



January 4, 2021

SUBMITTED ELECTRONICALLY VIA www.regulations.gov

Ms. Seema Verma
Administrator
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

RE: ITEM Coalition Comments on Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Policy Issues Proposed Rule (CMS-1738-P; RIN: 0938-AU17)

Dear Administrator Verma:

The undersigned members of the Independence Through Enhancement of Medicare and Medicaid (ITEM) Coalition Steering Committee appreciate the opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) proposed rule on durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) payment and policies for calendar year 2021.

The ITEM Coalition is a national consumer- and clinician-led coalition advocating for access to and coverage of assistive devices and technologies for persons with injuries, illnesses, disabilities, and chronic conditions of all ages. Our members represent individuals with a wide range of disabling conditions, as well as the providers who serve them, including such conditions as multiple sclerosis, paralysis, spinal cord injury, cerebral palsy, brain injury, stroke, spina bifida, myositis, limb loss, low vision and visual impairments, hearing and speech impairments, and other life-altering conditions.

The following comments respond to several provisions in the Proposed Rule, including:

- I. Codification of the Healthcare Common Procedure Coding System (HCPCS) Level II Application Process;
- II. Processes for DMEPOS Benefit Category and Payment Determinations;
- III. Adjustments to the DMEPOS Fee Schedule;
- IV. Revisions to the "In the Home" Requirement for Certain DMEPOS Items;
- V. Exclusion of Manual Complex Rehabilitative Wheelchairs from the Competitive Bidding Program; and
- VI. Coverage of Low Vision Aids Under the Medicare Program.

The ITEM Coalition Low Vision Group has also submitted more detailed comments focusing exclusively on the Medicare program’s regulatory interpretation of the statutory “eyeglass” exception, which serves to exclude coverage for low vision aids under the DMEPOS benefit. These comments have been submitted under separate cover.

I. HCPCS Level II Code Application Process

A. Summary of the Proposed Rule

Consistent with current practices, CMS is proposing to codify in regulation policies, processes, and procedures regarding the submission and evaluation of external HCPCS Level II code applications bi-annually, which CMS has carried out since January 2020. Any final coding changes would become effective approximately three months after issuance of a final coding decision. The rule also proposes processes for CMS to use to determine whether to add, revise, or discontinue a code for DMEPOS items and services. In addition to considering information contained in the application and supporting material, public meeting comments, evaluations conducted by CMS, and other research, CMS proposes first assessing:

- 1) Whether the item or service is already coded in a different medical data code set;
- 2) If the item or service is “primarily medical in nature”;
- 3) If the item has the appropriate marketing authorization from the Food and Drug Administration (FDA), or is exempt from premarket notification requirements; and
- 4) If there is a claims processing need by the Medicare program.

If an item or service satisfies the initial assessment for adding a code, CMS proposes to then determine the appropriate placement of the item or service within the Level II code set by assessing whether the item or service performs a “significantly different clinical function” compared to other items or services described by the code set and whether the use of the item or service results in a “significant therapeutic distinction” compared to the use of other similar items or services described by the code set.

Finally, CMS proposes to limit the number of HCPCS coding applications on the same device or technology to three applications, an initial application and two resubmissions.

B. ITEM Coalition Comments

Before we comment on specific issues raised in the proposed rule, we wish to raise several concerns with the existing HCPCS coding process that, over the years, have hampered the ability of manufacturers and innovators to efficiently and effectively engage in the CMS-led HCPCS coding process. Unfortunately, while the proposed rule seeks to improve and codify important aspects of the HCPCS coding process, many of these proposals miss the mark of addressing our most significant concerns.

The Health Insurance Portability and Accountability Act of 1996 (HIPAA), Pub. L. 104-191, established the “uniform code set” that public and private payers have used ever since to consistently code claims for payment. CMS administers this process for the development and maintenance of Level II HCPCS codes for DMEPOS items and related services. For decades, CMS has not pursued the establishment of an advisory body that is compliant with the Federal Advisory Committee Act (FACA) to seek outside coding expertise with respect to HCPCS coding applications. Instead, CMS created the HCPCS Coding “Workgroup” comprised of federal employees only, to assist CMS staff in developing and maintaining HCPCS codes. Although the identities of the individual members of this Workgroup are not made public, participants appear to be CMS employees and some employees from the U.S. Department of Veterans Affairs and Department of Defense.

