National Coalition For Assistive & Rehab Technology

September 27, 2019

Delivered electronically at http://www.regulations.gov

Administrator Seema Verma
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 following comments regarding Proposed Rule CMS-1713-P are submitted on behalf of the National Coalition for Assistive and Rehab Technology (NCART). NCART is a national association of suppliers and manufacturers of Complex Rehab Technology (CRT) products.

Our manufacturer members have decades of experience leading the development of CRT products designed to address the significant medical and functional needs of people with disabilities and are recognized industry leaders. Our supplier members operate over 350 accredited Medicare supplier locations across the country, collectively providing high quality products and critical support services to hundreds of thousands of Medicare beneficiaries in their communities.

NCART's mission is to ensure individuals with significant disabilities such as ALS, cerebral palsy, multiple sclerosis, muscular dystrophy, and spinal cord injuries have adequate access to the CRT products and related services that address their identified needs. CRT products include medically necessary and individually configured manual and power wheelchairs, seating and positioning systems, and other adaptive equipment. The proper provision of this specialized equipment requires evaluation, configuration, fitting, adjustment, and programming. Once delivered, these items need to be supported with ongoing adjustments, modifications, and maintenance.

Executive Overview

NCART appreciates the opportunity to provide comments and recommendations on this critical Proposed Rule. Our comments and recommendations relate to two sections: (a) "Section V. Establishing

Payment Amounts for New Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Items and Services (Gap-filling)" and (b) "Section VI. Standard Elements for a Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Order; Master List of DMEPOS Items Potentially Subject to a Face-to-Face Encounter and Written Order Prior to Delivery and/or Prior Authorization Requirements".

We have significant concerns with certain provisions and the negative impact they will have on (a) decreasing beneficiary access to quality CRT products and services, (b) reducing the availability of the specialized technology that they depend on, and (c) discouraging investment in research and development in this area. These negative consequences would result in undermining the availability and future development of products that play a major role in helping to reduce the costs of healthcare.

NCART supports the need to establish a more appropriate methodology to determine payment for new DME HCPCS codes, including those created for new technology. Unfortunately, the methodologies CMS has proposed seem primarily focused on minimizing reimbursement by using a budget neutral approach and comparisons to older technology. We believe that CMS should have the goal of ensuring access to medically necessary technology, promoting innovation that improves beneficiary outcomes, and reducing overall healthcare costs.

We encourage CMS to pause its efforts to institute alternative methodologies for establishing payment amounts for new DMEPOS. We strongly recommend that prior to publishing a final rule the agency work with industry representatives and engage experts in developing and evaluating payment methodologies.

Our detailed comments and recommendations are presented in subsequent sections. The following is provided as an Executive Overview:

1.) The establishment of a proper policy to establish payment amounts for new DME items is a critical CMS responsibility. The policy has broad impact on the national US healthcare system because the resultant payment amounts not only apply to Medicare beneficiaries, they also influence the payment amounts for tens of millions of others across the country as many payers, including state Medicaid programs, use the Medicare Fee Schedule as a reference point.

2.) The methodologies in the Proposed Rule are in stark conflict with recently announced CMS goals of empowering patients, focusing on positive outcomes, and unleashing innovation. As explained below they also have serious flaws and will not produce legitimate results. Given the significance of these policies and the concerns described in this letter, CMS should not move forward with a final rule on payment methodologies for DME until further work is completed.

3.) CMS should actively engage with stakeholder groups related to various technologies as well as experts outside of CMS to ensure that the agency has a sufficient understanding of the items, their clinical application and any features that exceed those on other items the agency may view as "comparable". All costs associated with the manufacturing, acquisition, and provision of the various types of technology classified under the DME benefit must be taken into account in the development of the corresponding payment amount for each new code.

