National Coalition For Assistive & Rehab Technology

January 4, 2021

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1738-P
P.O. Box 8013
Baltimore, MD 21244-8010
Submitted electronically at www.regulations.gov

Re: Proposed Rule CMS-1738-P "Medicare Program; Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Policy Issues and Level II of the Healthcare Common Procedure Coding System (HCPCS)"

To Whom it May Concern,

The following comments and recommendations regarding Proposed Rule CMS-1738-P are submitted on behalf of the National Coalition for Assistive and Rehab Technology (NCART) in support of needed policy changes related to HCPCS coding and payment for DMEPOS.

NCART is a nonprofit national association of suppliers and manufacturers of Complex Rehab Technology (CRT) products. We focus on education and advocacy with a primary focus on establishing and protecting appropriate coverage, coding, and payment policies to ensure people with significant disabilities such as ALS, spinal cord injury, cerebral palsy, multiple sclerosis, muscular dystrophy, and traumatic brain injury have adequate access to the specialized equipment and related supporting services they require.

Our supplier members operate over 780 accredited Medicare/Medicaid supplier locations across the country, collectively providing products and critical supporting services to hundreds of thousands of children and adults in their local communities. Our manufacturer members are recognized industry leaders who have decades of experience in the development of CRT products designed to address important medical and functional needs.

CRT HCPCS Coding and Payment Background

To meet the medical needs of people with disabilities, access to a full range of CRT products is necessary. People who require CRT items have disabilities that result in complex medical complications and needs. The lack of adequate HCPCS codes results in coverage and payment policies that create barriers to access. CRT products differ from standard DME in important ways:

- Design intent: Designed for full-time use multiple settings and environments, to accept seating and positioning items, to accept additional components to address orthopedic anomalies and abnormal tone.
- Construction: Adjustable or modifiable components to facilitate intimate fitting required for items to meet individual medical needs and accommodate changes in a beneficiary's condition. Fittings and adjustments can be performed to ensure the technology continues to meet the beneficiary's needs.
- Durability: Full-time and permanent use, must be able to withstand frequent and sometimes high-tone movement within the mobility device and seating system, and able to accommodate multiple settings, environments, and facilitate function. Due to total dependence on mobility and seating devices, product durability is critical to avoid breakdowns and frequent repair needs.
- Provision process: Best practice guidelines for the provision of CRT items and services is widely accepted to ensure the desired patient outcomes. The process requires a team approach, that involves the beneficiary, their physician, a licensed physical therapist or occupational therapist with experience performing wheeled mobility and seating evaluations, and a supplier-employed technology professional who has obtained the Assistive Technology Professional (ATP) credential who performs a technology assessment.

An individual who has a permanent disability and who requires the use of CRT mobility devices, seating and positioning items, and/or wheelchair components depends on this interdisciplinary team. The CRT team matches the person's medical and functional needs to the specific CRT items to provide an individually configured system that meets the identified medical needs and based on the person's routine activities, capabilities, and environments or use.

It is important to note, current HCPCS codes and Medicare coverage and payment policies frequently prevent access to identified technological solutions. The result is a negative impact on the health outcomes and quality of life for beneficiaries and increases healthcare costs. Adequate access to CRT plays a critical role in keeping health care costs down by reducing medical complications, clinical interventions, hospitalizations, institutionalizations, as well as the need for caregiver assistance and other services.

NCART Comments and Recommendations

The following comments are organized to address specific provisions, proposals, considerations, and statements in the Proposed Rule. Our comments are organized under Sections II, III, IV, V, VII, and VIII of the Proposed Rule and we have presented our specific recommendations at the end of each section.

Section II. - Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Fee Schedule Adjustments

C. Provisions of the Proposed Regulations

The purpose of this section is to establish the methodologies for adjusting the fee schedule payment

amounts for DMEPOS items and services furnished in non-competitive bidding areas (non-CBAs) on or after April 1, 2021 or the date immediately following the duration of the emergency period described in section 1135(g)(1)(B) of the Social Security Act (the Act) (42 U.S.C. 1320b–5(g)(1)(B)), whichever is later.

NCART supports the comments and recommendations submitted by the American Association for Homecare and strongly opposes continuation of the current rates because they are based on Single Payment Amounts (SPAs) established by a flawed bid methodology that were developed over six years ago.

Since those payment rates were created, CMS has made significant structural improvements to the payment methodology. CMS has abandoned the payment methodology which established the current rates and replaced it with a methodology that more closely resembles standard auction bid methodology. The current rates are based on SPAs that were set at the median of the initial contract offeror prices. Since then, CMS has replaced that SPA-setting methodology so that the SPAs are now established at the clearing price. Another flaw of the previous bid program that CMS has changed is the bid ceiling. Until CMS changed the policy, bidders had to bid below the previous CBP's SPAs. Therefore, during all CBPs except the one that was bid for Round 2021, bidders had to continually lower their bid prices to be in compliance with the bidding rules. The artificially low bid ceiling prevented bidders from bidding market rates.

The current rates that CMS proposes to extend in the former CBAs were established six years ago. Even if the SPA methodology had been corrected, they would still be outdated and not representative of current market rates, despite the modest Consumer Price Index (CPI) updates.

The current COVID-19 pandemic has dramatically changed the DME market. DME suppliers are incurring significant additional costs to take necessary precautions to safeguard employees and the patients they serve. Additional costs include increased freight and other supply chain costs, shipping delays, hazard pay for direct care employees, personal protective equipment (PPE), and software and hardware to enable employees to work remotely. By way of example, freight costs have increased dramatically – UPS, FedEx and the USPS have all imposed significant rate increases, ranging from $0.24 to $1.50 on every single package. In addition, these same carriers have imposed "COVID-19 surcharges," and have limited the amount of volume from large shippers, leaving more expensive expedited services as the only transit option.

Overall, DME suppliers report price increases of at least five percent starting in early 2019. These additional costs will likely continue throughout the pandemic. Some of these increased costs will invariably continue post-pandemic, such as increased PPE. Finally, it is unclear whether the "normal" market and cost factors will return after the PHE ends.

NCART Recommendation:

1. Payment Rates in former CBAs should be based on a 90/10 blended payment formula. The 90 percent should be based on the current payment rates in former CBAs (including the CPI-U

updates), and the 10 percent should be based on the 2015 unadjusted fee schedules. Setting the rates based upon a 90/10 blended rate would provide for a modest increase to compensate for the flawed SPA setting methodology, the fact that the rates are six years old and the market has changed dramatically over those years, and the increased costs caused by the COVID-19 pandemic.

