September 2, 2014

Marilyn Tavenner, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

Via electronic delivery to: http://www.regulations.gov

Re: Comments on Proposed Rule CMS-1614-P Medicare Program; End-Stage Renal Disease Prospective Payment System, Quality Incentive Program, and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies

Dear Administrator Tavenner,

The following comments are submitted on behalf of the National Coalition for Assistive and Rehab Technology (NCART) in regards to proposed rule CMS-1614-P "Medicare Program; End-Stage Renal Disease Prospective Payment System, Quality Incentive Program, and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies". NCART is a national association of suppliers and manufacturers focused on ensuring individuals with significant disabilities and chronic medical conditions have appropriate access to Complex Rehab Technology (CRT) products and services. Our members have over 300 CRT supplier locations across the country dedicated to serving their communities.

CRT products include medically necessary and individually configured manual wheelchairs, power wheelchairs, seating systems, and other adaptive equipment such as standing devices and gait trainers. This specialized equipment requires evaluation, configuration, fitting, adjustment, or programming to meet the individual's medical needs and maximize function and independence. In order to ensure access, NCART works with consumers, clinicians, and physicians along with federal, state, and private policy makers to establish and protect appropriate coverage, coding, and payment policies relating to CRT.

Overview of Comments

NCART acknowledges the challenges and complexities of administrating the Medicare DMEPOS benefit. In fact, NCART has met with CMS staff regarding several of the issues mentioned in the proposed rule which negatively impact beneficiaries, clinicians, and suppliers. However, we cannot emphasize strongly enough that many of the proposed solutions to these issues outlined in the proposed rule will not solve the current problems, but will in fact worsen them and further compromise quality and access.

NCART recognizes the legislative mandate for CMS to use information obtained through the Competitive Bidding Program (CBP) to establish pricing in certain areas outside of the Competitive Bid Areas (CBAs). However the legislation is not prescriptive as to the methodology and we believe CMS has the authority, flexibility, and obligation to adjust the fee schedule in a judicious manner. Care must be taken to protect beneficiary access to the high quality products and services that provide the best clinical outcomes.

We also have significant concerns with some of the alternative DME payment methodologies being proposed for comment. Extreme care must be exercised in making any such changes. Some of the proposals would create barriers to access to quality products and services rather than improve access.

The Medicare program and related complexities are the cumulative result of program and policy changes over many years, compounded by the CBP. A radical change in payment methodology will not resolve the issues. It is most important for CMS staff to identify the foundational program and policy issues and seek resolutions for these problems. For example, a key problem that impacts access and complicates the Medicare Program is that CMS over the last several years has changed thresholds for creating new HCPCS codes.

For codes created prior to HIPAA implementation, HCPCS codes delineated differences in technology and clinical application. The requirements for justifying a new HCPCS code are significantly higher today. This has caused dissimilar products to be classified into a single code. The CBP has only magnified the payment inadequacies for higher featured/functioning technologies bundled into generic codes.

NCART believes that overly generic and heterogeneous HCPCS codes are causing substantial problems that have reduced access to CRT products. Many of the current HCPCS codes for wheelchair options and accessories are too general, or the characteristics of the code are no longer valid or accurate to represent current technologies. We believe a viable option to multiple prices and modifier schemes for billing single HCPCS codes would be for CMS to work closely with CRT stakeholders to develop appropriate HCPCS codes to segregate DME from CRT products. This would allow for homogeneous codes for CRT products.

In addition to avoiding multiple prices for the same codes and complicated modifiers for billing, it would also align similar technologies, allowing for clear policies that appropriately address the needs of the small population of Medicare beneficiaries with significant disabilities who require these specialized items. Out of the 41 million enrolled in Medicare beneficiaries as of July 2012, only 9.4 million were people eligible based on disability. An even smaller number of those beneficiaries with disabilities would benefit from the use of CRT.

Within Section VI. of the proposed rule a comment is made that “hundreds of various wheelchair options and accessories is unnecessary and overly complex”. This is extremely concerning as it indicates a lack of understanding as to the real needs and benefits of enabling a person to get the proper manual or power wheelchair configuration. Without sufficient codes to distinguish unique features and characteristics along with unique clinical applications access is dramatically compromised. While we agree the current DMEPOS coding system established in 1993 no longer reflects current technology, random consolidation of codes is not the answer. We expand on this below.

