



Life Sciences Health Industry Alert

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CMS Prepares to Re-Launch Medicare DMEPOS Competitive Bidding—Tips for Potential Bidders

Are you Ready for DMEPOS Competitive Bidding?

In the coming months, the Centers for Medicare & Medicaid Services (CMS) is expected to re-launch its controversial competitive bidding program for Medicare suppliers of certain types of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS). This is the agency's second attempt to institute DMEPOS competitive bidding, after the first round of bidding was blocked by Congress last year. The turmoil surrounding the first round of bidding offers valuable lessons for suppliers, however, that should be reviewed in preparation for the upcoming bidding cycle.

This Client Alert provides a brief overview of the DMEPOS competitive bidding program, and highlights seven steps suppliers can take now to prepare for the coming bidding period.

Competitive Bidding at a Glance

The Medicare Modernization Act (MMA) requires CMS to implement a DMEPOS competitive bidding program, under which only suppliers who are successful bidders in specified regions and who meet program standards will be eligible to furnish certain categories of DMEPOS to Medicare beneficiaries (with very limited exception). Under competitive bidding, successful bidders will be paid based on the median of the winning suppliers' bids for each of the selected items in the region, rather than the Medicare fee schedule or supplier bid amount. The MMA calls for competitive bidding to be phased in geographically and by product category.

CMS conducted the first round of DMEPOS competitive bidding in 2007, applying the new reimbursement framework to 10 product categories in 10 geographic areas. In March 2008, CMS announced that the winning bid prices for the first round of competitive bidding averaged 26 percent below Medicare fee schedule amounts. In May 2008, CMS announced the names of the 325 suppliers that had signed contracts to provide competitively bid DMEPOS items in the first round of competitive bidding. The program briefly went into effect July 1, 2008, but there was widespread concern about the way CMS handled the first round of bidding. As a result, Congress enacted the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) July 15, 2008, which, among other things, required CMS to rebid the Round 1 contracts in 2009, and made a series of changes designed to improve the bidding process and safeguard beneficiary access to DMEPOS products.¹

MIPPA directs CMS to conduct the Round 1 rebid in the following metropolitan statistical areas (MSAs):

- Cincinnati – Middletown (Ohio, Kentucky and Indiana)
- Cleveland – Elyria – Mentor (Ohio)
- Charlotte – Gastonia – Concord (North Carolina and South Carolina)
- Dallas – Fort Worth – Arlington (Texas)
- Kansas City (Missouri and Kansas)
- Miami – Fort Lauderdale – Miami Beach (Florida)
- Orlando (Florida)
- Pittsburgh (Pennsylvania)
- Riverside – San Bernadino – Ontario (California)

These are the same MSAs that were included in the original Round 1 of bidding, except that Puerto Rico was excluded by MIPPA. MIPPA also specifies that the Round 1 rebid must include the following product categories:

- Oxygen Supplies and Equipment
- Standard Power Wheelchairs, Scooters, and Related Accessories

- Complex Rehabilitative Power Wheelchairs and Related Accessories (Group 2)
- Mail-Order Diabetic Supplies
- Enteral Nutrients, Equipment and Supplies
- CPAP, RADs, and Related Supplies and Accessories
- Hospital Beds and Related Accessories
- Walkers and Related Accessories
- Support Surfaces (Group 2 mattresses and overlays) in Miami

Again, these product categories generally overlap those that were included in the original Round 1 of bidding, except that MIPPA excluded negative pressure wound therapy from the Round 1 rebid, and Group 3 complex rehabilitative power wheelchairs are permanently excluded from bidding.

Competitive Bidding Timeline

As noted, under MIPPA, the Round 1 rebid must take place in 2009, but the legislation is not specific as to when in 2009 the competition must occur, or when bid prices will actually go into effect. MIPPA also delays Round 2 bidding in 70 additional areas until 2011, and allows the HHS Secretary to extend the program to additional areas after 2011, although national mail order bidding could take place after 2010.

On Jan. 16, 2009, CMS published an interim final rule with comment period to implement the MIPPA changes to the DMEPOS bidding program. After a brief delay to enable the Obama administration to review the regulation, CMS announced April 17, 2009 that it is proceeding with implementation of the rule, effective April 18, 2009. Although finalization of the rule does not have an immediate practical effect on the DMEPOS benefit, it clears the regulatory pathway for CMS to proceed with the bidding process.

CMS is convening a meeting of the DMEPOS Program Advisory and Oversight Committee (PAOC) June 4, 2009 to discuss the Round 1 rebid. CMS hopes that feedback from the session will assist the agency as it moves forward with competitive bidding. CMS is likely to release additional information about its timeline for the Round 1 rebid in connection with the PAOC meeting or shortly thereafter. The first step for suppliers will likely be registration as a bidder, followed by a 60-day window in which to submit actual bids.