Section III. - DMEPOS Fee Schedule Adjustments for Items and Services Furnished in Rural Areas from June 2018 through December 2018 and Exclusion of Infusion Drugs from the DMEPOS CBP

The purpose of this section is to address our intent to finalize and comments received on the May 11, 2018 interim final rule (83 FR 21912) entitled "Medicare Program; Durable Medical Equipment Fee Schedule Adjustments to Resume the Transitional 50/50 Blended Rates To provide Relief in Rural Areas and Non-Contiguous Areas" including comments related to the conforming amendment excluding infusion drugs from the DMEPOS CBP.

For rural contiguous areas and non-contiguous, non-CBAs, CMS proposes to make the current 50/50 blended rate methodology permanent. The 50/50 blended rates are comprised of 50 percent adjusted rates and 50 percent unadjusted rates. NCART commends the Agency for this proposal and fully supports CMS for its decision to maintain these higher fee schedules in sparsely populated areas to better assure beneficiary access.

For non-rural, non-CBAs, CMS did not propose any changes and is maintaining the current payment methodology that establishes payment rates at 100% of the adjusted rates. NCART does not support maintaining the current payment levels in non-rural, non-CBAs, for the same reasons we do not support them in former CBAs. These rates are based on an outdated and flawed CBP rate setting methodology that were established six years ago. Like the rates in former CBAs, since these rates were established, CMS has changed the CBP rate setting methodology from the median of the initial contractors' prices to the clearing price. CMS should not use rates that are based on outdated and flawed bid methodology, particularly when they are outdated and are not representative of the current market.

NCART Recommendation:

1. CMS should establish rates in non-rural, non-CBAs based on a 75/25 blended payment formula. The 75 percent portion should be based on the adjusted fee schedule, and the 25 percent portion of the blended payment formula should be based on the unadjusted fee schedule. Setting the rates based on this 75/25 blended payment methodology would provide for a modest increase in rates to compensate for the flawed SPA setting methodology, and the significantly changed market of 2020.

Section IV. - Healthcare Common Procedure Coding System (HCPCS) Level II Code Application Process

B. Proposals for HCPCS Level II Coding Procedures

1. Proposed HCPCS Level II Coding Cycles and Related Policies

a. Coding Cycles for Non-Drug, Non-Biological Items, and Services

NCART acknowledges and appreciates meaningful changes that CMS has made to the HCPCS code modification process, specifically, the ability for applicants to electronically submit HCPCS modification applications, and the ability to submit applications die non-drug, non-biological items, and services on a bi-annual basis. The ability to request codes more frequently is important for all stakeholders.

Additional Time to Evaluate Applications-NCART recognizes that complex applications may require more time to review and appreciate that CMS indicates this would be in limited circumstances. Rather than waiting to notify the applicant of the need to extend the time to review an application at the same time as preliminary decisions are announced for other items and services included in that coding cycle, NCART recommends that the applicant be contacted as soon as the need is identified. NCART suggests that the applicant may be able to answer questions, provide additional information, and identifying clinical experts. NCART also recommends that the applicant be provided as much detail as possible regarding what is needed to make a preliminary or final coding decision and that the applicant be allowed to present at the public meeting even without a preliminary decision.

The Use of Miscellaneous Codes- CMS notes that miscellaneous codes are available for assignment be insurers, if they deem appropriate, to allow suppliers to begin billing for an item or service (assuming FDA requirements are met). The use of miscellaneous codes increases the burden associated with claims submission and adjudication. State Medicaid programs struggle to determine appropriate payment for items billed with miscellaneous codes. Moreover, miscellaneous codes can also complicate claims processing for dual eligible beneficiaries.

d. Proposed Application Resubmission and Reevaluation

The HCPCS application process, even with instructions, is not intuitive for some manufacturers and innovators. An application that has been completed and submitted with the required documentation may still fail to provide the necessary information to reach an appropriate coding decision.

NCART recommends that negative coding decisions, preliminary and final, provide sufficient details regarding why the decision was made and should also include recommendations regarding additional information that would be useful in making a coding decision in the future.

NCART understands that the HCPCS application process requires significant resources (both for the applicant and CMS), however, placing an arbitrary limitation on the number of resubmissions ignores the fact that new or revised information could be available at a future time and has the potential of denying access to important medical technology.

2. Proposed Evaluation of HCPCS Level II Code Applications

CMS indicates that its primary objective is maintaining a code set that allows for efficient and timely processing of Medicare claims in accordance with the Medicare statute and regulations that are specific to the items for which a code is being requested. The granularity of what falls within code categories in the HCPCS level II code set is deeply tied to Medicare's "claims processing need." It is critical for the needs of non-Medicare payers be equally considered, and clear processes should be established to ensure the CMS HCPCS Workgroup is aware of these needs. In addition, people who qualify for Medicare based on disability rather than age, and who may be of working age, often have medical and functional needs that differ from the elderly Medicare beneficiary. It is important for the CMS HCPCS Workgroup to consider the significant role HCPCS codes play in providing the foundation for proper coding coverage and payment policies.

In addition, CMS states a goal to strike a balance between sufficiently identifying and differentiating items and services and producing a manageable system and set of codes for users to efficiently submit and process claims. Furthermore, CMS states that the intention is to describe an item in a way that is general enough so as not to be manufacturer specific, create a manageable number of codes, administrative simplification, and burden reduction. To make Medicare claims processing a primary goal has repeatedly created barriers to access to technology for people with disabilities. It is important to acknowledge that HCPCS codes are the foundation upon which coverage and payment policies are developed; it is important for the CMS HCPCS Workgroup to equally acknowledge the needs of the target population, the clinical application, and the intended use for items that are the subject of a HCPCS modification application.

Non-Medicare programs often have enrollees that differ from those enrolled in Medicare, such as children under age 21. In addition, Medicaid programs must consider community access and independence as elements of medical necessity. As a result, product distinctions that are important in meeting the unique medical necessity for people with disabilities must be considered by the CMS HCPCS Workgroup, especially when those differences would impact coverage policies, or payment policies, or claim processing needs for non-Medicare payors.

NCART encourages CMS to make additional changes to the process that will ensure the HCPCS code-set recognizes the unique needs of people with disabilities of all ages. For years, NCART has advocated for recognition in the HCPCS code set for the advanced features and function of CRT items. We strongly encourage CMS to properly distinguish CRT from standard DME in the HCPCS code-set.

NCART members have made attempts to obtain adequate HCPCS codes that identify CRT items and properly segregate them from more standard DME. Unfortunately, today CRT products are routinely grouped into HCPCS codes with standard DME items with long descriptors that do not recognize features and performance differences that meet important medical and functional needs of people with disabilities. In addition, due to the long-term use and environments of use, components and replacement parts for CRT must be more durable, higher performing and this often means they are more expensive to manufacture. Moreover, the fact that many CRT items are developed for small

populations of people with certain disabilities and medical or functional needs, and therefore lack manufacturing efficiencies that come with higher manufacturing volumes. Currently CRT items are in the same HCPCS code as standard items, and reimbursement for the CRT items are frequently inadequate and often fall below the supplier's acquisition cost.

