AAHOMECARE
American Association for Homecare

DMEPOS/Home Health Proposed Rule (CMS-1828-P) Fails to Provide Analysis on Small Business Impacts

OVERVIEW

The DMEPOS Competitive Bidding Program Proposed Rule includes major changes that would economically disadvantage small business and reduce Medicare beneficiary access to DME & supplies. CMS acknowledges that 98% of DME suppliers are "small business" by the Regulatory Flexibilities Act (RFA) definition, yet it failed to meet its legal obligation under the RFA to analyze how the rule would affect small businesses and to consider less harmful alternatives.

CMS Ignored Small Business Analysis Requirements

Under the RFA (5 U.S.C. §§601-612) agencies must study how proposed rules affect small businesses and evaluate less burdensome options. CMS had a legal duty to evaluate small business impacts but didn't. CMS:

- Conducted no meaningful analysis of the rule's impact on small businesses.
- Analyzed home health agencies instead, which is irrelevant to DME suppliers.
- Offered no alternatives or mitigation steps to reduce harm to small companies.

Proposed Rule's Economic Impact on Small Business

The Proposed Rule would create severe financial and operational strain for small suppliers across the country – threatening their capacity to continue serving their communities. The 2025 Proposed Rule was silent on the previous rounds' regulations that targeted 30% small businesses being offered contracts. In 2021, CMS acknowledged that any adverse impacts of the bid program on "small businesses exiting the market could be irreversible" and that "monitoring by its nature looks backward".

Key Impacts:

- **Program Design Favors Large Suppliers**
  The program is structured for economies of scale; CMS noted in the Proposed Rule that the new program design was to create an incentive for large businesses to bid more competitively. Larger suppliers can spread costs across multiple regions while smaller, community-based suppliers cannot.
- **Deep Reimbursement Cuts**
  CMS projects about $644 million in reduced reimbursements, which will hit smaller suppliers who operate on thin margins with little room to absorb losses.
- **Tripled Accreditation Costs & Burden**
  Requiring annual reaccreditation instead of every 3 years adds significant fixed costs, staff time, and operational disruptions – all of which weigh heavily on small suppliers.
- **New Product Categories**
  Adding urological, ostomy, tracheostomy, and CGM products to the bid program is a dramatic policy shift. Historically, new product categories faced average reductions of 50% off the FFS rates, a drastic economic impact on suppliers. Further, these are specialized product categories often served by niche suppliers with deep expertise but a narrower portfolio – meaning if smaller companies lose these contracts, they could lose their entire business.

- **Remote Item Delivery (RID) Model Locks Out Small Business**
  The RID program would centralize contacts among a handful of large suppliers, leaving small companies with no realistic way to participate. Meanwhile the few contracted companies would be forced to expand capacity 30-40x overnight – an impossible ask.
    Ex) CGM suppliers would drop from 800+ to 9 nationwide.
    Ex) Urological suppliers would drop from 190 to 7 nationwide.
    Ex) Ostomy suppliers would drop from 74 to 8 nationwide.
- **Fewer Contracts, Less Small Business Participation**
  Reducing the minimum number of contracts from 5 to 2 per region would eliminate many small businesses from participation entirely and consolidate market share.
- **Single Payment Amounts (SPA) Below Bid Amount**
  Changing to the 75th percentile formula for the SPA means that some contract awards are paid below the bids suppliers submitted – an unsustainable model.
- **Unrealistic CGM Payment Schedule**
  The Proposed Rule reclassifies CGM/pumps to Frequent & Substantial Servicing, which would change the payment structure and spread reimbursement over 5 years. This forces companies to front significant product costs they may not recover for years – a cash flow burden that most small companies cannot sustain.
- **Shortened Compliance Timelines**
  Cutting the response period for required reporting or enrollment issues from 90 to 30 days increases the administrative strain and risk of revocation for smaller companies with limited compliance staff.
- **Prior Authorization (PA) Rules Disadvantage Small Suppliers**
  To qualify for PA exemptions, suppliers would need a 90% approval rate. Large companies may have dedicated staff to manage PA tracking and documentation, while smaller suppliers have fewer administrative resources, making compliance more difficult.

The DME industry calls on CMS to pause consideration of the DMEPOS Competitive Bidding provisions included in the CY 2026 proposed rule meet statutory requirements to analyze impacts on Small Business DME suppliers and consider alternatives to mitigate those impacts.

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