DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 411 and 414

[CMS–1270–F]

RIN 0938–AN14

Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This final rule establishes competitive bidding programs for certain Medicare Part B covered items of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) throughout the United States in accordance with sections 1847(a) and (b) of the Social Security Act. These competitive bidding programs, which will be phased in over several years, utilize bids submitted by DMEPOS suppliers to establish applicable payment amounts under Medicare Part B.

DATES: *Effective Date:* This final rule is effective on June 11, 2007.

FOR FURTHER INFORMATION, CONTACT: Lorrie Ballantine, (410) 786–7543, Ralph Goldberg, (410) 786–4870, Karen Jacobs, (410) 786–2173, Michael Keane, (410) 786–4495, Alexis Meholic, (410) 786–5395, Linda Smith, (410) 786–5650.

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Alphabetical Listing of Acronyms Appearing in This Final Rule

ABN Advance Beneficiary Notice
BBA Balanced Budget Act of 1997, Pub. L. 105–33
BESS [Medicare] Part B Extract and Summary System
CBA Competitive bidding area
CBIC Competitive bidding implementation contractor
CBSA Core-based statistical area
CMS Centers for Medicare & Medicaid Services
CPI–U Consumer Price Index—All Urban Consumers
CPT [Physician] Current Procedural Terminology, Fourth Edition, 2007, copyrighted by the American Medical Association. CPT® is a trademark of the American Medical Association
CY Calendar year
DME Durable medical equipment
DME MAC Durable Medical Equipment Medicare Administrative Contractor
DMEPOS Durable medical equipment, prosthetics, orthotics, and supplies
DMERC Durable medical equipment regional carrier
DRA Deficit Reduction Act of 2005, Pub. L. 109–171
FAR Federal Acquisition Regulation
FEHB Federal Employees Health Benefits Program
FFS Fee-for-service
FTE Full-time equivalent
GAO Government Accountability Office
HCPCS Healthcare Common Procedure Coding System
HHA Home health agency
HHS Department of Health and Human Services
HIPAA Health Insurance Portability and Accountability Act of 1996, Pub. L. 104–191
IIC Inflation indexed charge
IRF Inpatient rehabilitation facility
MMA Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. 108–173
MSA Metropolitan Statistical Area
NAICS North American Industry Classification System
NF Nursing facility
NPWT Negative pressure wound therapy
NSC National Supplier Clearinghouse
OBRA '87 Omnibus Budget Reconciliation Act of 1987, Pub. L. 100–203
OIG Office of the Inspector General, HHS
OTS Off-the-shelf
PAOC Program Advisory and Oversight Committee
PEN Parenteral and enteral nutrition
POV Power-operated vehicle
RFB Request for bids
SADMERC Statistical Analysis Durable Medical Equipment Regional Carrier
SBA Small Business Administration
SGD Speech generating device
SNF Skilled nursing facility
TENS Transcutaneous electrical nerve stimulator

To assist readers in referencing sections contained in this document, we are providing the following table of contents:

Table of Contents

I. Provisions of the May 1, 2006 Proposed Rule
A. Summary of the Proposed Rule
B. Public Comments Received
II. Issuance of Final Rules
A. Issuance of the FY 2007 IRF Final Rule Which Finalized Certain Provisions Relating to Competitive Acquisition for DMEPOS and the Accreditation of DMEPOS Suppliers
B. Future Issuance of a Final Rule on Certain Other Provisions Addressed in the May 1, 2006 Proposed Rule
III. Payment for DMEPOS Under Medicare Part B: Background
A. Payment for DMEPOS on the Basis of Reasonable Charges
B. Payment for DMEPOS Under Fee Schedules
C. Use of the Healthcare Common Procedure Coding System (HCPCS)
IV. Medicare Competitive Bidding Demonstrations
V. Discussion of the Provisions of This Final Rule
VI. Medicare DMEPOS Competitive Bidding Program
A. Legislative Authority and Program Advisory and Oversight Committee
l. Legislative Authority
2. Program Advisory and Oversight Committee
B. Purpose and Definitions (§§ 414.400 and 414.402)
C. Competitive Bidding Implementation Contractors (CBICs) (§§ 414.406(a) and (e))
D. Payment Under the Medicare DMEPOS Competitive Bidding Program
1. Payment Basis (§§ 414.408(a), (c), and (d))
2. General Payment Rules
3. Special Rules for Certain Rented Items of DME and Oxygen (Grandfathering of Suppliers) (§ 414.408(j))
a. Process for Grandfathering Suppliers
b. Payment Amounts to Grandfathered Suppliers
(1) Grandfathering of Suppliers Furnishing Items Prior to the First Competitive Bidding Program in a CBA
(2) Suppliers That Lose Their Contract Status in a Subsequent Competitive Bidding Program
c. Payment for Accessories for Items Subject to Grandfathering
4. Payment Adjustments
a. Adjustment to Account for Inflation (§ 414.408(b))
b. Adjustments to Single Payment Amounts to Reflect Changes to the HCPCS (§ 414.426)
5. Authority to Adjust Payments in Other Areas
6. Requirement to Obtain Competitively Bid Items From a Contract Supplier (§ 414.408(e))
7. Limitation on Beneficiary Liability for Items Furnished by Noncontract Suppliers (§§ 414.408(e)(2)(iv) and (e)(3))
8. Payment for Repair and Replacement of Beneficiary-Owned Items (§ 414.408(l))
E. Competitive Bidding Areas (§§ 414.406 and 414.410)
1. Background
2. Methodology for MSA Selection for CYs 2007 and 2009 Competitive Bidding Programs (§§ 414.410(a) and (b))

