



**SUMMARY and ANALYSIS**  
**APRIL 2, 2007 CMS FINAL REGULATION**  
**COMPETITIVE ACQUISITION for CERTAIN DMEPOS,**  
**and OTHER ISSUES**

CMS released on its web site April 2, 2007 the long-awaited Final Rule on Competitive Acquisition for Certain DMEPOS (durable medical equipment, prosthetics, orthotics, and supplies), and Other Issues. The Final Rule was published in the April 10, 2007 *Federal Register*. The following summary provides highlights of the final rule, as well as a detailed summary of the final regulatory provisions. Many additional details will be available shortly in other documents that CMS will post on its web site and/or the Competitive Bidding Implementation Contractor (CBIC) web site.

CMS announced the initial ten metropolitan areas in which it will begin competitive bidding and the ten product categories that will be included:

**First 10 Cities**

- 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
- Riverside-San Bernardino-Ontario, CA
- Orlando-Kissimmee, FL
- Pittsburgh, PA
- San Juan-Caguas-Guaynabo, Puerto Rico

**Product Categories for First 10 Cities**

- Oxygen equipment and supplies
- Respiratory assist devices and CPAPs
- Standard Power wheelchairs, scooters and related accessories
- Rehabilitative power wheelchairs and related accessories



- Diabetic supplies (Mail Order Only)
- Enteral nutrition
- Hospital beds and accessories
- Walkers
- Negative pressure wound therapy devices
- Support surfaces, Group 2 and 3 mattresses and overlays (Only to be bid in Miami and San Juan)

CMS states that the program will be phased in over several years beginning in calendar year 2007 and payment under the competitive bidding program will go into effect in April, 2008.

Medicare expects to begin the bidding process in late April 2007, and bidding will close 60 days later. Suppliers must register in advance in order to receive a user ID and password that will allow them to submit bids electronically/on-line. Suppliers must also be accredited or have accreditation pending before they can submit bids. CMS expects to announce winning suppliers in early December and single payment amounts derived from the bidding process will go into effect in the CBAs in April, 2008.

You can download from the CMS web site a copy of the final regulation and additional information at:

<http://www.cms.hhs.gov/competitiveacqfordmepos/>

CMS received about 2129 comments on the proposed rule. The final rule summarizes the comments CMS received, and provides CMS' response to the comments.



## **TABLE OF CONTENTS**

<b>SUMMARY HIGHLIGHTS:</b> .....	<b>4</b>
SMALL BUSINESS .....	4
SUMMARY OF WINNING SUPPLIER SELECTION PROCESS .....	4
GRANDFATHERING RULES TO AMELIORATE BENEFICIARY OWNERSHIP RULES - MINIMUM NUMBER OF MONTHLY PAYMENTS .....	5
TOPICS NOT INCLUDED IN THIS FINAL RULE THAT WERE IN PROPOSED RULE .....	6
<b>SUMMARY OF FINAL RULE</b> .....	<b>7</b>
A. PURPOSE AND DEFINITIONS (§414.400 AND §414.402) .....	7
B. PAYMENT BASIS (§414.408).....	8
C. COMPETITIVE BIDDING AREAS .....	12
D. CRITERIA FOR ITEM SELECTION .....	14
E. SUBMISSION OF BIDS UNDER THE COMPETITIVE BIDDING PROGRAM (PROPOSED §414.412).....	15
F. CONDITIONS FOR AWARDING CONTRACTS (PROPOSED §414.414).....	17
G. DETERMINING SINGLE PAYMENT AMOUNTS FOR INDIVIDUAL ITEMS (§414.416).....	19
H. TERMS OF CONTRACTS (§414.422).....	20
I. ADMINISTRATIVE OR JUDICIAL REVIEW (§414.424).....	22
J. OPPORTUNITY FOR PARTICIPATION BY SMALL SUPPLIERS - NEW DEFINITION OF SMALL BUSINESS AND 30 PERCENT “SET ASIDES” .....	23
K. OPPORTUNITY FOR NETWORKS (§414.418) .....	23
L. EDUCATION AND OUTREACH .....	24
M. MONITORING AND COMPLAINT SERVICES FOR THE COMPETITIVE BIDDING PROGRAM.....	25
N. PHYSICIAN AUTHORIZATION/TREATING PRACTITIONER AND CONSIDERATION OF CLINICAL EFFICIENCY AND VALUE OF ITEMS IN DETERMINING CATEGORIES FOR BIDS .....	25



## **Summary Highlights:**

### **Small Business**

**Definition Change:** CMS has changed the definition of a “small supplier” to be a supplier that generates gross revenue of \$3.5 million or less in annual receipts, including Medicare and non-Medicare revenue, compared to the proposed rule’s \$6 million in revenues. CMS explains that it worked closely with the Small Business Administration to establish a new definition of small suppliers that is reflective of this area of the health care industry. CMS also states that small suppliers account for approximately 85 percent of DMEPOS suppliers enrolled in the Medicare program.

**Target Number of Small Suppliers to Participate:** CMS is establishing a methodology to set a target number for small supplier participation. The target number is equal to 30 percent of the number of “winning” suppliers or suppliers that have met the bidding requirements and whose composite bids are at or lower than the pivotal bid for each product category in each CBA. The number resulting from this determination represents the goal for small supplier participation for that product category. CMS will then count to see if the number of small suppliers whose composite bids are at or below the pivotal bid is equal or greater than the target number CMS has computed for that product category.

If the number of small suppliers is lower than the target number, CMS will give the small supplier whose composite bid is above the pivotal bid, but closest to it of all the small suppliers whose composite bids are above the pivotal bid for the product category, the option of accepting a contract to furnish the product category at the single payment amounts. If the target number is still not met, CMS will offer a contract to the small supplier whose composite bid is the next closest to, but above, the pivotal bid, and will use this methodology until the target number is reached or there are no additional small suppliers that submitted a bid for the product category.

**Networks:** CMS will allow small suppliers to form networks if they cannot service the entire CBA independently. Suppliers that do not meet the definition of a small supplier or small suppliers that can service the entire CBA independently may not form networks. Any network must comply with all applicable laws, including the federal antitrust laws. The small suppliers forming the network must have market shares at the time of bidding, when totaled, that do not exceed 20 percent of the expected beneficiary demand for the product category. No more than 20 small suppliers may participate in a network. A small supplier may join more than one network but cannot submit an individual bid to furnish the same product category in the same CBA as any network in which it is a member. A small supplier may not be a member of more than one network if those networks submit bids for the same product category in the same CBA.

