Submitted electronically to: www.regulations.gov

December 22, 2020

Ms. Seema Verma
Administrator
Centers for Medicare & Medicaid Services
200 Independence Ave., S.W.
Washington, D.C. 20201

Re: Comments on CMS-1738-P, "Medicare CY 2021 Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Policy Issues and Healthcare Common Procedure Coding System (HCPCS) Level II Proposed Rule (CMS-1738-P, 85 *Fed. Reg*. 70358, November 4, 2020), and CMS Announcement on Competitive Bidding Program

Dear Administrator Verma:

I. Introduction

The American Association for Homecare (AAHomecare) is pleased to submit comments on the Centers for Medicare and Medicaid Services' (CMS') above captioned Proposed Rule (CMS-1738-P), as well as CMS' October 27, 2020 announcement regarding the durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) competitive bidding program (CBP). AAHomecare is the national association representing DMEPOS suppliers, manufacturers, and other stakeholders in the homecare community. Our members are proud to be part of the continuum of care that assures Medicare beneficiaries receive cost effective, safe and reliable home care products and services.

Summary of Key Recommendations

a. 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, and the 10 percent should be based on the 2015 unadjusted fee schedule.

b. Rates in non-rural, non-CBAs should be based on a 75-25 blended payment formula. The 75 percent portion should be based on the current rates in former CBAs, and the 25 percent portion of the blended payment formula should be based on the unadjusted fee schedule.

c. CMS should eliminate its proposed limit on the number of times an applicant can re-submit applications for new or revised Level II HCPCS codes, as long as the applicant includes new data/information to support the request.

d. **CMS should add to its HCPCS code panel representatives from state Medicaid programs, and/or a representative from the National Association of Medicaid Directors, and representatives of commercial payers. CMS should also rely on the outside clinical experts**, for example, those it has established through MEDCAC.

e. **We recommend that CMS incorporate into its HCPCS code application process a public notice and comment for its gap-filling and comparability analyses after a positive preliminary HCPCS code decision**, to allow for both public input and for CMS to publicize the information it uses in making these payment determinations.

f. **CMS should permanently exempt accessories used with complex manual wheelchairs from competitive bid program-derived pricing,** as it did in 2017 for accessories used with complex power wheelchairs.

g. **We generally support CMS' proposal to expand coverage to adjunctive Continuous Glucose Monitors (CGMs), but urge the Agency to address a number of outstanding implications, and allow for public comment on those issues.**

II. Need for Transparency on CMS' Decision to Remove Product Categories from the CBP

AAHomecare commends CMS for its decision to not move forward with the 13 product categories in Round 2021 of the CBP. The current COVID-19 Public Health Emergency (PHE) has created unprecedented strains on the health care system, including our members and the entire DMEPOS community. Many COVID-19 patients are being prescribed home oxygen and other respiratory therapy, and our members are on the front lines assisting in ensuring that many of these patients avoid hospitalization and receive their health care in their homes.

We urge CMS to provide transparency about the single payment amounts (SPAs) that CMS calculated based upon bids received for the 13 product categories that have been removed from Round 2021 of the CBP. We request that the Agency provide us with the lead item SPA for each of the 13 product categories, in each of the 130 competitive bid areas (CBAs). The Agency has recently made significant strides in providing price transparency, and we believe this request is consistent with those policies.

III. Removal of 13 Product Categories from Round 2021

In an October 27, 2020 announcement that corresponded with the posting of this Proposed Rule, CMS revealed that the Agency is only moving forward with off-the-shelf (OTS) back braces and OTS knee braces for Round 2021 of the CBP. CMS is removing the remaining 13 product categories for Round 2021.[1] CMS announced the removal of non-invasive ventilator (NIV) from Round 2021 in a separate announcement on April 9, 2020.[2]

[1] "Round 2021 DMEPOS Competitive Bidding Program Single Payment Amounts and Contract Offers" Published October 27, 2020 at https://www.cms.gov/files/document/round-2021-dmepos-cbp-single-payment-amts-fact-sheet.pdf?#:~:text=Contract%20offers%20have%20been%20made,Round%202021%20contract%20performance%20period

[2] "CMS REMOVES NON-INVASIVE VENTILATORS FROM ROUND 2021 OF THE COMPETITIVE BIDDING PROGRAM"

