

### **O&P Profession Fares Well Under Competitive Bidding Final Rule**

Medicare's durable medical equipment, prosthetics, orthotics and supplies ("DMEPOS") competitive bidding program will *not* include off-the-shelf orthotics until at least 2009. Prosthetics and custom-made orthotics are already not included in competitive bidding by statute, so virtually no orthotics and prosthetics will be included in the initial round of competitive bidding. CMS released the final rule on DMEPOS competitive bidding on April 2, 2007, and it is effective on June 9, 2007.

The competitive bidding program, which was mandated by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA"), will replace Medicare's payment structure for certain DMEPOS. Instead of the current fee schedule, suppliers that wish to furnish items included in the competitive bidding program in a competitive bidding area ("CBA") will submit bids to CMS's contractor, Palmetto, GBA, to furnish these items. CMS will award contracts to certain bidders, and will use the winning bids to establish a single Medicare payment amount for competitively bid items in a given CBA.

Contrary to what was proposed in the draft regulation, CMS will *not* make an annual inflation update to these single payment amounts. Instead, the single payment amounts will remain the same for the length of the three-year contract. The first round of bidding will occur in 2007, and the new reimbursement levels will take effect in April, 2008. The highlights of the final rule are as follows:

#### **1. Metropolitan Statistical Areas ("MSAs")**

The competitive bidding program will initially take place in the following 10 Metropolitan Statistical Areas ("MSAs"), according to the CMS website:

- 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, FL
- Pittsburgh, PA
- Riverside-San Bernardino-Ontario, CA
- San Juan-Caguas-Guaynabo, PR

In 2009, the program will operate in 70 additional MSAs, and will expand to other MSAs after 2009.

## **2. Affected Product Categories:**

Initially, the competitive bidding program will include the following 10 DMEPOS product categories:

- 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 Supplies and Accessories
- Hospital Beds and Related Accessories
- Negative Pressure Wound Therapy (NPWT) Pumps and Related Supplies and Accessories
- Walkers and Related Accessories
- (Miami and San Juan Only) – Support Surfaces (group 2 and 3 mattresses and overlays)

CMS will expand the program to additional items after 2009. CMS will designate items included in the competitive bidding program through program instructions or other means, without the necessity to issue new formal regulations. However, the final rule explicitly states that “diabetic shoes and inserts, prosthetics for the foot, splints and casts, prosthetic devices that aid vision, and surgical dressings are not among the items and services described in section 1847(a)(2) of the [Social Security] Act and, therefore, cannot be included in the competitive bidding programs.” The reference to “prosthetics for the foot” is confusing because under the statute, all prosthetics are exempt from competitive bidding.

## **3. Supplier Participation**

To participate in the competitive bidding program, suppliers must meet quality standards and be accredited or pending accreditation. The supplier must also meet a long list of other requirements. The supplier must:

- (1) be in good standing with the Medicare program;
- (2) not be under sanctions by Medicare, a government agency, or an accreditation or licensing organization;
- (3) have an active National Supplier Clearinghouse (“NSC”) number;
- (4) have all state and local licenses required to provide services;
- (5) submit a bona-fide bid before becoming a winning supplier;
- (6) submit information to ensure that the supplier’s capacity meets beneficiary demand; and

(7) agree to service the entire CBA, even if the beneficiary cannot travel to the chosen contract supplier (servicing can take place through mail-order).

In addition, suppliers must meet certain financial standards. A supplier with multiple locations in a CBA must submit a single bid for all of its locations. If the supplier wins the bid, all of its locations will be considered contract suppliers, and must service the CBA.

#### **4. Exceptions and Grandfathering**

CMS created in the final rule an important exception from competitive bidding for certain suppliers. Physicians, treating practitioners (physician assistants, nurse practitioners, and clinical nurse specialists), and occupational and physical therapists can provide certain types of competitively bid items without submitting a bid. These items must be furnished to the provider's own patient as part of their professional practice. The items physicians and treating practitioners can provide are limited to crutches, canes, walkers, folding manual wheelchairs, blood glucose monitors, and infusion pumps that are all considered DME. The rule does not include off-the-shelf orthotics in this list of excepted devices.

With respect to physical and occupational therapists in private practice, the rule does not allow them to provide this same list of DME devices unless they participate in competitive bidding, but PTs and OTs *are* exempted from competitive bidding for purposes of off-the-shelf orthotics. The rule states:

A physical therapist in private practice (as defined in §410.60(c) of this chapter) or an occupational therapist in private practice (as defined in §410.59(c) of this chapter) may furnish competitively bid **off-the-shelf orthotics** without submitting a bid and being awarded a contract under this subpart, provided that the items are furnished only to the therapist's own patients as part of the physical or occupational therapy service.

42 C.F.R. § 414.404(b)(2) (emphasis added). The rule provides an exception from the competitive bidding requirement for PTs and OTs that allows them to furnish off-the-shelf orthotics to their own patients without having to participate in bidding and without becoming a contract supplier. Therefore, if and when off-the-shelf orthotics are competitively bid, they would be exempt from competitive bidding for the patients they are professionally treating.

The rule also contains a grandfathering provision to protect beneficiaries already renting certain DME items. These beneficiaries can continue to rent the items from "grandfathered suppliers," or non-contract suppliers, instead of switching to a contract supplier. These items include oxygen and oxygen equipment, items requiring frequent and substantial servicing, inexpensive or routinely purchased items, and capped rental items.

