

MEMORANDUM

TO: HEALTH CARE CLIENTS
DATE: January 9, 2008
RE: Expansion of Medicare DMEPOS Competitive Bidding Announced

I. INTRODUCTION

On January 8, 2008, CMS announced the second phase of Medicare competitive bidding for durable medical equipment (“DME”), prosthetics, orthotics, and supplies (“DMEPOS”). In this second round, competitive bidding will be implemented in 70 areas, including the nation’s largest cities. The complete list of areas can be found at Appendix 1. With very limited exception, only suppliers who are successful bidders in these regions and who meet program standards (including accreditation) will be eligible to furnish eight categories of DMEPOS to Medicare beneficiaries beginning next year. 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.

This expanded bidding program builds on the first phase of competitive bidding affecting 10 geographic regions and 10 product categories, which goes into effect July 1, 2008. Suppliers in the new bidding regions and other affected entities (including DMEPOS manufacturers, nursing homes, physicians) should take this opportunity to prepare for the bidding process to be conducted later this year, as discussed below.

II. BRIEF LEGISLATIVE & REGULATORY BACKGROUND

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (“MMA”) requires the Secretary of Health and Human Services to implement competitive acquisition programs for DMEPOS beginning in 2007. Eligible products include: (1) DME (including DME used with infusion and drugs, other than inhalation drugs) and supplies used in conjunction with DME; (2) enteral nutrients, equipment, and supplies; and (3) off-the-shelf

orthotics. The MMA excludes from competitive acquisition inhalation drugs; parenteral nutrients, equipment, and supplies; and Class III devices. Moreover, the Secretary may exempt rural areas and areas with low population density in urban areas (unless there is a significant national market through mail order for particular items), and items and services unlikely to result in significant savings.

The Secretary is directed to establish competitive bidding areas (“CBAs”), which may differ for different items and services. Competitive acquisition will be phased in geographically, applying to 10 of the largest MSAs in 2007, a total of 80 MSAs in 2009, and additional MSAs thereafter. The Secretary also may phase in competitive acquisition programs first among the highest cost and highest volume items and services or those that have the largest savings potential.

For each competitive acquisition area, the Secretary must solicit bids by suppliers to supply certain covered items. Only successful bidders may supply the covered items in the CBA, and they will be reimbursed based on the bid amount. The Secretary must ensure that small suppliers have the opportunity to be considered for participation under the program.

In order to be awarded a contract, bidding entities must meet new quality standards for suppliers, along with financial standards specified by the Secretary. Total amounts paid under the contracts are expected to be less than would be paid otherwise, and beneficiary access to multiple suppliers must be maintained. The Secretary may limit the number of contractors in a competitive acquisition area to the number needed to meet projected demand.

CMS published its proposed rule to implement the DMEPOS competitive bidding program on May 1, 2006, and it published the final rule on April 10, 2007.¹ Note that other important details regarding contracting and bidding, along with a variety of educational materials, are being released by Palmetto GBA, the Competitive Bidding Implementation Contractor (“CBIC”).²

¹ A Reed Smith client memo providing a detailed analysis of the final rule is available at <http://www.reedsmith.com/db/documents/hc0704.pdf>.

² See <http://www.dmecompetitivebid.com>.

III. PHASE ONE OF BIDDING

CMS conducted the first round of DMEPOS competitive bidding last summer, and the deadline for bidding was September 25, 2007. The first round covers the following 10 metropolitan statistical areas (“MSAs”): (1) Charlotte-Gastonia-Concord, NC-SC; (2) Cincinnati-Middletown, OH-KY-IN; (3) Cleveland-Elyria-Mentor, OH; (4) Dallas-Fort Worth-Arlington, TX; (5) Kansas City, MO-KS; (6) Miami-Fort Lauderdale-Miami Beach, FL; (7) Orlando-Kissimmee, FL; (8) Pittsburgh, PA; (9) Riverside-San Bernardino-Ontario, CA; and (10) San Juan-Caguas-Guaynabo, PR.

Ten categories of DMEPOS are included in phase one³: (1) Oxygen Supplies and Equipment; (2) Standard Power Wheelchairs, Scooters, and Related Accessories; (3) Complex Rehabilitative Power Wheelchairs and Related Accessories; (4) Mail-Order Diabetic Supplies; (5) Enteral Nutrients, Equipment, and Supplies; (6) Continuous Positive Airway Pressure Devices, Respiratory Assist Devices, and Related Supplies and Accessories; (7) Hospital Beds and Related Accessories; (8) Negative Pressure Wound Therapy Pumps and Related Supplies and Accessories; (9) Walkers and Related Accessories; and (10) Support Surfaces (Group 2 mattresses and overlays), although this category is subject to bidding only in Miami-Fort Lauderdale-Miami Beach, FL and San Juan-Caguas-Guaynabo, Puerto Rico.