The HCPCS coding process is not well understood by many of those who seek to avail themselves of new or modified HCPCS codes. The participants and processes used are not transparent. The standards that must be met to achieve a new code are not well-defined nor consistently interpreted. The preamble of the proposed rule and CMS staff responsible for the coding process acknowledge that there is a limit to how many HCPCS codes will be established and a bias against creating codes with too much specificity or granularity. This bias of the HCPCS Workgroup has created a set of HCPCS codes that describe broad categories of devices or technologies which makes it difficult to differentiate between devices within a particular code.

The result has been a HCPCS code set that lumps widely disparate variations of certain devices into one code with little appreciation for real variations in cost of production, intended purpose, materials and mechanisms utilized, manufacturing processes, functional distinctions between devices, quality and durability, or patient preference. This has created an outcome where dozens of orthotic HCPCS codes had to be “split” into two sets of codes beginning in 2014 because both custom fit and off-the-shelf (OTS) orthoses were combined in a small set of codes. Beneficiaries also have significant barriers accessing the specific mobility devices they need because a small number of HCPCS codes that describe mobility devices do not differentiate between significantly different features or materials used in these devices; many similar examples can be cited.

The fact that widely disparate devices are lumped together under one HCPCS code creates two major problems: (1) Payers do not know exactly what they are paying for; and (2) Suppliers are motivated to provide to patients the least expensive device within each code in order to maximize reimbursement under a uniform payment amount for each code. This does a disservice to the integrity of the Medicare program—as well as other payers—and the patients these payers serve. These two problems are exacerbated under a competitive bidding scenario, which CMS has implemented in the DMEPOS benefit category since 2012. Finally, codes that describe a wide variety of devices and technologies limit or eliminate the ability to conduct meaningful surveillance on device use, comparative effectiveness research, and identification of functional improvement using claims data.

The fact that primarily Medicare officials within CMS run the HCPCS coding process is another major issue that impacts access to DMEPOS items and services across all payers, not just

Medicare. The HCPCS Workgroup acknowledges that coding decisions are often based on their relevance to the patient population Medicare serves, primarily seniors over the age of 65, despite the fact that Medicare also covers approximately 8 million people with disabilities below age 65. In fact, the preamble of the proposed rule states, “We maintain the HCPCS Level II code set primarily to support the claims processing needs of Medicare, recognizing that other payers use HCPCS Level II codes as well.”¹

However, the HCPCS is supposed to be a uniform code set that *all payers* can use to consistently code, cover, and reimburse DMEPOS items and services. This emphasis on Medicare seniors impacts decisions made by the HCPCS Workgroup in a manner that disadvantages beneficiaries and enrollees from payers other than Medicare who must use the HCPCS codes to file claims, such as younger veterans, people with disabilities of all ages, children on Medicaid, and others on private insurance who may be negatively impacted by the decisions made with a Medicare senior population in mind.

The ITEM Coalition, therefore, calls on CMS to rectify this situation and offers the following recommended alternatives:

- (1) ***CMS should appoint a formal advisory body, compliant with the Federal Advisory Committee Act, to assist the HCPCS Workgroup in rendering coding and payment decisions.*** At the very least, CMS should ensure that it identifies expertise across the federal government and in the private sector as subject matter experts to advise the HCPCS Workgroup when needed.
- (2) ***Other federal agency representatives who understand classification systems and coding nomenclature should be added to the HCPCS Workgroup,*** such as representatives from the National Institute for Standards and Technology (NIST), the National Science Foundation (NSF), and the research agencies across the federal government that focus on rehabilitation and disability research.
- (3) ***CMS should publicly and affirmatively confirm that the number of newly granted HCPCS codes will no longer be artificially limited. CMS should also publicly confirm that it will no longer pursue a policy of lumping together a broad range of devices and technologies into one HCPCS code.*** CMS should strive to achieve greater specificity and granularity in DMEPOS coding to differentiate between devices and technologies in order to help payers identify exactly what they are covering, ensure that patients receive the particular device or technology that best meets their needs, and facilitate the development of an evidence base around new technologies to validate their use.

Specific Coding Process Improvements Proposed by CMS

The ITEM Coalition strongly opposes limits on the number of HCPCS coding applications that can be submitted by an applicant for a new device or technology. We acknowledge that applicants should be expected to raise additional issues, present new or more comprehensive

¹ Fed. Reg. Vol. 85, No. 214, p. 70385.

evidence, or present innovative arguments not previously heard by the CMS Workgroup when resubmitting an application, but in the absence of a meaningful appeals process to challenge decisions of the Workgroup, limiting resubmissions of HCPCS coding applications would be harmful to the process and would compromise patient access to new and innovative devices, technologies, and related services.

