



## **Frequently Asked Questions**

### **CMS Final Rule on Competitive Bidding**

#### **April 12, 2007**

On April 2, 2007 the Centers for Medicare and Medicaid Services (CMS) released the final rule that implements national competitive bidding program for Durable Medical Equipment and Prosthetic and Orthotic Supplies (DMEPOS), and published it in the April 10, 2007 *Federal Register*. The final rule and other documentation on competitive bidding can be found on CMS' web site at:

[http://www.cms.hhs.gov/competitiveacqfordmepos/01\\_overview.asp](http://www.cms.hhs.gov/competitiveacqfordmepos/01_overview.asp)

The following Frequently Asked Questions are based on CMS' final rule and other documents posted on CMS and the CBIC web sites.

### **General Questions**

#### **Q. Who is impacted by national competitive bidding (NCB)?**

A. Any supplier that provides bid items to beneficiaries in one of the 10 initial competitive bidding areas (CBAs) will be impacted. To continue to provide bid items to these beneficiaries, suppliers must submit a bid to provide those items and become a "contract supplier." Non-contract suppliers may still provide durable medical equipment (DME), but the beneficiary must also receive an Advanced Beneficiary Notice (ABN) stating that they may be liable for the full cost of the item. 42 CFR §414.408(e)(3)(ii).

#### **Q. What is the timeline for competitive bidding implementation?**

A. CMS expects to commence with the bidding process by issuing the Request for Bids (RFB) in the first 10 Metropolitan Statistical Areas (MSAs) at the end of April 2007, with bidding set to close 60 days later (end of June 2007). CMS plans to announce the winning suppliers in December 2007 with contract prices taking effect on April 1, 2008 in the initial 10 competitive bidding MSAs.

In 2008, CMS plans to begin bidding in 70 additional MSAs, which will include New York, Los Angeles, and Chicago (which were exempt from the first round of bidding). CMS also plans on adding another 10 MSAs in each of 2009 and 2010. Rural areas and areas with low population density within urban areas that are not competitive may be exempt, unless there is a significant national market through mail order for a particular item or service. 42 CFR §414.410(c).

#### **Q. What are the 10 MSAs that will be subject to the initial round of competitive bidding?**

A. Competitive bidding program will initially begin in the following 10 MSAs:

- Charlotte-Gastonia-Concord, NC-SC
- Cincinnati-Middletown, OH-KY-IN
- Cleveland-Elyria-Mentor, OH

- Dallas-Fort Worth-Arlington, TX
- Kansas City, MO-KS
- Miami-Fort Lauderdale-Miami Beach, FL
- Orlando-Kissimmee, FL
- Pittsburgh, PA
- Riverside-San Bernardino-Ontario, CA
- San Juan-Caguas-Guaynabo, PR

CMS is **not** including all zip codes in these MSAs in competitive bidding. To determine the exact boundaries of these MSAs click on to:

[http://www.dmecompetitivebid.com/cbic/CBIC.nsf/\(Pages\)/Competitive+Bid+Areas](http://www.dmecompetitivebid.com/cbic/CBIC.nsf/(Pages)/Competitive+Bid+Areas).

**Q. What product categories will be included in competitive bidding?**

Products selected for the first round of competitive bidding include:

- Oxygen equipment and supplies
- Respiratory assist devices and CPAP
- Standard power wheelchairs, scooters, and related accessories
- Complex rehabilitative power wheelchairs and related accessories
- Diabetic supplies (mail order only)
- Enteral nutrition
- Hospital beds and accessories
- Walkers
- Negative pressure wound therapy devices
- Support surfaces, Group 2 and 3 mattresses and overlays (*only to be bid in Miami and San Juan*)

**DME Quality Standards and Accreditation**

**Q. When will the new quality standards and accreditation be implemented?**

A. CMS released new quality standards for all DME suppliers last year. Moreover, CMS has also named the nationally recognized accreditation bodies that will survey suppliers to ensure that they meet the quality standards. The quality standards can be found at:

[http://www.cms.hhs.gov/CompetitiveAcqforDMEPOS/04\\_New\\_Quality\\_Standards.asp#TopOfPage](http://www.cms.hhs.gov/CompetitiveAcqforDMEPOS/04_New_Quality_Standards.asp#TopOfPage).