Our comments will be primarily focused on how the proposed provisions would impact access to CRT products and services used by the small percentage of Medicare beneficiaries who have significant disabilities and chronic medical conditions. While this is a small population, it is extremely important to address their medical needs and maximize their function and independence. Below is a summary of our main comments which are described in more detail under the Specific Comments and Recommendations section:

A. Comments regarding Proposed Rule Section V. – Methodology for Adjusting DMEPOS Payment Amounts Using Information from the Competitive Bidding Programs:

1.) Traditional payment amounts must be preserved for CBP accessories used with Complex Rehabilitation Manual and Power Wheelchairs.

2.) Medicare should not adjust payment amounts for items included in less than 10 CBAs.

3.) Different payment amounts for accessories used with different types of base equipment must be preserved and new payment amounts established for items supplied on initial wheelchair purchase and when an item is provided as a subsequent add-on or replacement.

B. Comments regarding Proposed Rule Section VI. – Proposed Payment Methodologies and Payment Rules for Durable Medical Equipment and Enteral Nutrition Furnished under the Competitive Bidding Program:

1.) Significant inadequacies within the existing HCPCS codes must be addressed before moving to developing alternative payment methodologies.

2.) Bundling of multiple HCPCS Codes into a single code for payment will hurt access and reduce the quality of products and services.

3.) Bundled payments pose significant risks to beneficiaries who require highly configured wheelchairs.

4.) Bundling of repairs into a continuous monthly payment will make the current beneficiary access problems worse, not better.

5.) A continuous monthly payment amount is unreasonable as CMS lacks the ability to provide critical data needed by suppliers to submit informed bids.

6.) Setting an artificially inadequate payment cap based on insufficient and misleading historical data will deny access.

<u>Specific Comments and Recommendations</u>

A. Comments regarding Proposed Rule Section V. – Methodology for Adjusting DMEPOS Payment Amounts Using Information from the Competitive Bidding Programs:

1.) Traditional payment amounts must be preserved for CBP accessories used with Complex Rehabilitation Manual and Power Wheelchairs.

NCART recognizes that Congressional legislation mandates that CMS use CBP pricing to adjust the national fee schedule for CBP items in non-bid areas. However these adjustments should not apply to CRT items since they were excluded from the CBP. We believe the fee schedule adjustments are limited to CB items and related accessories provided with CBP bases and that the traditional fee schedule must be maintained for related accessories provided with non-bid bases.

Congress recognized the differences between CRT and DME as well as the need to maintain access to CRT products that address unique medical and functional needs of people with disabilities. Accordingly it exempted CRT power wheelchairs (Group 3 and above) and related accessories from the CBP. CMS made a similar decision regarding CRT manual wheelchairs and related accessories.

Accordingly it is important that the DMEPOS billing system maintain modifiers or develop other mechanisms to allow for CBP wheelchair options and accessories that are furnished for use with non-CBP wheelchair bases to be paid at the traditional payment amount.

2.) Medicare should not adjust pricing for items included in less than 10 CBAs.

CMS uses adjustable wheelchair cushions and Complex Rehab Power Wheelchairs (Group 2) as examples of codes included in less than 10 CBAs. NCART is on record requesting CMS not to include adjustable wheelchair cushions in any future round of competitive bidding for the following reasons:

- Inadequate code definitions and insufficient testing requirements to ensure efficacy of products assigned to codes.
- Many physicians and clinicians still do not realize the wide variety of products assigned to the codes and assume that all will have equivalent efficacy; testing and clinical studies demonstrate this is not true.
- PDAC has not been effective in preventing ineffective products from being assigned to the codes.
- Adjustable cushion technology is designed and intended for use by people with existing pressure ulcers, or for people at risk for skin breakdown. To risk the clinical outcome and associated results and costs in order to adjust the fee schedule for these items is unreasonable.

In addition, NCART met with CMS to request that Group 2 Complex Rehab Power Wheelchairs HCPCS codes be made invalid for submitting to Medicare. During this meeting, we provided independent test data regarding Group 2 complex rehab power that showed products in this category to be unsafe. We requested that the LCD related to the products be modified to allow any individual that had a documented medical need for tilt, recline or a combination of tilt/recline access to Group 3 single or multi-power option bases Complex Rehab Power Wheelchairs.

The impact of these provisions, especially as they relate to CRT, are particularly problematic and would have a significant impact on the health, independence and quality of life for Medicare beneficiaries with complex disabilities who require CRT wheeled mobility and/or seating.