### **Summary of Winning Supplier Selection Process**

CMS will select contract suppliers as follows (1) establish a composite bid for each supplier (a composite bid is the sum of a supplier’s weighted bids for all items within a product category); (2) composite bids are ranked in order from lowest to highest; and (3) one of the composite bids is



selected to be the pivotal bid (the pivotal bid is the lowest composite bid based on bids submitted by suppliers for a product category that will include a sufficient number of suppliers to meet beneficiary demand for the items in that product category). The rule establishes a capacity limit for purposes of calculating the pivotal bid such that no supplier's capacity can be considered to meet more than 20 percent of the total beneficiary need. Suppliers whose composite bids are less than or equal to the pivotal bid are selected as winning suppliers if they meet all other program requirements. Thus, selection of the pivotal bid is used to determine the number of contract suppliers.

### **Grandfathering Rules to Ameliorate Beneficiary Ownership Rules - Minimum Number of Monthly Payments**

**Capped Rental Items:** For capped rental items furnished on a rental basis, CMS has a new rule for contract suppliers that must begin furnishing a capped rental item during the rental period to a beneficiary who is no longer renting the item from his or her previous supplier (because the previous supplier elected not to become a grandfathered supplier or the beneficiary elected to change suppliers) will receive 13 monthly rental payments for the item, regardless of how many monthly rental payments Medicare previously made to the prior supplier (assuming the item remains medically necessary). CMS states that this will ensure that the contract supplier can recover its costs because the 13 monthly rental payments for the capped rental item will be based on a single payment amount that reflects the purchase price for that item. At the end of this new 13 month rental period, the contract supplier will transfer title to the capped rental item to the beneficiary. This rule does not apply when a beneficiary who is renting a capped rental item from a contract supplier elects to obtain the same item from another contract supplier, because the grandfathering provisions only apply to those situations in which a beneficiary had been previously receiving the item from a non-contract supplier. In this case, the new contract supplier would be paid the single payment amount for the duration of the rental period.

**Oxygen:** For oxygen equipment, CMS has a new rule for contract suppliers that must begin furnishing oxygen equipment after the rental period has already begun to a beneficiary who is no longer renting the item from his or her previous supplier (because the previous supplier elected not to become a grandfathered supplier or the beneficiary elected to change suppliers) will receive at least 10 rental payments for furnishing the equipment. For example, if a contract supplier begins furnishing oxygen equipment to a beneficiary in months 2 through 26, CMS will make payments for the remaining number of rental months in the 36-month rental period, because the number of payments to the contract supplier would be at least 10 payments. In other words, a contract supplier that begins furnishing oxygen equipment beginning with the 20th month of rental will receive 17 payments (17 for the remaining number of rental months in the 36 month rental period). However, if a contract supplier begins furnishing oxygen equipment to a beneficiary in month 27 or later, CMS will make 10 rental payments assuming the equipment remains medically necessary. CMS states that it believe this is a reasonable solution because its data from the GAO and the OIG and data available through the Internet show that most oxygen equipment can be purchased for \$1,000 or less, and data from the competitive bidding demonstrations indicate that suppliers received more than \$1,000 over 10 months for furnishing oxygen equipment. Based on these data, CMS believes that 10 months is sufficient to cover the contract supplier's cost to furnish the equipment, irrespective of the modality that is used to administer the oxygen. This rule regarding the minimum number of rental payments does not apply



when a beneficiary switches from a contract supplier to another contract supplier to receive his or her oxygen equipment. In this case, the new contract supplier would be paid the single payment amount for the remaining number of months in the rental period.

### **Topics Not Included in this Final Rule that were in Proposed Rule**

Quality Standards: CMS did not include comments/issues about the quality standards/accreditation because it addressed many of these in a separate document when it issued the final Quality Standards August 15, 2007.

Gap-Fill Replacement: CMS did not include issues related to its proposal to replace its current gap-fill method which it uses to establish fees for new HCPCS codes; but states that it will address these at a later date.



## Summary of Final Rule

### **A. Purpose and Definitions (§414.400 and §414.402)**

Some of the important proposed new definitions:

- “*Composite bid*” means the sum of a bidding supplier’s weighted bids for all items within a product category for purposes of allowing a comparison across bidding suppliers.
- “*Contract supplier*” means an entity that is awarded a contract by CMS to furnish items under a competitive bidding program.
- “*Grandfathered item*” means any one of the following items for which payment is made on a rental basis prior to the implementation of a competitive bidding program.
  - (1) An inexpensive or routinely purchased item described in §414.220;
  - (2) An item requiring frequent and substantial servicing as described in §414.222;
  - (3) Oxygen and oxygen equipment described in §414.226; and
  - (4) A capped rental item described in §414.229.
- “*Grandfathered supplier*” a non-contract supplier "that chooses to continue to furnish grandfathered items to a beneficiary in a CBA.
- “*Item weight*” is a number assigned to an item based on its beneficiary utilization rate in a competitive bidding area when compared to other items in the same product category.
- “*Nationwide mail order contract supplier*” means a mail order contract supplier that furnishes items in a nationwide competitive bidding area.
- “*Network*” means a group of small suppliers that form a legal entity that submits a bid to furnish competitively bid items in a CBA, and that meets additional requirements.
- “*Regional mail order contract supplier*” means a mail order contract supplier that furnishes items to any Medicare beneficiary residing within a certain region(s) that are designated as CBAs and are located within the United States, its Territories, or the District of Columbia.
- “*Non-contract supplier*” means “a supplier that is not awarded a contract by CMS to furnish items included in a competitive bidding program.”
- “*Mail order contract supplier*” means a contract supplier that furnishes items through the mail to beneficiaries who maintain a permanent residence in a competitive bidding area.
- “*Pivotal bid*” "means the lowest composite bid based on bids submitted by suppliers for a product category that includes a sufficient number of suppliers to meet beneficiary demand for the items in that product category.”
- “*Product category*” means “a grouping of related items that are used to treat a similar medical condition.”
- “*Single payment amount*” means the allowed payment for an item furnished under a competitive bidding program.
- “*Small supplier*” means “a supplier that generates gross revenue of \$3.5 million or less in annual receipts including Medicare and non-Medicare revenue.”
- “*Weighted bid*” means the item weight multiplied by the bid price submitted for that item.



## **B. Payment Basis (§414.408)**

CMS did not make any substantive changes to this section from the proposed rule.

### **1. Payment Basis**

The payment amount for an item that is competitively bid will be based on the single payment amount for the item in the competitive bidding area where the beneficiary maintains a permanent residence. Suppliers will still be able to use ABNs.

### **2. General Payment Rules**

The current Medicare payment rules regarding whether an item is rented or purchased will continue to apply under the Medicare DMEPOS Competitive Bidding Program.

### **3. Additional payment to Certain Contract Suppliers for Capped Rental DME.**

For contract suppliers that take on the provision of capped rental items after the beneficiary's initial date of service, Medicare will make 13 monthly payments. The contract supplier must transfer title to the item to the beneficiary on the first day that begins after the 13th continuous month in which payments are made.