In addition, the standard items are often considered to be included in a base item of DME, yet the standard item does not meet the medical needs of people with disabilities. Having the higher featured CRT in the same HCPCS code as the standard item and deemed by policy to be included in the reimbursement for the base results in a lack of access. These HCPCS coding and payment policies have resulted in restricted access to medically necessary items and repairs to CRT items for Medicare beneficiaries with significant disabilities.

The deficiency in HCPCS codes can result in coverage policies that fail to address the unique needs of people with disabilities who have permanent and full time needs for technology. The performance and durability differences are critical in terms of meeting identified medical and functional needs and to avoid frequent repairs or replacement of components.

General Comment on the HCPCS Application Process- NCART acknowledges that the typical applicant for a HCPCS code is a single manufacturer seeking a HCPCS code for a new device. Regarding CRT items, manufacturers are often in agreement regarding HCPCS code needs. We believe it would be beneficial to all stakeholders, including the CMS HCPCS Workgroup, to allow manufacturers to collaborate in submitting joint HCPCS code applications. This would create more robust applications and reduce the resources needed to submit and review them. Much of the information required on the application would be duplicative for each manufacturer, such as descriptions of the product, clinical application, and setting of use, some information would need to be provided by each participating manufacturer, such as FDA information.

a. Proposed Evaluation Process for Applications to Add a Code

(1) Proposed Evaluation Process for Non-Drug, Non-Biological Applications to Add a Code

There are many Non-Drug, No-Biological items that are primarily intended for people who are no eligible for Medicare. The CMS HCPCS Workgroup previously consisted of members who represented the needs of non-Medicare payers. Now the group is solely comprised of federal employees. It is important that CMS modify the evaluation process to consider the needs of other payers as a formal step. In addition, there must be a formal process, outside of the public meeting, for other payers to provide input on HCPCS modification applications especially when the intended population is not a typical Medicare beneficiary. If the information should be or can be submitted by the applicant, the instructions and application should be revised to indicate what is needed and acceptable

(b) Proposed Process for Further Evaluating Non-Drug, Non-Biological Applications to Add a Code

(i) Significantly Different Clinical Function

CMS indicates in the proposed rule that if an application satisfies proposed 414.10(d)(1) or (d)(2) the focus of the evaluation shifts to assessing the functional and clinical differences of the subject item or service compared to other similar items in the HCPCS code set to determine whether a new code is needed. NCART believes it is important for CMS to identify clinical advisors with knowledge and current clinical practice in key policy areas to be available to provide clinical input during this part of the assessment. The CMS HCPCS Workgroup has made several decisions in the past to expand the description of an existing HCPCS code to include the words "any type" to allow an existing code to incorporate a disparate range of products. Having experienced and knowledgeable clinicians available to advise the workgroup would be beneficial in any clinical assessment of a product and its function.

CMS requested comments on whether certain factors would appropriately apply in the context of evaluating significant therapeutic distinction. Specifically, whether a product offers a treatment option for a patient population unresponsive to or ineligible for current technology or has contraindications, whether the item or service offers the ability to diagnose a medical condition in a patient population where that medical condition is currently undetectable, a demonstration of one or more specified outcomes, and whether increased compliance should be a factor considered in the coding decision.

NCART believes it is extremely important for the CMS HCPCS Workgroup to consider all the outlined factors as well as whether a product or group of products provide features or function that meet specific medical and functional needs, or clinical application that would not be met by standard technology. NCART is concerned about the information CMS will require to demonstrate a product provides these outcomes. For CRT, the difference is observable and can be identified during a clinical evaluation and technology assessment, product trial or simulation. Clinical studies are not needed to determine whether a different technology will meet the person's needs.

For example, for a beneficiary with quadriplegia or ALS, a headrest comprised of a single, non-adjustable pad will not support the head and prevent it from falling off the headrest. A multi-pad, multi-adjustable head support system is required and is intuitive to the clinician who routinely evaluates clients with similar diagnoses. The costs associated with manufacturing a complex multi-pad and multi-plane adjustable, head support system designed for a specific individual is much more than a prefabricated, single pad headrest. Yet, both technologies are in the same HCPCS code, have the same coverage limitations, and are reimbursed the same amount.

NCART also strongly supports consideration of technology that improves compliance, monitors use, and results of use. This type of information is important to the user of the item, clinicians who are providing ongoing care and alert both parties if product or programming modification are needed or if changes in usage are indicated.

b. Proposed Evaluation Process for Non-Drug, Non-Biological and Drug or Biological Applications to Discontinue an Existing Code

CMS indicates that when an applicant submits a request to discontinue an existing code, the CMS

HCPCS Workgroup will take steps to confirm that the code is duplicative of another HCPCS code or that the technology is obsolete or has essentially been discontinued. The proposed rule when on to say that additional information from contractors or other could be used to verify that products that are the subject of the modification application will not be marketed at a future date and there is no remaining stock available; establishing there is no longer a claims processing need.

NCART believes consideration should also be given to discontinuing a HCPCS code if the products are not generally safe, few models remain on the market and the remaining models do not meet beneficiaries' needs.

NCART Recommendations:

1. CMS should acknowledge differences in product features, design intent, clinical application, patient population, performance characteristics, durability, whether the item impacts the ability to perform activities of daily living, improves the quality of life, improves compliance, and features that improve function and independence when determining whether unique HCPCS codes for CRT items are needed and to ensure adequate access.
2. CMS should provide applicants with highly detailed information regarding all negative decisions to allow applicants to prepare thoroughly for the public meetings. If the final decision maintains a negative preliminary decision, as much detail as possible should be provided to the applicant to assist the applicant in understanding changes or additional information needed for a resubmission to be more effective.
3. CMS should identify clinical and product experts in the field to serve an advisory capacity to the CMS HCPCS Workgroup and who can provide important perspective regarding the clinical application and significant therapeutic distinction, and other information regarding HCPCS modification applications included in the bi-annual process
4. CMS should not limit the number of resubmissions. Following two re-submissions, additional information or changes in information may be required and annual submissions could be considered. The resubmission application process should continue to include a preliminary decision and included in the public meeting agenda.
5. CMS should establish a process for obtaining information regarding the needs of non-Medicare payors. If that information is to be provided by the applicant, that should be included in the instructions and applicants should be advised the best way to provide and validate the information.
6. CMS should consider whether a product or group of products provide features or function that exceed those of a standard product, and when a standard product would not meet specific clinical application or medical needs of the target population, in determining whether a product provides significant therapeutic distinction that justifies a unique HCPCS code.
7. CMS should add all the proposed outcomes including compliance monitoring and features that improve compliance to product differences that support and justify applicant claims of significant therapeutic distinction for creation of a unique HCPCS code.
8. CMS should revise the HCPCS modification application, and instructions. The revised forms should delineate sections based on HCPCS coding, benefit category, and payment. The instructions that accompany the application should provide examples of information that would

assist the CMS HCPCS Workgroup in making each of these decisions and aid applicants in a better understanding of the process.

