

# Proposed Rule to Implement Medicare Competitive Bidding Program & Other Payment Reforms for Durable Medical Equipment, Prosthetics, Orthotics, & Supplies

## **Introduction**

The Centers for Medicare & Medicaid Services ("CMS") has published its long-awaited proposed rule to implement the Medicare durable medical equipment ("DME"), prosthetics, orthotics, and supplies ("DMEPOS") competitive bidding program ("Proposed Rule").<sup>1</sup> CMS will accept comments on the Proposed Rule until June 30, 2006.

Under the proposed competitive bidding program, which was mandated by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA"), suppliers would be required to go through a bidding process and meet certain program standards in order to supply selected items to Medicare beneficiaries within the competitive bidding area. Suppliers would bid on all specified codes within a designated product category (e.g., oxygen, power wheelchairs), and their bids for each item would be aggregated into a composite bid for the category. CMS would select the lowest composite bids for each product category with enough capacity to meet expected demand in the area. Winning suppliers would be reimbursed a single payment amount for each item equal to the median of the winning suppliers' bids for selected items in the area, rather than the Medicare fee schedule amounts.

Although the Proposed Rule outlines the broad framework of the competitive bidding program, key elements of the program have not yet been announced. For instance, CMS intends to phase in geographically, as required by the MMA, beginning in October 2007 in 10 of the largest metropolitan statistical areas ("MSAs"). However, the Proposed Rule does not specify which MSAs would be included in the initial round under the complex criteria CMS intends to employ (although the agency is proposing to exclude New York City, Los Angeles, and Chicago from the first round of bidding). CMS also proposes to phase in competitive bidding by product category, focusing initially on groups of DMEPOS items with high cost and volume or largest savings potential. Yet again, CMS does not include the specific products that would be included in the initial phase of bidding or even the broader product categories to be adopted. Likewise, while CMS repeatedly references new DMEPOS supplier quality standards that are designed to protect beneficiaries in the new competitive bidding framework,<sup>2</sup> the final quality standards have not been released to date.

In addition to the direct impact the regulation would have on DMEPOS suppliers and beneficiaries in the competitive bidding areas, the Proposed Rule also could result in Medicare payment changes beyond the competitive bidding program. First, CMS is proposing to use pricing information it obtains through the bidding process to adjust payments outside of bidding areas. Moreover, CMS is proposing significant revisions to the longstanding "gap fill" methodology for calculating Medicare fee schedule amounts for new DMEPOS items provided under the traditional Medicare DMEPOS fee schedule.

Under the Proposed Rule, CMS or its contractors could base Medicare reimbursement amounts for new DMEPOS products on functional assessments, price comparisons, and medical benefits assessments. Furthermore, CMS proposes allowing this new methodology to be used to adjust prices that were previously established using the gap-filling methodology if CMS believes the resulting payment amounts do not reflect the cost of furnishing the item.

The following is an overview of the major features of the Proposed Rule. We would be pleased to provide you with additional information on any aspect of the proposal.

## **II. Statutory Background**

The Balanced Budget Act of 1997 ("BBA") authorized the Secretary of Health and Human Services ("Secretary") to implement up to five Part B competitive bidding demonstration projects. CMS used this authority to establish three DMEPOS competitive bidding projects, two in Polk County, Florida, and one in the San Antonio, Texas area. Under these projects, only suppliers that met the demonstration's quality standards and submitted competitive bids could serve Medicare beneficiaries using selected products in the demonstration areas – usually at rates significantly below the Medicare fee schedule amounts.

Building on the BBA provision, the MMA added a new requirement for the Secretary to implement competitive acquisition programs for DMEPOS beginning in 2007. Products to be included could include: (1) DME (including DME used with infusion and drugs, other than inhalation drugs) and supplies used in conjunction with DME; (2) enteral nutrients, equipment, and supplies; and (3) off-the-shelf orthotics. The MMA excludes from competitive acquisition inhalation drugs; parenteral nutrients, equipment, and supplies; and Class III devices.<sup>3</sup> Moreover, the Secretary is authorized to exempt rural areas and areas with low population density in urban areas (unless there is a significant national market through mail order for particular items), and items and services unlikely to result in significant savings.

The Secretary is directed to establish competitive acquisition areas, which may differ for different items and services. Competitive acquisition will be phased in, applying to 10 of the largest MSAs in 2007, 80 MSAs in 2009, and additional MSAs thereafter. The Secretary may phase in competitive acquisition programs first among the highest cost and highest volume items and services or those that have the largest savings potential.

For each competitive acquisition area, the Secretary must solicit bids by suppliers to supply certain covered items. Only successful bidders may supply the covered items in the acquisition area, and they will be reimbursed for such items at the bid amount. Beneficiary liability for items under the demonstration will be limited to 20 percent of the applicable contract award price. The Secretary must ensure that small suppliers have the opportunity to be considered for participation under the program. In determining the categories for bids, the Secretary may consider the clinical efficiency and value of

specific items within codes, including whether some items have a greater therapeutic advantage to individuals.

In order to be awarded a contract, bidding entities must meet new quality standards for suppliers, along with financial standards specified by the Secretary.<sup>4</sup> Total amounts paid under the contracts are expected to be less than would be paid otherwise, and beneficiary access to multiple suppliers must be maintained. The Secretary may limit the number of contractors in a competitive acquisition area to the number needed to meet projected demand. Any contract awarded must be open for competitive bidding at least every three years.

The Secretary is authorized, but not required, to allow physicians to prescribe a particular brand or mode of delivery of an item or service if the use of the particular item or service would avoid an adverse medical outcome. This could not affect the amount of payment otherwise applicable.

### **III. Proposed Competitive Bidding Rule**

#### **A. Implementation Contractor**

In the Proposed Rule, CMS proposes designating one or more "competitive bidding implementation contractors," or "CBICs" to implement the competitive bidding program.<sup>5</sup> The CBICs would share duties with the current DME regional carriers ("DMERCs") in the bidding regions. Specifically, CMS expects that the CBICs would prepare the request for bids ("RFB"), perform bid evaluations, select qualified suppliers, and set single payment amounts for all competitive bidding areas. The CBICs also would be charged with educating the DMERCs on the bidding process and procedures, and assisting CMS and the DMERCs in monitoring program effectiveness, access, and quality. The DMERCs would continue to process claims, provide outreach and education to beneficiaries and suppliers in their regions, apply the single payment amounts set by the CBICs for each competitive bidding area, and continue to be responsible for complaints related to claims processing.