4.) NCART supports the need to establish a more appropriate methodology to determine payment for new HCPCS codes. We believe that CMS should have a focus that includes ensuring access to medically necessary technology, promoting innovation that improves beneficiary outcomes, and reducing overall healthcare costs. Accordingly, an appropriate policy for establishing payment amounts should be developed and include the following components:

a.) A coding system that effectively groups items in the same code based on technological features, intended use, and clinical application and prevents dissimilar items from being used to establish payment amounts.

b.) Development and recognition of the "total cost" of providing an item which must include incorporating both the "product cost" and the required additional "operating expenses" needed to supply and support the item.

c.) Transparency in identifying, gathering, and analyzing the related data and active inclusion of stakeholders throughout the payment amount determination process.

The following are our detailed comments and recommendations.

V. Establishing Payment Amounts for New Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Items and Services (Gap-filling)

We provide the following comments and recommendations regarding this section of the Proposed Rule:

1.) CMS is proposing if the item has a "Fee Schedule Pricing History" it would crosswalk that amount to establish the fee schedule amount for the new item.

COMMENTS-

Manufacturers and suppliers of Complex Rehab Technology (CRT) 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 code structures are working or by changing the descriptor of an existing code to include "any type". This further groups heterogeneous technologies without recalculating the fee schedule to reflect the inclusion of higher featured and clinically relevant 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 these items results in a barrier to access for consumers who have a medical need for specific technology.

If the need to create the new HCPCS code is due to the mix of disparate products in the original code, CMS should initially analyze the Manufacturer's Suggested Retail Price (MSRP) for the items being moved out of the existing code to determine whether merely crosswalking an existing code will allow appropriate access. CMS also should consider factors that impact the costs to provide a product within the new code such as:

Feature and function differences- There are many examples and we will provide two. HCPCS Code E0955- Wheelchair accessory, headrest, cushioned, any type, including fixed mounting hardware, each. The current code contains a wide variety of headrests ranging from a standard single pad with fixed mounting and attaching hardware to a complex head support system consisting of multiple pads with multi-plane adjustable mounting and hardware. The product and provision costs are significantly different. HCPCS Code E2205-Manual wheelchair accessory, handrim without projections (includes ergonomic or contoured), any type, replacement only, each. The current code contains standard aluminum handrims that have historically been considered part of the basic equipment package, as well as much more specialized handrims such as plastic coated, and the Natural Fit, which were previously separately billable at initial issue. When the CMS HCPCS workgroup made a change to the code definition to state "any type," codes for the more specialized handrims were discontinued and the items were moved to the new code. A later change to the descriptor stated "replacement only. As a result, handrims that had been historically billable at initial issue are now only billable when replaced.

Clinical application and intended user population- In order to directly crosswalk payment the items should have similar clinical indicators and should essentially be interchangeable. Using the above examples, with HCPCS Code E0955 a beneficiary with limited ability to move their head, inability to hold their head upright, or with high or low tone, or with asymmetry would not be able to use a single pad non-adjustable head rest. At the same time, a beneficiary who only needs the headrest to prevent their head from moving posterior of the backrest may not require the more complex system. With HCPCS Code E2205 a beneficiary who is dependent in propulsion, or who is an intermittent or short-term wheelchair user, would typically only require a standard handrim such as the ones that are standard on the wheelchair. However, a permanent and long-term manual wheelchair user at some point is likely to require a different handrim due to limited function, or pain that frequently results from long-term propulsion. These complex handrims are never provided as standard on a wheelchair.

It is important to determine whether the pricing for the products being moved out of the original code were used to establish the original fee schedule amount. 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.

RECOMMENDATIONS-

a.) The first step for determining fee schedule amounts for new HCPCS codes should be a new and more reliable gap-filling methodology that incorporates the recommendations contained in our comments. Only if there is clear evidence that this does not produce appropriate results should CMS consider using "fee schedule pricing history" and such consideration must include the recommendations contained in these comments.

b.) CMS should not focus solely on budget neutrality when establishing payment. CMS must also verify and ensure beneficiary access and improved quality outcomes.

2.) CMS is proposing if there is no Fee Schedule Pricing History for the item it would determine if there are any "comparable items" with existing fee schedule amounts; comparable items would be determined by examining 5 components/attributes of existing items: physical components, mechanical components, electrical components, function and intended use, and additional attributes and features; if such comparable items exist, CMS would use those existing fee schedule amounts that amount to establish the fee schedule amount for the new item.