With respect to the proposal to codify a biannual coding cycle with a three-month effective date following publication of new HCPCS codes, ***ITEM Coalition supports this proposal because it expedites the ability of beneficiaries to gain access to new devices and technologies.*** With respect to the types of information CMS should utilize to make its coding determinations, we believe CMS needs to expand its current level of expertise by employing some of the tactics described immediately above, such as creating a FACA-compliant advisory committee that the HCPCS Workgroup can consult. In addition, individuals with expertise from other agencies throughout the federal government, as described above, should be invited to participate as members of the HCPCS Workgroup.

Finally, the phrases “significantly different clinical function” and “significant therapeutic distinction” are reasonable concepts to utilize in determining whether a new device or technology requires a new HCPCS code, but these concepts should not be so strictly interpreted as to serve as a bar to new and more appropriate coding than the current code set allows.

Initial Assessments of Coding Applications

Primarily Medical in Nature: The ITEM Coalition has serious concerns with CMS’s proposed approach to conducting an initial assessment to determine whether a new device or technology is appropriate for the next step in the coding process. The proposed rule states that, among other criteria, CMS will make a threshold determination as to whether a device or technology in a HCPCS coding application is “primarily medical in nature” before conducting further analysis to determine whether it has a significantly different clinical function or a significant therapeutic distinction as compared to another existing code. While we do not question CMS’s need to perform a threshold analysis, ***we do oppose use of the “primarily medical in nature” standard in this threshold inquiry.***

First, the FDA classification of the device or technology and the determination of whether the device is already coded in a different medical data code set should suffice to allow CMS to proceed with additional coding analysis. Second, determining whether the device is primarily medical in nature is, in effect, a summary benefit category determination (BCD) in that two of the required five prongs of the DME definition pertain to whether the device or technology is “primarily medical in nature.” In effect, this requirement for coding purposes overlaps with and confuses the proposed rule’s approach to rendering benefit category determinations.

Further, the requirement to be primarily medical in nature does not apply to orthotics and prosthetics. The benefit category of orthotics and prosthetics is specifically defined in regulation and guidance and once these specific definitions are met, the device or technology qualifies under this benefit category. Adding a requirement that orthotics and prosthetics also meet the “primarily medical in nature” standard exceeds CMS’s authority and is inconsistent with the

statute and regulations. *For all these reasons, we recommend that CMS eliminate a determination of whether a device or technology is primarily medical in nature from its initial assessment, or threshold determination, of coding applications.*

Claims Processing Need: Granting CMS the authority, as the proposed rule does, to deny a HCPCS coding application as a threshold matter, before the process meaningfully begins, because the requested code would not meet a Medicare “claims processing need,” is a major problem. This would give CMS authority to summarily dismiss any application it does not believe is in the sole interests of its contractors or its beneficiaries, leaving all other payers and beneficiaries of those payers with no ability to establish an appropriate code and gain access to a new device or technology. This is perhaps the clearest illustration of the inherent mismatch of CMS being the sole federal agency tasked with establishing and maintaining a “uniform code set” to be used by all payers while primarily basing coding decisions on its own patient population. *The ITEM Coalition opposes this proposal and urges CMS to reconsider use of this criterion as a threshold factor in its initial assessment of coding applications.*

II. Benefit Category and Payment Determinations for DMEPOS

A. Summary of the Proposed Rule

The rule includes a proposal to codify in regulation the processes for obtaining public input on Benefit Category Determinations (BCDs) as well as payment determinations for new items and services. Specifically, such consultation would apply for items and services that the requestor believes are DME under the existing statutory definition; surgical dressings, splints, casts, and related items; orthotics and prosthetics; and therapeutic shoes or inserts. The process would be rolled into the biannual HCPCS coding cycle. CMS proposes a four-step process for issuing BCDs and payment determinations for new items and services.

B. ITEM Coalition Comments

An appropriate benefit category determination (BCD) in the DMEPOS space can mean the difference between Medicare covering a benefit for beneficiaries or not. It can mean the difference between patient use of a device being confined to a patient’s home versus use in all aspects of life in the community. It can determine whether a device or technology is owned outright by a beneficiary and paid in a lump sum or rented over the course of a 13-month period. Yet, to date, CMS has had no effective, publicly accountable system in place to render benefit category determinations. Since a BCD is not considered a Local Coverage Determination, BCDs cannot even be appealed through the administrative appeals process, and yet they have been routinely determined for decades by CMS staff or Medicare Administrative Contractors without a transparent and accountable public process.