#### **B. Requirement to Obtain Competitively Bid Items from a Contract Supplier**

CMS is proposing that Medicare beneficiaries who maintain their permanent residence in a competitive bidding area ("CBA") would be required to obtain competitively bid items from a contract supplier for that area, subject to the following two exceptions:

A beneficiary could obtain an item from a supplier or a noncontract supplier in accordance with the competitive bidding program grandfathering provisions described below, and

A beneficiary who is outside of the CBA where he or she maintains a permanent residence could obtain an item from a supplier with a valid Medicare supplier number if he or she is either in another CBA that does not include the item in its program or is in an

area that is not a CBA. On the other hand, if the beneficiary is in another CBA where the item is included in competitive bidding, the beneficiary must obtain the item from a contract supplier. In either case, payment to the supplier would be based on the single payment amount for the item in the CBA area where the beneficiary maintains a permanent residence, and the claims jurisdiction would be based on the beneficiary's permanent residence.

Unless one of the exceptions discussed above applies, Medicare would not pay for the item. Likewise, if a noncontract supplier located in a CBA furnishes an item included in the competitive bidding program for that area to a beneficiary who maintains a permanent residence in that area, the beneficiary would have no financial liability to the noncontract supplier unless the grandfathering exception applies.<sup>6</sup>

CMS also notes that if a beneficiary is not visiting another area, but is merely receiving competitively bid items from a supplier located outside but near the boundary of the CBA, the proposed travel status exemption would not apply. CMS intends to monitor implementation of this program "to ensure that this type of abuse or circumvention of the competitive bidding process and requirements to obtain items from a contract supplier does not occur."

### C. Payment Basis

Payment to contract suppliers in CBAs would be based on the single payment amount for the item in the CBA where the beneficiary maintains a permanent residence.<sup>7</sup> Implementation of competitive bidding would not preclude the use of an advance beneficiary notice, as provided by the MMA.

#### 1. Grandfathering Suppliers

The Proposed Rule would implement the statutory requirement to allow a "grandfathering" process for rented DME and oxygen and oxygen equipment (but not enteral products) when these items are included under a competitive bidding program. The process would apply to suppliers that began furnishing the items to beneficiaries who maintain a permanent residence in an area prior to the implementation of the competitive bidding program. Beneficiaries would have a choice of whether to continue renting the item from the grandfathered supplier or a contract supplier (unless the grandfathered supplier is not willing to continue furnishing the item).

Suppliers who agree to be grandfathered suppliers for a specific item must agree to be a grandfathered supplier for all beneficiaries who request to continue to use their service for that item. For items requiring frequent and substantial servicing as well as oxygen and oxygen equipment, the grandfathered supplier could continue to furnish these items to beneficiaries in accordance with existing rental agreements or supply arrangements, except the grandfathered supplier would be paid the single competitive bidding payment amounts. For capped rental items and inexpensive or routinely purchased items furnished on a rental basis, the grandfathered supplier could continue furnishing the items in

accordance with existing rental agreements and continue to be paid under the applicable fee schedule. CMS also is proposing specific provisions for the continuation of rental agreements for suppliers that lose their contract status in a subsequent competitive bidding program in the same area.

Accessories and supplies used in conjunction with an item furnished under the grandfathering process also could be furnished by the grandfathered supplier, subject to specific payment rules. For supplies used with oxygen or oxygen equipment or items that require frequent and substantial servicing, payment would be based on the single payment amount established under competitive bidding. For accessories and supplies used in conjunction with capped rental and inexpensive or routinely purchased items, the payment amount generally would be based on the fee schedule amounts in effect prior to competitive bidding (with special provisions for payment to contract suppliers that lose their contract status).

## 2. Adjusting Payments for Inflation

CMS could award a competitive bidding contract for a term of up to three years. To facilitate bidding on multi-year contracts, CMS proposes applying an annual inflation amount to the single payment amount established under competitive bidding. Specifically, the single payment amount would be increased by the percentage increase in the consumer price index for urban consumers ("CPI-U") beginning with the second year of a contract.

## 3. Authority to Adjust Payments in Other Areas

Effective January 1, 2009, the MMA authorizes CMS to use payment information determined under competitive bidding to adjust fee schedule payments for items that are not in a CBA. CMS proposes to use this authority, but the agency has not yet developed a detailed methodology for such a process. CMS invites comments on a methodology for making such adjustment, including specific comments on: the threshold amount or level of savings that the Medicare program must realize before making such an adjustment; whether adjustments would be on a local, regional, or national basis; and whether adjustments of payment amounts in other areas would be based on a certain percentage of the single payment amount from the bidding areas.

Given the potential for this provision to have a widespread impact on Medicare payment amounts, interested parties should consider providing CMS with suggestions for reasonable parameters and procedural safeguards for such payment adjustments, potentially along the lines of the requirements for CMS's use of its inherent reasonableness authority.<sup>8</sup>

## D. Competitive Bidding Areas

### 1. MSA Selection

CMS is proposing to implement the MMA's timeframe to phase in the competitive bidding program geographically as follows:

10 of the largest MSAs in 2007 (CMS states that it intends to implement the competitive bidding program October 1, 2007); 80 of the largest MSAs in 2009; and additional areas after 2009.

CMS proposes to use the following steps in selecting the MSAs for 2007:

Identify the top 50 MSAs in terms of general population;

Focus on the 25 MSAs from step one with the greatest total of DMEPOS allowed charges;

Score the MSAs from step two based on combined rankings of DMEPOS allowed charges per beneficiary and suppliers per beneficiary, with lower scores indicating a greater potential for savings if programs are implemented in those areas.

Exclude the three largest MSAs in terms of population (New York, Los Angeles, Chicago) and any MSA that crosses DMERC boundaries.

Select the lowest scoring MSA from each DMERC region.

Select the next six lowest scoring MSAs regardless of DMERC region, but not more than two MSAs from one state.

Break ties in scores using DMEPOS allowed charges, selecting MSAs with higher total DMEPOS allowed charges.

CMS intends to use the most recent data available at the time it selects the 10 MSAs, and hence has not yet announced where the initial bidding would take place. CMS does point out, however, that the top MSAs based on data for 2003 (excluding New York, Los Angeles, and Chicago) are: Miami, Houston, Dallas, Riverside (CA), San Antonio, Charlotte, Orlando, San Juan, Atlanta, Tampa, Kansas City, Pittsburgh, Virginia Beach, St. Louis, San Francisco, Cincinnati, Cleveland, Detroit, Baltimore, Philadelphia, Washington DC, and Boston. The Proposed Rule discusses alternative methodologies CMS had considered to select the initial MSAs, along with its plans for selecting MSAs for the 2009 round of bidding. CMS solicits comments on other options for MSA selection.

## 2. Establishing Competitive Bidding Areas

The Proposed Rule discusses how CMS would exercise its authority to exempt from competitive bidding 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 for a particular item. CMS proposes to consider the following factors to determine that an

area is not competitive: low utilization of items in terms of number of items and/or allowed charges for DMEPOS in the area relative to other similar geographic areas; low number of suppliers of DMEPOS items subject to competitive bidding serving the area relative to other similar geographic areas; and/or low number of Medicare fee-for-service beneficiaries in the area relative to other similar geographic areas. CMS invites comments on this proposal.