AAHomecare fully supports CMS' decision to remove the 13 product categories, as well as NIVs, from Round 2021 of the CBP. As we have previously commented to the Agency, the current COVID-19 PHE has impacted health care providers across the country, including DMEPOS suppliers. Many COVID-19 or suspected COVID-19 patients have been prescribed home oxygen therapy or other types of respiratory therapy in the home, as a therapeutic response to the disease, and as a means to avoid hospital overflow issues. While many of these patients are not Medicare beneficiaries, the same home respiratory/DME suppliers that are taking care of these patients are also taking care of beneficiaries with home respiratory therapy needs and are providing critical home oxygen therapy to patients in their homes.

Remaining Product Categories Included in Round 2021 (OTS Neck Braces and OTS Back Braces)

Need for Transparency: For the two product categories that remain in Round 2021 of the CBP, we ask that CMS provide transparency regarding (1) number of bidders for each of these product categories in each of the CBAs; and (2) what the SPAs would have been in the few CBAs where CMS removed these product categories from the CBP due to the absence of significant savings. Disclosing this information would be consistent with CMS' price transparency policies.

Need to Monitor Access in CBAs with Lowest SPAs: The range of SPAs within each of these two product categories is quite broad. For example, the SPAs for OTS back braces (HCPCS code L0650) range from $238 to over $1300; and the SPAs for OTS knee braces (HCPCS code L1833) range from $254 to $745. Given the wide disparity of SPAs for the same HCPCS codes in these two product categories, we recommend that CMS closely monitor potential access issues, particularly in the CBAs with the lowest SPAs for these two product categories.

IV. DMEPOS Fee Schedule Adjustments – Proposed 42 C.F.R. § 414.210

Rates in Former CBAs: In its proposed rule, CMS states that for former CBAs, it is "seriously considering whether to simply extend application of the current fee schedule adjustment transition rules for all of the items and services that were included in Round 2021 of the CBP but have essentially been removed from the CBP."[3] CMS asks for comments on this proposal.

AAHomecare strongly opposes continuation of the current rates because they are based on 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.

Published April 9, 2020 at https://www.cms.gov/files/document/round-2021-dmepos-cbp-single-payment-amts-fact-sheet.pdf https://dmecompetitivebid.com/cbic/cbic2021.nsf/DocsCat/TXYEIKZ5FH

[3] 85 *Fed. Reg*. at 70371.

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.[4] 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, our members 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.

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.

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. AAHomecare 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. AAHomecare 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.

AAHomecare recommends that CMS 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.

[4] See 42 C.F.R. §414.210(g)(4)

Since CMS established payment rates in non-rural non-CBAs based on 100 percent of the SPAs in CBAs, AAHomecare has fundamentally disagreed with this payment policy. In a bidding program, there is a guarantee that there will be fewer competitors and larger volume of business. Neither of these facts exist in non-bid areas. There is therefore no logical nexus between rates established in CBAs and the costs to serve in non-CBAs. That fact, coupled with the fundamentally flawed feature of the previous CBPs where the SPA was based upon the median of the initial contractors' bids, means that the former CBA SPAs cannot be used as a proxy for supplier's costs of furnishing DMEPOS items in a non-CBA. There is simply no rational justification for a policy that establishes rates in non-bid areas based on 100 percent of the SPAs in CBAs.

It is important for Medicare to increase the rates in former CBAs and in non-rural non-CBAs to assure beneficiary access. While CMS presents its analysis to conclude there are no access issues in non-rural non-CBAs, the steady decreasing number of DME suppliers across the country indicates a dwindling number of suppliers and real potential access issues. AAHomecare therefore strongly urges the Agency to increase payment rates in all non-CBAs, and in former CBAs, to ensure appropriate beneficiary access and DME supplier financial viability. In 2018, CMS issued an interim final rule establishing higher payment rates in rural areas.[5] CMS did so due to its recognition that the decreased number of DME suppliers was evidence of declining financial viability which could result in beneficiary access issues, particularly in rural areas. Given the significant increased costs suppliers are incurring due to the COVID-19 PHE, AAHomecare is concerned that those same supplier viability issues are prevalent across the country, particularly with the increased financial pressures caused by the COVID-19 pandemic.

