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ATTORNEY-CLIENT PRIVILEGED

Memo

Date:	July 23, 2025
To:	Thomas Ryan, President and CEO, American Association for Homecare (AAHomecare)
From:	Tom Barker, Partner, Foley Hoag LLP Caroline Farrell, Counsel, Foley Hoag LLP Regina DeSantis, Associate, Foley Hoag LLP
Regarding:	Medicare Competitive Bidding Program Proposals in the Calendar Year (CY) 2026 Home Health Prospective Payment System Proposed Rule (CMS-1828-P)

You have asked for an analysis of the provisions in the CY 2026 Home Health Prospective Payment System Proposed Rule (90 Fed. Reg. 29108 (July 2, 2025)) ("Proposed Rule") that propose updates to the durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) competitive bidding program (the "bidding program" or "CBP").[1] Specifically, you have requested our legal opinion on the proposal from the Centers for Medicare & Medicaid Services (CMS) that revises the definition of "item" for purposes of the bidding program in order to subject ostomy, urological, and tracheostomy supplies to the bidding program.[2] In summary, our opinion is that CMS in the Proposed Rule lacks strong legal justifications to support its proposed reinterpretation of the scope of the items subject to the bidding program to include ostomy, urological, and tracheostomy supplies.

As background, Congress enacted the Competitive Bidding Program in 2003 and required that Medicare replace the fee schedule payment methodology for specific items with the bidding program. In enacting the bidding program, Congress limited the items that are subject to the program. The 2007 implementing regulations for the program expressly excluded ostomy, urology, and tracheostomy services from CBP. In the new Proposed Rule, however, CMS seeks to abandon its longstanding interpretation of covered items and broaden the items subject to the bidding program to include ostomy, urology, and tracheostomy supplies. CMS's purported justification for the CBP's expansion, as outlined in the Proposed Rule, disregards fundamental principles of statutory construction and relies on inappropriate information to support the revised interpretation.

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[1] CMS, CY 2026 Home Health Prospective Payment System Proposed Rule, 90 Fed. Reg. 29108 (Jul. 2, 2025), at 29230-79 (henceforth, the "Proposed Rule").

[2] These specific provisions can be found at 90 Fed. Reg. 29252-54 of the Proposed Rule (Jul. 2, 2025).

I. OVERVIEW OF THE DURABLE MEDICAL EQUIPMENT, PROSTHETICS, ORTHOTICS, AND SUPPLIES (DMEPOS) COMPETITIVE BIDDING PROGRAM (CBP).

Section 1847(a) of the Social Security Act (the Act), as amended by § 302(b)(1) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), requires HHS to enact competitive bidding programs (CBPs) in competitive bidding areas (CBAs) throughout the U.S. for contract award purposes to furnish competitively priced DMEPOS items and services. Pursuant to § 1847(a)(2) of the Act, the items and services that are included in the bidding program fall into four categories: (1) DME, as defined in § 1861(n), pursuant to § 1847(a)(2)(A); (2) items and services described in § 1842(s)(2)(D) other than parenteral nutrients, equipment, and supplies, pursuant to § 1847(a)(2)(B); (3) certain off-the-shelf (OTS) orthotics, pursuant to § 1847(a)(2)(C); and (4) lymphedema compression treatment items, defined in § 1861(mmm), "for which payment would otherwise be made under section 1834(z)," pursuant to § 1847(a)(2)(D).

Through implementing regulations in 2007, CMS was explicit that § 1847(a)(2)(A) does not mandate the inclusion of ostomy supplies, in response to public commenters' concerns that ostomy products and supplies did not meet the definition of DME, and therefore, are not part of competitive bidding programs.[3] CMS's justification in support of this conclusion meant that urological and tracheostomy supplies were also excluded from the scope of § 1847(a)(2)(A) of the Act and thus were also excluded from CBPs.[4]

II. LEGAL ANALYSIS.

In the Proposed Rule, CMS proposes to include ostomy, urological, and tracheostomy supplies in CBPs. Through this proposal, CMS is abandoning its longstanding interpretation of covered items, in reliance on: (1) legal justifications that disregard fundamental principles of statutory construction; and (2) inappropriate information to support the revised interpretation.

A. CMS in the CY 2026 Home Health Proposed Rule Errorneously Relies on a Statutory Section Title for Statutory Support.

In the CY 2026 Proposed Rule, CMS proposes to "clarify[ ] the definition of 'medical equipment items', to include ostomy, tracheostomy, and urological supplies."[5] Ultimately, CMS's explanation in support of its authority to propose a revised definition is that § 1847(a)(2)(A) is "ambiguous regarding whether ostomy products and supplies are to be included in the Medicare DMEPOS CBP" because the term "medical supplies," as used the § 1847(a)(2)(A) section heading, "could be interpreted either to modify the term 'durable medical equipment' (meaning that the medical supplies would have to be associated with the DME to be included)," or refer to

[3] *See* CMS, Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) (Final Rule), 72 Fed. Reg. 17992, 18023 (Apr. 10, 2007).