COMMENTS-

Simply because a new device has "same or similar" attributes does not mean the cost is equivalent. Over the past few years, CMS has used "comparable products" to determine payment. CRT examples are: HCPCS Code E1012- Wheelchair accessory, addition to power seating system, center mount power elevating leg rest/platform, complete system, any type, each; HCPCS Code E0953- Wheelchair accessory, lateral thigh or knee support, any type including fixed mounting hardware, each; and HCPCS Code E0954- Wheelchair accessory, foot box, any type, includes attachment and mounting hardware, each foot. While there is evidence that reimbursement for these CRT items is inadequate and prevents access, CMS has not taken steps to resolve the issues. The payment amount established for HCPCS Code E0954 is below acquisition cost and is a barrier to access.

While CMS has provided ways to analyze products to determine comparability, the agency has not demonstrated a deep understanding of the technology or its application to ensure that the results will protect a beneficiary's access to the technology they require.

Even by identifying key attributes there is no predictability in terms of how these attributes will be assessed. For instance, if CMS determined there are differences in materials (titanium, composite, and aluminum) nothing in this Proposed Rule indicates whether that one difference would deter CMS from considering these technologies comparable enough in terms of fee schedule development. CMS has not demonstrated a deep understanding of cost differentials or the costs generated by innovation. Therefore, there is no assurance this type of analysis would take actual costs into consideration.

CMS proposes that 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- It is important for CMS to recognize that components often have a different cost when provided at initial issue than when provided as part of a repair or replacement. The agency should consider either establishing a replacement fee schedule or a payment modifier that allows for higher reimbursement for replacement parts when there isn't a separate code to represent replacement.

CMS proposes that 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- CMS should complete an initial analysis of the MSRP for each item before applying historic fee schedule information that may be flawed. Any technologies that would have Medicare payment history and where competitive products exist, there is no incentive for a manufacturer to inflate MSRP. In fact, to do so would be counterintuitive.

While CMS does list out function and intended use as part of the analysis, 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 would further exacerbate this problem.

RECOMMENDATION-

a.) CMS should not establish single rules for payment development based on scenarios described in this Proposed Rule. The methodology for developing payment must be assessed on a code by code basis and include a goal for ensuring adequate access.

3.) CMS is proposing if there are no Comparable Items it would establish a fee schedule amount by using "supplier or commercial price lists" which are "available and verifiable"; commercial price lists would include catalogs, retail price lists, internet price lists, Medicare Advantage payment rates, supplier invoices, and non-Medicare payer data; if the price information is from a period other than the base period (1986/1987) deflation factors would be applied to approximate a base period price and that amount would be updated with inflation factors to establish the fee schedule amount for the new item.

COMMENTS-

All of the sources for pricing data are below MSRP, some do not account for services or overhead and other related costs beyond product acquisition. Using payers who historically discount off the Medicare Fee Schedule to determine their payment rates will only serve to inappropriately reduce Medicare payment amounts and create access problems.

RECOMMENDATIONS-

a.) CMS should work with stakeholders and outside experts to develop a revised gap-filling methodology to determine fee schedule amounts for all new codes, those for new technologies, and when new HCPCS codes are created to establish homogeneous groupings of products.

b.) The agency should adopt a new and more reliable gap-filling methodology that incorporates our recommendations and use this as the primary method for determining the fee schedule amounts for new HCPCS codes. For gap-filling to be reliable, CMS must ensure that new HCPCS codes only include homogenous products. In addition, if CMS determines to continue to deflate to 1986/87 and then inflate to current date, the full CPI-U for each of the years must be used in performing the inflation step of the calculations.

c.) CMS should only use "comparable products" or "technology assessments" incorporating the recommendations included in our comments to establish payment when there is reliable and justifiable evidence that applying the gap-fill method would result in grossly inappropriate fee schedule amounts.