9. CMS should modify the HCPCS decision tree to reflect the priorities and changes contained in the final rule and to add steps for benefit category and payment decisions.
10. CMS should increase the allotted time for applicants' primary and additional speakers to provide substantive responses to all preliminary decisions being addressed during the public meeting: HCPCS code, benefit category, and Medicare payment.
11. CMS should instruct the CMS HCPCS Workgroup to review all aspects of a modification application and identify all deficient areas in the preliminary decision. This would inform an applicant of all areas that would result in a negative determination. This would allow for a more informed decision regarding resubmission and reduce the number of resubmissions. If an applicant decides to resubmit, they would be better able to submit an application that addresses all identified weaknesses.
12. CMS should establish a process that would allow groups of manufacturers to submit a joint application or applications for similar technologies.
13. CMS should include additional consideration and justification for discontinuing a HCPCS code to include product safety, dramatically reduced models available on the market.

Section V. - Benefit Category and Payment Determinations for Durable Medical Equipment, Prosthetic Devices, Orthotics and Prosthetics, Therapeutic Shoes and Inserts, Surgical Dressings, Splints, Casts, and Other Devices Used for Reductions of Fractures and Dislocations

2. Section 531(b) of the Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act of 2000

NCART recognizes CMS' desires to expand the HCPCS modification process to include benefit category determinations and payment determinations.

CMS indicates that it has effectively been using the HCPCS process and the public meetings to obtain public comments regarding benefit category and payment determination. While there are questions in the modification application that provide answers related to the benefit category determination, it is not clear to applicants that this is the intent of the questions.

There continues to be a need for a benefit category determination as a component of a National Coverage Determination NCD) decision. This could happen without a HCPCS modification application. Therefore, it is important that CMS allow for a BCD request independent of an NCD request or a HCPCS request. If CMS desires to use the HCPCS public meeting as the forum for public comments on a BCD request, that is acceptable, but it is important for a BCD (request or appeal) process to be available independent of a HCPCS code request.

There are no questions on the current HCPCS application that address payment methodologies. The preliminary decisions have recently only addressed the payment category for Medicare payment, such as capped rental or inexpensive or routinely purchased. Payment category was defined in a

previous rule that limits items that would be classified as inexpensive or routinely purchased to items that cost less than $150 or acquired at least 75 percent of the time during the period July 1986 to June 1987. As a result, all new DME technology, which is where CRT is currently classified, that was not available during the period July 1986 to June 1987 and costs more than $150 is automatically classified as capped rental. This does not produce appropriate classifications. A new policy is needed to allow for items manufactured for a single, specific Medicare beneficiary to be classified as routinely purchased.

While CMS allows options and accessories used in conjunction with a Group 3 complex rehabilitative power wheelchairs to be billed as a purchase if the base is billed as a purchase, the same is not allowed for complex rehabilitative manual wheelchairs. As a result, there are situations where the wheelchair base is billed as a purchase and the accessories are billed as capped rental. Or where the base is billed as capped rental and accessories are billed as a purchase. This is confusing for suppliers, and beneficiaries, and increases claims processing costs. This policy requires revision. However, the more troubling aspect of payment determination is the methodology that CMS will use to determine the payment amount for the new HCPCS code.

While CMS proposes to make a preliminary payment determination regarding how the fee schedule amounts for a new item would be established, NCART believes that the HCPCS application must be modified to request information that would assist in making the preliminary decision regarding the payment methodology.

In CMS-1713-F it states," we are not finalizing §§ 414.110(d) and 414.238(d) to have the opportunity to consider additional information on the use of technology assessments in the gap-filling methodology for DMEPOS items and services. We will consider whether to include a revised proposal addressing the use of technology assessments in gap-filling in future rulemaking. Even so, if supplier prices are not available, we would not use a manufacturer's suggested price for their own product to gap-fill the fees. We would use information from the comparability analysis and any other pricing information that is available to establish the fee schedule amount so that it best reflects what the 1986/87 supplier charges for the item would have been if the item were on the market during the fee schedule base period." And "In addition, we are finalizing §§414.112 and 414.238 as proposed, with the exceptions of §§414.112(d) and 414.238(d), which outlined a process for using technology assessments to establish the fee schedule amounts for new DMEPOS items." CMS also provided Table 12 Comparable Item Analysis which provides "Components" and "Attributes" to provide some clarity regarding the process that would be used.

Unfortunately, there are several circumstances when CMS has used pricing for items deemed as comparable when in fact that were not comparable. This has resulted in inadequate fee schedules for CRT items. If the HCPCS application and public meeting processes are to be utilized for Medicare payment decisions, it is critical for further discussion and collaboration between stakeholders and CMS to ensure that fee schedules based on crosswalk or product comparability is done appropriately and accurately to establish adequate and reasonable payment amounts.

For applicants to provide meaning information or for the public meetings to allow for meaningful

comments from stakeholders, a significant about of information will need to be provided in the preliminary payment decisions.

NCART Recommendations:

1. CMS should modify the HCPCS modification application by creating and distinguishing sections related to HCPCS coding, benefit category determination, and payment determination. Each section should have questions that guide the provision of information that would assist the CMS HCPCS Workgroup and appropriate CMS staff in making each of these determinations.
2. CMS should modify HCPCS application instructions to clearly explain what information and data is considered relevant and to indicate how the information would be used.
3. CMS should allow the HCPCS process to serve as an appeal process for Benefit Category, and payment decisions if the HCPCS modification application is intended to be a process to make those initial decisions.
4. CMS should use its authority to allow all CRT items to be classified as purchase.
5. CMS should establish a policy that allows all wheelchair accessories used in conjunction with a complex rehabilitative manual wheelchair to be billed as a purchase.
6. CMS should provide details regarding the basis and data used to make any preliminary BCD, and payment decision. This should be included in the letters to the applicants as well as in the information for the relevant public meetings.