[4] *Id.*

[5] CMS, CY 2026 Home Health Proposed Rule, at 29252 (while not central to our analysis, we note that CMS in the Proposed Rule actually proposing to change a past interpretation, not "clarify[ing]" an existing definition).

a "separate category of items that are not associated with DME."[6] While CMS notes that "covered item" at § 1834(a)(13) of the Act means "durable medical equipment (as defined in section 1861(n) [of the Act])," CMS places undue influence on a section title without conducting a fulsome statutory analysis. Courts have been clear that titles are not dispositive, and thus reliance on titles without analyzing the text of the statute itself is inappropriate. *See, e.g.*, *Yates v. United States*, 574 U.S. 528, 552 (2015) (Alito, J., concurring) ("Titles, of course, are … not dispositive..."); *see also Bhd. of R.R. Trainmen*, 331 U.S. 519, 528 (1947) ("[H]eadings and titles are not meant to take the place of the detailed provisions of the text.").

B. CMS in the Proposed Rule Errorneously Relies on Legislative History without Explaining its Statutory Analysis or Why Reliance on Legislative History is Appropriate.

A fundamental textualist principle of statutory interpretation is that legislative history should be relied on sparingly, and only when the text of the statute is not clear, because the text of the law itself is what has been enacted by Congress.[7] As discussed in section II.A, above, CMS's proposal is nearly devoid of any analysis of the statutes governing the Medicare competitive bidding programs. Absent such an analysis and a clear demonstration of why questions about the interpretations it is debating are not answered by Congress in the plain text of the governing statute, it is not appropriate to look to and rely on language in a Congressional Committee report. While a Congressional Committee report reflects legislative intent, the report is not a substitute for the plain language of the statute itself, nor does a report trump a statute in its authority. *See, e.g., Garcia v. United States*, 469 U.S. 70, 76 (1984) (Rehnquist, J.); *see also Conroy v. Aniskoff*, 507 U.S. 511, 519 (1993) (Scalia, J., concurring) ("The greatest defect of legislative history is its illegitimacy. We are governed by laws, not the intentions of legislators.").

C. Additional Considerations Regarding the Agency's Statutory Authority.

Absent a more fulsome analysis of CMS's authority to include ostomy, urology, and tracheostomy supplies under the Medicare CBP, we are not able to assess the agency's views on its statutory authority. However, we wish to highlight that in the Medicare Payment Advisory Commission's (MedPAC's) 2018 *Report to the Congress*,[8] MedPAC shared its concerns and skepticism about CMS's authority to add items to the competitive bidding process:

> CMS has stated that it has the authority to include certain medical supplies in the CBP (Centers for Medicare & Medicaid Services 2007). However, compared with other products, the legal authority to do so appears to be less clear. An explicit grant of authority could accelerate the inclusion of these products into the CBP and protect the agency from potential legal challenges. In the case of orthotics, CMS has the authority to include only off-the-shelf products in the CBP…

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[6] *Id.* at 29252.

[7] *See, e.g.*, *King v. Burwell*, 576 U.S. 473, 486 (2015) ("If the statutory language is plain, we must enforce it according to its terms.").

[8] MedPAC, *Report to the Congress: Medicare and the Health Care Delivery System*, Chapter 6: Issues in Medicare's medical device payment policies, pg. 153 (Jun. 2018), available at: https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/jun18_ch6_medpacreport_sec.pdf.

> … If the Congress grants CMS additional authority, then requiring a date by which the products must be incorporated into the CBP could be helpful, but flexibility regarding the manner in which the products are incorporated is likely important. In the past, the Congress has mandated that CMS make changes to the CBP by certain dates, which, to some extent, protects the agency from industry pressure to delay the program. The deadline should reflect the level of effort required by CMS. For instance, the agency would need to design any special rules for the new product categories, solicit industry feedback, and incorporate the new products into its health status monitoring program. To expedite the inclusion of new products, the agency could be given the flexibility to phase in bidding in a small number of areas or bid out the new products only in a limited number of areas and use that information to adjust the fee schedule in the rest of the country.[9]

III. CONCLUSION.

CMS's bidding program proposal to include ostomy, urological, and tracheostomy supplies as items subject to bidding would abandon CMS's longstanding interpretation of the scope of covered items under this program. In the Proposed Rule, CMS inappropriately relies on legal justifications that disregard fundamental principles of statutory construction and inappropriate information to support the revised interpretation. Therefore, we find CMS's rationale for its proposal to include ostomy, urological, and tracheostomy supplies in the CBP, as set forth in the CY 2026 Home Health Proposed Rule, to be inadequate and vulnerable.

[9] *Id.* at 153-54.