CMS believes it is authorized to define a CBA to be concurrent with an MSA boundary, larger than an MSA, or smaller than an MSA. Thus, CMS could consider extending the boundaries of a CBA beyond the MSA's boundaries if the area is part of the normal service area or market for suppliers who also serve the MSA market in certain circumstances.

### 3. Mail Order Competitive Bidding

CMS proposes to allow mail order suppliers to submit bids to furnish items during the 2007 and 2009 competitive bidding phases for beneficiaries who elect to use a mail order supplier. Moreover, CMS proposes implementing nationwide or regional competitive bidding for mail order suppliers effective January 1, 2010. CMS is soliciting comments on the types of items that would be suitable for a mail order competitive bidding program. In addition, CMS is considering mandating mail order replacement of all supplies such as blood glucose test strips and lancets, and seeks comments on "whether the service of furnishing replacement test strips, lancets or other supplies can easily, effectively, and conveniently be performed by national mail order suppliers."

#### E. Criteria for Item Selection

As provided under the MMA, the following items are subject to competitive bidding: (1) DME (including DME used with infusion and drugs, other than inhalation drugs) and supplies used in conjunction with DME, but excluding class III devices<sup>9</sup>; (2) enteral nutrients, equipment, and supplies; and (3) off-the-shelf orthotics.<sup>10</sup>

CMS is proposing to phase in only those items of DMEPOS that it determines are among the highest cost and highest volume items during each phase of the competitive bidding program. When determining an item's potential savings as a result of competitive bidding, CMS would consider the following factors: annual Medicare DMEPOS allowed charges; annual growth in expenditures; number of suppliers; savings in the DMEPOS demonstrations; and reports and studies. However, items with high allowed charges or rapidly increasing allowed charges would be CMS's highest priority in selecting items for bidding.

To facilitate bidding, CMS is establishing "product categories" consisting of related products, and suppliers would submit a separate bid for each item within a defined category. CMS intends to include a "core" set of product categories in each CBA, while other product categories could be tested in a limited number of CBAs in order to determine their suitability for competitive bidding.

CMS does not identify the product categories it proposes to use in the initial phase of competitive bidding. For purposes of illustration, CMS references 64 DMERC "policy groups" identified by the Statistical Analysis DMERC ("SADMERC"), which are sets of Healthcare Common Procedure Coding System ("HCPCS") codes that describe related items under a DMERC medical review policy. For example, the "oxygen and supplies" policy group consists of approximately 20 HCPCS codes. CMS emphasizes, however, that competitive bidding product categories could be a subset of items from a policy group or a combination of items from different policy groups. Moreover, CMS would not include items in a product category if they are rarely used or billed to the program, or if inclusion of those items is unlikely to result in program savings. Product categories could differ from one CBA to another and in different rounds of bidding in the same CBA.

CMS estimates that approximately 10 product categories would be selected for the first round of competitive bidding, and as many as 7 or 8 would be among the 10 largest in terms of allowed charges. The remaining 2 or 3 product categories are expected to come from the top 20 product groups ranked by allowed charges. The following table illustrates the top 20 policy groups based on 2003 Medicare allowed charges for the items within each policy group that CMS could choose to include in competitive bidding, although CMS cautions that this ranking should not be interpreted as signifying which product categories will be selected for competitive bidding:

#### F. Submission of Bids under the Competitive Bidding Program

CMS intends to provide many of the details regarding the bidding program in the RFB in the particular CBA. Note that on May 5, 2006, CMS published a notice<sup>11</sup> announcing that it is seeking White House Office of Management and Budget ("OMB") clearance of a number of the forms it will be using in connection with the DMEPOS competitive bidding RFB. As part of this clearance request, CMS has released: the application form (which requires the bidding supplier to provide general information about the characteristics of its company, as well as financial information); the bidding sheet, (on which the supplier provides specific information about the prices it bids for specific product items and other product-category specific information); bank reference; a quarterly report; and a beneficiary survey.<sup>12</sup>

##### 1. Entities Furnishing DME

In order for a supplier to receive payment for competitively-bid items in a CBA, the supplier must have submitted a bid to furnish those particular items and must have been awarded a contract to do so by CMS (subject to limited exceptions for grandfathered suppliers and for beneficiaries traveling out of their areas). The Proposed Rule also states that providers that furnish Part B items and are located in the CBA must submit bids in order to furnish competitively-bid items in the CBA. Providers that are not awarded contracts must use a contract supplier to furnish these items to the beneficiaries to whom they provide services.

CMS is proposing special rules for the furnishing of DMEPOS items by physicians and skilled nursing facilities ("SNFs"). With regard to physicians, CMS proposes to require that physicians that are also DMEPOS suppliers must submit bids and be awarded contracts in order to furnish items included in the competitive bidding program, although they would not be required to furnish these items to beneficiaries who are not their patients if they choose not to function as commercial suppliers. If a physician does not become a contract supplier, the physician must use a contract supplier to furnish competitively bid items. CMS points out that "[p]hysicians who choose to participate in the competitive bidding process must ensure that their arrangements for referring for and furnishing DMEPOS items under a competitive bidding program comply with the physician self-referral law as well as any other Federal or State law or regulation governing billing or claims submission."

Likewise, CMS anticipates that SNFs could bid to provide certain Part B DMEPOS items to Medicare beneficiaries,<sup>13</sup> but CMS states that a SNF would not be required to furnish competitively bid items to beneficiaries outside of the SNF if it elects not to furnish as a commercial supplier. Note that CMS does not discuss further the many differences between furnishing DMEPOS in the home and SNF settings and whether items furnished to beneficiaries in the SNF setting are appropriate for inclusion in competitive bidding. Inclusion of SNFs in competitive bidding could be complicated by, among other things, the different clinical condition of the patients in the SNF setting, CMS's proposed exemption of SNFs from certain of the proposed supplier quality standards, and the different costs of furnishing DMEPOS in the SNF setting versus the home care setting that could distort the establishment of single bid prices. Likewise, CMS does not address the potential problems a SNF that is not a winning bidder could have in coordinating the care of its beneficiaries if it loses control over who could supply its residents. Indeed, while CMS included enteral products in the first round of the Polk County competitive bidding demonstration, CMS chose not to include enteral in subsequent rounds because most enteral are provided in the nursing home setting.<sup>14</sup>

## 2. Product Categories for Bidding Purposes

As noted above, CMS proposes to conduct bidding for items that are grouped into product categories, such as Breast Prosthesis, Dialysis Equipment and Supplies, Oxygen, and Power Wheelchairs. Suppliers would be required to submit a separate bid for all items, identified by HCPCS code, that CMS specifies in the product category. According to CMS's draft bid sheets, the bidder would be required to specify the model(s) to be provided within the HCPCS code. 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 (separate maintenance and servicing payments are available only for rented enteral nutrition equipment). Additional details about the items to be included in the product categories for bidding purposes would be detailed in the RFB. Suppliers would be allowed to bid only for the product categories they seek to furnish to enable suppliers to specialize in one or a few product categories.