We appreciate CMS' recognition, in the May 2018 Interim Final Rule, that the decreasing number of DME suppliers could present real issues for beneficiary access.[6] Suppliers that serve beneficiaries in non-rural areas are generally the same ones that serve beneficiaries in the rural areas. The issues of financial viability and beneficiary access do not start at the artificial "border" of the rural/non-contiguous and other remaining non-CBAs. We therefore urge CMS to increase rates in non-rural non-CBAs, based on the same methodology recommended above for rates in former CBAs. That is, rates in non-rural non-CBAs should be based upon the 75-25 blended payment formula where the 75 percent portion is based on the adjusted fee schedule, and the 25 percent is based on the unadjusted fee schedule.

In addition, in 2018 the American Thoracic Society (ATS) published a peer-reviewed paper demonstrating how competitive bidding rates resulted in a loss of beneficiary access to some types of home respiratory therapy and services. The ATS study found that beneficiaries experienced isolation and inactivity, which are essential to maintaining quality of life for beneficiaries.[7] As the figure below demonstrates,[8] access to oxygen therapy in particular was a problem across the United States.

[5] CMS Interim Final Rule, "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," (83. *Fed. Reg*. 21912, May 11, 2018).

[6] *Id*.

[7] *Id.* at 15.

[8] Susan S. Jacobs, *et al*, "Patient Perceptions of the Adequacy of Supplemental Oxygen Therapy. Results of the American Thoracic Society Nursing Assembly Oxygen Working Group Survey" 15 *Annals of the Am. Thoracic Soc.* 24-32 (Jan. 2018).

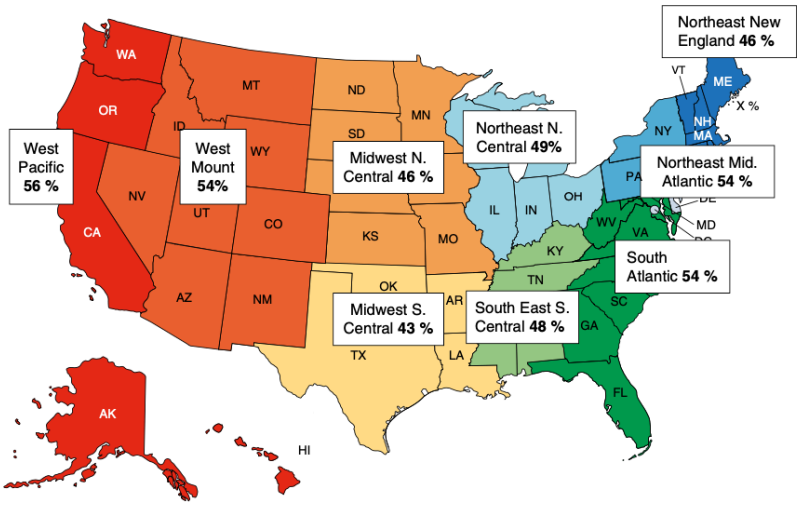


Figure 3. Percentage of respondents by region answering "yes" to having oxygen problems.

Patients reported reductions in access to licensed respiratory care practitioners in the home.[9] "While these reductions in many cases do not mean that Medicare beneficiaries no longer receive medically necessary equipment and supplies, it does mean that they do not receive the level of services they and their families received prior to the rates dropping below the cost of providing services."[10] Thus, it is important to ensure that the rates not only allow for the existence of suppliers, but cover the cost of providing the medically necessary equipment, supplies, and services they need.

Just a few years later, our country is in the midst of a PHE that requires many more patients to receive home respiratory therapy. We do not know how many of these patients will have longer term effects and require home respiratory therapy on a long-term basis. It is important for CMS to establish payment rates that will sustain a DME/home respiratory supplier market for now and over the longer term. As CMS publicly acknowledged in its 2018 Interim Final Rule,[11] a financially viable DME supplier market is necessary because "reduced access to DME may put beneficiaries at risk of poor health outcomes or increase the length of hospital stays."[12] CMS should therefore agree that it is important to provide payment relief across the country to ensure continued access for beneficiaries that reside in these areas.