We applaud CMS for seeking to rectify this lack of due process by codifying regulations that will establish publicly accountable procedures for CMS to make benefit category determinations. We believe running benefit category determinations through the HCPCS Coding Workgroup is a step

in the right direction in that such an approach at least represents a more accountable and transparent process. However, we are not convinced that the HCPCS Workgroup, as currently configured, has sufficient expertise to render or meaningfully advise CMS on these important matters. A FACA-compliant Advisory Committee could help advise the HCPCS Workgroup in rendering these decisions in a timely manner. We prefer this alternative to a full-blown public notice and comment regulatory process for each BCD which, we believe, would dramatically reduce the timeliness of approval of benefit category determinations for new devices and technologies, and consequently, access to care.

The ITEM Coalition views CMS's proposal to have the HCPCS Workgroup render preliminary pricing recommendations on new devices and technologies in the same manner. We believe such a process is a step in the right direction and affords greater accountability and transparency than the current procedure used by CMS to establish payment levels. We believe specific expertise on pricing is necessary if the HCPCS Workgroup is to also assume this function and encourage CMS to account for this in their deliberations in the future. Finally, the HCPCS Workgroup should not confine its work to determining pricing levels of only new devices and technologies. Applicants should be able to apply for a review of pricing levels of existing devices and technologies when current reimbursement levels restrict appropriate beneficiary access.

If the HCPCS Workgroup is to be used to render BCDs and reimbursement levels, then the same process should be available to subsequently challenge BCDs and pricing decisions that applicants believe were incorrectly decided. Consistent with our comments above in opposition to any limitations on the number of times an applicant can apply for a new code or reconsideration of a reimbursement level, we believe applicants should have no limit to how many times the HCPCS Workgroup should consider challenges to BCD determinations and reimbursement levels, assuming new evidence or circumstances arise that help inform a renewed application.

III. DMEPOS Fee Schedule Adjustments

A. Summary of Proposed Rule

CMS proposes an extension of existing adjustments in fee schedule payments 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 expiration of the COVID-19 public health emergency (PHE), whichever is later.

Current law requires CMS to revise fee schedule payments in non-CBAs based on competitively bid prices, with adjustments to account for complexities and regional variations in delivering DMEPOS in rural, non-rural, and non-contiguous non-CBAs. "Non-contiguous areas" are areas in Alaska, Hawaii, and U.S. territories. Currently, certain DME items and services furnished in certain non-CBAs are reimbursed through the application of a "blended" rate, utilizing both the adjusted and historic, unadjusted fee schedule amounts to protect beneficiary access.

CMS now proposes three separate methodologies for future adjustments based on where the items or services are furnished: non-contiguous non-CBAs, rural non-CBAs, and contiguous, non-rural non-CBAs. Specifically, for non-contiguous non-CBAs and rural, contiguous non-CBAs, CMS proposes to extend the transitional “50-50” blended rates currently in place for these areas. For contiguous, non-rural non-CBAs, CMS proposes to fully implement the adjusted payment amount.

In conjunction with the release of the proposed DMEPOS rule, CMS [issued](#) payment amounts and contract offers for Round 2021 of the DMEPOS Competitive Bidding Program (CBP). Originally, 16 product categories were set to be bid for Round 2021, two of which (OTS back and knee braces) were proposed for competitive bidding for the first time. In April 2020, CMS removed non-invasive ventilators from Round 2021 due to the COVID-19 public health emergency (PHE). Now, CMS has decided to not award competitive bidding contracts to any of the 13 Durable Medical Equipment product categories that were previously competed because “the payment amounts did not achieve expected savings.”

However, 16 OTS back brace HCPCS codes and 7 knee brace codes were awarded contracts in 127 of the 130 competitive bid areas (CBAs) for Round 2021. If CMS proceeds with the proposed extension of the current transitional methodologies, all DME items that went through earlier rounds of competitive bidding and off-the-shelf knee and back braces (represented by the 23 HCPCS codes) furnished in non-CBAs would be priced according to the proposed methodologies outlined above, while OTS orthoses (represented by the 23 HCPCS codes) furnished in CBAs would be priced according to the newly implemented competitive bidding contracts beginning January 1, 2021.

