

The Centers for Medicare and Medicaid Services (CMS) recently released a proposed rule that phases in a competitive bidding program for Durable Medical Equipment and Prosthetic and Orthotic Supplies (DMEPOS). The proposed rule can be found at: www.cms.hhs.gov/CompetitiveAcqforDMEPOS/Downloads/cms1270p_dme.pdf.

In an effort to garner a greater understanding of the proposed rule, the Power Mobility Coalition (PMC) has put together the following “Frequently Asked Questions” to help decipher this complex new reimbursement environment:

General Questions:

Q. Who is impacted by competitive bidding (CB)?

A. Any supplier that wishes to provide DME to beneficiaries in competitive bidding areas must subject themselves to the bidding process in order to participate in the Medicare program.

Q. What is the timeline for competitive bidding implementation?

A. Congress is requiring that the Centers for Medicare and Medicaid Services (CMS) begin phase-in of CB beginning in 2007 for 10 of the largest Metropolitan Statistical Areas (MSAs); in 80 of the largest MSAs in 2009; and all other areas after 2010.

CMS anticipates that the first round of bidding will occur in 2006 with prices taking effect in October, 2007, and the second round of bidding will occur in 2006 with prices taking effect January, 2009. Bidding contracts will be awarded in three year terms.

CMS hopes to announce the competitive bidding areas as well as what products and items will be subjected to competitive bidding with release of the final rule.

Q. Can I submit comments on the proposed rule? If so, how do I?

A. All PMD stakeholders are encouraged to submit comments to CMS on the proposed rule. Stakeholders have until June 30, 2006 to submit comments on CMS’ Proposed Regulation, CMS-1270-P “Competitive Acquisition for Durable Medical Equipment, Prosthetics, Orthotics, and Supplies and Other Issues,” published on May 1, 2006. Comments on the proposed information collection contained in CMS-10169 “Request for Bids for DMEPOS Competitive Bidding Program” posted on May 5, 2006 are due on July 5, 2006.

Comments on the proposed rule can be submitted via the internet at: <http://www.cms.hhs.gov/eRulemaking>.

Quality Standards

Q. When will the new quality standards be implemented?

A. CMS is expected to release supplier standards soon through Medicare program instructions. Latest indication from CMS is that the program instructions will be available via the CMS website (www.cms.hhs.gov) by the end of June.

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

A. 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.

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

A. The proposed rule states that suppliers who have already been accredited would be “grand-fathered” assuming they were originally certified by an accreditation body that is nationally recognized by CMS. There are no guarantees, however, that certain well known accreditation bodies (i.e. JACHO) will be “nationally recognized” for the purpose of accrediting Medicare DME suppliers.

Q. What can suppliers expect concerning the quality standards?

A. The quality standards will focus on a supplier’s accountability, business integrity, quality of product, and performance management. In addition, suppliers will be subject to “product specific” standards. Draft quality standards have already been published and can be found at: http://www.cms.hhs.gov/CompetitiveAcqforDMEPOS/downloads/dmepos_qualitystandards.pdf

Q. Can I bid if I am not accredited?

A. CMS will accept bids from suppliers who are not yet accredited, but winning suppliers must be accredited by the time the contract is awarded or the contract will be terminated.

Reimbursement under Competitive Bidding

Q. Who will administer and evaluate the bids?

A. CMS will contract with Competitive Bidding Implementation Contractors (CBICs) to administer the Medicare CB program. CBICs 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. Currently, CMS is soliciting contractors for this contract.

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

A. CBICs will issue single payment amounts for each item in the competitive bidding area based on the bids submitted and accepted for that item. The Medicare payment will equal 80% of the single applicable payment amount (with 20% accounting for the beneficiary’s copay). Payment rates determined through CB will be adjusted annually to account for inflation.

Q. What if a beneficiary lives in a competitive bidding area part of the year and in a non-competitive bidding area the rest of the year? Who supplies DME? How is reimbursement determined?

A. The general rule is that only a ‘contract supplier’ may supply competitively bid items within a competitive bidding area. However, CMS does propose an exception for beneficiaries who normally reside in a competitive bidding area, but travel or spend part of the year outside of the competitive bidding area (i.e. “snowbirds”).

When traveling, a beneficiary will abide by the Medicare structure in that area. If travel is to an area not included as a competitive bidding area, then any Medicare supplier may sell such items. If travel is to a different competitive bidding area, then the beneficiary must purchase items from the supplier that has been awarded a contract for that area.