### **4. Additional Payment to Certain Contract Suppliers for Oxygen Equipment**

For oxygen equipment, CMS has a new rule for contract suppliers that must begin furnishing oxygen equipment after the rental period has already begun to a beneficiary who is no longer renting the item from his or her previous supplier (because the previous supplier elected not to become a grandfathered supplier or the beneficiary elected to change suppliers) will receive at least 10 rental payments for furnishing the equipment.

For example, if a contract supplier begins furnishing oxygen equipment to a beneficiary in months 2 through 26, CMS will make payments for the remaining number of rental months in the 36-month rental period, because the number of payments to the contract supplier would be at least 10 payments. In other words, a contract supplier that begins furnishing oxygen equipment beginning with the 20th month of rental will receive 17 payments (17 for the remaining number of rental months in the 36 month rental period). However, if a contract supplier begins furnishing oxygen equipment to a beneficiary in month 27 or later, CMS will make 10 rental payments assuming the equipment remains medically necessary. CMS states that it believe this is a reasonable solution because its data from the GAO and the OIG and data available through the Internet show that most oxygen equipment can be purchased for \$1,000 or less, and data from the competitive bidding demonstrations indicate that suppliers received more than \$1,000 over 10 months for furnishing oxygen equipment. Based on these data, CMS believes that 10 months is sufficient to cover the contract supplier's cost to furnish the equipment, irrespective of the modality that is used to administer the oxygen. This rule regarding the minimum number of rental payments does not apply when a beneficiary switches from a contract supplier to another contract supplier



to receive his or her oxygen equipment. In this case, the new contract supplier would be paid the single payment amount for the remaining number of months in the rental period.

## 5. Special Rules for Certain Rented Items of DME and Oxygen (Grandfathering of Suppliers)

### a. Process for Grandfathering Suppliers

CMS will grandfather non-contract suppliers in bid areas where the supplier that began furnishing bid items to beneficiaries prior to the implementation of a competitive bidding program. CMS will give beneficiaries in bid areas the choice of deciding whether they would like to continue renting the item (the capped rental item or oxygen) from the grandfathered supplier or to rent the item from a contract supplier. If the grandfathered non-contract supplier is not willing to continue furnishing the item under the proposed terms, then a contract supplier would assume responsibility for continuing to furnish the item and will be paid based on the bid amount determined for that item under the competitive bidding program. In addition, the beneficiary could elect, at any time, to transition to a contract supplier and the contract supplier will be required to accept the beneficiary as a customer. 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.

### b. Payment Amounts to Grandfathered Suppliers

#### (1) Grandfathering of Suppliers Furnishing Items Prior to the First Competitive Bidding Program in an Area

For oxygen and items requiring frequent and substantial servicing, a grandfathered (non-contract) supplier may continue to provide these items to beneficiaries in accordance with existing rental agreements or supply arrangements. However, the grandfathered supplier will be paid the bid amount for these items. For rental cap items, grandfathered suppliers may continue to provide these items through the rental period, at the pre-existing fee schedule (state specific) reimbursement rate, not the new competitively bid rate.

#### (2) Suppliers That Lose Their Contract Status in a Subsequent Competitive Bidding Program

CMS will allow beneficiaries to continue renting items from their existing supplier, even if that supplier has lost its contract status under a subsequent competitive bidding program. However, where a supplier that is no longer a contract supplier continues to furnish a rental item or oxygen and oxygen equipment on a grandfathered basis, the Medicare payment amount for the item will be the new bid amount established under the new competitive bidding program for that area.



c. Payment for Accessories for Items Subject to Grandfathering

Accessories and supplies used in conjunction with an item, which is furnished under a grandfathering process, may also be furnished by the grandfathered supplier. Payment would be based on the bid amount established for the accessories and supplies if the item is oxygen or oxygen equipment or one that requires frequent and substantial servicing. For accessories and supplies used in conjunction with capped rental and inexpensive or routinely purchased items, the payment amounts would be based on the fee schedule amounts for the accessories and supplies furnished prior to the implementation of the first competitive bidding program in an area, or on the newly established competitively bid single payment amounts if the items are furnished by a grandfathered supplier that was a contract supplier for a competitive bidding program, but is no longer a contract supplier for a subsequent competitive bidding program in the same area.

This rule will not apply to accessories that are not an integral part of the base equipment. CMS explains: “For example, a standard mattress is an essential accessory for a hospital bed and may be furnished by a grandfathered supplier of a hospital bed, if the supplier has elected to be a grandfathered supplier for the hospital bed. However, a special, powered alternating pressure mattress furnished to prevent decubitus ulcers is not an essential part of the base equipment and is furnished in addition to the general service of furnishing the hospital bed.” Assuming the grandfathered supplier for the base equipment is willing to also furnish accessories or supplies for the base equipment, beneficiaries will be able to choose to obtain any competitively bid accessories or supplies from either the grandfathered supplier or a contract supplier. The amount to be paid under the Medicare DMEPOS Competitive Bidding Program will be the single payment amount, regardless of which supplier furnishes the accessories or supplies.

6. No Payment Adjustment to Account for Inflation

Despite its’ proposal to update the competitive bid amounts by the CPI inflation factor in years two and three of the contract, CMS has decided not to update the bid amount each year. Instead, CMS states that suppliers should bill inflation and other factors into their bid rates that will prevail during the entire bid period.

7. Authority to Adjust Payments in Other Areas

Under the law, starting in 2009 CMS has the authority to adjust payment amounts in non-bid areas based upon bid amounts in bid areas. CMS states that a more detailed plan will be developed for using this authority, and that CMS will conduct subsequent rulemaking prior to implementing these provisions. Subsequent rulemaking will provide a more detailed plan for using these authorities.



#### 8. Requirement to Obtain Competitively Bid Items From a Contract Supplier

For so-called “snowbird” beneficiaries that spend a portion of the year away from their primary residence, or are otherwise traveling away from home, they will be allowed to obtain items that they would ordinarily be required to obtain from a contract supplier for their competitive bidding area from a supplier that has not been awarded a contract to furnish items for that area. If the area that the beneficiary is visiting is also a competitive bidding area and the item is subject to the competitive bidding program in that area, he or she will be required to obtain the item from a contract supplier for that area. If the area that the beneficiary is visiting is not a competitive bidding area, or if the area is a competitive bidding area but the item needed by the beneficiary is not included in the competitive bidding program for that area, he or she will be required to obtain the item from a supplier that has a valid Medicare supplier number. In either case, payment to the supplier will be paid based on the bid amount for the item in the competitive bidding area where the beneficiary maintains a permanent residence. DMERC claims jurisdiction would continue to be based upon the beneficiary’s primary residence.

