

General Overview of the Final Rule for Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies

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BACKGROUND

- This final regulation establishes requirements for a new competitive bidding program for certain durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) as required by section 302 of the Medicare Modernization Act of 2003 (MMA). This program changes the way that Medicare pays for these items under Part B of the Medicare program by using bids submitted by DMEPOS suppliers to establish payment amounts.
- The MMA requires the competitive bidding program to be phased in beginning in 2007. Highlights of the regulation are outlined below.

SELECTION OF BID ITEMS

- The statute authorizes the Secretary to phase-in items for competitive bidding beginning with **high cost and high volume** items or those with the **largest savings potential**. The rule identifies the following factors that will be considered in selecting items to be phased in for competitive bidding:
 - Total Medicare expenditures (allowed charges) for the item;
 - Growth in Medicare expenditures;
 - Number of suppliers of the item;
 - Savings potential; and
 - Findings of reports and studies, such as by the Office of Inspector General (OIG) or the Government Accountability Office (GAO).
- Competitively bid items that are related and are used to treat a similar medical condition will be grouped into product categories, such as hospital beds and accessories. Suppliers are not required to submit bids for all product categories. For those product categories for which they choose to bid, they must bid on every item in the product category. Contract suppliers will be required to furnish all items within a product category so that beneficiaries will be able to receive related items in the product category from one supplier to minimize disruption of services.
- The product categories and bid items may vary by CBAs. For 2007, using 2005 data and the item selection criteria in the regulation, we have selected the following items for competitive bidding:
 - Oxygen Supplies and Equipment
 - Standard Power Wheelchairs, Scooters, and Related Accessories
 - Complex Rehabilitative Power Wheelchairs and Related Accessories
 - Mail-Order Diabetic Supplies
 - Enteral Nutrients, Equipment, and Supplies
 - Continuous Positive Airway Pressure (CPAP) Devices, Respiratory Assist Devices (RADs), and Related Accessories

- Hospital Beds and Related Accessories
- Negative Pressure Wound Therapy (NPWT) Pumps and Related Accessories
- Walkers and Related Accessories
- Support Surfaces (Group 2 and 3 mattresses and overlays)

Although the program will initially involve ten product categories, competitive bidding for support surfaces will only be conducted in the San Juan, Puerto Rico and Miami, Florida areas for the 2007 competitive bidding cycle.

SELECTION OF COMPETITIVE BIDDING AREAS

- The statute requires that competition under the program begin in 10 of the largest Metropolitan Statistical Areas (MSAs) in 2007, in 80 of the largest MSAs in 2009, and in other areas after 2009. The final rule requires a formula-driven methodology for selecting MSAs. From among the MSAs with the largest total populations, we identified the MSAs with the highest Medicare allowed charges for DMEPOS items. We scored these MSAs using criteria that equally weigh the allowed charges per beneficiary and the number of suppliers per beneficiary for an area.
- In selecting the MSAs for 2007, we excluded the largest MSA areas based on population (New York City, NY; Los Angeles, CA; Chicago, IL). We excluded these three MSAs to allow us to gain more experience with competitive bidding programs before we include them as CBAs. We have also excluded MSA areas that span more than one of the Durable Medical Equipment Medicare Administrative Contractors (DME MACs). For 2009, all of the largest MSAs will be evaluated in selecting an additional 70 MSAs. After 2009, we will designate additional CBAs. We will consider including regional areas or the entire United States as CBAs for items for which there is a significant national market through mail order.
- The boundaries of a CBA do not have to correspond exactly with the boundaries of an MSA. In selecting CBAs, the statute allows us to exempt rural areas and areas with low population density within urban areas that are not competitive
- Using 2005 data, the following CBAs have been selected for 2007:
 - 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, PR

QUALITY AND ACCREDITATION STANDARDS

- The MMA required the establishment of quality standards for all DMEPOS suppliers. These standards will be particularly important in ensuring that supplier quality is maintained during competitive bidding. The quality standards were posted on the internet for a 60-day public comment period that ended November 28, 2005. The Centers for Medicare & Medicaid Services (CMS) posted the new quality standards on August 14, 2006.
- A final rule published August 18, 2006, established the process for approving independent accreditation organizations to apply the MMA-required DMEPOS quality standards established by CMS. On November 22, 2006, CMS announced the deemed accreditation organizations. The names of the deemed accreditation organizations can be accessed through the CMS DMEPOS Competitive Bidding Program website.
- In order to be eligible to bid, a supplier is required to have an active supplier number issued by the National Supplier Clearinghouse and meet quality standards and accreditation requirements. For the first round of competitive bidding, suppliers must be accredited or be pending accreditation to submit a bid. CMS cannot accept a bid from any supplier that is not accredited or that has not applied for accreditation. We expect that all suppliers will have obtained their accreditation before they are awarded a contract under the Medicare DMEPOS Competitive Bidding Program.