A list of CMS-approved accreditation bodies can be found at:

[http://www.cms.hhs.gov/competitiveacqfordmepos/downloads/DMEPOS\\_Accreditation\\_Organizations.pdf](http://www.cms.hhs.gov/competitiveacqfordmepos/downloads/DMEPOS_Accreditation_Organizations.pdf).

**Q. If I do not wish to competitively bid, do I still need to adhere to the new quality standards and accreditation?**

A. Yes. All DME suppliers who participate in Medicare - even if you do not participate in a competitive bidding area - must be accredited by either a State agency or a nationally recognized accreditation body. This new accreditation requirement will be incorporated as a supplier standard and will be required to obtain a DME supplier number from the National Supplier Clearinghouse (NSC). CMS has not set a date by when all DME suppliers must be accredited.

**Q. I have already been accredited; do I have to be reaccredited to participate in the Medicare program?**

A. CMS has stated that the nationally recognized accreditation bodies will take into account previous accreditation, and that suppliers already accredited will be grandfathered. On the next regularly scheduled survey these suppliers will be surveyed for compliance with the new standards.

**Q. Can I bid if I am not accredited?**

A. CMS will only accept bids from suppliers who are accredited or pending accreditation. In the final rule, CMS stated that winning suppliers must be accredited by the time the contract is awarded or the contract will be terminated. 42 CFR §414.414(c).

**Payment under Competitive Bidding**

**Q. Who will administer and evaluate the bids?**

A. CMS has contracted with Palmetto GBA to be the first Competitive Bidding Implementation Contractor (CBIC) to administer the NCB program. The CBIC will have six primary functions, including: overall oversight and decision making, operation design function, bidding and evaluation, access and quality monitoring, outreach and education, and claims processing. The CBIC web site can be found at: [www.dmecompetitivebid.com](http://www.dmecompetitivebid.com).

**Q. How will winning bidders (known as “contract suppliers”) be paid?**

A. The CBIC will determine the winning bidders and establish a single payment amount for each item in the CBA based on the bids submitted for that item. The Medicare payment will equal 80% of the single applicable payment amount (with 20% accounting for the beneficiary’s copayment). 42 CFR §414.408(a); 42 CFR §414.416(b).

**Q. Who do contract suppliers submit claims to?**

A. While the CBIC will name the winning bidders and establish the single payment amount, contract suppliers will submit claims to the Durable Medical Equipment (DME) Medicare Administrative Contractor (MAC) for their region.

**Q. Will there be any adjustments made to this single payment amount?**

A. No. The single payment amount will not be adjusted based on geographic region within the CBA. Moreover, the single payment amount will not be adjusted for inflation or other economic factors. Contract suppliers should expect to receive the same single payment amount for the entire term of their Medicare contract.

**Q. What if a beneficiary lives in a CBA and travels to a non-CBA or visa-versa? Who supplies DME? How is reimbursement determined for these beneficiaries?**

A. Under NCB only a contract supplier may supply DME in a CBA. CMS, however, makes an exception for beneficiaries who normally reside in a CBA but travel or spend part of the year outside of the CBA (i.e. “snowbirds”). As a general rule, Medicare reimbursement is dependent on the area in which the beneficiary resides. If the beneficiary lives in a CBA, but travels to a non-CBA, then any Medicare supplier may furnish DME and the supplier will then be reimbursed the single payment

amount in the beneficiary's CBA. If travel is to a different CBA, then the beneficiary must purchase items from a contract supplier who will then be reimbursed the single payment amount based on the beneficiary's CBA. If the beneficiary resides in a non-CBA and travels to a CBA, the beneficiary must purchase DME from a contract supplier who will then be reimbursed the fee schedule amount in the area where the beneficiary permanently resides. 414.408(e)(2)(iii).