CMS expects the use of product categories would minimize disruptions for beneficiaries, since they would be able to receive all of their related products from one supplier, and would facilitate the participation of small suppliers in competitive bidding. Moreover, the use of product categories could help drive prices down even further, CMS observes, since "a supplier may be able to furnish a bundle of items at a lower cost than it can produce each individual item."

### 3. Bidding Requirements

CMS generally would follow current rules regarding whether a rental or purchase payment would be made for a competitively bid item and whether other requirements would apply to the furnishing of that item, with certain exceptions.

**Inexpensive or Other Routinely Purchased DME Items.** For inexpensive or other routinely purchased DME, CMS is proposing that bids be submitted only for the furnishing of new items in this category. Based on accepted bids, CMS would calculate a single payment amount for used items based on 75 percent of the payment amount for new items, and would calculate a single payment amount for the rental of these items based on 10 percent of the payment for new items. CMS would not establish a purchase option for new items in this category for purposes of competitive bidding.

**Items Requiring Frequent and Substantial Servicing.** CMS proposes that bids be submitted for the monthly rental of items in this payment category except for continuous passive motion exercise devices, for which bids would be submitted on a daily rental basis. Payment would be made on a rental basis.

**Oxygen and Oxygen Equipment.** If CMS includes oxygen and oxygen equipment in competitive bidding, the agency would calculate single payment amounts based on separate bids submitted and accepted for the furnishing on a monthly basis of each category of oxygen and oxygen equipment services (e.g., stationary oxygen equipment and oxygen contents, portable oxygen equipment only, stationary and portable oxygen contents only, and portable oxygen contents only).

**Capped Rental Items.** CMS proposes that bids for "purchase" amounts be submitted for the furnishing of new items in this category. Based on these bids, a single payment amount for purchase of a new item would be calculated for each item to determine the lump sum purchase of a new power wheelchair and to calculate the single payment amounts for the rental of all items in this category. If a beneficiary elects to purchase a used power wheelchair, the single payment amount for the lump sum purchase would be 75 percent of the payment for a new wheelchair. For items furnished on a rental basis, the single payment amount for rental of the item for months 1 through 3 would be based on 10 percent of the single payment amount for purchase of the item, and for months 4 through 13 would be based on 7.5 percent of the single payment amount (after which title transfers to the beneficiary). CMS proposes to make separate payment for reasonable and necessary maintenance and servicing of capped rental items only for beneficiary-owned DME. Payment for maintenance and servicing of rented DME would be included in the

single payment amount for rental of the item. CMS also proposes that the lump sum purchase option for power wheelchairs be retained under the competitive bidding program.

**Enteral Nutrition Equipment and Supplies.** Enteral nutrition equipment is currently paid on a purchase or rental basis. While Medicare reimbursement policy for rented enteral equipment is similar to the capped rental rules, payment may be made for 15 months and enteral equipment is not subject to the 25 percent reduction in payment for the fourth rental month and after. Under the Proposed Rule, however, CMS is proposing to adopt a payment reduction for enteral equipment rental payments after the third month. Specifically, CMS proposes that bids be submitted for the purchase of new items in this category. Based on accepted bids, CMS would calculate a single payment amount for rented items for months 1 through 3 based on 10 percent of the single payment amount for new items, with the rental payment reduced to 7.5 percent for rented items for months 4 through 15. For purchased enteral nutrition equipment, the single payment amount for new enteral nutrition equipment would be based on the bids submitted and accepted for new enteral nutrition equipment, and the payment for used equipment would be based on 75 percent of the single payment amount for the purchase of new equipment. CMS also states that based on the bids for new items, it "would calculate a single payment amount for purchase of enteral nutrients and supplies." Although this language could be read to indicate CMS is contemplating a bundled payment for both nutrients and supplies, the proposed regulatory text appears to indicate that CMS would establish a single payment amount for purchase of enteral nutrients and a separate single payment amount for supplies. This presumably will be clarified in the final rule.

**Maintenance and Servicing of Enteral Nutrition Equipment.** CMS proposes to establish the maintenance and service payments for enteral nutrition equipment so that they are equal to 5 percent of the single payment amounts for the purchase of new enteral nutrition equipment. CMS also proposes that the contract supplier to which payment is made in month 15 for furnishing enteral nutrition equipment on a rental basis must continue to furnish, maintain and service the pump for as long as the equipment is medically necessary.

**Supplies Used in Conjunction with DME.** CMS would calculate single payment amounts 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.

**Orthotics.** CMS proposes that bids be submitted for the purchase of off-the-shelf orthotics, and CMS would calculate single payment amounts for these items on a purchase basis.

## G. Conditions for Awarding Contracts

### 1. Quality Standards, Accreditation, Eligibility, and Financial Standards

The MMA requires the Secretary to develop quality standards for DMEPOS suppliers. Note that the quality standards will apply to all suppliers furnishing items under Medicare Part B, not only suppliers participating in the DMEPOS competitive bidding program. CMS issued draft quality standards in September 2005.<sup>15</sup> The lengthy and detailed standards include (1) business quality standards that apply to all Medicare suppliers, regardless of specialization (e.g., standards for administration; financial management; human resource management; beneficiary services; performance management; environment and safety; beneficiary rights/ethics; and information management); and (2) product-specific quality standards. As discussed at greater length in the Proposed Rule, the quality standards are to be applied by recognized independent accreditation organizations designated by the Secretary. The quality standards have not yet been finalized, but CMS officials have indicated that final standards may be released in June 2006. Many supplier organizations have raised concerns about the ability to comment constructively on the totality of the Proposed Rule without being able to review the final quality standards, since they are a critically-important component of the proposed competitive bidding program.

CMS proposes that it will not award a contract to any entity unless the entity meets applicable quality standards. A grace period could be granted for suppliers that have not had sufficient time to obtain accreditation before submitting a bid. If a supplier does not then successfully attain accreditation, CMS would suspend or terminate the supplier contract (note that CMS also could suspend or terminate contracts for certain other deviations from contract requirements). The length of time for the grace period would be determined by the accrediting organizations' ability to complete the accrediting process within each CBA and specified in the RFB. CMS is soliciting comments on the appropriate length of time for the grace period. CMS also proposes a process to grandfather certain accreditations obtained by suppliers before CMS-approved accreditation organizations are designated.