#### 9. Limitation on Beneficiary Liability for Items Furnished by Non Contract Suppliers

In general, if a non-contract supplier located in a competitive bidding area 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. There are some exceptions: first, unless the grandfathering exception applies; second unless the non-contract supplier has obtained a signed ABN because, if the beneficiary desires to receive this item from a supplier that is not a contract supplier, the ABN indicates the beneficiary’s knowledge and understanding that Medicare will not pay for that item. In this circumstance, a non-contract supplier cannot bill the Medicare program and receive payment for a competitively bid item provided to a beneficiary whose primary residence is in a CBA unless an exception discussed in this rule applies.. This rule would not apply if the noncontract supplier furnished items that are not included in the competitive bidding program for the area.

#### 10. Access to New Technology - New HCPCS Codes During Contract Period

If a new technology item or item receives a new HCPCS code during a contract period, that HCPCS code will not be added to the contract suppliers’ items. Instead, any supplier in the bid area will be able to provide that new technology.

#### 11. Payment for Repairs and Replacement of Beneficiary Owned Items

CMS will not require that repairs of beneficiary-owned competitively bid items be performed by contract suppliers. This policy will also apply to maintenance services required by the DRA. CMS will pay for maintenance and servicing of competitively bid items, including replacement parts that may be needed, that are performed by any supplier as long as those repairs are made by suppliers that have a valid Medicare billing number that enables them to



receive payment for covered Medicare services. Payment will generally be made for parts and labor consistent with the methodology CMS currently uses. However, if the part needed to repair the item is itself a competitively bid item for the CBA in which the beneficiary maintains a permanent residence, CMS will pay the supplier the single payment amount for the part because CMS does not believe that the payment amount for the part should be different from what it would otherwise be in the CBA solely because the part is furnished by a supplier that is not a contract supplier.

Consistent with its recent rule implementing the DRA payment provisions, CMS will make general maintenance and servicing payments to suppliers that service oxygen equipment (other than liquid and gaseous equipment) and an additional payment to a supplier that picks up and stores or disposes of beneficiary-owned oxygen tanks or cylinders that are no longer medically necessary.

### C. Competitive Bidding Areas

#### 1. Methodology for MSA Selection for 2007 and 2009 Competitive Bidding Programs (§414.410)

##### a. MSAs for 2007

CMS will identify the 50 largest MSAs in terms of total population in 2005 using population estimates published by the U.S. Census Bureau in its table of large MSAs from the Statistical Abstract of the United States. Second, the 25 MSAs out of the 50 MSAs identified in step one are eliminated from consideration based on CMS' determination that they have the lowest totals of DMEPOS allowed charges for items furnished in calendar year (CY) 2005. Third, CMS scores the MSAs based on combined rankings of DMEPOS allowed charges per fee for service beneficiary and the number of DMEPOS suppliers per number of beneficiaries receiving DMEPOS items (suppliers per beneficiary) in CY 2005, with equal weight (50 percent) being given to each factor. (The number of suppliers is based on suppliers with at least \$10,000 in allowed charges attributed to them for DMEPOS items furnished in the MSA in CY 2005. The number of beneficiaries would be based on the number of beneficiaries receiving DMEPOS items in the MSA in CY 2005.)

CMS is excluding from competitive bidding until 2009 the three largest MSAs in terms of population (New York City, Chicago and Los Angeles), as well as any MSA that is geographically located in an area served by two DMERCs. After gaining experience from the initial 2007 program, CMS plans to implement competitive bidding New York City, Chicago and Los Angeles in 2009. CMS is considering an alternative under which it would establish CBAs (competitive bid areas) that include portions of one or more of these MSAs (for example, by county). Finally, CMS will include at least one competitive bidding area in each DMERC region by first selecting the highest scoring MSA in each DMERC region.



Following is the MSA ranking based upon CY 2004 data: Miami, Houston, Dallas, Riverside-San Bernadino (CA), San Antonio, Los Angeles, Charlotte, Orlando, San Juan, Atlanta, Tampa, Kansas City, Pittsburgh, Virginia Beach, St Louis, San Francisco, Cincinnati, Cleveland, Detroit, Baltimore, Philadelphia, Washington, DC, Chicago, New York, and Boston.

b. MSAs for 2009

CMS will use the same criteria as for the 2007 selection, with the following changes: CMS will score all of the MSAs included in the table of large MSAs in the most recent publication of the U.S. Census Bureau's Statistical Abstract of the United States, and CMS will use the same criteria to score the MSAs as in selecting the MSAs for 2007, but use data from CY 2006.

2. Establishing Competitive Bidding Areas (§414.410)

a. Authority to Exempt Rural Areas and Areas with Low Population Density within Urban Areas (§414.410(c))

CMS will exempt areas from competitive bidding if data for the areas indicate that they are not competitive based on a combination of the following indicators:

- 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 FFS beneficiaries in the area relative to other similar geographic areas.

b. Establishing the Competitive Bidding Areas for 2007 and 2009 (§414.410(b))

CMS believes that the law allows it to extend individual competition areas beyond the MSA boundaries in 2007 or 2009. CMS proposes that an area (for example, a county, parish, zip code, etc.) outside the boundaries of an MSA be considered for inclusion in a competitive bidding area for 2007 and/or 2009 if all of the following apply:

- The area adjoins an MSA in which a competitive bidding program will be operating in 2007 or 2009.
- The area is not part of an MSA in which a competitive bidding program will be operating in 2007 or 2009.
- The area is "competitive"
- The area is part of the normal service area or market for suppliers who also serve the MSA market or areas within the boundaries of an MSA in which a competitive bidding program will be operating in 2007 or 2009.



CMS defines a CBA to be either concurrent with an MSA, larger than an MSA, or smaller than an MSA; CMS will detail in the request for bids the exact boundaries of each CBA.

c. Nationwide or Regional Mail Order Competitive Bidding Program (§414.410(d)(2))

CMS may establish a nationwide or regional competitive bidding program, effective for items furnished on or after January 1, 2010, for the purpose of awarding contracts to suppliers to furnish items across the nation or region to beneficiaries who elect to obtain them through the mail order outlet. The national or regional competitive bidding areas under this program would be phased in after 2009, and payment would be based on the bids submitted and accepted for the furnishing of items through mail order throughout the nation or region. Suppliers that furnish these 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. CMS asks for comments on what items would be good candidates for mail orders.

d. Additional Competitive Bidding Areas After 2009 (§414.410(d))

Beginning in 2010, CMS would designate through program instructions additional competitive bidding areas based on its determination that the implementation of a competitive bidding program in a particular area would be likely to result in significant savings to the Medicare program.