CMS currently is in the process of evaluating supplier bids from the first round. Under an evaluation process established in the final rule, CMS calculates a composite bid for each supplier, which represents the sum of a supplier’s weighted bids for all items within a product category. Composite bids of suppliers who otherwise meet the eligibility standards are ranked in order from lowest to highest, and the lowest composite bid for a product category that will include a sufficient number of suppliers to meet expected beneficiary demand is selected as the pivotal bid. Suppliers whose composite bids are less than or equal to the pivotal bid are selected as winning suppliers if they meet all other program requirements.

CMS expects to announce the winning suppliers and bid prices for the first round in February 2008. The program goes into effect July 1, 2008.

³ A detailed listing of the products included within each category is available at [http://www.dmecompetitivebid.com/cbic/CBIC.nsf/\(subpages\)/CBICSuppliersProduct+Categories](http://www.dmecompetitivebid.com/cbic/CBIC.nsf/(subpages)/CBICSuppliersProduct+Categories).

IV. PHASE TWO EXPANSION

On January 8, 2008, CMS announced the 70 MSAs and eight product categories that will be included in the second round of competitive bidding. The expanded bidding program will include the three largest MSAs - New York, Los Angeles, and Chicago. The complete listing of MSAs can be found at Appendix 1, and the specific zip-codes included in each CBA will be released in the future.

CMS is including eight of the 10 product categories from round one in the second round of bidding:

- 1 – Oxygen Supplies and Equipment
- 2 – Standard Power Wheelchairs, Scooters, and Related Accessories
- 3 – Complex Rehabilitative Power Wheelchairs and Related Accessories
- 4 – Enteral Nutrients, Equipment, and Supplies
- 5 – Continuous Positive Airway Pressure Devices, Respiratory Assist Devices, and Related Supplies and Accessories
- 6 – Hospital Beds and Related Accessories
- 7 – Negative Pressure Wound Therapy Pumps and Related Supplies and Accessories
- 8 – Walkers and Related Accessories

The specific codes to be included in this round have not yet been released, but are expected to be made available this spring. Suppliers can bid on one or more product categories, but must bid on all specified codes within the category. Note that although diabetes supplies are not listed in this round of bidding, CMS officials indicated in a January 8, 2008 press conference that they are preparing to conduct nationwide competitive bidding for diabetes supplies in the future.

CMS also announced that it will continue its controversial policy from round one of requiring nursing homes in CBAs to be winning bidders in order to supply covered DMEPOS items to their own residents under their own Part B supplier number. CMS will allow nursing homes to bid to serve their own residents exclusively, however, without having to meet a general requirement that suppliers serve an entire CBA. If a nursing home does not bid or if it is not a successful bidder, it will be required to use a winning bidder to furnish covered Part B items to its residents. In a related provision, CMS is continuing to allow physicians and certain other practitioners, along with physical therapists and occupational therapists in private practice, to furnish certain items exclusively to their patients at the single bid price without going through the bid process.

CMS plans to launch a 60-day bidding period later this year, with the second phase going into effect next summer. A more detailed timeline will be provided in the coming months.

V. **ACTION STEPS FOR POTENTIAL BIDDERS**

CMS's early announcement of the geographic regions and product categories for round two provides an important opportunity for suppliers and other potentially-affected entities to prepare for bidding.

- Most importantly, suppliers in upcoming CBAs should start the accreditation process if they have not already done so. While CMS recently announced that all Medicare suppliers will be required to be accredited as meeting DMEPOS quality standards by September 30, 2009, CMS has indicated that bidding suppliers will need to be accredited "well in advance of that deadline" in order to be awarded a contract.⁴
- Although the specific product codes for round two have not yet been announced, suppliers can use the round one codes 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.
- Potential bidders can use the round one bidding materials as a roadmap for compiling the extensive financial data and other documents that are required for the bid submission.⁵
- Small suppliers can familiarize themselves with the rules for forming networks to determine their eligibility and assess the potential benefits and drawbacks of network bidding.
- Manufacturers also should be preparing for changes in the marketplace in the CBAs. Among other things, manufacturers can plan to work with major suppliers

⁴ For information on the quality standards, see http://www.cms.hhs.gov/CompetitiveAcqforDMEPOS/downloads/CMS_DMEPOS_Quality_Standards_081406.pdf. A list of approved accreditation organizations is available at http://www.cms.hhs.gov/MedicareProviderSupEnroll/03_DeemedAccreditationOrganizations.asp.