B. ITEM Coalition Comments

In proposing to permanently extend the existing transitional methodologies for adjusting fee schedule amounts in non-CBAs, CMS notes that these proposals will result in higher rates for items and services furnished in rural and non-contiguous areas compared to those furnished in other areas. CMS also notes that stakeholders continue to express their belief that the fully adjusted fee schedule amounts are too low and would have a negative impact on beneficiary access, especially in rural areas. ***The ITEM Coalition strongly supports the extension of the transitional fee schedule adjustments because of the impact on access, quality, and choice of DME for Medicare beneficiaries, and urges CMS to implement a 50-50 blended payment amount for non-rural, contiguous non-CBAs as well.***

Over the past several years, CMS has made significant policy and regulatory changes to the Medicare DME benefit, including the continued expansion of the CBP. Many of these changes have been intended to save taxpayer money; however, many ITEM Coalition members report substantial negative effects across the country on beneficiary access to vital DME items and services that improve health and function. Extending the transitional methodologies for DME provided in non-CBAs will promote beneficiary access to and choice of quality DME.

Access and Choice

There are fundamental differences in providing DME in urban/suburban areas compared to rural areas (as well as underserved urban areas, whether or not they are in a CBA), differences that add significant costs to the provision of DME to Medicare beneficiaries. Medicare beneficiaries in rural areas are geographically dispersed, hard to reach, and do not have the same access to systems of care available in more populated areas. Tough terrain, long distances between patients and providers/suppliers, and fewer health care resources mean that DME suppliers must incur added costs to deliver the appropriate medical equipment and supplies to patients on a timely basis. Rural DME suppliers, quite literally, have to go the extra mile for their Medicare patients. This translates into added costs for transportation, delivery and clinical staff, fuel, and other expenses.

With the introduction of competitively bid rates in rural CBAs, some suppliers have been forced to shut down because they cannot afford to provide DME to patients in these areas. This exacerbates the problem of already-low numbers of DME suppliers in rural and non-contiguous areas, which creates an access problem for rural Medicare beneficiaries. Medicare beneficiaries have experienced interruptions in continuity of care and barriers to DME access as a result of this flawed approach to reimbursement of DME in rural areas. The extension of the blended rates promotes access for beneficiaries in rural areas, making it less likely suppliers will be forced to close or stop providing DME to Medicare beneficiaries. The blended rates also help to provide choices to beneficiaries to select from among a greater number of DME suppliers, as well as a greater variety of brand-name items and services that may meet their needs better than others.

Quality

Facing increased challenges of operating in rural areas, suppliers have to cut costs elsewhere to make ends meet. This means limiting the range of DME items provided to beneficiaries to less expensive, often lower quality DME, reducing staff, making home deliveries less often, delaying repair times, and using other methods to reduce supplier cost. All of these cost saving measures potentially compromise the quality of the existing Medicare DME benefit. The extension of blended pricing in the proposed rule will increase the likelihood that beneficiaries will receive quality DME, as rural suppliers will be less likely to be inadequately reimbursed for the costs of providing DME. Receiving DME as prescribed is essential, as patients depend on these items and services to function and live as independently as possible. The Medicare DMEPOS benefit has a profound impact on patients' quality of life.

Non-Rural, Contiguous Areas

In the proposed rule, for all areas that are currently non-CBAs, but are not rural or non-contiguous areas, CMS proposes that rates should be based on 100 percent of the adjusted fee schedule amounts. ***The ITEM Coalition disagrees with this proposal and urges CMS to extend the same 50-50 blended rates to all non-CBAs to ensure that beneficiaries have appropriate access and choice of quality DME items and services, including OTS orthoses subject to competitive bidding for the first time.*** An extension of the 50-50 blended rate to these areas as

well as the rural/contiguous and non-contiguous non-CBAs would help ensure that beneficiary access to DME products and services is more equitable and more accessible to Medicare beneficiaries.

Overall, the permanent extension of the transitional rates for certain non-competitive bidding areas has the potential to improve access for beneficiaries, improve choice for beneficiaries, and maintain the quality of durable medical equipment and off-the-shelf orthotics for beneficiaries. We thank CMS for recognizing the negative impact of the full fee schedule adjustment on beneficiaries in rural and non-contiguous CBAs and taking proactive steps to ameliorate this impact. We also encourage CMS to continue monitoring access to DMEPOS items and services once these new methodologies are implemented and revisit the pricing methodologies if any barriers to access are identified.