In a non-competitive bidding area, reimbursement will be determined by the fee schedule in the beneficiary’s home address.

Q. What about beneficiaries who are currently under contract? Am I obligated to service a PMD if I am not a contracted supplier?

A. CMS will allow the continuation of pre-existing rental agreement and supply arrangements made before implementation of CB. Both supplier and beneficiary, however, must agree to the grand-fathering and the beneficiaries may choose to drop the non-contracted supplier at anytime.

A supplier who agrees to continue servicing existing clients will be paid the single payment amount for the DME item provided.

Q. If I offer the same price as the contracted supplier, can I supply DME in a competitive bidding area?

A. No. According to CMS, the statute requires all contracted suppliers to go through the bidding process. Therefore, all non-contracted suppliers would be prohibited from serving beneficiaries in a competitive bidding area even if they agreed to honor the winning bid price.

Q. How will competitive bidding pricing impact the fee schedule in non-competitive bidding areas (like rural areas)?

A. According to CMS, the legislation allows CMS to adjust payment rates for items

included in CB areas outside of CB areas beginning in 2009. CMS plans to use this authority and develop a more detailed methodology on how these adjustments would be made after gaining experience from the initial CB bidding rounds.

Q. I understand suppliers can offer a “rebate” under certain circumstances; can you tell me about this “rebate” program?

A. Under the proposed rule, CMS will allow contracted suppliers who bid below the single payment amount to offer the difference as a rebate to beneficiaries. Participation in the rebate program will be voluntary, but suppliers must offer the rebate to all beneficiaries. To ensure that no anti-kickback laws are violated, suppliers will be prohibited from directly or indirectly advertising the rebate. CMS, however, will provide information to beneficiaries on those suppliers who are offering a rebate.

Competitive Bidding Areas and Products

Q. How will the first MSAs be chosen?

A. 10 of the largest MSAs will be chosen in 2007. The methodology for determining which 10 MSAs will have implementation in 2007 contains the following steps:

- 1) Identify the top 50 MSAs by total population in 2005
- 2) Eliminate the 25 MSAs (of these 50) that have the lowest total DME allowed charges
- 3) “Score” each MSA by combining its rankings for the following “stats”
 - a) Charges/beneficiary → will be based on beneficiaries that received some DMEPOS items in 2004
 - b) Supplier/beneficiary ratio → likely to be an indicator of competitiveness
- 4) Exclude the 3 largest MSAs by population & any MSA that includes an area serviced by more than one DMERC
 - a) The three largest MSAs (New York, Los Angeles, and Chicago) are so large that the logistics of starting up a new program is unmanageable
 - b) Having two DMERCs service the same competitive bidding area would further complicate the implementation process
- 5) Amongst the remaining MSAs, the competitive bidding areas will be chosen based on the score determined in Step 3 →
 - a) Select the highest ranking MSA in each of the DMERC regions; this allows for all DMERCs to gain experience leading up the later full-scale implementation

- b) Select the next 6 highest ranked MSAs, but do not include more than 2 MSAs in any one state
- i) Having MSAs in as many states and regions of the country as possible will allow for the most experience to be gained before the program is fully implemented

These criteria serve to allow for the easiest implementation of a new pricing program and to achieve the greatest possible cost savings and competition.

Q. Does CMS have the authority to extend the MSA to adjoining areas?

A. Yes. Under the proposed rule, CMS can include additional areas outside the MSA if:

- the area adjoins an MSA subject to CB in 2007 or 2009;
- the area is not part of a MSA in which CB will be operating in 2007 or 2009;
- the area is competitive; and
- the area is part of the normal service area or market for suppliers who also serve the MSA market in which CB will be operating in 2007 or 2009.

Q. What about mail order operations?

A. CMS is proposing to establish a national or regional mail order program after 2009. Prior to 2010, mail order suppliers will be required to bid in order to serve beneficiaries in competitive bidding areas.

Q. What DME items will be subjected to competitive bidding?

A. It is almost certain that PMDs will subject to competitive bidding in the initial phase. Virtually all PMDs will be covered items given that CMS has the authority to phase in first the highest cost and volume items that are likely to result in the greatest savings.

Q. What is a “product category?”

A. Item/product categories will be defined in the Request for Bid (RFB) issued in a particular CB area. CMS proposes to define the term “product category” as a group of similar items used in the treatment of a related medical condition (for example, hospital beds and accessories).