Under CMS's Proposed Rule, the Agency states: *if contracts and SPAs for low volume items included in a limited number of CBAs expire and the items are not included in future CBPs, we propose to use the information from the past competitions to adjust the payment amounts for these items nationally based on 110 percent of the average of the SPAs for the areas where CBPs were implemented. Even though the SPAs may no longer be in effect, we believe it is reasonable to use the information to reduce excessive payment amounts for items and services as long as the SPAs did not result in a negative impact on access to quality items and services while they were in effect and as long as the amounts are adjusted to account for increases in costs over time. For example, 4 codes for adjustable wheelchair seat cushions were included in the Round 1 Rebid, with SPAs that were approximately 25 percent below the fee schedule amounts being in effect in 9 CBAs from January 2011 thru December 2013. These items were not bid in future rounds due to the low volume of use relative to other wheelchair seat cushions. During the course of the 3-year contract period when the SPAs were in effect in the 9 areas, there were no reports of access problems and there were no negative health outcomes as a result of including these items under CBPs. For the future, savings for these items could be achieved by including them in future competitions or by using the previous SPAs, updated by an economic update factor to account for increases in costs. If the decision is made not to include these items in future competitions, we believe savings can and should still be obtained based on information from the previous competitions.*

CMS's assumptions are incorrect and, thus, the proposed methodology should not be applied. While the items referred to were included in the Round 1 Rebid (and only in the Round 1 Rebid), they were only bid in specific product categories when associated with standard power wheelchairs, or separately when associated with Group 2 power wheelchairs. Utilizing the single payment amounts (SPAs) for these items from these product categories alone fails to consider the impact on quality and access; does not provide a representative sample; does not consider the vast majority of wheelchair users; and, completely ignores the cost differential for providing such products at a time that is different than the delivery of the base equipment.

CMS's proposal for calculating national payment amounts for such items ignores the fact that the pricing and margins for these items were blended into suppliers' bidding strategy to win the standard power and Group 2 power wheelchair categories. These suppliers desire was to win the category so that they could provide the included power wheelchair categories – the other codes included in these product categories had little impact on the bidder's financial analysis and bidding strategy.

However, this Proposed Rule deals with the creation of national payments outside of competitive bidding areas. In such cases, a provider cannot anticipate greater sales volume to offset lower margins, as they would if they were a competitive bid winner. Further, the provision of these products outside of a CBA, and the competitively bid product category, grants the supplier no greater access to more lucrative business associated with the standard power wheelchair itself.

It is also not appropriate to assume that the amount bid for an item when used with a standard or Group 2 power wheelchair is representative of the price a supplier could afford to supply such items to beneficiaries utilizing a manual wheelchair or a complex power wheelchair, or when supplied independent of any wheelchair. In such cases gross profits are lower and provider costs are higher.

It is unreasonable to assume that the delivery, service and billing of a cushion or accessory always occurs at the same time as the delivery, service and billing of a wheelchair. To the contrary, due to the other medical necessity requirements that a beneficiary must meet it is very likely the beneficiary will meet medical necessity for the item at a separate point in time than they do the wheelchair. As such, the supplier will incur duplicate costs associated with delivery, service and billing with much less total revenue and margin available to offset those costs. Finally, it is unreasonable to assume that the data obtained from 2010 for nine metropolitan areas is representative of the entire United States.

NCART does NOT believe sufficient pricing information exists to adjust the national fee schedule for items included in less than 10 CBAs. For those items included in 10 or more CBAs, the methodology that CMS selects to facilitate the use of CBP pricing to adjust the national fee schedule is critical. NCART encourages CMS to carefully consider concerns that industry has raised regarding the bidding program when selecting a methodology for applying CBP pricing to the national fee schedule. The primary issue, and ultimately what will determine whether the adjusted payment amount is appropriate, is whether the bid amounts used to develop the SPA pricing are inherently reasonable to sustain long-term access to the related products and services.

3.) Different payment amounts for accessories used with different types of base equipment must be preserved and new payment amounts established for items supplied on initial wheelchair purchase and when an item is provided as a subsequent add-on or replacement.

In situations where an accessory or supply identified by a HCPCS code is included in one or more CBP Product Categories (PC) for use with more than one type of base equipment, CMS proposes (in Section V.B.3.) to use the weighted average of the SPAs from CBPs and PCs where the item is included for use in adjusting the payment amounts for the item (HCPCS code).

