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**PMC'S ANALYSIS OF CMS' PROPOSED RULE FOR ESTABLISHING A COMPETITIVE
BIDDING PROGRAM FOR MEDICARE DME AND SUPPLIES**

The Centers for Medicare and Medicaid Services (CMS) has recently released the proposed rule for establishing a national competitive bidding (CB) system for Durable Medical Equipment (DME) items and services. CMS hopes that establishment of CB will generate Medicare cost savings as well as reduce out-of-pocket costs to beneficiaries by lowering their overall co-payment amounts. In addition to CB, CMS has been mandated to establish new quality standards for DME suppliers. While all DME suppliers will be subject to these new quality standards, those suppliers who wish to participate in the first round of bidding will be subject to these new standards before they would be allowed to bid. These new quality standards are expected to be finalized and released this Spring. The following is a summary of some of the CB provisions in the proposed rule:

Quality Standards for DME Suppliers

DME suppliers must comply with the new quality standards to furnish any DME item under Medicare Part B. CMS will establish these standards through program instruction and post them on the CMS website when finalized. All suppliers must meet the quality standards if they are to be rewarded a contract under the CB program. As seen in the draft released last year, the quality standards will focus on a supplier's accountability, business integrity, quality of product, and performance management. In addition, there will be "product specific" standards.

Suppliers can choose between a State agencies or a CMS approved accreditation organization to survey them. CMS has yet to designate national accreditation bodies, but will subject their procedures for designating and supervising these organizations to public notice and comment. Further, CMS will publish guidance in a Federal Register notice on the grandfathering in of suppliers who have already been accredited.

Medicare DME Competitive Bidding Program

Overview

Under the proposed rule, suppliers in a competitive bidding area would submit bids for product categories and CMS would determine the winning suppliers based on these bids. The rule proposes a specific methodology for determining winning bid amounts based on the total capacity needed to meet Medicare demand for DME items in the area. The Medicare payment amounts would be the median of the winning

suppliers' bids for selected items. Suppliers whose bids are lower than the Medicare payment amount set under the competitive bidding program could offer a rebate to beneficiaries.

Competition under the program would be phased in beginning in Fiscal Year (FY) 2007 in 10 of the largest metropolitan statistical areas (MSAs), in 80 of the largest MSAs in FY 2009, and in other areas after FY 2009. Areas that may be exempt from competitive acquisition of DME include rural areas and areas with low population density within urban areas that are not competitive, unless there is a significant national market through mail order. CMS proposes that, for FY 2007, the New York City, Los Angeles, and Chicago MSAs would be excluded from competitive bidding. In addition, CMS will not include MSAs that cross DMERC regions because of the potential complications from having two DMERCs process the same claim.

Implementation Contractor

CMS would designate one or more competitive bidding implementation contractors (CBICs) for the purpose of implementing the Medicare competitive bidding program. CBICs will have six primary functions, including: overall oversight and decision-making, operation design functions, bidding and evaluation, access and quality monitoring, outreach and education, and claims processing.

Single Payment Basis

CMS is proposing that payment to the contract supplier would be based on the single payment amount for the item in the competitive bidding area where the beneficiary maintains a permanent residence. If an item that is included in a competitive bidding program is furnished to a beneficiary who does not maintain a permanent residence in a competitive bidding area, the payment basis for the item would be 80 percent of the lesser of the actual charge for the item, or the applicable fee schedule amount for the item.

CMS would also establish a "grandfathering" process by which rental agreements for those covered items and supplies entered into before the start of a competitive bidding may be continued in accordance with existing rental agreements or supply arrangements. CMS is also proposing that the grandfathered supplier be paid the single payment amounts determined for those items under the competitive bidding program because beneficiaries rent these items for extended time periods as long as the items remain medically necessary.

The fee schedule payment amounts for DME items are updated by annual update factors. The term of a competitive bidding contract may not exceed three years. CMS is proposing to apply an annual inflation update to the single payment amounts established for a competitive bidding program. Beginning with the second year of a CB contract, CMS would update the single payment amounts by the percentage increase

in the CPI-U for the 12-month period ending with June of the preceding calendar year.

Competitive Bidding Areas

CB would be phased-in beginning in fiscal year (FY) 2007 in the 10 largest MSAs, in 80 of the largest MSAs in 2009, and other areas to follow. (Rural areas and areas with low population density within urban areas would be exempt). CMS does not propose that CB cross DMERC regions because of the potential complications from having two DMERCs process claims for one area.