#### **D. Criteria for Item Selection**

CMS has not yet identified which items will be included in competitive bidding. CMS proposes to phase in only those items that it determines are among the highest cost and highest volume items during each phase of the Medicare DMEPOS Competitive Bidding Program. The selected product categories would be described in each RFB – Request for Bids. Suppliers will submit a separate bid for each item under a defined product category, unless specifically excluded in the RFB. CMS proposes to include a “core” set of product categories in each competitive bidding area. CMS may elect to phase in some individual product categories in a limited number of competitive bidding areas in order to test and learn about their suitability for competitive bidding.

CMS is proposing to use a combination of the following variables when making determinations about an item’s potential savings as a result of the application of competitive bidding.

- Annual Medicare DMEPOS Allowed Charges
- Annual Growth in Expenditures
- Number of Suppliers
- Savings in the DMEPOS Demonstrations
- Reports and Studies

Items with high-allowed charges or rapidly increasing allowed charges would be our highest priority in selecting items for competitive bidding.



## DMEPOS – Highest Expenditures (Policy Groups)

- |                                   |                               |
|-----------------------------------|-------------------------------|
| 1. Oxygen Supplies/Equipment      | 11. Nebulizers                |
| 2. Wheelchairs/POVs               | 12. Walkers                   |
| 3. Diabetic Supplies & Equipment  | 13. NPWT Devices              |
| 4. Enteral Nutrition              | 14. Commodes/Bed Pans/Urinals |
| 5. Hospital Beds/Accessories      | 15. Ventilators               |
| 6. CPAP Devices                   | 16. Spinal Orthoses           |
| 7. Support Surfaces               | 17. Upper Limb Orthoses       |
| 8. Infusion Pumps & Related Drugs | 18. Patient Lifts             |
| 9. Respiratory Assist Devices     | 19. Seat Lift Mechanisms      |
| 10. Lower Limb Orthoses           | 20. TENS Devices              |

### **E. Submission of Bids Under the Competitive Bidding Program**

#### 1 & 2. Providers and Physicians (§414.404 and 414.422)

Physicians and treating practitioners may furnish certain types of competitively bid items without submitting a bid and being awarded a contract under this subpart, provided that all of the following conditions are satisfied: (i) The items furnished are limited to crutches, canes, walkers, folding manual wheelchairs, blood glucose monitors, and infusion pumps that are DME. (ii) The items are furnished by the physician or treating practitioner to his or her own patients as part of his or her professional service. (iii) The items are billed under a billing number assigned to the physician, the treating practitioner (if possible), or a group practice to which the physician or treating practitioner has reassigned the right to receive Medicare payment.

#### 3. Product categories for bidding purposes

CMS will conduct bidding for items that are groups into product categories. A “product category” is a “group of similar items used in the treatment of a related medical condition (for example, hospital beds and accessories),” and which CMS will define for purposes of competitive bidding. CMS states that the supplier’s bidding amount should include all costs of providing item, “such as delivery, set-up, training, and proper maintenance for rental items.” Suppliers will be able to submit bids for one, some or all product categories in a bid area.

#### 4. Bidding Requirements

##### a. Inexpensive or other routinely purchased DME items

Bids must be submitted only for the furnishing of new items in this category that are included in a competitive bidding program.



b. DME items requiring frequent and substantial servicing

Bids must be submitted for the monthly rental of items in this payment category with the exception of continuous passive motion exercise devices, bids should be submitted for the daily rental of continuous passive motion exercise devices.

c. Oxygen and oxygen equipment

The 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 that were established in CMS' DRA oxygen payment rule that went into effect January 1, 2007. That is, bidders will submit bids for each of the following equipment categories: (i) Stationary oxygen equipment (including stationary concentrators) and oxygen contents (stationary and portable), (ii) Portable equipment only (gaseous or liquid tanks), (iii) Oxygen generating portable equipment only, (iv) Stationary oxygen contents only, and (v) Portable oxygen contents only.

d. Capped rental items

"Purchase" price bids must 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 will be calculated for each item in this category for the purpose of determining both the single payment amount for the lump sum purchase of a new power wheelchair, and for calculating the single payment amounts for the rental of all items in this category. There will be separate payment for reasonable and necessary maintenance and servicing for beneficiary-owned DME.

When the beneficiary elects to purchase a used power wheelchair the single payment amount for the lump sum purchase of the used power wheelchair would be based on 75 percent of the single payment amount for a new power wheelchair. In the case of all items in this category that are 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 the single payment amount for rental of the item for months 4 through 13 would be based on 7.5 percent of the single payment amount for purchase of the item.

e. Enteral equipment and supplies

Bids must be submitted for the purchase of new items in this category.

f. Maintenance and servicing of enteral infusion pumps

The monthly rental payments for enteral nutrition equipment for months 1 through 3 would be equal to 10 percent of the single payment amounts for the purchase of the new enteral nutrition equipment. For months 4 through 15, the monthly rental payment amounts would be equal to 7.5 percent of the single payment amounts for the purchase of new items. In addition, CMS will 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.

g. Supplies used in conjunction with DME

Bids must 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 will calculate single payment amounts for the furnishing of these items on a purchase basis.

**F. Conditions for Awarding Contracts (§414.414)**

1. Quality Standards and Accreditation

All suppliers will have to meet the CMS quality standards to be eligible to submit claims to the Medicare program, whether or not the supplier is in a competitive bidding area. The quality standards will be applied by recognized independent accreditation organizations designated by CMS. A grace period may 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 will suspend or terminate the supplier contract. The length of time for the grace period will be determined by the accrediting organizations' ability to complete the accrediting process within each competitive bidding area. The length of time of the grace period will be specified in the RFB for each competitive bidding program.

Suppliers that received a valid accreditation before CMS-approved accreditation organizations are designated will be considered to be "grandfathered" if the accreditation was granted by an organization that we designate. These suppliers will not need to be re-accredited until their next regularly scheduled accreditation.

2. Eligibility

The eligibility rules are the current Medicare Supplier Standards, which all bidding suppliers must meet. Bidding suppliers must also be enrolled in the Medicare Program, be in good standing and not under any current Medicare sanctions.

3. Financial Standards

CMS states that as part of the bid selection process, the RFBs will identify the specific information it will require to evaluate suppliers, which may 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.



#### 4. Evaluation of Bids (§414.414(e))

##### a. Market Demand and Supplier Capacity

CMS will first determine the demand based upon the past two years utilization, based upon claims history, plus projections for new beneficiaries and seasonal effects (e.g., snowbirds). CMS will evaluate supplier capacity based upon historical claims submission for product plus data the supplier provides to substantiate its ability to expand (e.g., bank letters for loans).

