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January 4, 2020

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

Re: Supplemental 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), Focus on Payment Rules for Accessories used with Manual Complex Rehabilitative Wheelchairs

Dear Administrator Verma:

I. Introduction

The American Association for Homecare (AAHomecare) is pleased to submit these supplemental comments on the Centers for Medicare and Medicaid Services' (CMS') above captioned Proposed Rule (CMS-1738-P). These comments, which supplement our December 22, 2020 comments, focus on Medicare payment rules for accessories provided with complex rehabilitative manual wheelchairs. AAHomecare is the national association representing durable medical equipment, prosthetics, orthotics, and supplies (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.

Exclusion of Complex Rehabilitative Manual Wheelchairs and Certain Other Manual Wheelchairs from the DMEPOS CBP

AAHomecare opposes using competitive bidding program (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, we assert that the adjusted payment rates for these items are inadequate and deny 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 its 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.

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

As the Agency moves forward with the CBP, AAHomecare 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* decision² and the Office of General Counsel's Advisory Opinion interpreting that decision. Although CMS does not

¹ See *id.* at 70360.

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

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, AAHomecare 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 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 CBP 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

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>.

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.

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. AAHomecare 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

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).

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).

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 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 adjustments to the fee schedule rates for such items when furnished outside of

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).

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 CBP 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 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.

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>.

- 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, AAHomecare 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 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**

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).

²³ *Id.*

²⁴ *Id.*

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 inasmuch 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. 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 as an interim policy while providing an opportunity to comment.

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, AAHomecare 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

²⁵ *Id.* (emphasis added).

²⁶ *Id.*

²⁷ See Social Security Act, § 1871(e)(1)(A)(ii).

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.

Recommendation:

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.

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

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)).