Section VII. - Expanded Classification of Eternal Infusion Pumps as DME

Section 5012 of the 21st Century Cures Act, Congress amended section 1861(s)(2) and added subsections 1834(u) and 1862(iii) to establish a new Medicare home infusion therapy services benefit. CMS proposes to expand the scope of Medicare Part B benefit for DME by revising the interpretation of the "appropriate for use in the home" requirement within the definition of DME at 42 CFR 414.202 specifically for certain drugs or biologicals infused in the home using an external infusion pump. CMS states in the proposed rule that it in practice, CMS has interpreted this requirement within the definition of DME items to those items which can be used by a patient or caregiver in the home without the assistance of a healthcare professional.

In practice, current NCD and LCD policies related to mobility devices has limited coverage to only what is necessary to function inside the four walls of the home. Clarifications have been issued that indicate there is no desire to force Medicare beneficiaries to be home bound and to inform beneficiaries they may use their devices outside their homes. NCART believes it is important to recognize that devices safe for use inside a home environment may not be safe or effective when use outside the home in various environments and terrains.

NCART and other stakeholders have made multiple attempts over the years to convince CMS to acknowledge Medicare beneficiaries' use inside and outside of the home to ensure they receive mobility devices that meet all of their medical and functional needs, is safe in all routinely encountered environments, and to minimize repairs that occur due to use beyond a product's design intent.

NCART Recommendation:

1. CMS should revise its current interpretation of "in the home" to allow beneficiaries access to DME that is essential for everyday life while allowing safe participation in necessary activities outside the home.

Section VIII. - Exclusion of Complex Rehabilitative Manual Wheelchairs and Certain Other Manual Wheelchairs from the DMEPOS CBP

NCART opposes using CBP pricing based on standard items used with standard wheelchairs to adjust payment for complex rehabilitative items used with complex rehabilitative wheelchairs that were not included in the CBP. Further, NCART members indicate that the adjusted payment rates are inadequate complex rehabilitative items and denies adequate access for Medicare beneficiaries with disabilities.

Accessories used with complex rehabilitative manual and power wheelchairs are different from those used with standard wheelchairs, even though they have been grouped together in the same HCPCS code for billing purposes. Complex rehabilitative items provide different features, performance, function, durability, and/or adjustability. These differences and the related services carry higher costs for manufacturers and suppliers.

Congress has acknowledged the differences between standard DME and complex rehabilitative items and enacted legislation in 2008 and in 2019 to exempt Group 3 complex rehabilitative power wheelchairs and accessories and complex rehabilitative manual wheelchairs and related accessories, respectively, from the CBP.

In addition, on September 29, 2020 Congress expressed their intent again by sending a formal request to CMS through a bipartisan letter to CMS Administrator Verma from 41 members of the House of Representatives. The letter requested that CMS take the necessary action to make a permanent policy change for accessories used with complex rehabilitative manual wheelchairs. This same request has also been made by a variety of national disability and medical professional organizations.

NCART supports the Centers for Medicare & Medicaid Services' (CMS) proposed implementation of Section 106 of the Further Consolidated Appropriations Act, 2020 (FCAA), as it relates to the competitive bidding program (CBP) for durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS). As CMS describes, section 106 "excludes complex rehabilitative manual wheelchairs and certain other manual wheelchairs and related accessories from the DMEPOS CBP as well as from fee schedule adjustments based on information from the DMEPOS CBP."[1] Congress' intent that CRT manual wheelchairs and related accessories be excluded from the CBP and from CBP-based adjustments ensures beneficiary access to these highly individualized technologies that

[1] *See id.* at 70360.

require evaluation, configuration, fitting, adjustment, and/or programming to meet each individual's unique medical needs.

As the agency moves forward with the CBP, NCART urges CMS to clarify via subregulatory guidance that CRT manual wheelchairs and related accessories will be permanently exempted from CBP-based adjustments under section 1834(a)(1)(F) of the Social Security Act (the Act).

As discussed in further detail below, the permanent exclusion from the CBP of CRT manual wheelchairs and related accessories under section 106 of the FCAA also *permanently* prohibits CMS from adjusting the fee schedule rates for CRT manual wheelchairs and related accessories. This is because section 1834(a)(1)(F) requires CMS to adjust the fee schedule rates for "covered items", defined as DMEPOS included in the CBP, when the same items are furnished outside of competitive bidding areas. But Congress excluded CRT manual wheelchairs and related accessories from the CBP, and therefore they cannot be "covered items" as defined by section 1834(a)(1)(F) that can ever be subject to CBP-based adjustments.

In 2017, CMS recognized the same implication in the context of CRT power wheelchairs and related accessories, which Congress excluded from the CBP and, by extension, prohibited any CBP-based adjustments to their fee schedule rates. The same rationale supports a permanent exemption for CRT manual wheelchairs and related accessories because of the enactment of section 106 of the FCAA and the corresponding exclusion of CRT manual wheelchairs and related accessories from the CBP.

Moreover, because the prohibition against making CBP-based adjustments to CRT manual wheelchairs and related accessories follows directly from the statute itself, clarifying subregulatory guidance on this issue is not subject to section 1871 of the Act, as interpreted by the Supreme Court's *Allina* decision[2] and the Office of General Counsel's Advisory Opinion interpreting that decision. Although CMS does not have the authority to issue any subregulatory guidance impacting the rates of CRT manual wheelchairs and related accessories, other than the clarifying guidance requested above that merely implements the statute, *if* CMS believes it must still go through notice and comment rulemaking, NCART requests that it do so by finalizing the requested guidance as part of an interim final rule with comment period.

I. BACKGROUND

A. 2017 Guidance for CRT Power Wheelchair Accessories

In 2008, Congress delayed and reformed the CBP for certain items of DMEPOS, and among other things, specified that "certain rehabilitative power wheelchairs recognized by the Secretary as classified within group 3 or higher (and related accessories when furnished in

[2] *Azar v. Allina Health Services*, 587 U.S. ___, 139 S. Ct. 1804 (June 3, 2019).

connection with such wheelchairs)" were to be excluded from competitive bidding.[3]

In November 2014, CMS finalized a statutorily mandated policy, effective January 1, 2016, wherein the agency would use pricing information from the CB program to adjust fee schedule payments for competitively bid items provided in non-competitive bid areas.[4] In CMS' words, section 1834(a)(1)(F) of the Act "requires adjustments to the payment amounts for all DME items subject to competitive bidding furnished in areas where CBPs have not been implemented on or after January 1, 2016."[5]

Shortly after publication of the final rule, CMS issued a Frequently Asked Questions (FAQ) document stating that, also beginning January 1, 2016, CMS intended to use bid pricing information obtained from the CBP for *standard* wheelchair accessories to "adjust" the payment amounts for CRT wheelchair accessories. Many stakeholders opposed CMS' CBP-based adjustments of CRT wheelchair accessories given Congress' clear intent that CRT power wheelchairs be excluded from the CBP. In June 2017, the agency partially walked its decision back and stated that "wheelchair accessories and back and seat cushions used in conjunction with group 3 complex rehabilitative *power* wheelchairs would *not* be adjusted based on [rates from the CB program]."[6] CMS' policy reversal, however, did not address the fee schedule rates for CRT *manual* wheelchair accessories. At the time, the exclusion of CRT wheelchairs from the CBP applied only to CRT power wheelchairs.

