

**SPECIAL
ALERT****Registration and Bidding Period for First Round of the
DMEPOS Competitive Bidding Program Extended:
Bids Due by July 20, 2007****HEALTH CARE AND
LIFE SCIENCES**

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On June 29, 2007, following requests from suppliers and others to modify the bidding deadline, CMS announced the following changes to the bid and registration deadlines for the first round of the DMEPOS competitive bidding:

- The original due date for bids was 9:00 p.m. prevailing Eastern Time on July 13, 2007. All bids are now due by 9:00 p.m. prevailing Eastern Time on July 20, 2007.
- Suppliers interested in bidding must first register and receive a User ID and Password before they can access the internet-based bid submission system. The original registration deadline was June 30, 2007. The registration deadline is now July 7, 2007.

The Centers for Medicare & Medicaid Services (CMS) issued a final rule on April 10, 2007, implementing a competitive acquisition program for certain types of Medicare Part B covered items in the categories of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS). For those health care providers, suppliers and manufacturers directly affected by this CMS Medicare Part B procurement initiative, the ramifications are direct and will be imminent. Other health care providers, suppliers and manufacturers not yet affected by this CMS Medicare Part B procurement initiative should become familiar with this new process as it is planned to be expanded both geographically as well as to other types of health care providers and suppliers and to other Medicare B covered items in the future.

Initially, in 2008, a competitive bidding program will operate in competitive bidding areas (CBAs) within ten specific Metropolitan Statistical Areas (MSAs) and will apply to ten DMEPOS product categories based on criteria outlined in the final rule. In 2009, the program will be expanded into 70 additional MSAs. After 2009, CMS will expand the program to additional areas and items. Bidding for this new program for 2008 opened on May 15, 2007 and will close on July 20, 2007. The specific MSAs and DMEPOS product categories subject to bidding are listed below:

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2007 MSAs	2007 DMEPOS
1. Miami-Fort Lauderdale-Miami Beach, FL	1. Oxygen Equipment and Supplies
2. Charlotte-Gastonia-Concord, NC-SC	2. Respiratory Assist Devices and Continuous Positive Airway Pressure Device and Accessories
3. Dallas-Fort Worth-Arlington, TX	3. Standard Power Wheelchairs, Scooters, and Related Accessories
4. Orlando, FL	4. Complex Rehabilitative Power Wheelchairs and Related Accessories
5. Riverside-San Bernardino-Ontario, CA	5. Diabetic Supplies (Mail Order Only)
6. Pittsburgh, PA	6. Enteral Nutrition Formulas, Pumps, and Supplies
7. Kansas City, MO-KS	7. Hospital Beds and Accessories
8. Cincinnati-Middletown, OH-KY-IN	8. Walkers
9. San Juan-Caguas-Guaynabo, PR	9. Negative Pressure Wound Therapy Devices and Accessories
10. Cleveland-Elyria-Mentor, OH	10. Support Surfaces (Group 2 and 3 mattresses and overlays) as a target item in Miami and San Juan, Puerto Rico

Suppliers of competitive bidding products supplying the affected CBA will not be permitted to be reimbursed under Medicare Part B for these covered items unless they submit a bid and are selected by CMS as a bidder. Generally speaking, in lieu of the fee schedule, the single payment amount for each competitively-bid item in the CBA will be the median of the “winning” bids for that item.

Quality Standards and Accreditation

DMEPOS suppliers must meet certain quality standards and be accredited by a CMS-approved accreditation organization in order to participate in the Medicare DMEPOS Competitive Bidding Program. CMS released final quality standards on August 14, 2006.¹ There are two main categories of quality standards with several sub-categories under each.

Business Services	<ul style="list-style-type: none"> ■ Administration ■ Consumer services ■ Financial management ■ Human resource management ■ Information management ■ Performance management ■ Product safety
General Product-Specific Service Standards	<ul style="list-style-type: none"> ■ Delivery and setup ■ Follow-up ■ Preparation ■ Training/instruction to beneficiary & caregiver

These quality standards are applied by recognized independent accreditation organizations that CMS announced in November 2006.² In order to submit a bid, suppliers must be accredited or *be pending accreditation*. To be awarded a contract for this first round of competitive bidding suppliers should apply for accreditation immediately to allow adequate time to process their applications. However, suppliers will need to be accredited by August 31, 2007 (not simply pending accreditation).