The Proposed Rule also would require bidders to meet eligibility rules to be considered for selection, including being enrolled as a Medicare supplier and meeting DMEPOS supplier standards. Bidders could not be under current Medicare sanctions, and they must certify that high-level employees, chief corporate officers, members of board of directors, affiliated companies, and subcontractors are not and have not been sanctioned by any governmental agency or accreditation or licensing organization. Alternatively, the bidding supplier must disclose information about prior or current legal actions, sanctions, or debarments at the federal, state, or local levels. Bidder also must have all state and local licenses required to furnish the items that are being bid, and agree to the terms of the contract. CMS could suspend or terminate a contract if a supplier loses its good standing with CMS or any other government agency.

Suppliers also must meet applicable financial standards specified by the Secretary. The RFBs would identify the specific information CMS would require to evaluate suppliers, which could include: a supplier's bank reference that reports general financial condition, credit history, insurance documentation, business capacity and line of credit to successfully fulfill the contract, net worth, and solvency. CMS welcomes comments on

the financial standards, in particular the most appropriate documents that would support these standards. CMS notes that its goal is to "obtain as much information as possible while minimizing the burden on bidding suppliers and the bid evaluation process."

CMS would ensure that suppliers meet the established quality and financial standards prior to considering bid amounts and selecting contract suppliers.

## 2. Market Capacity

CMS intends to select the number of contract suppliers necessary to meet the projected demand for DMEPOS items in the geographic area. To determine expected demand, CMS would examine Medicare claims data to determine the number of units of each item furnished during the past two years, and then estimate the number of new beneficiaries that have entered the market during the last two years. CMS also would consider seasonal fluctuations in demand and other trends in beneficiary demand for products in an area.

To gauge the necessary number of suppliers to meet expected beneficiary demand, CMS intends to examine suppliers' current capabilities and the number of units the supplier is willing and capable of supplying at the bid price in the CBA. CMS would require evidence of financial resources to support market expansion, such as letters from investors or lending agents. CMS would compare expected capacity and Medicare volume to determine how many suppliers it would need in an area. CMS cites consultations with industry representatives that suggest that "most DMEPOS suppliers would be able to easily increase their total capacity to furnish items by up to 20 percent and the increase could be even larger for products like diabetes supplies that require relatively little labor." CMS invites comments on its proposed approach for calculating market demand and estimating supplier capacity, especially information that would help the agency compare current Medicare volume with potential capacity.

CMS's consideration of a supplier's expansion capabilities has the potential to result in significant consolidation of suppliers in CBAs. Moreover, CMS does not discuss the potential impact of mail order suppliers on its estimates of the number of suppliers necessary to serve an MSA, which could further limit the number of retail suppliers with which CMS intends to contract, nor does CMS suggest that it is considering convenient beneficiary access to suppliers as a factor in determining the appropriate number of winning bidders in an area.

## 3. Composite Bids

CMS would use composite bids to aggregate a supplier's bids for individual items (i.e., HCPCS codes) within a product category into a single bid for the whole product category. This would allow CMS to determine which suppliers could offer the lowest expected costs for all items in a product category. CMS would weight individual items within the product categories based on utilization of the item by Medicare beneficiaries. To compute a composite bid, CMS would multiply a supplier's bid for each item in the product category by the item's weight and sum the numbers across items.

CMS seeks comments on the best method of weighting individual items within a product category to determine the composite bid. CMS suggests the following two options, but notes that other methods could be appropriate: (1) setting the weight for each item based on the volume of the individual item's share compared to the total utilization of the product category, or (2) setting the weight based on the payment amounts attributable to each DMEPOS fee schedule item relative to the overall payment amount for the total product category.

#### 4. Bid Selection/Determining the Pivotal Bid

CMS would array the composite bids from lowest to highest. CMS then would establish as the "pivotal bid" the point where the expected combined capacity of the bidders is sufficient to meet expected demands of the beneficiaries for the items in the product category. All bidders who are eligible for selection and whose composite bid for the product category is less than or equal to the pivotal bid would be selected as winning bidders.<sup>16</sup> CMS notes that this methodology could leave out suppliers with very close but slightly higher bids than the pivotal bids. CMS considered a number of other approaches to determine the winning suppliers, including establishing the pivotal bid at the median bid from eligible suppliers or basing the pivotal bid on a target number of winners or target composite. CMS does not support these approaches, however, because they would not provide the appropriate capacity levels or result in the most competitive bid prices.

#### 5. Assurance of Savings and Multiple Contractors

CMS proposes not to accept any bid for an item that is higher than the current fee schedule amount for the item. CMS notes that an alternative interpretation of its statutory requirement to pay "less than the total amounts that would otherwise be paid" would be to provide that the total payment for the product category must be less than otherwise would have been paid. CMS is concerned that the alternative approach would not result in adequate savings and could encourage the shifting of utilization from one item to another higher priced item. CMS solicits comments on methods for assuring savings under the Medicare DMEPOS competitive bidding program.

CMS also states that it is interpreting the MMA's requirement for multiple winning entities in a CBA to mean that there must be at least two suppliers in each bidding area for each product category. CMS does not specify whether one or more of the suppliers must be a retail supplier, rather than a mail order supplier.

#### H. Determining Single Payment Amounts for Individuals Items

##### 1. Setting Single Payment Amounts

Once CMS has selected contract suppliers for a product category based on the composite bid and the pivotal bid, CMS would establish single payment amounts for each individual item (by HCPCS code) in the product category. CMS's preferred approach would

determine the single payment amounts for individual items by using the median of the supplier bids that are at or below the pivotal bid for each individual item within each product category.

CMS asserts that this methodology would result in a single payment amount "that is representative of the winning bids for that item." Moreover, CMS observes that this proposal would reduce the effect of excessively high or excessively low bids. Note, however, that CMS already is proposing to exclude the highest bids by applying the pivotal bid threshold, and CMS's proposal would by definition result in approximately half of winning suppliers being reimbursed less than they bid for a particular item, and the other half being paid more. CMS is soliciting comments on other possible approaches, including using adjustments to average amounts to ensure that the overall payment amounts that winning suppliers received are at least as much as their bids, or using the minimum or maximum winning bid as the single payment amount.

## 2. Rebates

In a controversial provision, CMS is proposing to allow contract suppliers that submit bids for an individual item below the single payment amount to provide the beneficiary with a rebate equal to the difference between the supplier's actual bid and the single payment amount. Contract suppliers that submitted bids above the single payment amount would not be permitted to issue such rebates. CMS is soliciting comments on how to handle cases in which the rebates would exceed the beneficiary copayment amount.