In addition, beneficiaries who own an item included in the competitive bidding process can receive maintenance and servicing for these items from non-contract suppliers with valid Medicare billing numbers. However, if a part needed to repair the item is included under competitive bidding, Medicare will pay the amount that would have been paid under the competitive bidding process for the part. Beneficiaries must obtain replacements of an item from a contract supplier.

## **5. Appeal Rights**

The final rule establishes that there will be no administrative or judicial review of determinations made under the competitive bidding program, including the:

- Establishment of payment amounts;
- Awarding of contracts;
- Designation of CBAs;
- Phased-in implementation of the program;
- Selection of items for the program; and
- The bidding structure and number of contract suppliers selected.

## **6. “Off-the-Shelf” Orthotics Defined**

The term “off-the-shelf orthotics” is defined as “orthotics described in section 1861(s)(9) of the [Social Security] Act that require minimal self-adjustment for appropriate use and do not require expertise in trimming, bending, molding, assembling or customizing to fit a beneficiary.” 42 C.F.R. § 402.

The final rule added a definition for the term “minimal self-adjustment.” It is defined to mean “an adjustment that the beneficiary, caretaker for the beneficiary, or supplier of the device can perform and does not require the services of a certified orthotist (that is, an individual certified by either the American Board for Certification in Orthotics and Prosthetics, Inc., or the Board for Orthotist/Prosthetist Certification) or an individual who has specialized training.” 42 C.F.R. § 402.

This definition appears to be a potential double-edged sword. CMS has explicitly recognized the importance of ABC/BOC certification as a measure for more complex orthotic and prosthetic care, but this definition also potentially expands the types of orthoses that may be considered “off-the-shelf.”

Payment for off-the-shelf orthotics, if and when it is included in competitive bidding, will be based on the bids submitted and accepted.

## **7. Quality Standards**

The final rule does not finalize in regulation the DMEPOS quality standards, and CMS reserves the right to change these standards by program instruction or otherwise. In

addition, the final rule notes that the quality standards apply to all suppliers, not just suppliers participating in the competitive bidding program.

## **8. Effect on Suppliers**

CMS expects DMEPOS suppliers to be significantly affected by the final rule, in one of three ways:

- Suppliers that wish to participate in competitive bidding will have to incur the cost of submitting a bid;
- Suppliers that furnished items in the past who do not receive contracts to participate in competitive bidding in the future will now see a decrease in revenue;
- Contract suppliers will see a decrease in revenue per item due to lower allowed charges from lower bid prices. However, with fewer contracted suppliers, the volume of items a contract supplier provides will presumably increase.

## **9. Rebates**

Rebates will not be authorized under the competitive bidding program, contrary to a controversial proposal included in the draft rule.

## **10. Small Suppliers**

Small suppliers are provided some additional relief under the final rule. A “small supplier” is considered a supplier that generates gross revenue of \$3.5 million or less in annual receipts. 42 C.F.R. § 414.402. Medicare data from 2003 showed that at least 90 percent of suppliers had less than \$1 million in allowable charges, so this definition encompasses a significant amount of suppliers. CMS’s target number of small suppliers participating in the competitive bidding program is 30 percent of all suppliers participating in each product category in each CBA. If the number of suppliers does not reach the target number, CMS will give the small supplier whose bid is higher than, but close to the winning bid, the option of accepting a contract to provide items in that product category at the single payment amounts.

Small suppliers can also form networks, or several companies joined together through a legal contractual relationship, to participate in the competitive bidding process. 42 C.F.R. § 418. The networks can consist of least 2 but not more than 20 small suppliers. The following conditions apply to networks:

- The network must form a single legal entity that submits the bid. The network must submit to CMS any agreement entered into for the purposes of forming a network.
- Each member of the network must satisfy eligibility requirements to bid (i.e., meet quality standards). A small supplier that is a member of a network cannot submit an individual bid for the same product category in the same CBA as any

network in which it is a member. Similarly, a small supplier may not be a member of more than one network if those networks submit bids to furnish the same product category in the same CBA.

- The network cannot be anticompetitive.
- A network bid must include a statement from each member certifying that the network member joined the network because it is unable to independently furnish all of the items in the product category for which the network is submitting a bid to beneficiaries throughout the entire geographic area of the CBA.

### **Preliminary Conclusion**

The O&P Alliance does not support Medicare DMEPOS competitive bidding because this system takes the emphasis off of patient satisfaction and focuses on price alone. The Alliance continues to have serious concerns with the impact that DMEPOS competitive bidding will have on the quality of care and supplier choice available to Medicare beneficiaries.

However, from an O&P perspective, other than potentially expanding the definition of “off-the-shelf” orthotics to include adjustments that a supplier (who is not certified by either ABC or BOC) could make, the final competitive bidding rule represents a fairly good outcome for the O&P profession. CMS adopted two of the O&P Alliance’s primary comments offered during the public comment period on the proposed rule last June. CMS chose not to implement competitive bidding for any orthotics and prosthetics, at least in the first rounds of bidding, and it delayed publication of new rules that would redefine how reimbursement levels are set for new or revised HCPCS billing codes.

The O&P Alliance will continue to work with CMS to improve the O&P quality standards, raise the bar for the accrediting agencies purporting to be qualified to oversee suppliers of O&P services, and seek regulatory refinements to ensure that the term “off-the-shelf orthotics” are appropriately defined.