V. HCPCS Level II Code Applications – Proposed 42 C.F.R. §§ 414.8, 414.9, and 414.10

CMS is proposing to codify certain longstanding policies and procedures regarding application procedures and evaluation processes for external HCPCS Level II code applications. While AAHomecare generally supports the codification of these policies, we have a number of recommendations to improve the process and increase the transparency of these processes. Given the significant impact of CMS HCPCS code decisions, we encourage increased transparency and additional opportunities for public input on these CMS proposals. Our recommendations are as follows:

[9] *Supra,* note 1 at 15.
[10] *Id.*
[11] 83. *Fed. Reg*. 21912, May 11, 2018.
[12] I*d*. at 21918.

Eliminate Limit on Number of Re-Applications: We strongly disagree with CMS' proposal to limit an applicant who is dissatisfied with CMS' final coding decision to two resubmissions. As long as there is new information, such as clinical data or other supporting information for a new or revised HCPCS code, CMS should not impose any limit on the number of times an applicant can resubmit an application for a new or revised HCPCS code. As technology is introduced into the market, more clinical and other supporting data will emerge as time progresses, and applicants should be able to submit additional applications for new or revised HCPCS codes based on that new information. If CMS imposes an arbitrary limit on the number times an applicant can resubmit an application, particularly where there is new information to support a new or revised HCPCS code, CMS is thwarting the ability of the Level II HCPCS system to keep pace with technology developments and may be denying beneficiary access to important new technology. Therefore, *AAHomecare strongly recommends that CMS modify its proposal and eliminate its proposed limit on the number of times an applicant can re-submit applications for new or revised HCPCS codes, as long as the applicant includes new data/information to support the request.*

Provide Applicants 45-Days' Notice of Preliminary Decision in Advance of Public Meeting: CMS' current process has allowed applicants only about two weeks between the date when the applicant is informed of CMS' preliminary decision and the date when CMS holds its Level II HCPCS public meeting. Applicants need more time to prepare, which often includes obtaining external experts to dispute CMS' preliminary decision. *We therefore recommend that CMS provide applicants at least 45 days prior notice to the public meeting to allow applicants adequate time to fully prepare for their presentation.*

CMS Should Include Other Payer Representatives on the CMS HCPCS Panel: We were discouraged to learn that CMS changed the composition of the HCPCS panel in recent years to eliminate representatives of non-Medicare payers. Previously, the HCPCS panel included representatives from state Medicaid programs and commercial payers, but, without any explanation, eliminated all of these non-Medicare payer positions on the panel. While CMS acknowledges that other payers also use the HCPCS Level II set, its decision to limit input from other payers restricts CMS' ability to understand other payers' needs and perspectives regarding HCPCS codes. For example, an item may be designed to be used primarily by pediatric patients, and state Medicaid programs may be the primary payer for the item. Similarly, a device may be used primarily by patients younger than 65 who are insured by commercial payers. In both these instances, CMS will not have the benefit of understanding the need for a new or revised HCPCS code from these other payers.

Since all payers follow the decisions of the Level II HCPCS code panel and use the same HCPCS codes for claims processing, *we strongly urge CMS to again include representatives from non-Medicare payers on the HCPCS code panel. We recommend that CMS add to the panel representatives from state Medicaid programs, and or a representative from the National Association of Medicaid Directors.*

CMS Should Rely on Outside Clinical and Technological Experts: We expect there are instances where the CMS members of the panel may not have the relevant clinical and/or technological expertise to adequately assess the clinical application and therapeutic benefit of new medical devices. We recommend in these instances that CMS have a pipeline of outside clinical and/or technological experts upon whom it can rely to provide relevant input. CMS already has access to such a group of outside clinical experts through its Medicare Evidence Development and Coverage Committee (MEDCAC), which is designed to provide independent guidance and expert advice to CMS on specific clinical topics. *CMS should identify external technological and product experts to serve an advisory capacity to the HCPCS Workgroup 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 and*

standard application. CMS could, for example, rely on the outside clinical experts that participate in CMS' Medicare Coverage Advisory Committee, if such individuals have the relevant clinical and technical expertise.