CMS is proposing that the rebates be voluntary, although it considered making the rebates mandatory. However, if a contract supplier chooses to offer a rebate, it must offer the rebate to all Medicare beneficiaries receiving the competitively bid item to which the rebate applies. Indeed, once a contract supplier decides to provide rebates, the rebates would become a binding contractual condition for payment during the term of the contract with CMS, and the supplier could not amend or otherwise alter the provision of rebates during the term of the contract.

CMS states that contract suppliers would be prohibited from directly or indirectly advertising these rebates to beneficiaries, referral sources, or prescribing health care professionals. However, this would not preclude CMS from providing to beneficiaries comparative information about contract suppliers that offer rebates.

CMS notes that it "will continue to evaluate the fraud and abuse risks of the proposed rebate program," and CMS specifically solicits comments on such risks. CMS does not elaborate, however, on how it reconciles its proposal with the statutory prohibition on beneficiary inducements. Section 1128A(a)(5) of the Social Security Act prohibits the offering or transfer of "remuneration" -- including waiver of coinsurance -- that the entity knows or should know is likely to influence the beneficiary's selection of a particular Medicare provider, practitioner, or supplier. While the definition of "remuneration" contains a number of specific exceptions, including non-routine, unadvertised waivers of

copayments or deductible amounts based on individualized determinations of financial need or exhaustion of reasonable collection efforts, none of these statutory exceptions appear to apply to the rebate provision CMS is proposing. Although CMS presumably has been consulting with the HHS Office of Inspector General ("OIG") in developing this proposal, it is unclear how the fraud and abuse concerns associated with the rebates would be resolved.

While CMS states that its reason for permitting rebates is to allow beneficiaries to "realize additional savings and the full benefits of the Medicare DMEPOS Competitive Bidding Program," CMS undoubtedly hopes that the competitive advantage of being able to offer a rebate (even if not directly advertised by the supplier) would further drive down supplier bids.

#### I. Other Contracting Provision

The Proposed Rule includes additional details about the terms and conditions of competitive bidding contracts. Among other things, the Proposed Rule would provide that:

Repair or replacement of patient-owned items subject to a competitive bidding program must be furnished by a contract supplier.

A contract supplier cannot refuse to furnish items and services to a beneficiary residing in a CBA based on the beneficiary's geographic location within the CBA.

A contract supplier must agree to accept as a customer a beneficiary who began renting the item from a different supplier regardless of how many months the item has already been rented; suppliers must factor the cost of furnishing items in these situations into their bid submissions.

With regard to inexpensive or routinely purchased DME and competitively bid power wheelchair, the contract supplier must agree to give the beneficiary the choice of either renting or purchasing the item.

#### J. Change in Ownership

CMS wants to ensure that suppliers do not "adopt a strategy of circumventing the regular bidding process by gaining winning status through acquisitions of or mergers with contract suppliers or to violate any anti-competition prohibitions." CMS therefore is proposing that contract suppliers notify CMS in writing 60 days prior to any changes of ownership, mergers, or acquisitions being finalized. CMS states that it has the discretion to allow a successor entity after a merger with or acquisition of a contract supplier to function as contract supplier if --

There is a need for the successor entity as a contractor to ensure Medicare's capacity to meet expected beneficiary demand for a competitively bid item;

CMS determines that the successor entity meets all the requirements applicable to contract suppliers; and

The successor entity agrees to assume the contract supplier's contract, including all contract obligations and liabilities that may have occurred after the awarding of the contract to the previous supplier.

The successor entity would be legally liable for the non-fulfillment of obligations of the original contract supplier. In addition, CMS would only allow the successor entity to function as a contract supplier if it executed a novation agreement.

#### K. Physician Authorization/Clinical Efficiency and Value

CMS is not requiring a contract supplier to provide every brand of product or mode of delivery included within a HCPCS code, and indeed, the agency expects suppliers to choose to offer only certain brands within a code. Under the Proposed Rule, a physician or treating practitioner<sup>17</sup> would be authorized to prescribe in writing a particular brand of an item or mode of delivery of an item if he or she determines that it would avoid an adverse medical outcome for the beneficiary. CMS proposed that Medicare would not make an additional payment to a contract supplier that furnishes a particular brand as directed by a prescription.

When a particular brand or mode of delivery is specified, the proposed regulatory text states that the supplier must make a "reasonable effort" to furnish the particular brand or mode of delivery prescribed by the physician/practitioner. In the preamble to the Proposed Rule, CMS specifies that the supplier would be required to furnish the item or mode of delivery, assist the beneficiary in finding another contract supplier in the CBA that could provide the item, or consult with the physician/practitioner to find a suitable alternative product or mode of delivery for the beneficiary. Any change to a prescription must be memorialized in a revised written prescription. A contract supplier would be prohibited from billing Medicare if it furnishes an item different from that specified in the written prescription.

CMS cites an OIG report, mandated by the MMA, that will examine the extent to which (if any) suppliers subject to competitive acquisition are soliciting physicians to prescribe certain brands or modes of delivery of covered items based on profitability. CMS states that it will evaluate the need for a specific process for certain brand names or modes of delivery after the OIG issues this report. Note, however, that the OIG report is not due to Congress until July 1, 2009.

CMS also observes that the statute provides authority to establish separate categories for items within HCPCS codes if the clinical efficiency and value of items within a given code warrants a separate category for bidding purposes. CMS declines to propose exercising this authority, however, stating that "the HCPCS process has worked well in the past, and we believe that it adequately separates items based on their function." CMS

welcomes public comment on this issue. We would point out, however, that many HCPCS codes encompass a wide range of products, and many manufacturers and suppliers believe there should be greater differentiation within codes to recognize advanced and different medical technologies. Moreover, CMS has created new codes based on criteria other than "function." An example of an area that may require attention is blood glucose test strips; there is one HCPCS code for blood glucose test strips, despite the range of features and accuracy levels of the products on the market. CMS is likely to be urged to explore developing subcategories for bidding purposes to appropriately recognize differences in technology, as well as function, within codes.

#### L. Revisions to HCPCS Codes during a Bidding Cycle

CMS is proposing the following rules regarding changes in HCPCS codes during a bidding cycle:

If a new HCPCS code is added, CMS would use a new process (discussed below) to establish a fee schedule payment for the item until it is added to a product category subject to competitive bidding. Any qualified Medicare supplier would be allowed to supply this item until the next bidding cycle, at which time CMS would set a new single payment amount for the item.

If a single HCPCS code is divided into multiple codes for the components of that item, the sum of payments for these new codes would not be higher than the payment for the original item. Contracted suppliers also would provide the components of the item. During the subsequent competitive bidding cycle, suppliers would bid on each new code for the components, and CMS would determine new single payment amounts for the components.

If a single HCPCS code for two or more similar items is divided into two or more separate codes, the payment amount applied to these codes would continue to be the same payment amount applied to the single code until the next competitive bidding cycle, when suppliers would bid on the new separate codes.