##### b. Composite Bids

CMS use a composite bid to compare all of the suppliers' bids submitted for an entire product category in a CBA. Using a composite bid is a way to aggregate a supplier's bids for individual items within a product category into a single bid for the whole product category. To compute the composite bid for a product category, CMS will multiply a supplier's bid for each item in a product category by the item's weight and sum these numbers across items. The weight of an item will be based on the utilization of the individual item compared to other items within that product category based on historic Medicare claims. Item weights will be used to reflect the relative market importance of each item in the product category. CMS will select item weights that ensure that the composite bid is directly comparable to the costs that Medicare will pay if it bought the expected bundle of items in the product category from the supplier. The sum of each supplier's weighted bids for every item in a product category will become the supplier's composite bid for that product category.

##### c. Determine the Pivotal Bid

The pivotal bid is the point where the expected combined capacity of the bidders is sufficient to meet the expected demands of beneficiaries for items in a product category.

##### d. Assurance of Savings

The statute prohibits CMS from awarding contracts to any entity unless the total amounts to be paid to contractors in a competitive bidding area are expected to be less than the total amounts that would otherwise be paid. CMS interprets this requirement to mean that contracts will not be awarded to any entity unless the amounts to be paid to contract suppliers in a competitive bidding area are expected to be less for a competitively bid item than would have otherwise been paid. Therefore, CMS will not accept any bid for an item that is higher than the current fee schedule amount for that item. This approach requires that single payment amounts for each item in a product category be equal to or less than the current fee schedule amount for that item.



e. Assurance of Multiple Contractors

The statute requires CMS to award have multiple suppliers as winning bidders in an area. CMS interprets this to mean at least two suppliers for each product category included in the bid program. In the final rule, CMS states that it will select at least 5 winning suppliers for each product category in a CBA. If there are not 5 qualified suppliers, then it will award the contract to two suppliers.

f. Selection of New Suppliers After Bidding

In situations where CMS determines that there is an unmet demand for items, for example, if CMS terminates a contract supplier's contract, CMS will contact the remaining contract suppliers for that product category to determine if they could absorb the unmet demand. If the remaining contract suppliers could not absorb the unmet demand in a timely manner, CMS would then refer to the list of suppliers that submitted bids for that product category in that round of competitive bidding in that competitive bidding area, use the list of composite bids that CMS arrayed from lowest to highest, and proceed to the next supplier on the list. CMS will contact that supplier to determine if it would be interested in becoming a contract supplier. If the supplier were interested, CMS will require the supplier to provide updated information to ensure its continued eligibility for participation. A condition for acceptance of a contract will be that the supplier must agree to accept the already determined single payment amounts for the individual items within the product category in the competitive bidding area. CMS will continue to go down the list until it was satisfied that the expected demand will be met and beneficiary access to the items in the product category will not be a problem

**G. Determining Single Payment Amounts for Individual Items (§414.416)**

1. Setting Single payment amounts for Individual Items

CMS is adopting the following principles to determine the single payment amounts for individual items in a product category:

Principle 1: Bid amounts from all winning bids for an item in a CBA will be used to set the single payment amount for that item in the CBA.

Principle 2: CMS 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 the current fee schedule amounts for individual items within a product category.



CMS will 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. The individual items will be identified by the appropriate HCPCS codes. The median of the bids submitted by the contract suppliers for a particular item will be the single payment amount that CMS will establish under the competitive bidding program for the HCPCS code that describes that item. In cases where there is an even number of winning bidders for an item, CMS will employ the average (mean) of the two bid prices in the middle of the array to set the single payment amount.

## 2. Rebate Program

CMS abandoned this proposal in the final rule.

## **H. Terms of Contracts (§414.422)**

The statute requires CMS to recompete contracts at least every 3 years; CMS states that it proposes to specify the length of each contract in the Request for Bids.

### 1. Terms and Conditions of Contracts

CMS states that the competitive bidding contracts will contain, at a minimum, provisions relating to the following:

- Covered product categories and covered beneficiaries, operating policies.
- Subcontracting rules.
- Cooperation with us and our agents.
- Potential onsite inspections.
- Minimum length of participation.
- Terms of contract suspension or termination.
- CMS discretion not to proceed if it finds that the Medicare program will not realize significant savings as a result of the program.
- Compliance with changes in Federal laws and regulations during the course of the agreement.
- Non-discrimination against beneficiaries in a competitive bidding area (so that all beneficiaries inside and outside of a competitive bidding area receive the same products that the contract supplier would provide to other customers).
- Supplier enrollment and quality standards.
- The single payment amounts for covered items.

CMS explains that the specific information to be collected from suppliers will be detailed in the RFB. CMS will be requesting information such as: the supplier's identifying information; information regarding the items that the supplier would



furnish if awarded a contract; financial information; and corporate integrity information.

2. Nondiscrimination provision

CMS will include in each contract it enter into with a supplier under the Medicare DMEPOS competitive bidding program a non-discrimination provision.

3. Furnishing of Items

A contract supplier must agree to furnish the items included in its contract to all beneficiaries who maintain a permanent residence or who visit the competitive bidding area and request those items from the contract supplier.

4. Furnishing Items to Beneficiaries Whose Permanent Residence is Within a CBA

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. The 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. The contract supplier must agree to give the beneficiary or his or her caregiver the choice of either renting or purchasing the item and must furnish the item on a rental or purchase basis as directed by the beneficiary or the beneficiary's caregiver. Suppliers must factor the cost of furnishing these items on both a rental and purchase basis into their bid submissions.

5. Furnishing Items to Beneficiaries Whose Permanent Residence is Outside a CBA

In order to obtain medically necessary DMEPOS or other equipment, a beneficiary whose permanent residence is located outside of a CBA must use a contract supplier to obtain all items subject to competitive bidding in the competitive bidding area that he or she visits.

6. Change in Ownership (§414.422(d))

If a contract supplier is considering or negotiating a change in ownership, the contract supplier must notify CMS 60 days before the anticipated effective date of the change. If the supplier that acquires or merges with the contract supplier wishes to itself become a contract supplier, it must meet all of CMS' requirements, including compliance with applicable quality standards, accreditation, eligibility standards, and financial standards, and must submit certain required documentation. The new supplier that seeks to become a contract supplier must also submit a novation agreement to CMS 30 days prior to the anticipated effective change of ownership, indicating that it will assume all duties and obligations of the previous contract supplier. These provisions are intended to provide CMS with assurance that the successor entity meets all of CMS'



requirements before CMS can consider it to be eligible to assume the previous contract supplier's contract.

7. Suspension or Termination of a Contract (§414.422(f))

If CMS concludes that the contract supplier has breached its contract, the actions CMS might take include, but are not limited to, asking the contract supplier to correct the breach condition, suspending the contract, terminating the contract for default (that may include reprocurement costs), precluding the supplier from participating in the competitive bidding program, or availing itself of other remedies permitted by law. CMS will provide further guidance regarding the appeal procedures available to contract suppliers for termination actions, as well as other enforcement actions involving contract supplier contracts, at a future date. Finally, CMS states that it recognizes the hardships may arise for contract suppliers and CMS will take this into consideration as we decide what appropriate actions should be taken in the event of a breach.