NCART understands CMS's desire to establish one single payment amount. However the issue is not merely that suppliers bid different pricing for the same HCPCS code when provided with a manual wheelchair or a power wheelchair. With accessories and replacement parts, the costs truly do vary between manual wheelchair types as well as power wheelchairs; in some cases the differential is significant.

There is also a meaningful difference in costs of accessories and components (replacement and initial issue) between products provided with standard wheelchairs and CRT wheelchairs. Moreover, if multiple products are being provided at the same time, as would be the case with initial issue of the base wheelchair and related accessories, the overall costs can be spread across all of the products being provided. However, if an add-on item is needed, all of the service and billing related costs apply to the single item being provided.

The proposed rule identifies a wheelchair tray as an example of when an accessory or supply identified by a HCPCS code is included in one or more PC under the CBP for use with more than one type of base equipment and raises concerns about the complexity of administrating multiple prices for the same HCPCS coded accessories based on the type of wheelchair base. Again, we are not clear on where this has occurred. But, staying with CMS's wheelchair tray example, the technology that is identified by the single code varies significantly.

The differences between products within the same code are not merely technological, but also in clinical application and costs. Yet, there is one single code. Suppliers that bid on this code in the CBP would have used standard wheelchair trays to inform their bid amounts since the wheelchair bases included in the CBP were standard power and standard manual wheelchairs. It is extremely rare for a person that uses a standard manual or power wheelchair to require a complex or individually modified tray. If bid amounts based on standard products within a HCPCS code are then subsequently used to adjust the national fee schedule for all products grouped within that code, the result will reduce or eliminate access to more featured and more complex products.

In Maryland, for example, suppliers providing a wheelchair tray with a CRT manual wheelchair base today should be paid at $113.68 using the KE modifier. We recognize that CMS would use a different methodology to determine the adjusted fee schedule amount using CB pricing, but if you simply compare the KE fee schedule amount to the SPA amount in the Maryland CBA of $75.00, reimbursement for these items would drop almost 35% for complex wheelchair trays. Wheelchair trays routinely provided with complex rehab bases range in retail pricing from $250.00 to $500.00 as custom cut-outs or padding and upholstery are routinely required. A supplier's cost merely to acquire the wheelchair tray, (not considering other costs related to intake, set-up, delivery or billing etc.) exceeds the current fee schedule amount, but an adjusted fee schedule would guarantee that only those individuals that could pay for the item themselves could receive one.

Wheelchair trays are just one example where Medicare reimbursement has already reduced the availability of CRT products. To have reimbursement adjusted further will eliminate access for many more products.

Over the last decade, NCART has made numerous attempts to obtain adequate HCPCS codes for CRT wheelchair bases and related accessories. Unfortunately, the CMS Workgroup has denied requests to create new codes for this technology. There are a number of coding inadequacies within the current HCPCS code set that, due to corresponding fee schedule amounts for those codes already deny access to wheelchair bases, related accessories, as well as replacement parts. This is due to the fact that current reimbursement levels are too low to allow access to the various technologies grouped within a single code.

Fee schedules established using supplier charges would not have reflected current CRT products as the growth in CRT products started in the mid-to-late 1980's. Moreover, gap-filling, when used to establish pricing for codes with heterogeneous products, will result in inadequate reimbursement for the CRT products. Simply because the population of people requiring DME is much higher than those requiring CRT, far more DME products than CRT products are classified in any given HCPCS code. As a result, the median price for any heterogeneous HCPCS code will

correspond with a DME product. Therefore, the established fee schedule often becomes a barrier to access for many CRT products required by people with disabilities.

In addition, repairs are difficult to obtain for patient owned equipment primarily because replacement parts can cost a supplier more to purchase from a manufacturer than the allowed reimbursement amount from Medicare. The reason for this mirrors the example above with one additional problem. Most of the fee schedules were gap-filled using MSRP for accessories ordered at the time the wheelchair was ordered. When those items have to be repaired or replaced, the costs can be dramatically different.

Further, in considering the pricing for accessories, it appears evident that CMS initially recognized that the price for accessories would vary depending upon the base equipment it was associated with and that CMS incorporated this logic into the competitive bidding program. It was CMS that created the bidding categories, which resulted in accessories being included in multiple bidding product categories, with multiple SPAs.