d.) MSRP is reliable and verifiable and should be used for establishing payment amounts. Manufacturers develop MSRP by considering direct and indirect manufacturing costs, as well as supplier direct and indirect provision costs. MSRP is the basis for determining selling price to the supplier network. Manufacturers must also consider market dynamics, market size, and competitive products when determining MSRP. Even in the case of innovative technology, any increase in cost of a new item must be in line with increased features or functional benefits to the consumer.

e.) Commercial pricing is routinely based off the Medicare Fee Schedule. Therefore, to use commercial pricing to establish Medicare payment amounts creates an inevitable domino effect. Commercial pricing is not a valid data source for Medicare to apply and should not be used.

4.) CMS is proposing if supplier or commercial price lists are "not available or verifiable" it would establish a fee schedule amount by using "technology assessments"; these technology assessments would be conducted by biomedical engineers, CMS, and others "to determine the relative cost of the items and services described by the new codes to items and services with existing fee schedule amounts"; that pricing percentage would be applied to the current fee schedule amounts for codes with existing fee schedule amounts to establish the fee schedule amount for the new item.

COMMENTS-

NCART 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 CRT products. Examples of these higher costs relate to direct and indirect labor, 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 (example, ISO 14001) and ISO-13485 which allows a company to demonstrate that it consistently meets customer needs and medical device regulatory requirements and complies with local legislation. The FDA intends to publish a Proposed Rule in 2019 to harmonize and modernize the Quality System regulation for medical devices. The revisions will supplant the existing requirements with the specifications of an international consensus standard for medical device manufacture, ISO 13485:2016.

There have also been significant cost increases to suppliers that did not exist 30 years ago. None of these are represented in any of the proposed methodologies. For example, the requirement of a certified Assistive Technology Professional (ATP) employed by the supplier to be directly involved in the technology assessment and selection of CRT items has added a significant cost associated with providing CRT. We recognize the importance of this requirement and believe it results in better outcomes, but it is a significant additional cost that is not reflected in existing fee schedules.

It is important for CMS to recognize that reductions in reimbursement resulting from policy changes and pricing obtained through competitive bidding have created access challenges for existing CRT. To use payment for older technology to determine the payment amount for new technology is inherently flawed and will further prevent companies from investing in innovation and prevents

beneficiaries from having access to technology that addresses unmet medical need and improves their function in performing daily activities.

All of the proposed methodologies are biased toward establishing low reimbursement rates even when there is an identified risk that the fee schedule rate would prevent access to medically necessary technology. It is extremely important for CMS to increase transparency, due diligence, and public input. 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. This is an inadequate and inappropriate process for providing meaningful input regarding Medicare Fee Schedule amounts.

RECOMMENDATIONS-

a.) CMS should consider modifications to the HCPCS code application that would require information to support payment determination at the time of submission. This could include a list of competitive products and contact information to allow CMS to obtain additional pricing information for other products that would be billed using a newly established HCPCS code.

b.) CMS should establish an additional segment of the HCPCS public meeting that would be closed to the public that would allow the applicant to submit and discuss payment information with the appropriate CMS payment staff.

5.) <u>CMS is proposing if supplier or commercial price lists are used to establish the fee schedule amount for the new item and these prices decrease by less than 15% in the first 5 years, a second gap-filling calculation would be done using the new prices to determine a revised fee schedule amount; this only applies if the prices decrease, not if prices increase.</u>

COMMENTS-

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. As stated above, commercial pricing is typically based on the Medicare fee schedule. Commercial pricing does not reflect a decrease in manufacturing costs or in the costs that suppliers incur to provide technology to consumers. To use artificially reduced payment in a second gap-filling process guarantees a circular and declining payment that will deny access.

When the prices are deflated to the 1986/87 base period 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.

RECOMMENDATIONS-

a.) CMS should use the criteria in its inherent reasonableness process (see 42 C.F.R. §405.502(g)(4) to review payment amounts for new technology to determine if the payment amount is grossly excessive or deficient.

b.) For items to be grouped together for pricing, they should be the same or similar in terms of service/delivery costs. Complex rehab technology (CRT) requires assessment, configuration, modification, adjustments and other critical services. These services are not only at the initial assessment or delivery, they are often necessary to ensure that the technology continues to meet the beneficiary's changing needs.