**I. Administrative or Judicial Review (§414.424)**

The statute provided that there would be no administrative or judicial review related to:

- Establishment of payment amounts under a competitive bidding program;
- Awarding of contracts under a competitive bidding program;
- Designation of competitive bidding areas for the Medicare DMEPOS Competitive Bidding Program;
- Phased-in implementation of the Medicare DMEPOS Competitive Bidding Program;
- Selection of items for a competitive bidding program.

CMS made no changes to the proposed rule, it states that this rule has no impact on current beneficiary or supplier right to appeal denied claims, however, neither the beneficiary nor the supplier would be able to bring such an appeal if a competitively bid item was furnished in a competitive bidding area in a manner not authorized by this rule.

CMS states that it intends to conduct an extensive education and outreach program to ensure that suppliers are educated about the rules and provisions for the program. In addition, CMS is developing a quality assurance system to ensure that bids submitted to us are correctly identified and recorded. CMS intends to allow bidders to submit electronic bids. Bidders will have an opportunity to review their bids and certify their accuracy prior to submission. Bidders will be able to modify or change their bids at any time during the bidding window. In addition, the CBIC will have in place an auditing system and quality assurance program to monitor and ensure that it accurately records and calculates the information furnished by suppliers.



## **J. Opportunity for Participation by Small Suppliers - New Definition of Small Business and 30 Percent “Set Asides”**

Information available to CMS on the size distribution of businesses that provide DMEPOS indicates that the majority of suppliers in the DMEPOS industry qualify as small businesses according to the SBA definitions. CMS’ analysis of DMEPOS claims data suggests that at least 90 percent of DMEPOS suppliers had Medicare allowed charges of less than \$1 million in CY 2003. The figure of \$1 million could be an underestimate of total receipts because it does not include non-Medicare receipts and non-DMEPOS receipts, but it does suggest that most DMEPOS suppliers are small.

To ensure the participation of multiple suppliers and storefront locations, beneficiary access, and increased participation by small suppliers, CMS has revised its rules as follows:

- The definition of a “small supplier” is a supplier that generates gross revenue of \$3.5 million or less in annual receipts.
- To help small suppliers to have an opportunity to participate in the Medicare DMEPOS Competitive Bidding Program and to generally support HHS' goals for contracting with small businesses, CMS has also established a target number for DMEPOS small supplier participation in each competitive bidding program. CMS’ target number for small supplier participation will be determined by multiplying 30 percent times the number of suppliers that have met CMS’ bidding requirements and whose composite bids are at or lower than the pivotal bid for each product category in each CBA. The number resulting from this multiplication represents CMS’ goal for small supplier participation for that product category. CMS will then count to see if the number of suppliers whose composite bids are at or below the pivotal bid is equal or greater than the target number we have computed for that product category. If the number of suppliers is lower than the target number, CMS will give the small supplier whose composite bid is above the pivotal bid, but closest to it of all the small suppliers whose composite bids are above the pivotal bid for the product category, the option of accepting a contract to furnish the product category at the single payment amounts. If the target number is still not met, CMS will offer a contract to the small supplier whose composite bid is the next closest to, but above, the pivotal bid, and will use this methodology until CMS reaches the target number or there are no additional small suppliers that submitted a bid for the product category.

## **K. Opportunity for Networks (§414.418)**

Small suppliers have the option to form networks for bidding purposes. Networks are several companies joining together via some type of legal contractual relationship to submit bids for a product category under competitive bidding. CMS believes this option would allow suppliers to band together to lower bidding costs, expand service options, or attain more favorable purchasing terms. CMS is limiting network participation to small suppliers which, as explained previously, will now be defined as suppliers that generate gross revenue of \$3.5 million or less in annual receipts.



If suppliers do decide to form networks, the following rules must be met:

- A legal entity must be formed for the purpose of competitive bidding, such as a joint venture, limited partnership, or contractor/subcontractor relationship, which would act as the applicant and submit the bid.
- All legal contracts must be in place and signed before the network entity can submit a bid
- Each member of the network must be independently eligible to bid.
- Each member must meet any accreditation and quality standards that are required.
- The network cannot be anti-competitive. The network members' market shares for competitive bid item(s) when added together, cannot exceed 20 percent of the Medicare market within a competitive bidding area, at the time of bidding.
- A supplier may only join one network and cannot submit individual bids if part of a network. The network must identify itself as a network and identify all members in the network.
- Each network member will be responsible for billing Medicare and receiving payment.
- In response to comments voicing concern that the network formation process could implicate the Federal antitrust laws, CMS will now require that each network member sign a statement in the bid submitted by the network certifying that the supplier joined the network because it is unable to 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.
- The size of each network will be limited to 20 suppliers because with 20 suppliers, each network member would generally be responsible for furnishing items to no more than 5 percent of the geographic area of the CBA.

#### **L. Education and Outreach**

CMS has established the following web site where RFBs and other pertinent program information will be posted and we plan to alert the supplier community by email of all postings on this web site.

[https://www.cms.hhs.gov/competitiveacqfordmepos/01\\_overview.asp](https://www.cms.hhs.gov/competitiveacqfordmepos/01_overview.asp)

In addition, we will be providing education and outreach to suppliers on requirements for submitting RFBs. Suppliers must fully complete the RFB in order to be considered for participation in a competitive bidding program. The RFBs will require suppliers to complete, at a minimum, such documents as an application, bidding sheet, bank and financial information, and referral source references.

CMS will establish an administrative process to ensure that all information that the supplier submitted is accurately captured and considered in the bid evaluation process. This process will ensure that all the information submitted by each supplier is included as part of the bid evaluation process.



#### **M. Monitoring and Complaint Services for the Competitive Bidding Program**

CMS made no changes to the proposed rule. CMS will establish a formal complaint monitoring system to address complaints in each competitive bidding area. Beneficiaries, referral agents, providers, and suppliers, including physicians, hospitals, nurses, and home health agencies, will be able to report problems or difficulties that they encounter regarding the ordering and furnishing of DMEPOS in a competitive bidding area.