B. 2019 Statutory Exclusion from the CBP of CRT Manual Wheelchairs, Certain Manual Wheelchairs, and Related Accessories

In 2019, Congress enacted legislation excluding CRT *manual* wheelchairs from the CB program.[7] More specifically, Congress excluded "complex rehabilitative manual wheelchairs…and certain manual wheelchairs", such that "complex rehabilitative manual wheelchairs…[]and related accessories when furnished in connection with such complex…manual wheelchairs[]" are excluded from the definition of "covered items" under the CBP.[8] In other words, Congress' intent is that CRT power and manual wheelchairs, certain manual wheelchairs, and related accessories be excluded from the CBP.

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[3] "Medicare Improvements For Patients and Providers Act of 2008," Pub. L. No. 110-275 (July 15, 2008), § 154(a)(1)(B), 122 Stat. 2494, 2562 – 63 (amending § 1874(a)(2)(A) of the Social Security Act).
[4] "Medicare Program; End-Stage Renal Disease Prospective Payment System, Quality Incentive Program, and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies," 79 Fed. Reg. 66119 (Nov. 6, 2014); *see also* Social Security Act, § 1834(a)(1)(F).
[5] "Medicare Program; End-Stage Renal Disease Prospective Payment System, Quality Incentive Program, and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies," 79 Fed. Reg. 66119, 66224 (Nov. 6, 2014).
[6] Frequently Asked Questions on Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) 2015 Medicare Payment Final Rules (CMS-1614-F)," (June 23, 2017), https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/DMEPOSFeeSched/Downloads/2015-DMEPOS-FR-FAQs.pdf.
[7] "Further Consolidated Appropriations Act, 2020," Pub. L. No. 116-94 (Dec. 20, 2019), § 106(a) (amending § 1847(a)(2)(A) of the Social Security Act).
[8] Social Security Act, § 1847(a)(2)(A).

Furthermore, Congress also specifically prohibited CMS from adjusting the fee schedules for "wheelchair accessories (including seating systems) and seat and back cushions when furnished in connection with complex rehabilitative *manual* wheelchairs", and it authorized the Secretary to implement its provisions by "program instruction or otherwise."[9] The prohibition against adjusting the fee schedule rates for CRT manual wheelchair accessories expires on June 30, 2021.[10] However, as discussed in more detail below, notwithstanding the expiration of that particular provision, the only possible reading of the statute following the amendments of section 106 of the FCAA requires CMS to permanently exclude CRT manual wheelchair accessories from any CBP-based adjustments because CRT manual wheelchairs and accessories can no longer be in the CBP.

II. NCART requests that CMS clarify, via subregulatory guidance, that the fee schedule rates for CRT manual wheelchairs and related accessories will *not* be adjusted using CBP-based information on a permanent basis so long as Congress continues to exclude CRT manual wheelchairs and related accessories from the CBP.

A. CMS *must* permanently exempt CRT manual wheelchair accessories from being adjusted with information from the CBP because CRT manual wheelchair accessories are excluded from the CBP by statute, and therefore CMS lacks an appropriate source to adjust fee schedule rates for CRT manual wheelchair accessories.

Section 1834(a)(1)(F) of the Act establishes payment rates for both DMEPOS that are included in the CBP, and for items that are not included in the CBP. Specifically, the statute provides that in the case of "covered items" furnished on or after January 1, 2011 that are in a "competitive acquisition program" in a "competitive acquisition area", the applicable payment amount is "the payment basis determined under such competitive acquisition program."[11] Furthermore, beginning January 1, 2016, Congress requires that for "covered items" *not* furnished in a "competitive acquisition area" under section 1847, including "additional covered items [that] are phased in or information is updated," the agency *must* "use information on the payment determined under [the CBP] to adjust the payment amount otherwise recognized under [the ordinarily applicable fee schedule] for an area that is not a competitive acquisition area under section 1847…."[12]

Importantly, the requirement under section 1834(a)(1)(F) to "adjust" fee schedule rates based on CBP information of the Act applies only to *certain* "covered items," namely those that are included in the CBP, but are furnished in a geographic area outside of competitive bidding areas. This reading logically follows from the introductory sentence of section 1834(a)(1)(F) which immediately defines the subject of the subparagraph to be covered items

[9] Further Consolidated Appropriations Act, 2020, § 106(b) (emphasis added)
[10] *Id.*
[11] Social Security Act, § 1834(a)(1)(F)(i).
[12] Social Security Act, § 1834(a)(1)(F)(ii)-(iii).

that *are* included in the CBP.[13] In clause (ii), which provides the authority for the Secretary to adjust fee schedule rates based on CBP-based information, Congress reinforces the narrow applicability of such authority to DMEPOS otherwise included in the CBP but furnished outside of a competitive acquisition area. Specifically, Congress states that the Secretary shall "use information on the payment determined under such competitive acquisition programs to adjust the payment amount otherwise recognized under subparagraph (B)(ii) *for an area that is not a competitive acquisition area under section 1847*…."[14] In other words, Congress narrowed the subject of subparagraph (F) to "covered items" included in the CBP furnished in a competitive bidding area, and in clause (ii) and (iii), requires the Secretary to adjust fee schedule rates for those same covered items when furnished outside of a competitive bidding area.

Under section 106 of the FCAA, however, CRT manual wheelchairs and related accessories are *not* "covered items", and they are *not* included in the CBP. "Covered items" are defined broadly under section 1834(a)(13) to mean "durable medical equipment" as broadly defined by section 1861(n). But under section 1847(a)(2)(A), which sets forth the items subject to the CBP, Congress borrows the definition of "covered item" applicable under section 1834(a)(13), and then modifies it to exclude CRT manual wheelchairs and related accessories, among other things:

"(A) Durable medical equipment and medical supplies.—Covered items (as defined in section 1834(a)(13)) for which payment would otherwise be made under section 1834(a), including items used in infusion and drugs (other than inhalation drugs) and supplies used in conjunction with durable medical equipment, **but excluding** class III devices under the Federal Food, Drug, and Cosmetic Act, excluding certain complex rehabilitative power wheelchairs recognized by the Secretary as classified within group 3 or higher, **complex rehabilitative manual wheelchairs (as determined by the Secretary)**, and certain manual wheelchairs (identified, as of October 1, 2018, by HCPCS codes E1235, E1236, E1237, E1238, and K0008 or any successor to such codes) **(and related accessories when furnished in connection with such complex rehabilitative power wheelchairs, complex rehabilitative manual wheelchairs, and certain manual wheelchairs)**, and excluding drugs and biologicals described in section 1842(o)(1)(D)."[15]