⁵ For more information on the actual application and document submission requirements, see [http://www.dmecompetitivebid.com/cbic/CBIC.nsf/\(subpages\)/CBICSuppliersBid%20Application%20Tool%20Kit](http://www.dmecompetitivebid.com/cbic/CBIC.nsf/(subpages)/CBICSuppliersBid%20Application%20Tool%20Kit).

in key geographic areas to ensure their particular products are included in the suppliers' bid sheets.

- Nursing homes in the new CBAs should assess their options for furnishing covered items to their Medicare residents, either through participating as a bidder (in which case the nursing home must be an accredited Part B supplier) or contracting with a winning supplier.
- Affected parties should continue to monitor the CMS and CBIC web sites for announcements regarding specific items and locations to be included in round two, along with pre-registration requirements and the opening of the bidding window.⁶

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The contents of this Memorandum are for informational purposes only, and do not constitute legal advice.

⁶ See http://www.cms.hhs.gov/competitiveacqfordmepos/01_overview.asp and [http://www.dmecompetitivebid.com/cbic/cbic.nsf/\(pages\)/home](http://www.dmecompetitivebid.com/cbic/cbic.nsf/(pages)/home), respectively.

Appendix 1: Competitive Bidding Round 2 Metropolitan Statistical Areas

West	Midwest	South	Northeast
Albuquerque, NM	Akron, OH	Asheville, NC	Allentown-Bethlehem-Easton, PA-NJ
Bakersfield, CA	Chicago-Naperville-Joliet, IL-IN-WI	Atlanta-Sandy Springs-Marietta, GA	Bridgeport-Stamford-Norwalk, CT
Colorado Springs, CO	Columbus, OH	Augusta-Richmond County, GA-SC	Hartford-West Hartford-East Hartford, CT
Denver-Aurora, CO	Dayton, OH	Austin-Round Rock, TX	New Haven-Milford, CT
Fresno, CA	Detroit-Warren-Livonia, MI	Baton Rouge, LA	New York-Northern New Jersey-Long Island, NY-NJ-PA
Las Vegas-Paradise, NV	Flint, MI	Beaumont-Port Arthur, TX	Scranton--Wilkes-Barre, PA
Los Angeles-Long Beach-Santa Ana, CA	Grand Rapids-Wyoming, MI	Birmingham-Hoover, AL	Syracuse, NY
Sacramento--Arden-Arcade--Roseville, CA	Huntington-Ashland, WV-KY-OH	Cape Coral-Fort Myers, FL	
Salt Lake City, UT	Indianapolis-Carmel, IN	Charleston-North Charleston, SC	
San Diego-Carlsbad-San Marcos, CA	Milwaukee-Waukesha-West Allis, WI	Chattanooga, TN-GA	
San Francisco-Oakland-Fremont, CA	Minneapolis-St. Paul-Bloomington, MN-WI	Columbia, SC	
San Jose-Sunnyvale-Santa Clara, CA	Omaha-Council Bluffs, NE-IA	Deltona-Daytona Beach-Ormond Beach, FL	
Visalia-Porterville, CA	Toledo, OH	El Paso, TX	
	Wichita, KS	Greensboro-High Point, NC	
	Youngstown-Warren-Boardman, OH-PA	Greenville-Mauldin-Easley, SC	
		Houston-Sugar Land-Baytown, TX	
		Jackson, MS	
		Jacksonville, FL	
		Knoxville, TN	
		Lakeland, FL	
		Little Rock-North Little Rock-Conway, AR	
		Louisville/Jefferson County, KY-IN	
		McAllen-Edinburg-Mission, TX	
		Memphis, TN-MS-AR	
		Nashville-Davidson--Murfreesboro--Franklin, TN	
		New Orleans-Metairie-Kenner, LA	

		Ocala, FL	
		Oklahoma City, OK	
		Oklahoma City, OK	
		Palm Bay-Melbourne- Titusville, FL	
		Raleigh-Cary, NC	
		Richmond, VA	
		San Antonio, TX	
		Tampa-St. Petersburg- Clearwater, FL	
		Tulsa, OK	
		Virginia Beach-Norfolk- Newport News, VA-NC	