B. Comments regarding Proposed Rule Section VI. – Proposed Payment Methodologies and Payment Rules for Durable Medical Equipment and Enteral Nutrition Furnished under the Competitive Bidding Program

The proposed rule indicates a belief that bundling payment for all items and services associated with furnishing certain DME into one monthly payment would greatly simplify the program, improve beneficiary access to quality items and services, and contribute to greater savings associated with implementation of the CBP.

We agree that the CBP has become quite convoluted and burdensome for the agency, its contractors, as well as suppliers. However, the broad bundling of items and services does not support the best clinical outcomes for beneficiaries because it does not ensure ongoing access to high quality medically necessary technology and related services as specified by the clinical team. The concept of one monthly payment for all products and services needed each month would serve as a barrier to access for beneficiaries. Any belief that the payments balance out is unrealistic given the multiple variables that impact cost.

CMS states, “The SPA for the monthly rental of DME would include payment for each item and service associated with the rental equipment including the ongoing maintenance and servicing of the rental equipment, and replacement of supplies and accessories that are necessary for the effective use of the equipment.” CMS further proposes that future competitions for standard manual wheelchairs and standard power wheelchairs in no more than 12 CBAs , where payment would be based on bids submitted for furnishing the wheelchairs and all accessories used in conjunction with the wheelchairs on a monthly basis. In addition, CMS proposes that the suppliers would submit a single bid for each HCPCS code describing the wheelchair for each CBA for furnishing the wheelchair and all accessories and services needed on a monthly basis.”

The bundling program that CMS has proposed has two distinct components and each must be carefully reviewed.

First, CMS has proposed bundling products; either maintaining base codes and bundling options or accessories used with the bases into a single code, or creating one code that would represent a full array of items and all related options and accessories. We believe that the more items that are bundled together the more difficult it will be for suppliers to bid an adequate, sustainable payment amount. In addition, the more items that are bundled under one code and one payment, the greater the risk that access to a full range of products will be dramatically decreased.

As we have stated in several sections of these comments, the current coding system makes bundling of all wheelchair accessories inappropriate because it would limit access to the full array of heterogeneous products classified into each code. Since the products classified into any given code are not equal, access to a single product within a HCPCS code does not mean the beneficiary would receive a product that meets their medical needs. This has significant implications for Medicare beneficiaries, especially those with disabilities and would negatively impact their function, and overall clinical outcome.

Second, CMS has proposed bundling the base products, such as wheelchairs, all related accessories and services and paying on a continuous monthly basis. The inclusion of repairs and other critical services into a continuous monthly payment and developing a bid limit indicates that CMS fails to recognize that current reimbursement for repair components is insufficient and continues to be a significant driver in reduced access to repairs.

The following are our detailed comments and recommendations relating to Section VI. of the proposed rule:

1.) <u>Significant inadequacies within the existing HCPCS must be addressed before moving to developing alternative payment methodologies</u>.

In regard to CRT products an inadequacy in the current HCPCS creates foundational problems. The current code set and product classification does not recognize technology distinctions, differences in clinical application, processes and services in identifying and providing the necessary products, and other important differences between CRT and DME as outlined below:

- Technology: Parts or accessories for standard mobility devices versus complex mobility devices often vary in features, design intent, manufacturing costs, durability requirements and other issues related to various manual wheelchairs and power wheelchairs, as well as costs issues related to whether an item is provided at initial issue, as an add-on, or as a repair/replacement.
- Clinical Application: CMS uses wheelchair trays as a product example in the proposed rule. A flat wheelchair tray made of wood or acrylic that is provided with a standard mobility device is different in many ways from a padded, upholstered wheelchair tray with cut-outs to accommodate anatomical anomalies and/or drive controls for use with CRT and as part of an overall mobility system that address functional and postural needs. The features and functional differences between these different wheelchair trays carry significant cost variables; a single code with a single reimbursement amount has resulted in inadequate reimbursement for the more complex trays. The key to understanding the implications of this issue is recognizing that all products classified within a single HCPCS code do not address the same medical and functional needs. Just

because a beneficiary can receive a product within a specific HCPCS code, it does not mean their needs will be addressed. Unless fee schedule amounts allow access to all products within a HCPCS code, then access to the medically needed device may be denied.