Therefore, CRT manual wheelchairs and related accessories are not "covered items" that may be included in the CBP under *any* circumstances, and therefore the adjustment mandate of section 1834(a)(1)(F) cannot apply to CRT manual wheelchairs and related accessories because they are not CBP items that are furnished outside of a competitive bidding area. That is to say, CRT manual wheelchairs and related accessories are not CBP items *at all*, and there is no data from the CBP in competitive bidding areas that can appropriately inform

[13] *See id.* (The language reads: "In the case of covered items…that…are included in a competitive acquisition program in a competitive acquisition area under section 1847(a)…."
[14] Social Security Act, § 1834(a)(1)(F)(ii).
[15] Social Security Act, § 1847(2)(A) (emphasis added).

adjustments to the fee schedule rates for such items when furnished outside of competitive bidding areas. Indeed, there can be no other reading of the statute as any other reading would involve adjusting CRT manual wheelchairs and related accessory fee schedule rates using CBP-based information that has *nothing* to do with competitively bid CRT manual wheelchair and related accessory rates; because they do not exist, by Congress' intent. **In short, it would be unlawful to adjust the fee schedule rates of CRT manual wheelchairs and related accessories.**

B. CMS applied similar reasoning in 2017 when it permanently exempted CRT power wheelchair accessories from CBP-based adjustments due to Congress' exclusion of CRT power wheelchairs from the CBP.

CMS adopted identical reasoning as the one described above to support permanently exempting CRT *power* wheelchair accessories from CBP-based adjustments in 2017. As discussed above, CMS implemented section 1834(a)(1)(F) in 2014 rulemaking wherein the agency stated that, effective January 1, 2016, it would use pricing information from the CB program to adjust fee schedule payments for competitively bid items provided in non-competitive bid areas.[16] At the time, complex rehabilitative power wheelchairs were excluded from the CBP by Congress pursuant to section 154(a)(1)(B) of the "Medicare Improvements for Patients and Providers Act of 2008" (MIPPA).[17] Stakeholders requested that CMS take this fact into consideration and exempt CRT power wheelchair accessories from CBP-based adjustments given their exclusion from the CBP itself.

In 2017, CMS recognized the statutory implication and, via subregulatory guidance posted on its website, stated that the statutory exclusion of CRT power wheelchairs and related accessories under section 1847(a)(2)(A) should "inform [the agency's] implementation of section 1834(a)(1)(F)…such that fee schedule amounts for wheelchair *accessories and seat cushions* used in conjunction with group 3 complex rehabilitative power wheelchairs would not be adjusted based on the methodologies in section 414.210(g)(5)."[18] In other words, CMS recognized that Congress' exclusion of CRT power wheelchairs and related accessories from the CBP prohibited the agency from adjusting the fee schedule rates for the same accessories and seat cushions (when used in connection with CRT power wheelchairs).

Here, an identical statutory implication arises based on Congress' exclusion of CRT *manual* wheelchairs and related accessories, as provided by section 106 of the FCAA. Just as the agency recognized and clarified via subregulatory guidance that Congress' exclusion of CRT *power* wheelchairs and related accessories must inform the agency's implementation of section 1834(a)(1)(F) of the Act, CMS should recognize and clarify in a similar manner here

[16] 79 Fed. Reg. at 66119; *see also* Social Security Act, § 1834(a)(1)(F)(iii).
[17] Section 154(a)(1)(B), Medicare Improvements for Patients and Providers Act of 2008, Pub. L. No. 110-275 (July 15, 2008) (amending section 1847(a)(2)(A) of the Social Security Act), *supra* n. 4.
[18] Frequently Asked Questions on Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) 2015 Medicare Payment Final Rules (CMS-1614-F)," (June 23, 2017), https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/DMEPOSFeeSched/Downloads/2015-DMEPOS-FR-FAQs.pdf.

that Congress' exclusion of manual power wheelchairs and related accessories from the CBP means that the unadjusted fee schedule rates for the same items of DME cannot be adjusted based on non-existent CBP-based information. As noted above, the statute *compels* a reading that the agency cannot adjust fee schedule rates for an item of DME using CBP-based information when there is no such information for that item to be derived or obtained, since these items are excluded from the CBP.

C. CMS clarifying via subregulatory guidance that CRT manual wheelchairs and related accessories are permanently exempted from CBP-based adjustments is not subject to the procedure requirements of section 1871 of the Act, as interpreted in *Allina*, and it is consistent with OGC's Advisory Opinion regarding the applicability of *Allina* because it does not involve creating a "non-statutory or non-regulatory" norm.

At the outset, we note that CMS' 2017 subregulatory guidance on CRT power wheelchairs and related accessories indicates that the agency did not feel that such clarifying guidance was subject to the notice-and-comment procedural requirements of the Administrative Procedure Act (APA). Otherwise, the agency would not have issued its clarification via subregulatory guidance.

Following the *Azar v. Allina Health Servs*.[19] decision, however, NCART understands potential reservations concerning whether the same subregulatory clarification in the context of CRT manual wheelchairs and related accessories would be subject to notice-and-comment rulemaking as required by section 1871 of the Act. In 2019, the Supreme Court in *Azar v. Allina Health Servs*.[20] held that, contrary to longstanding assumptions, the Medicare Act's separate procedural requirements under section 1871 of the Social Security Act do *not* incorporate the "interpretive rule exemption" applicable under the APA. Thus, following the *Allina* decision, CMS can no longer rely on the "interpretive rule" exemption for subregulatory guidance that it issues and must submit to notice-and-comment rulemaking any "**rule[s], requirement[s], or other statement of policy that establishes or changes a substantive legal standard governing the scope of benefits, the payment for services, or the eligibility of individuals, entities, or organizations to furnish or receive services or benefits under [Medicare].**"[21]

On December 3, 2020, the OGC of the Department of Health and Human Services (HHS) issued an advisory opinion clarifying the agency's approach and implementation of *Allina*'s requirements regarding notice-and-comment rulemaking.[22] OGC states that it interprets the phrase "substantive legal standard" in section 1871(a)(2) to mean any issuance that:

> "(1) defines, in part or in whole, or otherwise announces binding

[19] *Azar v. Allina Health Servs.*, 139 S.Ct. 1804 (June 3, 2019), *supra* n.3.
[20] *Id.*
[21] Social Security Act, § 1871(a)(2).
[22] Advisory Opinion 20-05 on Implementing *Allina*, Department of Health and Human Services Office of the General Counsel (Dec. 3, 2020).