**Q. What about beneficiaries residing in CBAs who are being served by a non-contract supplier at the date the NCB program is implemented? Are non-contract suppliers obligated to service DME if they had a pre-existing relationship?**

A. The beneficiary has the choice to allow the continuation of existing rental agreement and supply arrangements made before implementation of NCB. The non-contract supplier also must choose to continue servicing all or none of the existing beneficiaries receiving bid products. If the non-contract supplier chooses to be a "grandfathered" supplier and continues to serve beneficiaries, the non-contract supplier will be paid the the "old" fee schedule amount for capped rental items, and the bid payment amount for oxygen items. If a non-contract is not willing to continue the relationship, a contract supplier must assume the existing arrangement with the beneficiary. The beneficiary can elect at anytime to transition to a contract supplier. 42 CFR §414.408(j).

**Q. How will existing capped-rental payments be reimbursed to contract suppliers?**

A. Contract suppliers will receive the all 13-month rental payments, regardless of how many rental payments Medicare has previously made. The rental payments will be based on the single payment amount. 42 CFR §414.408(h).

**Q. What about pre-existing oxygen agreements taken over by contract suppliers which are paid on a 36-month rental basis?**

A. At a minimum, contract suppliers will be guaranteed at least 10 rental payments for providing oxygen services. If, however, a contract supplier begins furnishing oxygen to a beneficiary in months 2 through 26, Medicare will make the payments for the rest of the 36-month rental period. 42 CFR §414.408(i)(2).

**Q. If a non-contract supplier agrees to accept the single payment amount; can the non-contract supplier provide Medicare reimbursed DME in a CBA?**

A. No. According to CMS, the statute requires all contract suppliers to go through the bidding process. Therefore, all non-contract suppliers would be prohibited from serving beneficiaries in a competitive bidding area even if they agreed to honor the winning bid price. The only exceptions are "grandfathered" suppliers or suppliers who provide items not subjected to competitive bidding in a CBA. 42 CFR §411.15(s).

**Q. How are payments made for maintenance and service, repair and replacement of beneficiary-owned DME?**

A. Any supplier can perform maintenance and service or repair beneficiary-owned DME that was competitively bid. CMS will pay the supplier the bid payment amount for the part (assuming it's a competitively bid item) and any reasonable and necessary charges for labor. If the beneficiary needs to obtain a replacement DME, they must use a contract supplier if they reside in a CBA. 42 CFR §414.408(l).

**Q. Under the proposed rule there was a “rebate” program where contract suppliers could provide beneficiaries the difference between their bid amount and the single payment amount (assuming the bid price was lower than the single payment amount). Can you tell me about this “rebate” program?**

A. Under the final rule, CMS heeded comments from stakeholders who voiced concerns that rebates may violate anti-kickback laws and did away with the rebate program.

## **Competitive Bidding Areas and Supplier Capacity**

**Q. How many suppliers will be chosen per MSA area? How will CMS know how many suppliers are needed?**

A. CMS proposes to select only as many suppliers as are needed to ensure that capacity is fulfilled. The legislation requires, however, that multiple suppliers be chosen per product category. CMS states that they will award at least five contracts for each DME product category, if there are five qualified suppliers. If there are not five qualified suppliers, CMS will contract with a minimum of two suppliers. 42 CFR §414.414(h).

The “pivotal bid” will determine how many suppliers receive contracts for a particular product. Starting with the lowest composite price, CMS will add the estimated capacity of each successive bidder until total capacity meets or exceeds peak estimated market demand.

In determining a supplier’s individual capacity, the Request for Bid (RFB) forms will ask each supplier to report the number of units they are willing to supply and at what price. Suppliers can expand their capacity numbers on the RFB so long as they document how they are going to expand. 42 CFR §414.414(e).