SELECTION OF SUPPLIERS

- The final rule establishes a methodology for selecting contract suppliers that requires the selection of a sufficient number of suppliers to meet the expected demand for competitively bid items within a CBA.
- Based on bids received, we will establish a composite bid for each supplier by product category (a composite bid is the sum of a supplier's weighted bids for all items within a product category) and rank composite bids in order from the highest to the lowest. The lowest ranked composite bid that includes a sufficient number of qualified suppliers to meet beneficiary demand for the items in a product category will become the pivotal bid. Qualified suppliers that meet all of our requirements and whose composite bids are less than or equal to the pivotal bid will be selected as contract suppliers.
- For purposes of establishing a composite bid for a supplier, we will use an item weight, which is a number assigned to an item based on its beneficiary utilization rate when compared to other items in the same product category. The item weight is multiplied by the bid price that the supplier submits for that item. This becomes the supplier's weighted bid for that item. A composite bid is the sum of a supplier's weighted bids for all items within a product category. The composite bid is used for purposes of an overall comparison of the bid prices that suppliers have submitted for the items within a particular product category.

- Contracts will be awarded to multiple suppliers for each product category in each area and will be re-competed at least once every three years. Contract suppliers are required to furnish all of the items in a product category to beneficiaries throughout the entire geographic area of a CBA for which they have been awarded a contract. However, an exception to the requirement has been made for skilled nursing facilities and nursing facilities that submit a bid in the competitive range and are selected as contract suppliers. They will be allowed to provide competitive bid items just to their respective patients.

DETERMINATION OF PAYMENT AMOUNTS

- The law requires that the Secretary determine a single payment amount for each item in each CBA. No contract can be awarded if the single payment amount for an item is expected to be higher than the amount that would have been paid for the same item under the fee schedule methodology.
- The regulation requires that the single payment amount be determined by using the median of the winning suppliers' bids for each item in each product category.

GRANDFATHERING PROVISIONS; SPECIAL RULES FOR PHYSICIANS/PRACTITIONERS

- The final rule also includes a grandfathering provision for certain rental items and oxygen that allows beneficiaries to choose to continue receiving an item from a supplier that furnished the item to them just prior to implementation of competitive bidding if that supplier agrees to be a grandfathered supplier.
- Under the final rule, non-contract suppliers are excluded from furnishing competitively bid items to beneficiaries unless a competitive bidding grandfathering provision applies or the supplier qualifies for the special physician/practitioner exception. This exception allows physicians, physician assistants, nurse practitioners, clinical nurse specialists, and physical therapists and occupational therapists in private practice to receive payment for certain competitively bid items furnished to their own patients as part of the professional service even though they have not submitted a bid and have not been selected as a contract supplier.
- A non-contract supplier's billing privileges will be limited to non-competitively bid items unless the grandfathering provision or one of the other exceptions mentioned above applies.

CONSIDERATIONS FOR SMALL SUPPLIERS

- CMS, in cooperation with the Small Business Administration, has established for competitive bidding purposes a new definition of a small supplier. Under this definition, a small supplier is a supplier that generates gross revenues of \$3.5 million or less in annual receipts, including Medicare and non-Medicare revenue.