CMS proposes to select the actual MSAs for FY 2007 using US Census Bureau population data published as of July 1, 2005, and DME-allowed charge data for items furnished in CY 2004.

Top 25 MSAs Based on Total DME Medicare-Allowed Charges for 2003 MSA Allowed Charges:

New York-Northern New Jersey-Long Island, NY-NJ-PA (New York) \$312,124,291*

Los Angeles-Long Beach-Santa Ana, CA (Los Angeles) \$253,382,483*

Miami-Fort Lauderdale-Miami Beach, FL (Miami) \$221,660,443

Chicago-Naperville-Joliet, IL-IN-WI (Chicago) \$173,922,952*

Houston-Baytown-Sugar Land, TX (Houston) \$149,060,607

Dallas-Fort Worth-Arlington, TX (Dallas) \$139,910,862

Detroit-Warren-Livonia, MI (Detroit) \$121,444,298

San Juan, PR \$108,478,208

Philadelphia-Camden-Wilmington, PA-NJ-DE-MD (Philadelphia) \$97,487,063

Atlanta-Sandy Springs-Marietta, GA (Atlanta) \$75,860,276

Tampa-St. Petersburg-Clearwater, FL (Tampa) \$71,309,635

Boston-Cambridge-Quincy, MA-NH (Boston) \$62,467,094

Washington-Arlington-Alexandria, DC-VA-MD-WV (DC) \$61,416,109

Baltimore-Towson, MD (Baltimore) \$59,714,310

Pittsburgh, PA \$56,612,095

St. Louis, MO-IL \$55,931,373

Riverside-San Bernardino-Ontario, CA (Riverside) \$52,910,209

Cleveland-Elyria-Mentor, OH (Cleveland) \$52,237,312

Orlando, FL \$51,982,164

San Francisco-Oakland-Fremont, CA (San Francisco) \$45,565,320

San Antonio, TX \$44,113,886

Cincinnati-Middletown, OH-KY-IN (Cincinnati) \$41,582,961

Kansas City, MO-KS \$41,310,326

Virginia Beach-Norfolk-Newport News, VA-NC (Virginia Beach) \$41,016,726

Charlotte-Gastonia-Concord, NC-SC (Charlotte) \$37,874,144

* - denotes areas (NY, Chicago, and LA) that have been specifically excluded from the initial CB areas.

Nationwide or Regional Mail Order CB

CMS proposes to establish a nationwide or regional competitive bidding program, effective for items furnished mail order items delivered on or after January 1, 2010. Suppliers that furnish DME items through mail order, on either a national or regional basis, would be required to submit bids to participate in any competitive bidding program implemented for the furnishing of mail order items.

Criteria for Item Selection

CMS proposes to include a “core” set of product categories in each competitive bidding area. Because CMS has not yet identified the product categories for competitive bidding, it lists items using policy groups developed by the statistical analysis DMERC (or SADMERC) for purposes of illustration. The SADMERC has defined a set of 64 DMERC policy groups. A policy group is a set of Healthcare Procedural Coding System (HCPCS) codes that describe related items that are addressed in a DMERC medical review policy. For example, the policy group, oxygen and supplies, consists of approximately 20 HCPCS codes.

Although the product categories subject to competitive bidding will not necessarily correspond to these policy groups, CMS has presented data for these policy groups and items, for the purpose of identifying the highest cost and highest volume DME items that may be subject to competitive bidding.

CMS will conduct competitive bidding for items grouped into product categories, and will consider DME-allowed charges and volume at the product category level for the purpose of selecting which items to phase in first under the competitive bidding programs. The table below provides data for the top 20 policy groups based on Medicare-allowed charges for the items within each policy group:

Rank Policy Group 2003 Percent of DME:

1. Oxygen Supplies/Equipment	\$2,433,713,269	21.3%
2. Wheelchairs/POVs	\$1,926,210,675	16.9%
3. Diabetic Supplies & Equipment	\$1,110,934,736	9.7%
4. Enteral Nutrition	\$676,122,703	5.9%
5. Hospital Beds/Accessories	\$373,973,207	3.3%
6. CPAP Devices	\$ 204,774,837	1.8%
7. Support Surfaces	\$193,659,248	1.7%
8. Infusion Pumps & Related Drugs	\$149,208,088	1.3%
9. Respiratory Assist Devices	\$133,645,918	1.2%

