

August 29, 2025

Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
7500 Security Boulevard  
Baltimore, MD 21244-1850

**Comments to CMS-1828-P: CY 2026 Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program Updates**

Dear CMS,

The Large Urology Group Practice Association (LUGPA) has represented more than 150 independent urology group practices for almost two decades. With practices across the country, our physician members treat the entire spectrum of urologic pathology in men, women and children. While our members' concerns are less commonly directed to in-home care, we are writing to express concern with our patients' ability to continue to access urological supplies if CMS moves forward with its proposal in the above-captioned rule to include urological supplies in the DMEPOS Competitive Bidding Program (CBP).

We fear that including urological supplies in the CBP would have a negative effect on our members' ability to supply certain items directly to their patients; would restrict patients' ability to obtain the right supplies for their individual condition; and would run contrary to the intent of Congress and statutory language that did not extend the CBP to urological supplies.

Accordingly, we write to request that CMS not finalize its proposal to redefine "item" under 42 C.F.R. § 414.402 to include urological supplies.

**1. Including Urological Supplies in Definition of 'Item' Would Lead to Poor Outcomes for Patients**

LUGPA strongly believes that the inclusion of urological supplies as an "item" subject to competitive bidding would significantly jeopardize patient access and safety. Urological supplies should be analyzed in light of their distinct clinical use and individualized patient needs. Unlike many commoditized DME items that serve a broader and more uniform population, urological supplies must be carefully matched to each beneficiary's unique characteristics including anatomy, medical condition, and functional status. Urological supplies are critical to the daily management of complex and often permanent conditions that affect the Medicare-eligible community, and any disruption in access to the appropriate product can result in serious medical complications, infections, emergency care, or hospitalization. Apart from being bad for patients, these effects cost CMS more money than any savings it may obtain from competitive bidding of urological supplies.

In fact, CMS's own Final Report to Congress: Evaluation of Medicare's Competitive Bidding Demonstration for Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (2004) identified "large, negative and statistically significant" impacts on beneficiary access to training for urological supplies during the demonstration projects. This report underscores the tangible

risks to patient care when competitive bidding is applied to product categories where clinical oversight and education are central to safe use.

Furthermore, proper training for both patients and caregivers is vital for using urological supplies safely and effectively. Properly educating users on usage, hygiene, and troubleshooting can be the difference between stable at-home management and costly medical interventions for urological conditions.

To avoid these limitations on patient access and quality care, LUGPA requests that CMS not include urological supplies in any competitive bidding program in the future.

## **2. Including Urological Supplies in Definition of ‘Item’ is Legally Unsound**

LUGPA also objects to the proposed changes to the definition of “item” at 42 C.F.R. § 414.402. CMS’s proposal to expand the term “item” to include “[o]ther medical equipment described in section 1861(m)(5) of the Act, including urological supplies”<sup>1</sup> is a significant reinterpretation of statutory language, which exceeds the authority granted by Congress to CMS. The expanded definition also goes against the Trump administration’s stated goal of curbing agency and regulatory overreach.

While the Balanced Budget Act of 1997 (BBA) authorized competitive bidding demonstrations for “all items and services” under Medicare Part B (except for physician services), later, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) narrowed the scope of the current competitive bidding program to only three categories of items and services, notably omitting prosthetic devices such as urological supplies from the competitive bidding domain. Urological supplies do not fall within any of the three categories of items and services that the Social Security Act explicitly authorizes for inclusion in the DMEPOS Competitive Bidding Program under SSA §1847(a)(2). These products are not classified as “durable medical equipment,” nor are they “supplies used in conjunction with” such equipment. Instead, CMS has consistently recognized these supplies as prosthetic devices. Had Congress intended to include urological supplies in competitive bidding, it could have done so by including prosthetic devices in the same manner that it included “durable medical equipment.” Congress did not, and we urge CMS against overreach by redefining “item” outside the delegated authority from Congress.

Given this statutory framework, CMS’s proposal to broaden the definition of “item” to include urological supplies raises significant legal concerns beyond the patient care concerns expressed above. LUGPA requests that CMS not finalize the proposed revision to the definition of ‘item’. Without explicit Congressional action, this change lacks a valid statutory foundation and could create substantial legal uncertainty for suppliers, reduce market transparency, and potentially impact beneficiary access to these necessary products.

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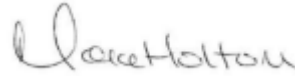
<sup>1</sup> 90 Fed. Reg. at 29108

LUGPA appreciates the opportunity to provide our members' perspective on the issue of access to urological supplies.

Thank you,

A handwritten signature in dark ink, appearing to read "Scott Sellinger MD".

Scott Sellinger, MD, FACS  
President

A handwritten signature in dark ink, appearing to read "Mara Holton".

Mara Holton, MD  
Chair, Health Policy