6.) CMS states an underlying premise that innovation should be reimbursed at a level equal to technology available 30 years ago.

In the Proposed Rule, CMS stated, "We believe using the relative cost of new items versus older items keeps all DMEPOS items (old and new) on a level playing field and priced in accordance with the historic reasonable charges for DMEPOS in general. We believe this method also helps foster innovation since new items that cost more would be priced based on these higher costs relative to older items with lower costs. Once the relative cost of the new item is determined, a pricing percentage would be established based on the results of the technology assessment to establish the fee schedule amount for the new DMEPOS item." NCART strongly disagrees with CMS' position that there is a valid link between new and old technology from a pricing perspective. This false assumption is at the foundation of each of the methodologies the agency proposed.

To hold new technology in line with 30-year-old technology fails to acknowledge differences in manufacturing costs, the cost of services to provide technology and supporting services to beneficiaries, and a myriad of other economic factors. CMS should not use payment as a form of controlling utilization. Instead, the agency should ensure appropriate coverage policies guide access.

RECOMENDATIONS-

a.) CMS should consider payment amounts using the total product costs and required operating expenses associated with providing the new technology.

b.) Coverage policies should be developed to establish adequate and appropriate access for new technology.

7.) The HCPCS public meeting is designed for input from the applicant and other stakeholders specific to HCPCS modification applications but this could be expanded to include payment amount data.

The HCPCS public meeting is designed for input from the applicant and other stakeholders specific to HCPCS modification applications. It is the only current means for reconsideration of the preliminary coding decision. Since HCPCS codes are universal and must be used by all payers, CMS should not include Medicare payment discussion in this portion of the meeting. Instead, CMS should add a segment at the end of the day or following day for the purpose of focusing on the development of the Medicare fee schedule. It is important for this to be a separate segment/meeting. The payment portion should be closed to the public and should allow for meetings with the applicant and scheduled meetings with others who can provide data to inform the payment development. This would offer time for CMS payment staff to ask questions of manufacturers and suppliers of the item. CMS should post data used to establish the fee schedule.

CMS should also include the payment data used to develop the fee schedule amount in the final HCPCS decision letter sent to the applicant.

8.) HCPCS codes should be established for homogeneous technologies with similar features and function.

HCPCS codes should be established for homogeneous technologies with similar features and function in order to: (a) facilitate the development of appropriate coverage and payment policies; (b) support the needs of all payers, especially those that insure children and people with disabilities; (c) allow beneficiary choice; and (d) facilitate comparative effectiveness research between HCPCS codes.

VI. Standard Elements for a Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Order; Master List of DMEPOS Items Potentially Subject to a Face-to-Face Encounter and Written Order Prior to Delivery and/or Prior Authorization Requirements

We provide the following comments and recommendations regarding this section of the Proposed Rule:

1.) We are supportive of the Medicare Prior Authorization (PA) program for CRT items as long as there is a timely review and response to the PA requests and timely access for Medicare beneficiaries is not compromised. The current Medicare policies provide this timeliness.

2.) We thank CMS and support the change to allow a PA decision to cover accessories furnished with Power Mobility Devices even if those accessories are not on the Master List. As the Proposed Rule states "Any accessory included on a prior authorization request submitted for an item on the Required Prior Authorization List, may nonetheless receive a prior authorization decision for operational simplicity even if the accessory is not on the Required Prior Authorization List."

****

NCART members are willing and have the expertise needed to assist CMS in developing appropriate policies that protect both the Medicare program and access to the important CRT products and services for Medicare beneficiaries with significant disabilities. Thank you for your serious consideration of the above comments and recommendations.

Sincerely,

Donald E Clayback

Donald E. Clayback
Executive Director
716-839-9728
dclayback@ncart.us |www.ncart.us