Many HCPCS Codes Have Become Too Broad: We agree with CMS' comment that the HCPCS Level II code set is intended to be broad and not manufacturer specific. CMS must, however, balance the need for a manageable set of HCPCS codes to ensure access against the need for efficient claims processing. CMS has recently made many DME HCPCS codes too broad, by adding the term "any type" to the HCPCS code descriptor language. Unfortunately, in many of these "any type" HCPCS codes, there are a wide variety of items, with different clinical applications and widely varying costs. While we agree that the code set needs to be administratively simple for claims processing, it also needs to be discrete to differentiate among products that are not alike. In addition, since HCPCS codes are the foundation upon which coverage and payment policies are developed, it is important to maintain HCPCS codes that reasonably describe like technology. We *urge CMS to solicit public comment when it initiates a change to a HCPCS code description, particularly when CMS adds the "any type" verbiage.*

CMS Should Create HCPCS Codes for "Deluxe" Items of DME: We are aware of at least two DME MAC LCDs (refractive lenses and therapeutic shoes) that include separate HCPCS codes for "deluxe" items. These are items that can be added to the base item and are items that are generally not covered by the Medicare program. This would better enable beneficiary choice and access. In addition, even though Medicare does not provide coverage for "deluxe" features on items, other payers may provide coverage for the feature. [*Refractive lenses: "When billing claims for deluxe frames, use code V2020 for the cost of standard frames and a second line item using code V2025 for the difference between the charges for the deluxe frames and the standard frames." HCPCS code A5508 "For Diabetics Only, deluxe feature of off-the-shelf depth-inlay shoe or custom-molded, per shoe]*

CMS Delay of Consideration of Applications: CMS states that it may choose to delay its consideration to the next cycle for more complicated applications. *While we understand some applications may take additional time to review, we recommend that CMS limit any delay to only one cycle, that CMS publicize the reason for the delay during the initial cycle, and that CMS delay consideration of HCPCS code application only if it meets pre-defined and publicized definition of what a "complicated" application is.* We suggest that a good rationale would be if CMS needed to consult with external experts (e.g., MEDCAC) to conduct its review of a HCPCS code application.

VI. Benefit Category and Payment Determinations - Proposed 42 C.F.R. §§414.114 and 414.240

CMS proposes to put into regulations the benefit category and payment determination procedures for new DMEPOS and other items and services under the Part B benefit. CMS proposes to hold public meetings to make benefit category determinations (BCDs) and payment determinations. CMS proposes the BCD public meetings will be part of the bi-annual HCPCS Level II public meetings. CMS also proposes to "specifically solicit and invite consultation on preliminary BCDs for each item or service in addition to the consultation on preliminary payment and coding determinations for new items and services."

CMS proposes to define benefit category determination as "a national determination regarding whether an item or service meets the Medicare definition of prosthetic device at section1861(s)(8) of the Act or is a splint, cast, or device used for reduction of fractures or dislocations subject to section 1842(s) of the Act and the rules of this subpart and is not otherwise excluded from coverage by statute" at §414.114 and "a national determination regarding whether an item or service meets the Medicare definition of durable

medical equipment at section 1861(n) of the Social Security Act, a prosthetic device at section 1861(s)(8) of the Social Security Act, an orthotic or leg, arm, back or neck brace, a prosthetic or artificial leg, arm or eye at section 1861(s)(9) of the Social Security Act, is a surgical dressing, or is a therapeutic shoe or insert subject to sections 1834(a), (h), or (i) of the Act and the rules of this subpart and is not otherwise excluded from coverage by statute" at §414.240.

CMS indicates that it has effectively been using the HCPCS code application process and the public meetings to obtain public comments regarding benefit category and payment determination. While CMS includes in its preliminary HCPCS code determination its decision regarding the benefit category (e.g., DME) and payment category (e.g., capped rental), the application process has never been publicized by CMS as one in which CMS is also making decisions beyond HCPCS codes, specifically the fee setting process. For example, there are no questions on the current HCPCS code application that address payment methodologies. The preliminary decisions have only addressed the payment category for Medicare payment, such as capped rental or inexpensive or routinely purchased. CMS should therefore revise its HCPCS code application and incorporate questions related to benefit category and payment category determinations. Finally, CMS should allow the HCPCS code application process to serve as an appeal process for BCD and payment decisions if the HCPCS modification application is intended to be a process to make those initial decisions.

Based on These Changes, CMS Needs to Revise Its HCPCS Code Application and Instructions: CMS should add to its HCPCS code application instructions information about the benefit category and payment category determinations and explain to applicants the types of information that would be helpful for the Agency to make these determinations. CMS should modify the HCPCS modification application by creating 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 HCPCS Workgroup and appropriate CMS staff in making each of these determinations. 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.