10. Lower Limb Orthoses	\$122,813,555	1.1%
11. Nebulizers	\$98,951,212	0.9%
12. Walkers	\$96,654,035	0.8%
13. NPWT Devices	\$88,530,828	0.8%
14. Commodes/Bed Pans/Urinals	\$51,372,352	0.5%
15. Ventilators	\$42,890,761	0.4%
16. Spinal Orthoses	\$40,731,646	0.4%
17. Upper Limb Orthoses	\$29,069,027	0.3%
18. Patient Lifts	\$26,551,310	0.2%
19. Seat Lift Mechanisms	\$15,318,552	0.1%
20. TENS Devices**	\$15,258,579	0.1%
Total for 20 Groups	\$7,830,384,538	68.6%
Total for DME	\$11,410,019,351	

Submission of Bids under the Competitive Bidding Program

In order for a supplier that furnishes competitively bid items in a competitive bidding area to receive payment for those items, the supplier must have submitted a bid to furnish those particular items and must have been awarded a contract to do so by CMS. There are limited exceptions to this requirement for beneficiaries who reside in a competitive bidding area but are out of the area and need items. There is also an exception for suppliers that are grandfathered to continue to provide and service certain items.

Providers and Physicians Who Also Supply DME

CMS is proposing that health care providers and practitioners (like home health agencies and physicians) that furnish Part B items are located in a competitively bidding area and are also DME suppliers must submit bids in order to furnish competitively bid items to Medicare beneficiaries. Providers that are not awarded contracts must use a contract supplier to furnish these items to the Medicare beneficiaries to whom they provide services. A skilled-nursing facility (SNF), however, would not be required to furnish competitively bid items to beneficiaries outside of the SNF, if it elected not to function as a commercial supplier.

Product Categories for Bidding Purposes

CMS proposes to conduct bidding for items that are grouped into product categories. Suppliers would be required to submit a separate bid for all items that are specified in a product category. The submitted bid must include all costs related to the furnishing of each item such as delivery, set-up, training, and proper maintenance for rental items. Suppliers, however, would only be required to submit bids for the product

categories that they are seeking to furnish under the program.

Bidding Requirements

Suppliers are required to have a Medicare supplier billing number to submit claims for Medicare payment. The supplier must also be accredited by a CMS-approved organization to ensure they meet applicable quality standards. Under the rule, suppliers also have an opportunity to develop a network to collectively bid to furnish items in a given product category under the program.

Suppliers will be required to submit bids for all items in the specified product category that they are seeking to furnish to Medicare beneficiaries. The submitted bid must include all costs related to furnishing each item such as delivery, set-up, training, and proper maintenance for rental items.

CMS will use a composite bid structure to compare all suppliers' bids submitted for an entire product category. By aggregating the bids, CMS can best determine which suppliers can offer the lowest expected costs to Medicare for all items in a product category. Each item would be weighted by utilization levels; this weight would be multiplied by each supplier's bid and summed across items to determine the composite bid for each product category. Composite bids would then be ranked from lowest to highest in order to select winners within a competitive range.

a. Inexpensive or Other Routinely Purchased DME Items

The current fee schedule amounts for these items are based on average reasonable charges for the purchase of new items, purchase of used items, and rental of items from July 1, 1986 through June 30, 1987. In those cases where reasonable charge data from 1986/87 is not available, the fee schedule amounts for the purchase of new items are generally based on retail purchase prices deflated to the 1986/1987 base period by the percentage change in the CPI-U, the fee schedule amounts for the purchase of used items are generally based on 75 percent of the fee schedule amounts for the purchase of new items, and the fee schedule amounts for the monthly rental of items are generally based on 10 percent of the fee schedule amounts for purchase of new items. This method of establishing fee schedule amounts in the absence of reasonable charge data has been in use since 1989.