Rates in Former CBAs

CMS notes in the Proposed Rule that it is considering simply extending the current payment methodologies for items and services furnished in CBAs and “former CBAs” that were originally proposed but no longer included in the 2021 round of the CBP. ***The ITEM Coalition strongly opposes this proposal without modification of the transitional methodologies.*** The current rates are based on outdated single payment amounts calculated using the original competitive bidding methodology, which has rightfully been revised and updated by CMS since the program’s implementation. The original methodology contributed to artificially low rates, which will present significant concerns for beneficiary access for many of the same reasons outlined above. If CMS moves forward with this proposal for CBAs and former CBAs, we urge CMS to implement a blended payment rate for these areas as well, incorporating a portion of the unadjusted fee schedule rates into the current payment rates for former CBAs. This would ensure that rates are appropriate to reflect changes in the market, the original bidding methodology, and additional costs faced by manufacturers and suppliers.

Off-the-Shelf Orthotics

As noted above, on January 1, 2021, CMS will be implementing competitive bidding for off-the-shelf orthotics for the first time. We understand that CMS intends to implement the proposed fee schedule adjustment methodologies for OTS orthotics furnished in non-CBAs, based on the newly awarded competitive bidding contracts, beginning on April 1, 2021 (or the end of the public health emergency, whichever is later).

The ITEM Coalition has long expressed concerns about the potential negative impact of decreased, competitively bid rates on patient access to orthotics and prosthetics. Congress acknowledged these concerns by exempting all orthotics and prosthetics from competitive bidding except those orthoses subject to “minimal self-adjustment.” After CMS expanded the breadth of orthotics exposed to competitive bidding through regulation, we raised serious concerns with the scope of the orthoses eligible to be competitively bid, given the fact that certified and/or licensed orthotists identify several of the HCPCS codes subject to competitive bidding as “custom fit” orthoses that require a higher degree of clinical care than OTS orthoses, despite CMS’ depiction of these codes as off-the-shelf. Additionally, we have noted that the

competitively bid rates submitted by suppliers, upon which the new contracts are based, were submitted well before the pandemic began, in a completely different health care marketplace.

Given these concerns, and the general uncertainty caused by the COVID-19 pandemic, we urge CMS to consider postponing the implementation of the fee schedule adjustment methodologies for the 23 orthotic codes scheduled to be competitively bid in Round 2021.

Instead, these orthoses provided in non-CBAs should continue to be paid at the unadjusted fee schedule rate as Round 2021 is implemented. This delay would allow CMS and stakeholders in the field to monitor the provision and utilization of these orthoses at the new competitively bid rates in CBAs and ensure that these reimbursement rates do not present any additional barriers to patient access. There are significant differences between the provision of DME and O&P care in urban/suburban areas and the rural or non-contiguous areas that make up the majority of non-CBAs. Our recommendation would recognize these differences and allow more time for CMS and stakeholders to assess the impact of the OTS competitive bidding program.

We acknowledge that CMS seems to be aware of these differences in the provision of care and plans to address these by implementing the transitional methodologies on a permanent basis. However, with regards to the 23 orthotic codes in particular, we believe that the fully unadjusted fee schedule amounts are appropriate for at least the first two years of Round 2021 of the CBP. These codes represent the first time the OTS orthotic benefit is included in competitive bidding and special attention should be paid to any patient impact these new rates will have.

For instance, while DME is largely provided by DME suppliers, OTS orthotics are routinely provided by physicians, therapists, orthotists, DME suppliers, pharmacies, and a number of companies with sales forces that ship OTS orthoses to patients' homes. Immediately incorporating these competitively bid rates to payment for these orthoses in non-CBAs could expand the ripple effects of the CBP for OTS orthoses before they are fully understood, potentially harming patient access during a time of upheaval in the health care system.

IV. Revisions to the “In the Home” Requirement to Provide for Expanded Classification of External Infusion Pumps as DME

A. Summary of Proposed Rule

CMS proposes to revise the interpretation of the requirement that DME be “appropriate for use in the home” in order to allow coverage specifically for certain drugs or biologicals that are infused in the home via an external infusion pump. CMS states that this proposed interpretation would expand coverage of drugs or biologicals as supplies under the DMPEOS benefit and impact home infusion therapy services, specifically in furtherance of the agency’s goal of increased value-based care.