AAHomecare supports incorporating its payment amount determinations in the HCPCS code application process to increase transparency and public input: CMS states in the proposed rule that it "will consider whether to include a revised proposal addressing the use of technology assessment in gap-filling in future rulemaking." CMS has recently codified its gap-fill methodology and comparability process that it uses to determine payment rates for DME items with new HCPCPS codes.[13] *We recommend that CMS incorporate into its HCPCS code application process its gap-filling and comparability analyses along with its preliminary determination that a new HCPCS code will be created.* This will allow for both public input and for CMS to publicize the information it uses in making these payment determinations. These payment decisions have significant impacts on stakeholders, including beneficiary and their ability to access new technologies. As part of the process, CMS should publicly disclose the data it uses, its calculations, and allow for public input and comment. This process can be incorporated into its HCPCS code, benefit category, payment category determination process to ensure beneficiary access to new technology in a timely manner.

VII. Classification and Payment for Continuous Glucose Monitors

[13] *See* 42 C.F.R. § 414.238

CMS proposes to classify all continuous glucose monitors (CGMs) as routinely purchased DME. Due to CGMs having the same functions as blood glucose monitors, CMS proposes to continue to use the fee schedule rates in CMS-1682-R which is based on the 1986/87 average reasonable charges for blood glucose monitors.[14] For supplies and accessories used with CGMs, CMS proposes two separate monthly payments for 2021:

1. For supplies and accessories used with adjunctive CGMs: [supplier prices for sensors and transmitter] – [monthly fee schedule amounts for average quantity and types of blood glucose monitoring supplies]
    i. 2020 fee schedule amounts to be increased by 2021 fee schedule update factor
2. For supplies and accessories used with non-adjunctive CGMs: 2020 fee schedule amount

AAHomecare supports CMS' initiative to expand coverage to adjunctive CGMs. We appreciate CMS' recognition of the importance of establishing coverage for new technology. We do, however, have some concerns about CMS' payment policies that will need to be developed to more fully implement this expanded coverage.

Currently, beneficiaries who choose to try CGMs cannot switch back to a blood glucose monitor; we assume that this expanded coverage will require CMS and its contractors to make the appropriate policy changes to address this issue. We would like CMS to confirm that when an adjunctive CGM is provided to a beneficiary, that the Medicare program will continue to cover and pay for strips used with blood glucose monitors. *We recommend that CMS establish an additional public forum to invite stakeholder input on this change; given the many additional issues that must be addressed to fully implement the expanded coverage.*

VIII. Expanded Classification of External Infusion Pumps as DME

CMS proposes to expand coverage for external infusion pumps by revising the interpretation of the "appropriate for use in the home" requirement in the definition of DME as it relates to external infusion pumps. CMS proposes to interpret the "appropriate for use in the home" requirement to be met if:

1. the Food and Drug Administration (FDA)-required labeling requires the associated home infusion drug to be prepared immediately prior to administration or administered by a health care professional or both;
2. a qualified home infusion therapy supplier (as defined at §486.505) administers the drug or biological in a safe and effective manner in the patient's home (as defined at §486.505); and
3. the FDA-required labeling specifies infusion via an external infusion pump as a possible route of administration, at least once per month, for the drug.[15]

CMS also proposes that if the above three requirements are met, the external infusion pump will satisfy the definition of DME, even if the beneficiary and/or caregiver is not able to administer the drugs. If finalized, CMS expects more drugs and biologicals will be covered as supplies under the DME benefit and it will also impact home infusion therapy services.

[14] 85 *Fed. Reg*. at 70402.
[15] 85 *Fed. Reg*. at 70404.

