



Medicare Competitive Bidding and Patient Harm

WHY OSTOMY AND UROLOGICAL SUPPLIES MUST BE EXEMPTED

AUGUST 11, 2025

Agenda

- Welcome and Introductions
- Overview of the Medicare Competitive Bidding Program (CBP)
- Proposal to Expand Competitive Bidding to Ostomy and Urological Supplies
- Why Ostomy and Urological Supplies Should be Exempted from the CBP
- Clinical and Patient Perspectives
- How ITEM Members Can Help
- Q&A

Speaker Introductions



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What is Medicare Competitive Bidding?

The Medicare CBP was created to lower Medicare spending on selected medical equipment and supplies by forcing suppliers to compete for limited contracts in designated areas.

The CBP can reduce reimbursement levels, which impacts copayments, it also limits beneficiaries to using only contracted suppliers, which restricts:

- . Patient access;
- . Choice of item; and
- . Quality of care.

What is Medicare Competitive Bidding?

How It Has Worked in the Past:

- **Geographic Areas** – CMS designates certain “competitive bidding areas”(CBA) around the country.
- **Supplier Bidding** – Bidders compete to become contract suppliers by submitting bids to provide designated DMEPOS items throughout a CBA. CMS evaluates bids based on several factors, including the supplier’s financial stability and bid prices.
- **Awarded Contracts** – CMS awards contracts to suppliers that offer the most competitive price. Suppliers that do not win a competitive bidding contract cannot supply those DMEPOS items to Medicare beneficiaries in the designated CBA.
 - The number of contracts is determined based on satisfying patient need in a CBA.

History of Medicare Competitive Bidding

Calendar Year	Round 1 Areas (9 Metropolitan Statistical Areas (MSAs))	Round 2 Areas (90 MSAs) and National Mail Order
2011	Round 1 1/11/2011 - 12/31/2013	--
2012		
2013		
2014	Round 1 Recompete 1/1/2014 - 12/31/2016	Round 2 & National Mail Order 7/1/2013 - 6/30/2016
2015		
2016		
2017	Round 1 2017 (recompete) 1/1/2017 - 12/31/2018	
2018		
2019	Temporary Gap Period	
2020		
2021	Round 2021 (recompets for Round 1 and Round 2) 1/1/2021 - 12/31/2023	
2022		
2023		
2024	Temporary Gap Period	
2025		

New Proposal on Medicare CB

- . On June 30th, CMS issued a rule proposing to update the framework governing the DMEPOS CBP—signaling that the agency is contemplating the next round of competitive bidding.
- . As part of the proposed rule, CMS suggested that off-the-shelf orthoses would be included.
- . CMS also proposed to expand the list of items CMS may subject to competitive bidding to include ostomy, tracheostomy, and urological supplies.
- . ITEM Coalition strongly opposes inclusion of these items in further rounds of competitive bidding.

Extending CB Exceeds CMS's Authority

- Expanding competitive bidding to ostomy and urological supplies tests the bounds of CMS's legal authority.
- Congress deliberately confined the scope of the CPB to three specific categories:
 - DME and medical supplies used in conjunction with DME;
 - Enteral nutrients, equipment, and supplies; and
 - Off-the-shelf orthotics (no custom fabricated or fit orthotics or prosthetics).
- In the proposed rule, CMS appears to advance an interpretation of the statute that ostomy and urological supplies fall under the first category.
- However, under the Medicare program, ostomy and urological supplies are considered “prosthetic devices,” not DME.
- Congress has amended the CBP statute multiple times without explicitly settling this issue.

CB of Ostomy and Urological Supplies

- In 2004, HHS drafted a report on competitive bidding determining that urological supplies are “not as well suited” for competitive bidding.
- The president’s Fiscal Year 2017 budget proposal requested the expansion of Medicare’s competitive bidding program to include ostomy and urological supplies.
- Major stakeholders worked to keep ostomy and urological supplies out of competitive bidding and succeeded.
- Wide variety of products and personalized/customized care makes CB inappropriate for ostomy and urological care.
- Example: Three HCPCS billing codes describe 1,300 different intermittent catheters, with three additional codes coming online January 1, 2026.

