestration adjustments) and fee schedule reductions which are reflected in the gap-filling formula.

Public Consultation and Stakeholder Input

In its proposed rule, CMS suggested that the "public meetings for preliminary coding and payment determinations could be used to obtain public consultation on gap-filling issues such as the comparability of new items versus older items, the relative cost of new items versus older items and additional information on the pricing of new DMEPOS items."

We disagree in that the HCPCS public meeting should be limited to input solely on HCPCS codes. Currently, the HCPCS application submitter only has 15 minutes of time as the primary speaker and secondary speakers are only allowed 5 minutes. Therefore, there would not be time to adequately address these issues. Moreover, this information regarding pricing would be proprietary and confidential and not appropriate for a public discussion. The HCPCS Public meetings are an inadequate and inappropriate process for providing meaningful input regarding Medicare fee schedule rates. CMS should consider allowing HCPCS code applicants to provide information to support payment determination at the time of submission and additional pricing information during the HCPCS determination process.

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.

Marcia Nusgart R.Ph.
Executive Director