- Required Services: A clinical and technological team approach has emerged as best practice for the assessment and selection of CRT. CMS has acknowledged the need for special education and experience for suppliers of CRT in the quality standards by requiring that all CRT bases be provided by suppliers that employ rehab technology professionals (RTPs) with an ATP credential and that the credentialed individual must be directly involved in the selection of the technology. NCART has strongly supported these additional requirements. However, current reimbursement does not reflect these additional costs. In addition, other services related to CRT products such as repeated fittings, adjustments and programming are often required and may necessitate visits to the beneficiary's residence or seating clinic. These costs are notably higher than those needed to provide standard DME.
- Pricing: CMS routinely refers to HCPCS as a billing mechanism, a means for submitting a claim. However, a fee schedule is developed for each code based on the products within that code. Therefore, it is disingenuous to ignore the impact coding has on payment. CRT items and required services are more complex and will always be significantly above the median price when grouped with DME items.

NCART strongly recommends that CMS collaborate with CRT stakeholders to review the current HCPCS codes for wheelchairs, wheelchair options and accessories, and wheelchair seating to ensure that homogeneous products are grouped together before applying CBP pricing to the national Medicare fee schedule for the items (HCPCS codes) included in the CBP.

In addition to the above issues, there are insufficient wheelchair accessory codes to recognize initial issue versus replacement costs. The initial issue and replacement fee schedule amount is the same for many wheelchair accessories, even in situations where costs are significantly different. Manufacturer Suggested Retail Price (MSRP) for many options and accessories are up-charges above standard items at the time the wheelchair is ordered. In contrast, replacement items, whether provided as an add-on, replacement or as a repair, carry full charges.

2.) <u>Bundling of multiple HCPCS into a single code for payment will hurt access and reduce the quality of products and services</u>.

The proposed rule acknowledges issues associated with repairs of manual and power wheelchairs and complexities related to billing, claims processing, payment and bidding of wheelchairs and the myriad related options and accessories. Specifically, CMS requests comments on the use of a single code to represent all standard manual wheelchairs (K0001-K0004, K0006 and K0007) and one for all standard power wheelchairs and all related accessories. Or, whether continuing to use the current codes and bundling all related accessories would be most appropriate.

NCART is opposed to any bundling methodology that would include combining existing wheelchair base codes. NCART is also opposed to any bundling methodology of wheelchair

options and accessories with the related wheelchair base code, except in limited situations as described below.

While on the surface these may seem like viable solutions, the fact is that these solutions indicate that CMS may not clearly understand foundational problems or the full impact of what is proposed. While some standard manual wheelchairs may be similar, variances in features, options, quality, and other aspects may be significant when compared to other wheelchairs such as high strength lightweight (K0004), or the heavy duty and extra heavy duty wheelchairs (K0006, K0007) as well as for power mobility. To attempt to merge these technologies into a single HCPCS code would have a profound negative impact on access to medically necessary features.

As far back as the competitive acquisition demonstration project in San Antonio, Texas, access to K0004 manual wheelchair models with more features was reportedly eliminated in the demonstration area. The differences between models classified in the same code can be significant and the ability to access a full range of models is important for Medicare beneficiaries. In addition, recent product placement decisions moved CRT manual wheelchair bases into heavy duty and extra heavy duty codes (K0006 and K0007) purely based on the wheelchair's patient weight capacity while ignoring other important technology differences such as the ability to adjust the propulsion wheels on the horizontal plane for center of gravity adjustment, a critical feature for full time users that have the ability to self-propel.

NCART believes there may be some opportunity to reduce the number items billed for manual wheelchair claims by expanding the use of basic equipment packages, such as was created for power wheelchairs. However, for CRT, it is critical for these items to be ones that are consistently ordered at the same time. It continues to be in the best interest of the Medicare program and Medicare beneficiaries to have knowledgeable and experienced clinicians identify medical and functional needs and then match the technology solution to those needs. This process ensures that Medicare only pays for what is needed and allows access to items when they are supported by medical documentation.

In addition, due to the need to add certain items after initial issue or as a replacement or repair, the ability to bill for items individually would still be required. These decisions require a comprehensive review of the codes for each Product Category with stakeholder participation. And, this review must also take into consideration those categories where the numbers of codes, descriptors, code requirements or testing requirements are inadequate.

We are acutely concerned about any efforts to bundle a large number of accessories or options with a base item purely because they are in the same Product Category. We are also deeply concerned with bundling of multiple accessories or options that may or may not be needed by most beneficiaries.