If the HCPCS codes for several components of one item are merged into one new code for the single item, the payment amount of the new code would be equal to the total of the separate payment amounts for the components. Contract suppliers would continue to supply the item using the new code. During the subsequent bidding cycle, suppliers would bid on the new code and CMS would determine a new single payment amount.

If multiple codes for different, but related or similar items are placed into a single code, the payment amount for the new single code would be the average (arithmetic mean) weighted by frequency of payments for the formerly separate codes. Suppliers providing the items originally also would provide the item under the new single code. During the subsequent bidding cycle, suppliers would bid on the new single code and CMS would determine a new single payment amount for this code.

## M. Other Provisions Related to Competitive Bidding

Administrative or Judicial Review -- As specified under the MMA, the Proposed Rule provides that there would be no administrative or judicial review related to: establishment of competitive bidding payment amounts; awarding of contracts; designation of CBAs; the phased-in implementation schedule; selection of items; or the bidding structure and number of contract suppliers selected.

Small Suppliers -- CMS considered allowing a small supplier that has fewer than 10 fulltime equivalent employees to designate a geographic service area that is smaller than the entire CBA. CMS is not proposing this for a number of reasons, including its concern that it would provide small businesses with an unfair market advantage by allowing the selection of more favorable market areas. CMS seeks comments on this issue and on other ways to ensure small businesses have an opportunity to participate in the program.

Supplier Networks -- CMS is proposing allowing suppliers to form networks for bidding purposes if a number of conditions are met. Among other things, a legal entity, such as a joint venture, limited partnership, or contractor/subcontractor relationship, must be formed for the purposes of competitive bidding that would act as the applicant and submit the bid. Each member of the network must be eligible to participate and meet any accreditation and quality standards. CMS also proposes that the network member's market share cannot exceed 20 percent of the Medicare market within the CBA. A supplier could only join one network and could not submit individuals bids if part of a network.

Education and Outreach -- CMS proposes a wide range of supplier and beneficiary education initiatives related to the competitive bidding program.

Monitoring and Complaint Services -- CMS is proposing to establish a formal complaint monitoring system to address complaints in each CBA. Examples of problems that CMS would consider to be serious include contract suppliers furnishing items of inferior quality than those that they bid to furnish. CMS also proposes to monitor Medicare claims data to ensure that competitive bidding does not negatively impact beneficiary access to medically necessary items, and to identify changes in utilization patterns within a product category.

## **IV. Other Provisions**

### A. Payment for New Technology/"Gap Filling" Reform

As part of the DMEPOS competitive acquisition rule, CMS is proposing significant revisions to its current "gap fill" pricing policy that would affect DMEPOS fee schedule amounts in areas not subject to competitive bidding. Moreover, while CMS entitles this section as "Establishing Payment Amounts for New DMEPOS Items," CMS proposes using this new process to reconsider established pricing policies.

By way of background, CMS has used a gap filling process since 1989 to calculate payments for specific items of DME and supplies that are not listed on a Medicare fee schedule and which have no associated 1986-1987 base charge data. The process essentially involves calculating a new 1986-1987 base period by deflating current prices to approximate the base year price and then reinflating those amounts by any inflation update provided for in the statute for the intervening years. CMS is concerned that this method can lead to very high or very low fee schedule amounts without validation that these amounts are realistic and equitable relative to the cost of furnishing the item. For instance, CMS points out that most base fees have been gap filled using either supplier price lists or manufacturer's suggested retail prices, and the agency believes that manufacturers can establish inflated retail prices that lead to inflated payment amounts.

CMS has undertaken an initiative to ensure fair treatment across technologies and "recognize those technologies that provide a demonstrated clinical benefit and clearly identify the additional benefits over existing technologies." It has engaged contractors to compile the technical information needed to evaluate technologies for the purpose of making payment and HCPCS coding decisions for new items. The technologies studied were assessed in terms of the following three main areas:

**Functional Assessment** -- This step involved evaluating the device's operations, safety, and user documentation relative to the Medicare population. Interviews were conducted with health care providers to determine how and under what circumstances they would prescribe the product for a Medicare beneficiary.

**Price Comparison Analysis** -- A comparative cost analysis determined how the cost of this product compared to similar products on the market or alternative treatment modalities.

**Medical Benefit Assessment** -- This step focused on the effectiveness of the product in doing what it claims to do. Scientific literature reviews and interviews with health care providers were conducted to determine if the product significantly improved clinical outcomes compared to other products and treatment modalities.

CMS is proposing to use these three types of assessments to help set fee schedule amounts for DMEPOS (including parenteral and enteral nutrients, equipment, and supplies). Specifically, CMS would discontinue the gap fill practice of deflating supplier prices and manufacturers' suggested retail prices to the fee schedule base period. Instead, payment for new items could be based on:

The median retail price for items and services classified under the new HCPCS code (CMS determines the retail price for an individual item and service based on supplier price lists, manufacturer suggested retail prices, or wholesale prices plus an appropriate mark-up);

Fee schedule amounts for comparable items; and/or

A functional technology assessment of the items or services, taking into account one or more of the following factors: functional assessment; price comparison analysis; and/or medical benefit assessment.

Moreover, CMS would be authorized to use the technology assessment process to adjust prices that were previously established using the gap-filling methodology at any time on or after January 1, 2007 if it is determined that those pricing methods resulted in payment amounts that do not reflect the cost of furnishing the item.

This process has implications for both coding and pricing determinations. CMS states that the functional technology assessments would enable the agency to ensure that "HCPCS codes reflect current technology and functional differences in items and that new products are included within the appropriate HCPCS code." Moreover, this process would allow CMS "to compare older, similar products already on the market and newer more expensive products," and help the agency determine the need to create unique HCPCS code categories. Likewise, price comparison analyses would enable CMS to "determine if manufacturers' suggested retail prices are overly inflated, will provide a basis for establishing adequate payment amounts for new items, and will assist in establishing payment amounts for new items that are introduced after a bidding cycle has begun."

CMS has not yet provided key details on the criteria it would use in performing functional technology assessments, such as how it would determine appropriate "similar products" for comparison purposes, how it defines "significantly improved clinical outcomes," or its evidentiary standards in making such determinations. The rights of manufacturers in this process are not defined, nor does CMS mention how it intends to ensure the transparency of the decision-making process. More significantly, CMS does not discuss potentially far-reaching implications of the convergence of reimbursement, coding, and coverage determinations.

## B. Home Dialysis Supplies and Equipment

CMS is proposing to implement a fee schedule payment methodology for home dialysis supplies and equipment, which currently are reimbursed based on reasonable charge.