#### **N. Physician Authorization/Treating Practitioner and Consideration of Clinical Efficiency and Value of Items in Determining Categories for Bids (§414.420)**

The statute authorizes CMS to establish a process for certain items under which a physician may prescribe a particular brand or mode of delivery of an item within a particular HCPCS code if the physician determines that use of the particular item would avoid an adverse medical outcome on the individual. The physician or treating practitioner would determine that a particular item would avoid an adverse medical outcome, and that the physician or treating practitioner would have discretion to specify a particular product brand or mode of delivery. When a physician or other treating practitioner requests a specific item, brand, or mode of delivery, contract suppliers will be required to furnish that item or mode of delivery, assist the beneficiary in finding another contract supplier in the CBA that can provide that item, or consult with the physician or treating practitioner to find a suitable alternative product or mode of delivery for the beneficiary. If, after consulting with the contract supplier, the physician or treating practitioner is willing to revise his or her order, that decision must be reflected in a revised written prescription. However, if the contract supplier decides to provide an item that does not match the written prescription from the physician or treating practitioner, the contract supplier should not bill Medicare as this would be considered a non-covered item. For the Medicare DMEPOS Competitive Bidding Program, CMS is clarifying the process that contract suppliers must follow to address the situation where a physician or treating practitioner orders a specific brand or mode of delivery to avoid an adverse medical outcome. If a physician or treating practitioner prescribes a brand name item or specific mode of delivery to avoid an adverse medical outcome, the contract supplier must make a reasonable effort to furnish that brand name item or mode of delivery. If the contract supplier cannot furnish that brand name item or mode of delivery, it must contact the physician or treating practitioner to determine if a substitution can be made (and if so, the contract supplier must obtain a revised written prescription). If a substitution cannot be made, the contract supplier must assist the beneficiary in finding another contract supplier that can furnish the brand name item or mode of delivery prescribed by the physician or treating practitioner.



**Additional Information - From Final Rule -**

**Regulatory Impact Analysis**

“We estimate that 28,960 suppliers will provide competitive bid items in the CBAs that we initially designate. If suppliers furnish products in more than one MSA, we counted them more than once because they are affected in more than one MSA. Not all products are subject to competitive bidding; therefore, we estimate that 68 percent of suppliers will furnish products subject to competitive bidding and will be affected by competitive bidding during the initial round of competitive bidding. This means in CY 2007, the remaining 32 percent of suppliers in the 10 selected CBAs will not be affected by competitive bidding because they do not furnish products subject to competitive bidding. However, the actual percentage of affected suppliers may be smaller if we do not select all eligible product categories for competitive bidding.

**Number of Small Suppliers<sup>1</sup>  
(\$3.5 Million or Less in Medicare Allowed Charges)**

<b>Bidding Year</b>	<b>Number of Affected Small Suppliers</b>	<b>Total Number of Affected Suppliers</b>	<b>Percent</b>
2007	16,762	19,720	85%
2008	90,500	106,470	85%
2009	97,031	114,154	85%
2010	103,562	121,838	85%
2011	103,562	121,838	85%
2012	103,562	121,838	85%

<sup>1</sup>Some suppliers furnish products in more than one selected MSA. Consequently, some suppliers may be counted more than once.

**Assumptions:**

The first round of bidding will occur in CY 2007, with prices taking effect in April 2008, and the second round of bidding will occur in CY 2008, with prices taking effect in April 2009. CMS also assumes re-bidding will only occur every 3 years.

**Implementation Costs:**

We will incur initial startup costs. CMS estimates internal costs and costs to its contractors to be approximately \$1 million in immediate fixed calendar year costs for contractor startup and system changes for the initial competitive bidding phase in CY 2007. Many of the variable costs associated with bid solicitation and evaluation will ultimately depend on how many suppliers choose to participate in competitive bidding. Because of this uncertainty, we are not able to estimate bid solicitation and evaluation costs at this time.

According to the DMEPOS evaluation report, it took about 9.4 hours during the demonstration to evaluate each bid and the supplier to ensure that only quality suppliers were selected.



### **Program Savings:**

In our estimates, we have taken into account that some DMEPOS prices have been adjusted downward since CY 2000. We assume that if prices for an individual item have already been reduced by 10 percent after the demonstrations were completed, prices would most likely fall 10 percent rather than 20 percent. Therefore, we found that the median pricing rule would have produced fees that were approximately 5 percentage points lower than those produced by the demonstration method, assuming that the median pricing rule would not have affected the number of winning bidders who signed contracts or the suppliers' bidding strategies. We have incorporated the effects of the median pricing rule into our estimates of savings from the program. We assumed a 25 percent savings in the estimate because of the median pricing methodology. We netted out any statutory reductions in prices that have already occurred, such as the CY 2005 reductions in oxygen supplies and equipment. These numbers also reflect the reductions in Medicare payments that resulted from the DRA provisions on capped rental DME and oxygen payment, as well as the wheelchair recoding initiative recently undertaken by CMS.

The impact analysis builds in the statutory reimbursement cuts into the baseline DME spending. For instance, the DRA section 5101 is estimated to yield \$880 million savings over 5 years (2008 through 2012). The FEHBP reductions are built into the baseline DME spending and yielded a 5 year savings (2008 through 2012) of \$2,180 million. We believe that the demonstrations are an appropriate gauge for estimating projected savings. We also believe that the competitive bidding financial standards and the DMEPOS quality standards we have issued will result in more efficiently operating DMEPOS suppliers.

### **CMS on Affected Suppliers**

We estimate that 28,960 suppliers will provide DMEPOS items in the CBAs that we initially designate.... we estimate that 68 percent of suppliers will furnish products subject to competitive bidding and will be affected by competitive bidding during the initial round of competitive bidding. We assumed that 90 percent of suppliers that furnish items that we choose to include in the program would submit a bid. We assumed the remaining 10 percent of suppliers would not bid based on the low level of the Medicare revenue received for the items subject to competitive bidding or because they had not received the necessary accreditation.

There will be 15,973 suppliers who will submit a bid because they will want the opportunity to continue to provide these products to Medicare beneficiaries and to expand their business base. We also assume, based on the results of the demonstration, that at least 60 percent of bidding suppliers will be selected as winners in at least one product category. This assumption is slightly different than our assumption in the proposed rule, where we stated, "We also assume, based on the results of the demonstration, that 50 percent of bidding suppliers will be selected as winners because approximately 50 percent of those who submitted bids during the demonstration were selected as contract suppliers." The 50 percent in the proposed rule was based on the demonstration experience within individual product categories; approximately 50 percent of the bidders who submitted a bid in a product category were selected as a winner in that product category. Overall during the demonstration, about 60 percent of suppliers who submitted bids in



any categories were selected as winners in at least one product category. We believe the 60 percent figure represents a more accurate assessment of the probability that a bidding supplier will be selected as a winning bidder in at least one product category. The bidding DMEPOS suppliers that are not awarded a contract because they did not submit a winning bid would represent about 22 percent of the total DMEPOS suppliers in these CBAs. We expect that losing bidders will be distributed roughly proportionately across the selected CBAs, but the exact distribution will depend on the distribution of bids received and the number of winners selected in each CBA. We also note that if a supplier submitted a bid in multiple product categories, its probability of becoming a contract supplier would increase.