B. ITEM Coalition Comments

The ITEM Coalition notes that this proposal does not impact the overarching “in the home” requirement, which many stakeholders, including the ITEM Coalition, have long identified as a

barrier to access for some DMEPOS, especially mobility assistive equipment. Traditionally, CMS has interpreted this requirement as restricting Medicare coverage of DMEPOS to only items and services that are medically necessary within the four walls of the beneficiary's home, excluding any broader needs of the beneficiary, such as participation in employment, education, or community activities. We have urged CMS in the past to revise its interpretation of this requirement or remove it entirely in order to facilitate broader coverage of DMEPOS that supports the full range of patient's medical and functional needs. ***We do not oppose this tailored change to enable access to home infusion drugs; however, the provision in the proposed rule does not address these broader concerns, which we address here.***

The Medicare statute defining the Durable Medical Equipment benefit states that DME includes "iron lungs, oxygen tents, hospital beds, and wheelchairs... *used in the patient's home*" (emphasis added).² The associated regulations further define the "five prongs" of the DME benefit, one of which being that the equipment "is appropriate for use in the home."³ The ITEM Coalition has long held that the clear congressional intent in enacting the "in the home" requirement was to distinguish the DME benefit from equipment used in the hospital and, therefore, separately reimbursable under Medicare Part A.

However, CMS has interpreted this provision to restrict beneficiaries from accessing a wide range of critical equipment that is not exclusively utilized within the four walls of a beneficiary's home. This has been a particular barrier in the realm of mobility equipment, in which CMS has restricted access to equipment that would allow beneficiaries with mobility impairments to perform important everyday activities such as participating in employment and in the community. ***Instead of making minor modifications to the "in the home" requirement to allow coverage for individual items and services, we urge CMS to rethink its narrow interpretation of this restriction to allow beneficiaries better coverage of DME that is essential for everyday life while encouraging full community integration.***

V. **Exclusion of Complex Rehabilitative Manual Wheelchairs and Certain Other Manual Wheelchairs from the CBP**

A. Summary of Proposed Rule

CMS' fee schedule adjustment methodology, when initially implemented, was set to apply adjusted rates dependent on the competitive bidding program to complex rehabilitative technology (CRT) wheelchair bases, as well as components utilized with these bases known as "accessories." CRT power wheelchair technology was excluded from competitive bidding, but the associated adjusted rates could be applied to CRT wheelchair accessories. The 21st Century Cures Act temporarily extended the application of unadjusted fee schedules to CRT power wheelchair accessories.

² Social Security Act, Sec. 1861. 42 U.S.C. § 1395(x)(n).

³ 42 C.F.R. § 414.202.

On June 23, 2017, CMS issued a policy clarification that the agency would not apply competitively-bid reimbursement levels to CRT Group 3 *power* wheelchair accessories, making permanent the temporary policy in the 21st Century Cures Act. The ITEM Coalition strongly supported this change, which averted significant cuts in reimbursement that were scheduled to go into effect July 1, 2017 and avoid drastic reductions in access to this specialized mobility technology for Medicare beneficiaries with significant, long-term mobility impairments.

Unfortunately, CMS did not extend this change to CRT *manual* wheelchairs, leaving a discrepancy between the treatment of these two categories of wheelchair accessories. In 2019, Congress passed legislation⁴ permanently excluding manual CRT wheelchair bases from the competitive bidding program (CBP) to match the treatment of power wheelchair bases. The proposed rule includes language implementing this change, which the ITEM Coalition supports. This legislation also instituted an 18-month suspension of competitively bid rates for manual CRT wheelchair accessories. This suspension is currently scheduled to expire on June 30, 2021.

B. ITEM Coalition Comments

The ITEM Coalition urges CMS to make permanent the temporary suspension of adjusted payments for manual CRT wheelchair accessories and components. While we support CMS' proposal to implement the permanent exemption of manual CRT wheelchair bases from the CBP, the price adjustments for manual CRT wheelchair accessories are not addressed in the proposed rule. CMS' 2017 action clearly recognized that congressional intent in excluding power CRT *wheelchairs* from competitive bidding should extend to the treatment of power CRT wheelchair *accessories*, which are integrated into the base and are critical for the proper functioning of the device and to ensuring the user receives the full benefit of this technology. Now that Congress has extended this exemption to manual CRT wheelchairs, CMS should extend this payment policy to ensure that patient access to manual CRT wheelchair accessories is also protected.

Action by CMS is urgently needed to permanently help Medicare beneficiaries who are manual CRT wheelchair users to obtain medically necessary CRT accessories and components before the reduced rates go back into effect on July 1, 2021. Prior to congressional action in the *Further Consolidated Appropriations Act*, the decision by CMS to not permanently extend these payment rates led to a significant disparity in access. This adversely impacts Medicare beneficiaries with mobility impairments by unfairly penalizing manual CRT wheelchair users, limiting their access to essential wheelchair accessories and components.