Q. With PMDs subject to new HCPCs codes, how will historic pricing data be collected for these new codes?

A. In establishing payment rules related to new codes (as is happening with power mobility devices), CMS will employ a modified “gap-filling” methodology. This gap-filling methodology will be modified by:

- making effort to utilize existing fee schedule amounts, if applicable, in establishing payment amounts for new HCPCS codes, including pricing from comparable items;
- discontinuing the practice of deflating supplier prices back to the time of the fee schedule base period;
- using functional technology assessment, in part or in whole, as another pricing method.

If new codes are added in the middle of a contract period, any enrolled supplier may provide the item.

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 project capacity is fulfilled. The legislation requires, however, that multiple suppliers be chosen per product category.

The “pivotal bid” will determine how many suppliers receive contracts for a particular product. Starting with the lowest composite price, sum 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 RFB 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.

Bidding Rules

Q. What are the supplier bidding rules?

A. Under the proposed rule, the following are the bidding rules applicable to all suppliers:

- 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 oxygen which is paid for on a monthly basis);
- bids must include all costs related to furnishing of the item, including all services directly related to furnishing the item;
- bidders must agree to provide DME items and services to all beneficiaries residing in the competitive bidding area (with the exception of SNFs serving as DME suppliers, physicians serving as DME suppliers, and contracted supplier networks);
- **bids cannot be for more than the fee schedule amount;** and
- bidding will be done on a “Request for Bid” (RFB) form developed by CMS.

Q. What information will suppliers have to provide on the Request for Bid (RFB)?

A. On the RFB, 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 with the RFB including:

- supplier financial statements (reviewed statements from small suppliers; audited statement from large suppliers);
- financial references;
- credit report and score;
- business expansion plans (if applicable);
- subcontractor information;
- resumes of key personnel;
- signed legal contracts with network suppliers (if small network supplier);
- settlement agreements or corporate integrity agreement (if applicable)

CMS is considering establishing an electronic bid submission process.

Q. How long will contracts be awarded to winning bidders? What are any additional terms of every winning contract?

A. Contract length will vary by product category, and will be announced in the RFB. However, the proposed rule contemplates a length of three years in between RFBs and suppliers will be required to serve the full length of the contract. In addition, contacted suppliers will be required to repair and replace items. 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.

Q. Are all suppliers eligible to bid?

A. In order to submit an RFB, a supplier must meet all current Medicare eligibility rules; be a supplier in good standing with no current sanctions; disclose any previous 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.

Q. How will bids be evaluated?

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

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, CMS 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.

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 2nd-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 2 suppliers. An example is provided in the preamble to the rule:

Table 7 Determine the Pivotal Bid

Point where beneficiary demand is met by supplier capacity – For this example, beneficiary expected demand is 1000 units - Supplier 10’s bid is the pivotal bid

Supplier Number	Eligible for Selection	Composite Bid	Supplier Capacity	Cumulative Capacity
2	Yes	\$100	100	100
3	Yes	\$115	300	400
1	Yes	\$120	400	800
10	Yes	\$135	300	1100
4	Yes	\$140	500	1600

In this example, Suppliers #10 has the pivotal bid. All suppliers with equivalent or lower bids will be awarded contracts. CMS specifies that this system will lead to some bidding suppliers not being awarded a contract despite bidding only a slightly higher amount than the pivotal bid.

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

A. No, suppliers have no right to appeal the contract award. CMS is considering, however, to allow losing bidders to question the CBIC concerning their bid application so that they may be better prepared during the next bidding round.

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

A. In addition to serving beneficiaries, contracted suppliers must also submit an initial report, as well as quarterly reports detailing the number of items supplied including; HCPC codes; manufacturer; make; model number. The CBIC also plans to monitor beneficiary satisfaction through customer surveys.

Impact on Small Suppliers

Q. Does CMS make any concessions for small DME suppliers? If so, what does CMS consider a small supplier?

A. The legislation requires CMS to take “appropriate steps” to ensure that small suppliers have an opportunity to serve in competitive bidding areas. CMS considers suppliers with less than \$6 million in annual receipts as “small” suppliers.

CMS held a series of “focus groups” with small DME companies who identified the following concerns with competitive bidding for small suppliers:

- that suppliers have to serve the entire competitive bidding area;
- small suppliers are at a distinct disadvantage of supplying technical or highly specialized items in a particular product category;
- mail order business often lack store fronts; and
- small suppliers lack financial management systems, especially those suppliers who use cash base accounting methods.

To help ensure small supplier participation CMS stated that there will be multiple winners in each competitive bidding area; that there will be separate bidding competitions for each product category; and that small suppliers can form supplier networks to help serve entire competitive bidding areas.

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