¹ Available online at http://www.cms.hhs.gov/CompetitiveAcqforDMEPOS/downloads/CMS_DMEPOS_Quality_Standards_081406.pdf
² Available online at http://www.cms.hhs.gov/CompetitiveAcqforDMEPOS/downloads/DMEPOS_Accreditation_Organizations.pdf

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As part of the accreditation process, supplier organizations will be expected to submit a variety of documentation, including corporate materials and specific organizational policies and procedures. In addition, accreditation organizations will perform unannounced surveys on site at each supplier location. Once awarded, accreditation cannot be transferred upon merger, acquisition, or sale, and if accreditation is revoked or lapses, the Medicare supplier number may be revoked as well.

Financial Standards

In order to be awarded a contract, a supplier must also submit certain financial documentation for CMS' review. According to CMS, applying financial standards to suppliers assists CMS in assessing the expected quality of suppliers, estimating the total potential capacity of selected suppliers, and ensuring that selected suppliers are able to meet the market demand for the duration of their contracts. For the initial round of competition, bids must include the following financial documentation:

- Certain tax return schedules
- A copy of 10K filing reports
- Certain financial statement reports, such as cash flow statements
- A current credit report.

All documents that are not prepared as part of a tax return must be certified as accurate by the supplier and must be prepared on an accrual or cash basis of accounting. In addition, suppliers must disclose legal actions, sanctions, and program-related convictions, including those of company executives; provide licenses required to perform the services the supplier identifies in its bid; and comply with the supplier enrollment standards provided in 42 CFR 424.57(c).

The Bidding Process

A bid must disclose ownership and controlling interest information; and all commonly-owned or controlled suppliers may submit only one bid per product category in a CBA. A bid must also include each commonly-owned or controlled supplier located in the CBA and locations outside the CBA that would be furnishing items in the CBA. A supplier does not need to have a physical location in a CBA to submit a bid to furnish items in that area.

Two forms are required when submitting a bid: Form A (Application) and Form B (Bid Sheet). Form A must be completed before progressing to Form B. Also, a Form A must be completed for each CBA in which a supplier intends to do business. However, only one Form A is required for each entity (e.g., individual supplier, network member, etc.). If the supplier has multiple locations or is a part of a network bid, only one Form A is required, but it must include the information for all locations/network members.

A supplier must complete Form B for each product category on which the supplier bids. In sum, Form B requires the supplier to provide information on the:

- Total revenue for the product category for the CBA and percentage of revenue that was collected from Medicare
- Total number of customers for the product category for the CBA and percentage that were beneficiaries
- Counties the supplier currently services for the product category
- Number of product units (per HCPCS code designated by CMS) provided to customers in the CBA
- Percentage increase in volume the supplier/network is capable of providing for product category and total estimated Medicare capacity

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- If applicable—plans for business expansion and/or subcontracting (including letters of intent if subcontracting).

A supplier which has not previously furnished items and services within a CBA must also provide an expansion plan that indicates how it will be able to furnish services within the CBA. The supplier's expansion plan may contain projected financial information, including costs. While a new or "start-up" company may also bid, it must provide a proposal similar to an expansion plan which demonstrates a capacity to provide the services, as well as projected financial information.

The supplier must specify manufacturer and model name and number of items available to beneficiaries. CMS recognizes that suppliers may change model numbers later on and will post a list of manufacturers and models on the Internet to allow beneficiaries to make an informed choice.

The bid price is also submitted on Form B. The price proposed by the supplier must include the cost of:

- Furnishing the covered item throughout the CBA
- Providing the covered item and any requisite service associated with the covered item (e.g., training, shipping, education, delivery)
- Providing the covered item during the full duration of the bidding period
- Provisions that address assurances that all Medicare beneficiaries in a CBA have the same choice of covered items that the supplier would provide to other customers.

Once a bid is received by CMS, a supplier will be notified via email. During the 60-day bid window (May 15, 2007 – July 20, 2007) a supplier may change bids as many times as necessary.

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If you would like additional information regarding this topic, please contact George B. Breen at 202/861-1823 or ggreen@ebglaw.com; Leah Kendall at 202/861-4197 or lkendall@ebglaw.com; or John Eriksen at 202/861-1884 or jeriksen@ebglaw.com in the firm's Washington, DC office or the Epstein Becker & Green attorney who regularly handles your legal matters. For further information about Epstein Becker & Green's Health Care & Life Sciences Practice, or to see back issues of Special Alerts, please visit our website at www.ebglaw.com.

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