

Key Issues on CMS-1828-P and the DMEPOS Competitive Bidding Program

On June 30, 2025, the Centers for Medicare and Medicaid Services (CMS) released a Proposed Rule on DMEPOS and Home Health (CMS-1828-P) that includes provisions related to re-starting the DMEPOS Competitive Bidding program (CBP) for Medicare. DMEPOS stakeholders have identified several issues where they believe clarification and potential corrections are warranted.

1. Change to 75th Percentile

CMS has emphasized the importance of aligning Medicare DMEPOS rates with market-based pricing. However, the proposal to setting the single payment amount (SPA) to the 75th percentile of bids and reducing the winners by approximately 25% appears to drive down the price below market levels. In addition, setting bid limits based on prior SPAs would further push down rates over time. **How is CMS evaluating whether this approach will support long-term viability of the DMEPOS industry and ensure continued access to critical services and products for beneficiaries?**

2. Inclusion of Medical Supplies (Including Urological, Ostomy, Tracheostomy)

It has been a longstanding interpretation that medical supplies, such as urological, ostomy, and tracheostomy supplies, do not meet the definition of 'medical equipment items' and therefore are not eligible to be included in the CBP. **How does the Agency reconcile this shift with the clear statutory language and prior CMS determinations excluding these supply-based products from the Program?**

3. Inclusion of CGMs and Insulin Pumps

The proposal to include CGMs to competitive bidding raises significant concerns given the limited number of manufacturers and the evolving nature of the technology. In light of the broader structural changes being proposed to the program, **can the Agency consider deferring the inclusion of new product categories such as CGMs until the impact of the bidding reforms can be fully evaluated and appropriate safeguards are established to ensure continued patient access?**

4. Lack of Consideration for Supplier Experience

The proposed rule outlines parameters for evaluating supplier capacity, but it does not appear to consider a supplier's historical experience, either in the product category or within a specific bidding area. Given that past performance is an essential indicator of a supplier's ability to meet beneficiary needs and maintain Medicare compliance, **why is CMS excluding these factors in determining the number of contracts to be awarded?**

5. Arbitrary Determination of Contract Awardees

The proposed methodology for determining the number of contract awards appears to arbitrarily limit the total number of winning suppliers. For example, the national RID CBP for CGMs and insulin pumps is anticipated to only have 7-10 contract awardees nationwide. **What is the policy rationale for capping supplier participation at such low levels, especially in considering potential disruptions like product recalls?**

6. Small Supplier Participation

CMS is statutorily required to provide small suppliers a fair opportunity to be considered for participation in the DMEPOS CBP and CMS has historically aimed to target at least 30% of contract awards to go to small suppliers. **How does CMS intend to meet this obligation under the current proposals, which would significantly reduce the number of contract awardees to as few as two per competition? How will CMS balance these changes with its statutory requirement to promote inclusion of small suppliers?**

7. Shift to Annual Reaccreditation (Not CBP Specific)

The proposal to require annual reaccreditation is being justified as a means to strengthen program integrity. However, this level of frequency will be logistically unworkable for accrediting organizations and suppliers. Additionally, accreditation organizations are tasked with evaluating compliance with Medicare's Quality Standards, not regulatory or legal enforcement. **How does CMS intend to handle the operational strain this creates, and what evidence supports that more frequent accreditation will effectively reduce fraud and abuse?**

8. Non-Invasive Ventilators

The patient population utilizing non-invasive ventilation (NIV) is medically fragile, often experiencing chronic respiratory failure and progressive conditions. In light of the recent significant changes to the National Coverage Determination, including NIV in the CBP risks disrupting access to this highly specialized, life-sustaining therapy. **Access is already constrained by the limited number of suppliers with the clinical expertise required to serve these beneficiaries, CMS should not take actions that can further threaten access to care.**

7/21/25