

CMS-1828-P: Competitive Bidding Overreach

Congressional Oversight Needed to Protect Medicare Beneficiaries

On June 30, 2025, the Centers for Medicare and Medicaid Services (CMS) released a Proposed Rule on DMEPOS and Home Health (CMS-1828-P) stating that CMS plans to include urological, ostomy, and tracheostomy supplies in the DMEPOS Competitive Bidding program (CBP). This proposal exceeds CMS's statutory authority and undermines Congress' intent to not include these items in the CBP.

Statutory Authority: Clear Limits Ignored

Adding these new product categories to the CBP exceeds CMS's legal authority under the Social Security Act (SSA).

- SSA Section 1847(a)(2) limits the CBP to:
 - Durable Medical Equipment (DME) under SSA §1834(a)
 - Parenteral and enteral nutrients, equipment, and supplies
 - Off-the-shelf orthotics under SSA §1861(s)(9)
- Urological, ostomy and tracheostomy supplies are covered under a separate section of the SSA as prosthetic devices, §1861(s)(8).
- Congress has amended the CBP law multiple times and has never added these items, demonstrating clear Congressional intent and **reinforcing the fact that CMS does not have the legal authority to unilaterally expand the scope of competitive bidding to include items Congress has not authorized.**

Patient Risks

- Prescribed ostomy and urological products are used to manage medical conditions that interfere with or do not allow for normal bowel and/or bladder function. The complexity and uniqueness of a product is needed to meet the distinct and highly variable needs of patients to appropriately manage biological waste.
- High quality tracheostomy products are designed to ensure patient comfort, safety, and effective airway management.
- Ostomy, urological, and tracheostomy products all require a high degree of specialized care and support to prevent infections and other serious complications.
- Competitive bidding could force specialized suppliers with expertise to support vulnerable patient cohorts out of the market.
- Competitive bidding will reduce choice and continuity of care for individuals with complex medical needs.
- Commoditized, low-margin pricing will reduce innovation and incentivize suppliers to seek the lowest-cost products, minimizing consumer choice and access to the most medically appropriate item.

CMS Demonstration Project Spotlights Challenges for Urologicals

- CMS completed a competitive bidding demonstration project in 2003 that included urological supplies and concluded they are “not well suited” for competitive bidding.
- CMS’ report notes that “Quality may suffer if several of the winning suppliers are inexperienced, perceived access may fall if patients prefer local suppliers and several of the winning suppliers are located outside the area, and product selection could be reduced if several winning suppliers adopt more limited product lines.”

Legal Vulnerability

- CMS’s proposal is ultra vires (“beyond the powers”) and invites litigation.

Congress Can Remedy

- Reaffirm the statutory boundaries of the DMEPOS Competitive Bidding program.
- Direct CMS to withdraw any proposal that includes unauthorized product categories.
- Consider legislative clarification to prevent future regulatory overreach.

For More Information

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