AAHomecare fully supports the comments of the National Home Infusion Association (NHIA). Specifically, AAHomecare supports NHIA's recommendations:

1. CMS should reconsider the strategy of expanding access to home infusion for healthcare professional-administered drugs through the DMEPOS program.
2. CMS should create a demonstration project to study expanding home infusion access to Part D covered drugs that are administered intravenously or subcutaneously for an administration period of 15 minutes or more.
3. CMS should remove the requirement that drugs be "prepared immediately prior to administration" in order to be eligible for coverage.
4. If CMS does not move forward with modernization of the home infusion therapy benefit as NHIA recommends, CMS should base coverage for home infusion therapy drugs on the need for a pump and health care professional, and limit the benefit to on-label indications.
5. If CMS moves forward with the changes to coverage of home infused drugs discussed in this proposed rule, we agree with using the LCD determination process for eligibility.
6. CMS should implement sufficient reimbursement for home infusion therapy services to promote access to home infusion therapy drugs.
7. CMS should clarify that in revising its interpretation of the "appropriate for use in the home" requirement, it is not revising the policy for dug current covered under the DMEPOS benefit. If CMS does intend for the revised interpretation to apply to drugs currently covered under the DMEPOS benefit, we request that CMS state this explicitly and provide for additional comment period to give stakeholders an opportunity for comment prior to implementing any changes to the drugs currently covered under the existing DMEPOS benefit.

IX. Permanent Exemption from CBP of Complex Manual Wheelchairs and Exclusion from CBP Pricing of Accessories used Complex Rehabilitative Manual Wheelchairs– Proposed 42 C.F.R §414.402

Through this proposed rule, CMS is implementing the changes Congress required in Section 106(a) of the Further Consolidated Appropriations Act, 2020 (Pub. L. 116-94) that was signed into law on December 20, 2019. The statute required CMS to permanently exclude complex rehabilitative manual wheelchairs and certain other manual wheelchairs from CBP, effective January 1, 2020. This applies to the following HCPCS codes: E1235, E1236, E1237, E1238, and K0008 and any successor codes. The same law also required CMS to exempt wheelchair accessories (including seating systems) and seat and back cushions furnished with complex rehabilitative wheelchairs (HCPCS codes: E1161, E1231, E1232, E1233, E1234, and K0005) and certain manual wheelchairs (HCPCS codes: E1235, E1236, E1237, E1238, and K0008) from CBP rate adjustments from January 1, 2020 to June 30, 2021.

CMS should permanently exempt accessories used with these complex manual wheelchairs from competitive bid program-derived pricing, as it did in 2017 for complex power wheelchair. Complex rehabilitative manual wheelchairs are individually configured mobility and seating systems. These wheelchairs allow a small group of beneficiaries, representing only seven percent of all Medicare manual wheelchair users, to manage their medical needs and fully participate in their lives. Without access to complex wheelchairs and the accessories that are integral to their function, many beneficiaries would be bed confined.

In the Further Consolidated Appropriations Act, 2020, Congress has prohibited CMS from using CBP-derived rates to adjust payment rates for accessories used with complex rehabilitative manual

wheelchairs, for an 18-month period until June 30, 2021. Congress has now communicated to CMS that the application of CBP payment rates to CRT wheelchair accessories is contrary to its intent. This 18-month time period provides CMS the opportunity to administratively make this policy change on a permanent basis.

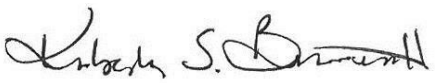
Congress has acknowledged the differences between standard DME and complex rehabilitative items and enacted legislation in 2008 and in 2019 to exempt Group 3 complex rehabilitative power wheelchairs and accessories and complex rehabilitative manual wheelchairs and related accessories, respectively, from the CBP. To apply CBP pricing based on standard items used with standard wheelchairs to complex rehabilitative items used with complex rehabilitative wheelchairs that were not included in the CBP results in inadequate pricing for these complex rehabilitative items and denies adequate access for the population of Medicare beneficiaries with disabilities.

In 2017, CMS used its authority to permanently exempt accessories used with Group 3 complex rehabilitative *power* wheelchairs from CBP-derived rates. When CMS issued this policy, it stated that, "[b]y continuing these higher payments, this new action will help to protect access to complex rehabilitative power wheelchair accessories on which people with significant disabilities depend."[16] It is now time for CMS to make this same policy change for complex rehabilitative *manual* wheelchairs, for the very same reasons: complex manual wheelchairs are used by people with significant disabilities. CMS would then be providing equal access to complex rehabilitative manual wheelchairs as it does for complex rehabilitative power wheelchairs.

X. Conclusion

Thank you for the opportunity to comment. Please contact me at kimb@aahomecare.org if you have any questions.

Sincerely,



Kimberley S. Brummett
VP, Regulatory Affairs

[16] See CMS DME Center (Visited Dec. 2, 2020).