Bundling is a methodology that has demonstrated savings in other areas of health care. We certainly understand why this would be of interest to CMS and why CMS would want to use its authority to test its outcomes for certain specified DME. However, NCART cautions CMS to limit the scope of any such program. Further, NCART does not believe this is a scheme that is applicable for CRT products and services for many reasons:

- The broad range of products, highly variable related costs, and HCPCS codes that represent heterogeneous products make it difficult for CMS or suppliers to determine a reasonable cost spread across months of rental payments.
- CRT is complex and based on the unique needs of each person.
- Highly variable costs associated with assessing, modifying, adjusting and configuring these products initially and on an on-going basis and a void of meaningful data documenting these costs.
- Highly variable costs associated with populations and markets served. Many CRT suppliers focus on certain populations or markets and ensuring adequate reimbursement is critical to ensure access.
- Inability to account for a beneficiary's diagnosis or whether the prognosis is stable or progress. Progressive diseases, such as ALS, result in changes in condition, acuity, and functional levels impact equipment needs and associated service costs, and often require equipment change.
- No or limited data to inform bidders regarding CRT products and services to ensure that resulting payment amounts are adequate and sustainable, and protect access as well as beneficiary outcomes. Important information that is required includes:
    - HCPCS codes utilization by ICD-9 code in their geographical market.
    - The frequency and nature of service/repair related to an item over its useful life based on population served- supplier case mix (client profile, age, diagnosis, acuity, activity level, environments of use, etc.).
    - Classification of ICD-9 codes by acuity levels; the same diagnosis can have very functional levels associated with them. It would be important for suppliers to be able to identify acuity level and percentages for various ICD-9 codes such as through the use of the World Health Organization (WHO) Functional Levels.
    - An activity rating scale to factor in level of usage as this directly impacts service/repair and lifecycle of equipment.

3.) <u>Bundled payments pose significant risks to beneficiaries who require highly configured wheelchairs</u>.

CMS requested comments regarding beneficiary impact of bundled arrangements for users of highly configured manual wheelchairs. CMS specifically requested comments on what safeguards and monitoring approaches that should be used to ensure that access to these items is not disrupted for individuals transitioning between settings and/ or residing in remote areas.

NCART opposes any bundled arrangement that would include any complex rehab base wheelchair, all accessories and all services. Variability in product, evolving technology needs, ongoing services related to modifications, adjustments and programming as well as replacements and repairs vary greatly and a single payment amount on a continuous monthly basis could not adequately ensure access. We feel that transition between settings and remote areas already create barriers for individuals who require individually configured and customized technologies.

When transitioning between settings, such as home to skilled nursing facilities (SNF) or admission to hospitals occurs, it is critical for people with disabilities to have their unique

technology with them. If these items are classified as capped rental, as is the case today for tilt-in-space manual wheelchairs (E1161), it is important for Medicare to continue to reimburse for these items. They have been ordered to the meet the unique medical, functional and anatomical needs to the individual and would not be replaced by a hospital or SNF with equal technology.

For individuals living in remote areas, availability of accredited suppliers with credentialed staff is minimal or even in some remote areas, non-existent. Seating and Mobility clinics have closed in rural areas and large urban areas as well due to inadequate funding and documentation demands. Any additional funding reductions would only serve to further threaten access to CRT.

4.) Bundling of repairs into a monthly payment will make the current beneficiary access problems worse, not better.

NCART does agree with CMS regarding the complexity of billing of capped rental items and the need to resolve repair issues associated with patient owned wheelchairs of all types. CMS recently reclassified several HCPCS codes for replacement parts as capped rental. These codes will only be billed for patient owned wheelchairs. Many suppliers are unwilling to "rent" expensive parts for patient owned equipment due to issues related to upfront costs and implications caused by breaks in service. However, the inclusion of repairs in a bundled payment adds unrealistic and unsustainable risk for suppliers and adds complexity to the bid process-extent and frequency of repairs has a direct correlation to equipment use, environments of use and characteristics of the consumer, such as age, diagnosis and activity level. More important, this proposal would not solve current issues related to obtaining repairs for patient owned wheelchairs nationally.

NCART continues to recommend that all CRT products and related accessories provided at initial issue, add-on, repair, and replacement should be classified as routinely purchased with an option to rent products on a short-term basis to facilitate hospital discharge or until the appropriate long-term technology solution can be identified.

The proposed rule does not acknowledge that suppliers of DME and CRT products have a strong desire to service the products they provide to Medicare beneficiaries. However, inadequate reimbursement, onerous documentation requirements, and other regulatory burdens have forced suppliers to stop servicing patients they did not provide the base item to and limit service even in situations where they did provide the base item.