CMS is proposing that bids be submitted only for the furnishing of new items in this category that are included in a competitive bidding program. Based on the bids submitted and accepted for these new items, CMS is proposing to also calculate a single payment amount for used items based on 75 percent of the single payment amount for new items. In addition, CMS is proposing to calculate a single payment amount for the rental of these items based on 10 percent of the single payment amount for new items.

b. DME Items Requiring Frequent and Substantial Servicing

CMS is proposing that bids be submitted for the monthly rental of items in this payment category with the exception of continuous passive motion exercise devices. CMS is proposing that bids be submitted for the daily rental of continuous passive motion exercise devices. Coverage of continuous passive motion exercise devices is limited to 21 days of use in the home following knee replacement surgery; therefore, payment can only be made on a daily basis as opposed to a monthly basis for this item.

c. Oxygen and Oxygen Equipment

CMS is proposing that single payment amounts for oxygen and oxygen equipment be calculated based on separate bids submitted and accepted for furnishing on a monthly basis of each of the oxygen and oxygen equipment categories of services.

d. Capped Rental Items

With the exception of power wheelchairs, payment for items that fall into this payment category is currently made on a rental basis only. The rental fee schedule payments for months one through three are based on 10 percent of the purchase price for the item. The rental fee schedule payments for months four through fifteen are based on 7.5 percent of the purchase price for the item. Because the Deficit Reduction Act of 2005 (DRA) change does not apply to beneficiaries using a capped rental item prior to January 1, 2006, these beneficiaries may still elect either to take ownership of the item after 13 months of continuous use or to continue renting the item beyond 13 months of continuous use. However, with regard to all other capped rental items for which the rental period begins after January 1, 2006, the DRA requires suppliers to transfer title to the item to the beneficiary after 13 months of continuous use.

CMS is proposing that separate payment for reasonable and necessary maintenance and servicing only be made for beneficiary-owned DME. Payment for maintenance and servicing of rented equipment would be included in the single payment amount for rental of the item. CMS is proposing that the lump-sum purchase option for power wheelchairs be retained under the Medicare DME competitive bidding program.

e. Supplies Used in Conjunction with DME

CMS is proposing that bids be submitted for the purchase of supplies necessary for the effective use of DME, including drugs (other than inhalation drugs). Based on the bids submitted and accepted for these items, CMS would calculate single payment amounts for the furnishing of these items on a purchase

basis.

f. Off The Shelf (OTS) Orthotics

CMS is proposing that bids be submitted for the purchase of OTS orthotics. Based on the bids submitted and accepted for these items, CMS would calculate single payment amounts for the furnishing of these items on a purchase basis.

New DME Items

In establishing payment for new DME items (i.e. HCPCS codes representing categories for items where there is no historic Medicare pricing data) 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.

Evaluation of Bids

CMS states that it “must expect to pay less for each individual item than [it] would have otherwise paid for that item under the current fee schedule. Single payment amounts cannot be higher than [its] current fee schedule amounts for individual items within a product category.”

Medicare Cost Savings

CMS expects “large savings” from the CB program, noting that reimbursement items under the CB demonstration projects saved an average of 20% when compared to the Medicare fee schedule. CMS estimates that CB will save the Medicare program \$110 million in FY '08; \$620 million in FY '09; \$990 million in FY '10; and \$1.23 billion in FY '11.

While CMS acknowledges that it incur \$1 million in initial start up costs to implement CB, no figures or estimates were given for CMS’ costs to maintain and expand the program.

Effect on Beneficiary

CMS notes that while Medicare DME beneficiaries may experience some decrease in choice of supplier, they should have no access issues. CMS also anticipates an improvement in quality since they “will more closely scrutinize the suppliers before, during and after implementation of the [CB] program.”

CMS does anticipate that some beneficiaries may have to switch suppliers, but they state there should be minimal disruptions given the existence of grandfather policies for capped rental items.

Effect on Suppliers

CMS acknowledges that CB will have a profound impact on all DME suppliers. CMS assumes suppliers will be impacted since they will have to incur the cost of submitting bids; suppliers who are not contracted will see a loss of revenue since they will no longer be serving Medicare beneficiaries; and contracted suppliers will see a decrease in expected revenue per DME item as a result of the bidding process. CMS estimates that it will cost suppliers \$2, 187.50 to submit a bid.

CMS estimates that there are 27,540 suppliers in the initial CB areas and that 90% will submit bids. Of the 16,500 plus that will submit bids, CMS predicts that 8,300 suppliers would be awarded contracts.

Effect on Small Suppliers

The Small Business Administration characterizes suppliers with less than \$6 million in revenues as “small” suppliers. CMS mentions several options for small suppliers to minimize the impact of a CB system. Some of these options include: networking (forming with other suppliers to make bids) and recommending that small suppliers not bid on every product category. CMS noted that they were prohibited by statute in allowing suppliers to participate in the Medicare program if they match the bid price stating that Congress specifically required all contracted suppliers to go through the bidding process.