## **Bidding Rules**

**Q. What are the supplier bidding rules?**

A. The following are the bidding rules apply to all suppliers submitting bids:

- Suppliers can choose to bid for multiple product categories;
- Suppliers will not be required to submit a bid for every product category;
- Suppliers must submit a bid price for every item in the product category;
- All bids should be for the purchase of a new item with the exception of capped rental items). For PMDs that have both a rental and purchase option, suppliers must provide both rental and purchase price bids;
- Bids must include all costs related to furnishing of the item – delivery, set-up, training and all other services directly related to furnishing the item;
- Bidders must agree to provide DME items and services to beneficiaries residing in the CBA;
- Bids cannot be for more than the fee schedule amount; and
- Bidding will be done on a “Request for Bid” forms developed by CMS.

**Q. What information will suppliers have to provide in the bids**

A. Suppliers will have to provide general and business information, capacity and bid information,

bank or financial reference information. Suppliers will also have to provide additional documentation including:

- Supplier financial statements (certified as accurate by the supplier);
- Credit reports and score;
- Business expansion plans (if any);
- Subcontractor information;
- Resumes of key personnel;
- Signed legal contracts with network suppliers (if a small supplier network);
- Settlement agreements or corporate integrity agreements.

**Q. Specifically what type of financial disclosure is necessary? Does type of financial disclosure depend on what type of supplier I am?**

A. Suppliers that file individual returns that include business taxes are required to submit their Schedule C from their Form 1040 for the past three years. In addition, these suppliers must submit a Compiled Balance Sheet, a Cash Flow Statement and a Statement of Operations. Limited partnerships must submit their Schedule L from their Form 1065 from the past three years along with the financial documentation that suppliers who file individual returns must disclose. Suppliers that file corporate returns are required to provide their Schedule L for the past three years along with the other documentation required by other suppliers. Publicly traded suppliers must submit their 10-K Filing Reports for the past three years. If the supplier is a wholly-owned subsidiary of a publicly-traded company, must submit the parent company's 10-K reports.

If a supplier does not have financial documentation for one or more of the three years prior to the bid, the supplier must provide projected financial statements that are based on key financial assumptions of the present and must include a description of these assumptions.

For supplier networks, the legal entity that submits the bid, must submit the financial information on behalf of each network member.

**Q. How long will contracts be awarded to winning bidders? What are any additional terms of every winning contract? Can contract suppliers transfer ownership through merger or acquisition?**

A. CMS will re-bid the contracts every three years. Contracts can continue under a change of ownership so long as all contract requirements continue to be met. Contracts can be suspended or terminated if there is a deviation from contract requirements. In addition CMS retains the right to terminate a contract if a breach occurs or it is in CMS' best interest. In case of a breach, CMS may: require a correction by the supplier; suspend contract performance; terminate the contract; or revoke the supplier's Medicare participation number. 42 CFR §414.422(b); 42 CFR §414.422(d); 42 CFR §414.422(f).

**Q. Are all suppliers eligible to bid?**

A. In order to submit an RFB, a supplier must meet all current Medicare eligibility rules; be in good standing with no current sanctions; disclose any previous or current legal actions, sanctions or disbarments of employees, officers or subcontractors; have all relevant State and local licenses; and agree to terms and length of the contract. 42 CFR §414.414(b)-(c).

**Q. Does the supplier need to be physically located in the CBA to bid?**

A. There is no need for a supplier to maintain a physical location in the CBA to submit a bid in that CBA. Suppliers must, however, have the capacity to serve beneficiaries in the CBA.

**Q. How will bids be evaluated?**

A. Submitted bids are evaluated by product categories. First, the CBIC ranks all composite bids within a product category from the lowest to the highest. Second, the pivotal bid for the product category is evaluated. CBIC will then narrow its selection process down to all suppliers that: 1) have composite bids below the pivotal bid: and 2) meet the supplier standards. 42 CFR §414.414(e).

**Q. What is a “composite” bid?**

A. CMS will award contracts for product categories, not for individual items covered by Medicare. To allow for comparisons among bidders, the CBIC will establish the “composite bid” for each supplier. The composite bid will be based on the sum of each item’s bid amount times its weight for the entire category. The weight of an item is based on volume (utilization levels) compared to other items within the product category. 42 CFR §414.414(e)(3)-(4).