7 Steps You Can Take Now to Prepare for the Round 1 Rebid

Suppliers seeking to participate in the Round 1 rebid—including winning suppliers from the original Round 1 of bidding—will need to submit a new bid application when the competition is relaunched later this year in order to become an eligible supplier for competitively bid items in MSAs subject to bidding. Although the bidding period has not yet started, suppliers can take a number of steps now to get ready to bid, including the following:

1. **Review Lessons Learned from Round 1.** Suppliers can use this time to gather available intelligence for their market sector and their own company. What did they learn? What would they do differently? More specifically, suppliers can use the Round 1 codes and payment amounts as a guide to begin considering what models/brands they would be able to supply in each category, potential pricing strategies, and their expected capacity to furnish the items. Suppliers also should assess the impact of various reimbursement scenarios on their business, since ultimate payment amounts may vary from a supplier's submitted bid.
2. **Get Accredited.** MIPPA requires all Medicare DMEPOS suppliers to be accredited as meeting the DMEPOS quality standards by Sept. 30, 2009 (with exceptions for certain health care professionals). The accreditation requirement applies whether or not a supplier is furnishing services in a competitive bidding area. Because the accreditation process can take months to complete, any Medicare supplier that has not started the process should do so immediately or risk being ineligible to bid and having their supplier billing privileges revoked Oct. 1, 2009.
3. **Assemble Financial Information.** Potential bidders can use the Round 1 bidding materials as a roadmap for compiling the extensive financial data and other documents that are required for the bid submission. Note that in the January 2009 interim final rule, CMS indicated that it intends to require one, rather than three, years of financial records to be submitted with future bids, which should ease compliance. Moreover, MIPPA requires CMS to notify bidders in the case of certain missing financial documentation. Nevertheless, this is an area that tripped up numerous bidders during Round 1, and careful attention needs to be paid to submitting required materials.

4. **Verify NSC, Licensure, and Insurance Information, and Supplier Standard Compliance.** Complex corporate structures and/or multiple provider locations can result in disparities between information on file with the National Supplier Clearinghouse (NSC) and with the Internal Revenue Service, and can complicate the completion of required bid forms. Use this time to verify this data, including the NSC number for each physical location that may be supplying items under the bidding program. Also make sure that all state and local licenses are in place and issued to the right entities, and that insurance information is up-to-date. Bidders also are required to comply with the supplier enrollment standards set forth at 42 C.F.R. §424.57(c), including the surety bond requirement. In a related development, the NSC has stepped up its on-site visits of suppliers, so it is important to make sure the location is in compliance with all of the supplier standards (including signage, posting hours of operation, complaint resolution process, and the like). If a supplier number is deactivated and not reactivated prior to the date bids are due, the supplier will not be able to submit a bid.
5. **Identify Key Personnel.** CMS requires a certification statement signed by the authorized official, who must be the supplier's general partner, chairman of the board, chief financial officer, chief executive officer, president, direct owner of the supplier organization or other person holding a position of similar status and authority within the supplier's organization. This official is authorized by the supplier to enroll it in the Medicare program and update the supplier's status, verify correctness of information on the bid, commit the supplier to fully abide by all Medicare policies, and submit a competitive bid on behalf of the supplier. Suppliers also may choose to designate another competitive bidding "point person" who is responsible for monitoring all CMS and Competitive Bidding Implementation Contractor (CBIC) guidance, preparing bid documents, and shepherding the supplier through the mechanics of submitting the bid.
6. **Review Potential Subcontractor and Other Contractual Arrangements.** CMS allows suppliers to enter into arrangements with subcontractors to assist in the furnishing of items and services under a competitive bidding contract. While CMS did not require subcontractors to be accredited in the first round of bidding, MIPPA extends the accreditation requirement to subcontractors. MIPPA also requires suppliers to disclose all subcontracting arrangements. If a potential bidder intends to use subcontractors to help fulfill the terms of its contract with CMS, it should evaluate its proposed subcontractors and, among other things, ensure that the subcontractor is accredited or has started the accreditation process. Similarly, suppliers should assess how they intend to supply products in the areas in which they intend to bid, which may include contracting directly with manufacturers for certain products.
7. **Stay Informed.** Potential bidders should carefully watch the CMS and CBIC websites for announcements regarding the opening of the bidding window, updates to required documentation, and other program guidance. During the initial round of bidding, the CBIC guidance and bidding requirements were frequently updated and revised, sometimes necessitating changes to bids even after the bids were submitted. Suppliers should also participate in CMS-sponsored Open Door conference calls on competitive bidding.

The new competitive bidding program can be expected to have a significant impact on Medicare DMEPOS pricing and consolidation of suppliers within the competitive bidding areas. Reed Smith attorneys and policy analysts are actively involved in this area and would be pleased to answer any questions you may have about the program.

Endnotes

- 1 A detailed Reed Smith analysis of the MIPPA DMEPOS competitive bidding provisions is available at http://www.reedsmith.com/_db/_documents/hc0804.pdf.

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