> parameters governing, (2) any legal right or obligation relating to the scope of Medicare benefits, payment by Medicare for services, or eligibility of individuals, entities, or organizations to furnish or receive Medicare services or benefits, and (3) sets forth a requirement not otherwise mandated by statute or regulation."[23]

OGC goes on to explain that where HHS "unilaterally issues discrete, binding criteria purporting to explain statutory or regulatory requirements, that statement of policy will usually be viewed as creating a new norm [subject to *Allina*]."[24] However, where a "**statute or regulation is drafted narrowly enough to create the relevant norm, the agency can provide additional clarity through guidance without creating a new non-statutory or non-regulatory norm**" that is subject to *Allina*.[25]

Here, CMS' subregulatory clarification that CRT manual wheelchairs and related accessories would not be adjusted based on CBP information is the type of "additional clarity" that OGC indicates CMS can issue without notice-and-comment rulemaking because the *statute* itself is "drafted narrowly enough to create the relevant norm." As discussed above, subparagraph (F) of section 1834(a)(1) unambiguously narrows the subject of its directive to "covered items" that are included in the CBP, and clause (ii) and (iii) of subparagraph (F) do not expand the subject insomuch as they add a condition: if the "covered item" that is included in the CBP (i.e. the subject) is furnished outside of a competitive bidding area, then such rates shall be adjusted using information from the "covered item" that is included in the CBP and furnished in a competitive bidding area. Because CRT manual wheelchairs and related accessories cannot be included in the CBP, they can never be "covered items" as defined in section 1834(a)(1)(F), and CMS cannot adjust the fee schedule rates for such items based on CBP information.

Therefore, the "relevant norm"—that CRT manual wheelchairs and related accessories cannot be adjusted under section 1834(a)(1)(F) because they cannot be subject to the CBP—flows from the statutory language itself and does not involve any agency discretion. In providing subregulatory guidance clarifying this logical implication, CMS would merely be providing "additional clarity through guidance **without creating a new non-statutory or non-regulatory norm**" that would be subject to the procedural requirements of section 1871 as interpreted in *Allina*.

D. <u>Even if CMS believes that the requested subregulatory guidance must be subject to notice-and-comment rulemaking, CMS can ensure swift implementation by finalizing the requested interpretation in the Final Rule an as interim policy while providing an opportunity to comment.</u>

[23] *Id.*
[24] *Id.*
[25] *Id.* (emphasis added).

Under the APA, agencies engaging in informal rulemaking must generally abide by certain notice-and-comment procedural requirements outlined at § 553 of the APA. However, Congress also expressly recognized that agencies may sometimes bypass notice-and-comment rulemaking "when the agency for good cause finds (and incorporates the finding and a brief statement of reasons therefor in the rules issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest."[26] Section 1871 of the Act incorporates this exception as well as it relates to the public interest.[27]

Here, although CMS does not have the authority to issue any subregulatory guidance impacting the rates of CRT manual wheelchairs and related accessories, other than the clarifying guidance requested above that merely implements the statute, *if* CMS believes it must still go through notice and comment rulemaking, NCART requests that it do so by finalizing the requested guidance as part of an interim final rule with comment period. CMS could finalize the requested guidance as part of an interim final rule with comment period and cite the fact that the current expiration of the prohibition against adjusting CRT manual wheelchairs and related accessories rates expires June 30, 2021, which is typically months in advance of when CMS issues and finalizes annual rulemaking related to DMEPOS. To prevent confusion regarding payment of CRT manual wheelchairs and related accessories after June 30, 2021, CMS must use this regulatory vehicle to clarify the payment status of such items of DME because the next opportunity CMS will have will be June 30, 2021. In other words, it would be contrary to the public interest to provide notice-and-comment for the requested clarification because it would cause a delay that affects beneficiary access to CRT manual wheelchair and related accessories as providers are uncertain what their payment for such items of DME will be after June 30, 2021.[28]

Moreover, courts have found that the "interim" nature of a rule is a "significant factor" in evaluating an agency's good cause claim, and that a post-promulgation opportunity for comment serves to ensure that stakeholder input is adequately considered before a permanent final policy is adopted.[29] Here, CMS would allow stakeholders to provide feedback on whether they agree with CMS' implementation of the statute and the resulting exemption of CRT manual wheelchairs and related accessories from CBP-based adjustments.

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[26] *Id.*
[27] *See* Social Security Act, § 1871(e)(1)(A)(ii).
[28] *See Mid-Tex Elec. Coop., Inc. v. FERC*, F.2d 1123, 1132 (D.C. Cir. 1987) (citing concerns about "regulatory confusion" in the absence of an interim final rule); *Nat'l Women, Infants, & Children Grocers Ass'n v. Food & Nutrition Serv.*, 416 F. Supp. 2d 92, 107 (D.D.C. 2006).
[29] *See Univ. Health Servs. of McAllen, Inc. v. Sullivan*, 770 F. Supp. 704, 721 (D.D.C. 1991) ("Although post-promulgation opportunity for comment is not a substitute for pre-promulgation notice and comment, failure to comply with the pre-promulgation procedures of § 553 of the APA may 'be cured by an adequate later notice' if 'the agency's mind remain[s] open enough at the later stage.'") (quoting *McLouth Steel Prods. Corp. v. Thomas*, 838 F.2d 1317, 1323 (D.C. Cir. 1988)).

NCART Recommendation:

1. CMS should issue subregulatory guidance clarifying that there will be no adjustments to the fee schedule rates for CRT manual wheelchairs and related accessories because Congress excluded them from the CBP and therefore do not fall within the universe of DMEPOS items subject to the adjustment directive of section 1834(a)(1)(F). The clarification should include an explanation that such an outcome is compelled by the statutory language itself. Because such a subregulatory clarification does not involve changing a "non-statutory" or "non-regulatory" norm, it is not subject to the procedural requirements of section 1871, and even if it were, CMS could adopt the clarification via an interim final rule with comment period to ensure stakeholders have adequate clarity regarding payment for CRT manual wheelchairs and related accessories.

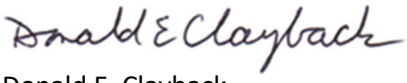
Closing Comments

Medicare coverage, coding, and payment policies have a significant impact on whether people with significant disabilities have adequate access to CRT items and related services. Over the past two decades, these policies have increasingly limited access for these Medicare beneficiaries.

We believe CMS has an opportunity to make significant and needed changes through the rule making process that would improve access and thereby improve outcomes for this small but important beneficiary group.

NCART has a sincere desire to collaborate with CMS to produce the best outcomes for the Medicare program and enrolled beneficiaries with significant disabilities and chronic medical conditions. We are happy to provide additional information and would be available to discuss our comments further.

Sincerely,



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