**Q. What is a “pivotal” bid?**

A. The “pivotal” bid is essentially the cut-off point for CMS to award contracts. CMS will start with the lowest bid, and then include the 2<sup>nd</sup>-lowest, etc. until the cumulative supply capacity of such bidders is sufficient to satisfy the expected demand for the items being bid upon. Any eligible suppliers with bids below the pivotal bid will be awarded a contract, and this will always include at least two suppliers. 42 CFR §414.414(e).

**Q. Can losing suppliers appeal the award decision of the CBICs?**

A. No. Suppliers have no right to appeal the awarding of contracts, how the CBAs were determined, how the items subject to bid were selected, or how the bidding structure and number contracts awarded were determined. 42 CFR §414.424.

**Opportunity to Participate by Small Suppliers**

**Q. Who does CMS consider a small DME supplier?**

A. CMS defines a “small supplier” as a supplier with gross revenues of less than \$3.5 million. 42 CFR §414.402.

**Q. How Will CMS Determine if A DME Supplier is “Small”?**

A. CMS will require suppliers that submit bids to also submit three years of tax returns. Information regarding the supplier’s total gross revenues will be included in these documents.

**Q. What steps have CMS taken to ensure participation by small suppliers?**

A. To aid small suppliers in the bidding process, CMS will allow small suppliers to form networks; not require suppliers to bid for every product category; establish a 30% target for small supplier participation; and streamline the financial disclosure for small suppliers. 42 CFR §414.418; 42 CFR §414.414(g)(1).

**Q. How do supplier networks work?**

A. In order to form a network, small suppliers must:

- establish a legal entity for the purpose of competitive bidding;
- all suppliers in the network must be independently eligible to bid;
- networks will be limited to 20 small suppliers;
- each member of the network must be accredited and meet DME quality standards;
- the network must not comprise more than 20% of the Medicare market within a CBA;
- suppliers may join more than one network, but a small supplier cannot join more than one network that submits a bid to furnish items in the same product category in the same CBA; and
- individual suppliers within the network will submit claims and be paid directly by the DME MACs. 42 CFR §414.418.

**Monitoring Suppliers and Beneficiary Outreach**

**Q. Aside from meeting the terms of the contract, what else is expected from contract suppliers?**

A. In addition to be willing to serve all beneficiaries in the CBA, contracted suppliers must also submit quarterly reports detailing the number of items supplied including; HCPC codes; manufacturer, make and model number.

**Q. What protections will be implemented to safeguard beneficiaries who live in CBAs?**

A. CMS will be establishing an ombudsman program to identify, investigate and resolve complaints made by beneficiaries. In addition, the CBIC plans to monitor beneficiary satisfaction through customer surveys. CMS expects to name two ombudsmen to each DME MAC. The CBIC will be responsible for oversight of the ombudsman program and beneficiary satisfaction.

**CMS Estimates on Supplier Burdens and Cost of Implementation**

**Q. What are CMS' assumptions regarding costs to suppliers for participating in the NCB program?**

A. CMS estimates that it will take suppliers 68 hours to prepare a bid at the cost of \$2,300 per bid. CMS estimates that in 2007 the CBIC will review close to 16,000 RFBs and that 81% of eligible suppliers will submit a bid. Further, CMS predicts that 60% of suppliers who bid in the initial NCB round will be awarded a contract for at least one product category.

**Q. What are CMS' costs to implement the NCB?**

A. In calendar year 2007, CMS expects to spend \$1 million in contractor start up costs and system changes for the initial NCB round of bidding. CMS estimates that, in future years, cost to maintain competitive bidding will be considerably less (except every three years when the bidding is open). In addition, CMS estimates that it will take the CBIC 9.4 hours per bid to evaluate each bid and supplier and anticipates that there will be close to 16,000 bids submitted in the initial round.

**Q. How much does CMS think NCB will save the Medicare Program?**

A. CMS expects on average a 12.9% savings in the product categories. CMS estimates that the “total allowed charges lost” by losing suppliers will be \$275 million in 2008 and close to \$2 billion by 2011.