Number of Contracts Awarded and Remote Item Delivery (RID) CBP

- CMS is seeking to **limit the number of contract suppliers** in the next round of competitive bidding.
- In addition, CMS proposes to create a new RID CBP, under which contract **suppliers would provide items primarily via remote delivery to Medicare beneficiaries**.
 - Instead of establishing hundreds of local contracts, CMS is proposing to establish either a single nationwide RID CBP or a few large regional RID CBPs.
- CMS signaled that if competitions were held today for a nationwide RID CBP as proposed, CMS would award only **seven** contracts for urological supplies and **eight** contracts for ostomy supplies. The agency also surmises that most contract suppliers would have a limited number of local storefronts.

RID CBP (Cont'd)

- Under the RID model, beneficiaries could be compelled to use distant, mail-order suppliers, as CMS has acknowledged that RID items would typically be shipped from supplier locations hundreds of miles away.
- This compromises prompt access to ostomy and urological supplies. Individuals who require ostomy and urological supplies often need immediate, local access to a wide array of products that meet the patient's individualized needs.
- Ostomy and urological supplies are highly time-sensitive, and any delay—due to shipping disruptions, rural delivery limitations, or natural disasters—could lead to serious health consequences.
- Although CMS has suggested that such disruptions would be rare, delays in delivery are not uncommon and should be taken seriously.

RID CBP (Cont'd)

- Notably, CMS has stated that in situations where a beneficiary loses or is temporarily without supplies that Medicare has already paid for, the supplier of the replacement supplies would ask the beneficiary to sign an Advance Beneficiary Notice of Noncoverage (ABN) **making the beneficiary liable for the cost of the replacement supplies in the event the claim is denied.**
- **The beneficiary would be forced to appeal the denial of the claim for the replacement supplies,** indicating the reason why the replacement supplies were needed, and the claim denial could potentially be overturned on appeal.

Calculating Payment Amounts

- Prior to Round 2021, CMS calculated the single payment amounts (SPA) for each item in the product category based on the median of the winning contract suppliers' bids for each item.
- Beginning with Round 2021, the agency changed the methodology for calculating SPAs, using the maximum winning contract supplier bid amount for a “lead item,” which was used to calculate the SPAs for *all* items in the category.

Calculating Payment Amounts

- . CMS is now proposing to modify the methodology for establishing SPAs for lead and non-lead items.
 - . Lead: Changing the SPA to the 75th percentile of winning bids
 - . Non-lead items in CBAs (other than a nationwide or regional CBA):
The calculation would involve multiplying the lead item SPA by a relative ratio
- . CMS should discontinue the use of lead item bidding and allow for bidders to bid on individual HCPCS codes to better reflect sustainable pricing to protect access for Medicare beneficiaries

Ostomy and Urological Supplies

- Ostomy and urological supplies are essential medical products designed to support patients who face challenges with waste elimination due to medical conditions or surgical interventions.
- These medical products are absolutely critical, highly personal, and clinically diverse for a wide variety of people with bladder and bowel dysfunction, including individuals with paralysis, spina bifida, stroke, and many other conditions.
 - Ostomy supplies are prescribed to individuals who have undergone ostomy surgery, a procedure that creates an opening in the abdomen to allow the discharge of bodily waste when the pathway is unavailable or impaired. These supplies include specialized pouches, skin barriers, and seals that help patients manage their stomas comfortably while maintaining skin integrity, personal hygiene, and independence.
 - Urological supplies comprise a wide range of medical devices and products utilized in the management of urinary dysfunction and incontinence. These supplies are essential for patients who require assistance with bladder emptying or urine diversion due to neurological conditions, urological disorders, postoperative care, or other medical indications.