Data from a recent survey of over 400 Medicare supplier locations, conducted prior to the temporary suspension of the price adjustments for manual CRT wheelchair accessories, show that nearly two-thirds of respondents indicated the reimbursement cuts for these components had “significantly reduced [their] ability to provide the right wheelchair accessories to Medicare beneficiaries who require Complex Rehab Manual Wheelchairs.”⁵ If the reduced fee schedule

⁴ H.R. 1865, the *Further Consolidated Appropriations Act*, P.L. 116-94.

⁵ “New Medicare CRT Supplier Survey Identifies Major Decrease in Access to Critical Components (Accessories) Used with CRT Manual Wheelchairs,” The National Coalition for Assistive and Rehab Technology (NCART),

rates for these components are allowed to go into effect in July 2021, the ensuing decrease in access to manual CRT wheelchair accessories would be detrimental to many wheelchair users that rely on Medicare to provide these essential components.

The ITEM Coalition strongly supports this policy change of implementing the permanent exemption of manual CRT wheelchair bases from the CBP and wishes to emphasize the importance of protecting patient access to accessories used with both *power* and *manual* CRT wheelchairs. Regardless of injury, illness, disability, or chronic condition, all Medicare beneficiaries with mobility impairments should be eligible for the same access to medically necessary mobility devices, services, and accessories. Anything less can have serious consequences for beneficiaries. ***We therefore urge CMS to permanently exempt components and accessories used with CRT manual wheelchairs from the reduced fee schedule rates tied to the Competitive Bidding Program.***

VI. Medicare Coverage of Low Vision Aids

Individuals with low vision and other vision-related impairments face significant obstacles in carrying out activities of daily living (ADLs). Literature also suggests significant association between visual impairment and a variety of physical and mental comorbidities, including depression, social isolation, incidence of falls, and dementia.^{6,7} Various forms of assistive devices exist to treat visual impairment, such as hand-held magnifiers, video monitors, and other technologies that utilize lenses to enhance vision. These tools are often essential for individuals with visual impairments and can allow these individuals to perform essential tasks such as reading prescription labels, mail, financial documents, and other important materials.

Despite the availability of such low vision devices and the numerous benefits to health and function they afford to beneficiaries with visual impairments, CMS unnecessarily and preemptively denied coverage of any technology that uses “one or more lenses for the primary purpose of aiding vision” in its CY 2006 proposed and 2008 final DMEPOS rules. This restrictive policy goes far beyond congressional intent in defining the Medicare benefit and denies critical and medically necessary assistive devices for an entire diagnostic category of beneficiaries (i.e., beneficiaries with vision impairments) with specific medical and functional needs.

As such, the ITEM Coalition urges CMS to rescind the “low vision device exclusion” and reconsider this preemptive benefit category determination that dramatically underserves beneficiaries with vision impairments. Coverage of low vision aids should be determined

September 2018. Available online at <http://blog.access2crt.org/congress-needs-to-see-new-data-showing-crt-accessissues/>. NCART is an ITEM Coalition member.

⁶ See., e.g., Court H., McLean G., et al. (2014). Visual Impairment is associated with Physical and Mental Comorbidities in Older Adults: A Cross-Sectional Study. *BMC Med.* 12:181. Doi: 10.1186/s12916-014-0181-7.

⁷ Wood. J., Lacherez, P. et al. (2011) Risk of Falls, Injurious Falls, and Other Injuries Resulting from Visual Impairment among Older Adults with Age-Related Macular Degeneration. *Investigative Ophthalmology & Visual Science* 52 (5088-5092). Doi: 10.1167/iops.10-6644.

through the National and Local Coverage Determination processes already in place at CMS.
The ITEM Coalition's Low Vision Group has also prepared and submitted more detailed comments on this issue under separate cover.

We appreciate your consideration of our comments. Should you have further questions regarding this letter, please contact the ITEM Coalition coordinators at Peter.Thomas@PowersLaw.com and Joseph.Nahra@PowersLaw.com or by calling 202-466-6550.

Sincerely,

The Undersigned Members of the ITEM Coalition Steering Committee

ALS Association
Amputee Coalition
Christopher & Dana Reeve Foundation
Paralyzed Veterans of America
Spina Bifida Association
United Spinal Association