- It may be difficult for small suppliers to furnish all of the product categories for which we conduct competitive bidding; therefore, we do not require suppliers to submit bids for all product categories. However, they will be required to submit bids for all items within a product category for which they are bidding
- Small suppliers that are not able to furnish independently all of the items in a product category throughout an entire geographic area of a CBA will be allowed to form networks with other small suppliers to share the responsibility of servicing an entire CBA. A network must be comprised of at least 2 but not more than 20 small suppliers that collectively submit a single bid to furnish the items in a product category under a competitive bidding program. Each member of the network must be independently eligible to bid and meet any applicable accreditation and quality standards. A small supplier may not be a member of more than one network if those networks submit bids for the same product category in the same CBA. To avoid anti-competitive bidding practices, at the time a network submits a bid, the network's total market share for a product category must not exceed 20 percent of the Medicare demand for that product category within the CBA. After a contract is awarded, the network is not limited in the volume of business that it actually provides in a CBA. Also, each network contract supplier will submit its own claims and receive payment directly from Medicare for the items that it furnishes.
- The regulation requires a target number for participation in competitive bidding programs by small suppliers. There will be a target number for small supplier participation for each product category. The target number will be determined by multiplying 30 percent by the number of qualified suppliers whose composite bids are at or lower than the pivotal bid. The number resulting from this multiplication will be the target number for small supplier participation for that particular product category. If this target number is not achieved through the competitive bidding process, CMS will offer contracts to small suppliers whose composite bids are above the pivotal bid that agree to accept the single payment amount. We will begin with those small suppliers whose composite bids are closest to the pivotal bid. We will offer contracts to these suppliers until the number of small suppliers that agree to accept contracts is sufficient to meet our 30 percent target number or there are no more eligible small suppliers. If the 30 percent target is not met because an insufficient number of small suppliers are willing to accept the single payment amount, we will proceed with the competitive bidding program with the number of additional small suppliers that accept a contract.

BENEFICIARY PROTECTIONS

- Competitive bidding will reduce the amount Medicare pays for DMEPOS and bring the payment amounts more in line with that of a competitive market. Also, contract suppliers must submit claims for competitive bidding items on an assignment basis. These factors will help limit the burden on beneficiaries by reducing their out-of-pocket expenses.

- Contract suppliers will meet the newly established DMEPOS quality standards and will follow a business model that is beneficial to beneficiaries (such as meeting financial standards).
- A sufficient number of contract suppliers will be selected to meet beneficiary demand.
- The performance of contract suppliers will be monitored through beneficiary satisfaction surveys that measure their level of satisfaction with the services they receive under the competitive bidding program.
- Beneficiaries are protected from financial liability when a non-contract supplier furnishes them with a competitively bid item.
- When a physician specifically prescribes a particular brand name product or mode of delivery to avoid an adverse medical outcome, contract suppliers are required either to furnish that item or mode of delivery, to assist the beneficiary in finding another contract supplier in the CBA that can provide that item or service, or to consult with the physician to find a suitable alternative product or mode of delivery for the beneficiary.
- Beneficiaries will be able to obtain repairs of equipment they own from either a contract or non-contract supplier. Replacement parts needed to repair beneficiary owned equipment may also be obtained by a beneficiary from either a contract or non-contract supplier, even if the parts are competitively bid items.
- Contract suppliers are required to make available the same range of products to beneficiaries that they make available to non-Medicare customers. For transparency, we will post on our web site a list of brands furnished by each contract supplier.
- Under the grandfathering rules, a beneficiary will have the opportunity to make arrangements with a non-contract supplier that will allow the beneficiary to continue to receive a rented item from the same supplier (grandfathered supplier) that had been furnishing the item to the beneficiary before the implementation of a competitive bidding program, provided the supplier is willing. If a supplier agrees to furnish "grandfathered" items to one beneficiary, it must furnish those items to all.
- Beneficiaries will be allowed to use an Advance Beneficiary Notice (ABN) to make informed consumer choices regarding whether to agree to be financially liable for special deluxe features that Medicare does not consider medically necessary.

BUDGET SAVINGS

- The new competitive bidding program will offer beneficiaries in the designated CBAs access to quality DMEPOS products and services, and will lower out-of-pocket costs. When fully implemented by 2010, the program is projected to save Medicare about \$1 billion annually.

ADDITIONAL INFORMATION

Additional information about the Medicare DMEPOS Competitive Bidding Program, including the CBAs and items for the first round of competitive bidding is available via the links on the left.

The Competitive Bidding Implementation Contractor (CBIC) performs many important functions, including supplier education, bid evaluation, ombudsman program, and more. The CBIC toll-free number is 1-877-577-5331 and a link to the CBIC web site can be found below.

People with Medicare may call 1-800-MEDICARE (1-800-633-4227) or go to <http://www.medicare.gov>