Medicare beneficiaries' inability to obtain repair services cannot be solved by mandating that suppliers repair what they sell or by bundling repairs into a monthly payment amount. Especially when there is a bid limit established that inherently would not consider the additional costs associated with CRT products within a single, yet heterogeneous code. The only way to genuinely address repair issues is to resolve the complex problems that have forced suppliers to stop or dramatically reduce provision of these services.

An industry repair workgroup has been meeting with CMS since last fall regarding repair problems. The following are recommendations that must be addressed in order to resolve wheelchair repair issues:

- Modify current policy to allow the beneficiary to sign an "abandonment attestation statement" when they are no longer able to get service that would start a new capped rental period so the beneficiary can receive services from another supplier and allow a new supplier to bill for repairs and services.
- As in the case of Medicaid and private payers, Medicare should allow a qualified supplier to provide and bill for a wheelchair repair solely based on a detailed written order signed by the physician indicating the chair continues to be medically necessary and repairs are needed.
- Remove the repair and replacement part HCPCS codes from Competitive Bidding which would restore traditional rates and allow all suppliers to provide all repair and replacement parts.
- Any add-on item, replacement or repair accessory or component for use with a beneficiary owned wheelchair should be paid for as a purchase.

5.) A continuous monthly payment amount is unreasonable as CMS lacks the ability to provide critical data needed by suppliers to submit informed bids.

Costs can vary greatly based on the level of technology, services and repairs required for each individual. Suppliers may serve certain populations due to facilities in their market, i.e. ALS clinics, spinal cord centers, or traumatic brain injury centers etc., which will impact their costs. Specific details regarding the beneficiary are not made available. SPAs established from bids submitted by suppliers serving different markets and populations would not allow for adequate access to a full array of products and services.

6.) Setting an artificially inadequate payment cap based on insufficient and misleading historic data will deny access.

CMS proposes to "establish the bid limits for enteral nutrition, oxygen and oxygen equipment, standard manual wheelchairs, standard power wheelchairs, and hospital beds that would be paid in accordance with the proposed payment rules in sections 1 and 2 above based on average monthly expenditures per beneficiary in an area for the items and services related to furnishing the DME.

For example, the bid limit for the continuous monthly rental of a standard manual wheelchair in a CBA would be based on the total payment amounts per month in the area for the wheelchair, repair, maintenance and servicing of the wheelchair, and accessories used with the wheelchair, divided by the unduplicated number of beneficiaries receiving these items and services. We propose to revise § 414.412 to specify that the supplier's bid for furnishing enteral nutrition, oxygen and oxygen equipment, standard manual wheelchairs, standard power wheelchairs, and hospital beds on a continuous monthly rental basis could not be higher than the average monthly payment made in the area for the items and services prior to the start of the competition."

NCART has significant concerns with the proposed methodology for establishing bid limits. The proposed method does not consider the fact that there have been significant access issues relating to wheelchair repairs on a national basis. Medicare billing and payment for wheelchair

repairs prior to the start of the competition would not reflect the level of needed repairs or even the actual repairs to beneficiary owned equipment that may have been paid for out-of-pocket or by other funding sources. Moreover, the current reimbursement amounts are a primary reason that repairs to beneficiary owned wheelchairs are difficult to obtain. To set an artificial limit on the bid amount prevents suppliers from providing CMS with legitimate, adequate and sustainable bids.

The Right Solutions Will Come Through Collaboration

NCART acknowledges the specific requirement for CMS to use information obtained through the CBP to develop pricing for bid items in non-bid areas. We do not agree that this would replace the national fee schedule however, as separate pricing must continue to be paid for options and accessories provided with non-bid bases. Our particular concern relates to the options and accessories furnished for use with complex rehabilitation manual and power wheelchairs.

We appreciate CMS's perspective and concerns related to billing and claims processing complexity, the need to ensure that the Medicare program is paying an appropriate amount, and growing concerns regarding access to repairs for patient owned wheelchairs. However NCART believes that it is necessary for CMS to address the foundational problems that exist at the HCPCS code level before resulting problems can be addressed. Merely adding complexity or mandating services will only exacerbate the current problems. These points have been further described above.

NCART members are willing and have the expertise needed to assist CMS in addressing the HCPCS coding issues and seeking solutions to the identified problems while protecting access to CRT products and services. We strongly encourage CMS to work with stakeholders to implement needed changes outlined herein.

Thank you for your serious consideration of the above comments and recommendations.

Sincerely,

Don Clayback

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