Clinical Examples of Patient Harm

- Ostomy and urological supplies are carefully tailored to meet each patient's unique and often complex medical needs.
- Proper use of these supplies reduces the risk of complications such as infections and skin breakdown—common issues that often lead to emergency care or hospital admissions.
- Clinical examples

Clinical Examples of Patient Harm



The Patient Perspective

- .Catheters are not just any product
- .Competitive bidding increases the risk of medical complications
- .Disruption to established care
- .Creates a threat to independence and quality of life
- .Unlikely to save money in the long run
- .CB is particularly harmful for Medicare beneficiaries

Threat to Access, Choice, & Quality

- **Empowering patients with a broader selection of appropriate supplies is essential to ensuring personalized care, promoting independence, and preventing avoidable health complications.**
- Under CMS's proposed rule, the number of contract suppliers would be dramatically reduced—losing the connection between patients and local suppliers.
- This would limit patient choice and compromise continuity of care. This may lead to inadequate and cheaper supplies, loss of choice of brand-named products, increased discomfort, and higher risk of complications such as skin irritation and infections.
 - These complications often result in increased hospitalizations, longer recovery times, and higher overall healthcare costs—jeopardizing patient adherence to treatment regimens and diminishes overall satisfaction with care.
- Unsustainably low pricing pressures may discourage innovation within the industry and will drive suppliers to prioritize the lowest-cost, less-quality products. This dynamic can restrict patient access to the most clinically suitable and effective medical supplies.

Limited Savings in Medicare Expenditures

- CMS has not demonstrated that competitive bidding of these items would yield significant Medicare savings without harming beneficiaries. Expanding competitive bidding to ostomy and urological supplies may result in only modest or no meaningful savings for Medicare, while risking more costly complications and unnecessary medical care.
- CMS's assertion that the CBP has led to 10%-20% reduction in fraud, waste, and abuse lacks factual support and appears to be fully speculative.
- The fraud and abuse that occurred in the intermittent catheter benefit in 2024 can be addressed much more directly than through competitive bidding.

Implementation Timeline

- Comment submission deadline is August 29th
- Final Rule likely to be released around November 1, 2025
- Final Rule effective January 1, 2026

ITEM Coalition's Efforts

The ITEM Coalition is undertaking a comprehensive campaign to raise awareness of CMS's proposal and facilitate opposition from patient advocacy groups, healthcare professionals, and disability stakeholders.

- ITEM Coalition will circulate to its member organizations a comment letter opposing the proposed expansion of competitive bidding.
- We will distribute template draft comment letters and assist individual organizations, as requested, to help facilitate submission of unique comments to CMS by August 29th.
- Coordinate with member organizations to support the development of strong, well-founded arguments opposing the expansion of competitive bidding.
- Launch a campaign empowering ITEM Coalition members and their corresponding communities to submit individual comment letters and contact Members of Congress.
- Engage directly with Congress to inform representatives about the negative impacts of competitive bidding of these benefits and mobilize opposition to CMS's proposal.

Call to Action!

1. Please sign-on to the ITEM Coalition comment letter opposing inclusion of ostomy and urological supplies in Medicare competitive bidding by August 29th.
2. Seriously consider submitting an individual comment letter on your own organization's letterhead and alert the ITEM Coalition if you need assistance.
3. Sign-on to the ITEM Coalition letter to Congress urging leaders to convey opposition to CMS on this proposal.
4. Widely distribute the Call to Action (on your own letterhead if you wish) to your members to generate unique comment letters from individuals impacted by this policy. Template forms are discouraged as CMS considers identical letters signed by different people as only one comment.

The deadline to submit all comments is **August 29, 2025.**

Submit comments via the Federal Register:

<https://www.federalregister.gov/documents/2025/07/02/2025-12347/medicare-and-medicaid-programs-calendar-year-2026-home-health-prospective-payment-system-hh-pps-rate>



Call to Action!

- Directly contact your Members of Congress to educate them about the potential for patient harm with this policy and urge them to convey opposition to CMS.
- Find your Congressional representatives:
<https://www.congress.gov/members/find-your-member>.

Questions?