## C. Covered Item Update for Class III DME for 2007 and 2008

The MMA authorized CMS to determine the appropriate fee schedule update percentages for calendar years 2007 and 2008 for DME that are class III medical devices, classified by the FDA as those that support or sustain human life, are of substantial importance in preventing impairment of human health, or present unreasonable risk of illness or injury (e.g., osteogenesis or bone growth stimulators, implantable infusion pumps, external defibrillators, and ultraviolet light therapy systems). These determinations, the Secretary was required to consider recommendations by the Government Accountability Office ("GAO").

On March 1, 2007, the GAO released its report on reimbursement for class III medical devices.<sup>18</sup> The GAO found that while manufacturers of class III devices generally have higher premarketing costs than do manufacturers of similar class II devices, the Medicare DME rate-setting methodology accounts for such costs in a consistent manner. The GAO recommends that the Secretary establish a uniform payment update in 2007 for class II and class III devices, and that Congress consider establishing a uniform DME payment update in 2008 for both categories of devices. CMS agreed with GAO's recommendations.

In the Proposed Rule, CMS is soliciting comments on how to determine the appropriate fee schedule percentage change for these devices for 2007 and 2008, which it would consider in conjunction with the GAO's recommendations.

#### D. Low Vision Aids and Therapeutic Shoes

The Medicare regulations currently exclude from coverage eyeglasses and contact lenses, except for: post-surgical prosthetic lenses customarily used during convalescence for eye surgery in which the lens of the eye was removed; prosthetic lenses for patients who lack the lens of the eye because of congenital absence or surgical removal; and one pair of conventional eyeglasses or conventional contact lenses furnished after each cataract surgery during which an intraocular lens is inserted. The Proposed Rule would clarify that the scope of the eyeglass coverage exclusion encompasses all devices irrespective of their size, form, or technological features that use one or more lens to aid vision or provide magnification of images for impaired vision.

CMS also is proposing to codify an MMA provision establishing Medicare fee schedule amounts for therapeutic shoes, inserts, and shoe modifications.

#### V. Conclusion

Competitive bidding could be expected to have a significant impact on Medicare DMEPOS pricing in the CBAs in which it is instituted. CMS expects competitive bidding to reduce Medicare spending by \$38 million in 2007, rising to \$844 million in 2009 when bidding is expanded to 80 MSAs, and \$1 billion or more annually beginning in 2010. The new program also could result in changes in the distribution of DMEPOS, with consolidation of suppliers within individual CBAs, the potential increase in use of mail-order suppliers, and the prospect of more complicated supplier arrangements for SNFs.

Of particular concern to many DMEPOS manufacturers are the incentives within the competitive bidding structure for suppliers to bid on the least expensive products within a particular HCPCS code – particularly if suppliers are permitted to offer beneficiary rebates. While CMS would provide a process for physicians to prescribe a particular brand within a code, it is unclear how onerous this process would be for clinicians or whether a supplier's "reasonable efforts" to fulfill the prescription would be adequate to ensure beneficiary access to the most clinically-appropriate products.

Moreover, the Proposed Rule could be expected to result in pricing pressures beyond the MSAs in which competitive bidding is implemented by enabling CMS to use pricing information it obtains through the bidding process to adjust payments outside of bidding areas. Perhaps even more significantly, CMS has proposed a pricing methodology for all new DMEPOS that is based on vague functional and medical benefits criteria that could further blur distinctions between coding, reimbursement, and coverage decisions and impose new hurdles for manufacturers seeking Medicare coverage and adequate pricing for new medical technology. This methodology also could be applied to long-established pricing determinations, extending the potential impact of this proposal.

As previously noted, CMS is accepting comments on the Proposed Rule until June 30, 2006.

#### Footnotes

1 71 Fed. Reg. 25,654 (May 1, 2006). The text of the rule is available at: <http://a257.g.akamaitech.net/7/257/2422/01jan20061800/edocket.access.gpo.gov/2006/pdf/06-3982.pdf>.

2 Note that the quality standards will apply to all Medicare DMEPOS suppliers regardless of whether they participate in competitive bidding.

3 Note that the preamble to the Proposed Rule states that surgical dressings are "not eligible for competitive bidding"; CMS does not elaborate on the grounds for this exclusion.

4 Failure to implement the new quality standards may not delay implementation of the competitive acquisition program. CMS issued draft quality standards in September 2005 but they have not yet been finalized.

5 CMS has issued its request for proposal for the CBIC; see: <http://www.fbo.gov/spg/HHS/HCFA/AGG/RFP%2DCMS%2D2006%2D0018/Modification%2001.html>

6 This rule would not apply if the noncontract supplier furnished items that are not included in the competitive bidding program for the area.

7 If a competitively bid item 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.

8 For additional information on CMS's inherent reasonableness authority, go to <http://www.reedsmith.com/db/documents/hc0224.pdf>.

9 CMS states that surgical dressings are "not eligible for competitive bidding," but does not elaborate.

10 Off-the-shelf orthotics would be defined as those which require minimal self-adjustment for appropriate use and do not require expertise in trimming, bending, molding, assembling, or customizing to fit the individual. CMS is proposing that minimal self-adjustment would mean adjustments that the beneficiary, caretaker for the beneficiary, or supplier of the device can perform without the assistance of a certified orthotist. CMS will consult with experts in orthotics to determine which items would be classified as OTS orthotics. CMS invites comments on a process for identifying OTS orthotics subject to competitive bidding.

11 See <http://a257.g.akamaitech.net/7/257/2422/01jan20061800/edocket.access.gpo.gov/2006/pdf/E6-6808.pdf>.

CMS will accept comments on the proposed information collections until July 5, 2006.

12 For copies of the draft forms, see <http://www.cms.hhs.gov/PaperworkReductionActof1995/PRAL/itemdetail.asp?filterType=none&filterByDID=-99&sortByDID=2&sortOrder=descending&itemID=CMS063052>

13 While Part B coverage is not available for most DME furnished in a SNF setting because a SNF is not considered a patient's "home," a limited number of items including enteral nutrients and supplies, urologicals, and surgical dressings may be furnished under Part B in the nursing home setting in stays that are not covered under Part A.

14 CMS established special rules allowing nursing homes to continue to use nondemonstration suppliers if they accepted demonstration fees.

15 The draft standards are available at [http://www.cms.hhs.gov/CompetitiveAcqforDMEPOS/downloads/dmepos\\_qualitystandards.pdf](http://www.cms.hhs.gov/CompetitiveAcqforDMEPOS/downloads/dmepos_qualitystandards.pdf).

16 CMS is proposing a special process to select additional contracted suppliers if necessary to meet beneficiary demand or if a supplier's contract is suspended or terminated.

17 CMS defines treating practitioner to include physician assistants, nurse practitioners, and clinical nurse specialists.

18 The report is available at <http://www.gao.gov/cgi-bin/getrpt?GAO-06-62>.