a. MSAs for CY 2007
b. MSAs for CY 2009
3. Establishing Competitive Bidding Areas and Exemption of Rural Areas and Areas With Low Population Density Within Urban Areas (§ 414.410(c))
4. Establishing Competitive Bidding Areas for CYs 2007 and 2009 (§§ 414.406(b) and (c))
5. Nationwide or Regional Mail Order Competitive Bidding Program (§§ 414.410(d)(2) and 414.412(f) and (g))
6. Additional Competitive Bidding Areas After CY 2009 (§ 414.410(e))
F. Criteria for Item Selection (§§ 414.402 and 414.406(d)(1))
G. Submission of Bids for Competitively Bid DMEPOS (§§ 414.404, 414.408, 414.412. and 412.422)
1. Furnishing of Items (§§ 414.412(c) and 414.422(e))
a. Furnishing of Items to Medicare Beneficiaries Who Maintain a Permanent Residence in a CBA
b. Furnishing of Items to Medicare Beneficiaries Whose Permanent Residence Is Outside a CBA
2. Requirement for Providers to Submit Bids (§§ 414.404(a)(2) and 414.422(e)(2))
3. Physicians and Certain Nonphysician Practitioners (§§ 414.404(a) and (b))
4. Product Categories for Bidding Purposes (§§ 414.402 and 414.412(b) Through (e))
5. Bidding for Specific Types of Items and Associated Payment Rules (§§ 414.408(f) Through (j))
a. Inexpensive or Other Routinely Purchased DME Items (§§ 414.408(f) and (h)(6))
b. DME Items Requiring Frequent and Substantial Servicing (§ 414.408(h)(7))
c. Oxygen and Oxygen Equipment (§§ 414.408(i) and (j))
d. Capped Rental Items (§ 414.408(h))
e. Enteral Nutrients, Equipment, and Supplies (§§ 414.408(f), (g)(2), and (h))
f. Maintenance and Servicing of Enteral Nutrition Equipment (§§ 414.408(h)(5) and (i)(5))
g. Supplies Used in Conjunction With DME (§ 414.408(g)(1))
h. Off-the-Shelf Orthotics (§ 414.408(g)(4))
VII. Conditions for Awarding Contracts for Competitive Bids
A. Quality Standards and Accreditation
B. Eligibility (§ 414.414(b))
C. Financial Standards (§ 414.414(d))
D. Evaluation of Bids (§ 414.414(e))
1. Market Demand and Supplier Capacity (§§ 414.414(e)(1) and (e)(2))
2. Composite Bids (§§ 414.414(e)(3) and (e)(4))
3. Determining the Pivotal Bid (§§ 414.414(e)(5) and (e)(6))
4. Assurance of Savings (§ 414.414(f))
5. Assurance of Multiple Contractors (§ 414.414(h))
6. Selection of New Suppliers After Bidding (§ 414.414(i))
VIII. Determining Single Payment Amounts for Individual Items
A. Setting Single Payment Amounts for Individual Items (§§ 414.416(a) and (b))
B. Rebate Program
IX. Terms of Contracts
A. Terms and Conditions of Contracts (§§ 414.422(a) Through (c))
B. Change in Ownership (§ 414.422(d))
C. Suspension or Termination of a Contract (§§ 414.422(f) and (g))
X. Administrative or Judicial Review of Determinations Made Under the Medicare DMEPOS Competitive Bidding Program (§ 414.424)
XI. Opportunity for Participation by Small Suppliers (§ 414.414(g))
XII. Opportunity for Networks (§ 414.418)
XIII. Education and Outreach for Suppliers and Beneficiaries
XIV. Monitoring and Complaint Services for the Medicare DMEPOS Competitive Bidding Program
XV. Physician or Treating Practitioner Authorization and Consideration of Clinical Efficiency and Value of Items in Determining Categories for Bids (§ 414.420)
XVI. Other Public Comments Received on the May 1, 2006 Proposed Rule
XVII. Collection of Information Requirements
XVIII. Regulatory Impact Analysis
A. Overall Impact
1. Executive Order 12866
2. Regulatory Flexibility Act (RFA)
3. Small Rural Hospitals
4. Unfunded Mandates
5. Federalism
B. Regulatory Flexibility Analysis
1. Summary
2. The Need for and Objective of the Final Rule
3. Comments Regarding Small Suppliers
a. Comments on Small Supplier Focus Groups
b. Comments on the Definition of Small Supplier
c. Comments on the Protections for Small Suppliers
d. Comments on Bidding Requirements for Physician and Other Providers
e. Comments on Bidding by Product Category
f. Comments on Financial Standards
g. Comments on Supplier Networks
4. Description and Estimate of the Number of Small Entities
5. Projected Reporting, Recordkeeping, and Other Compliance Requirements
6. Agency Efforts to Minimize the Significant Impact on Small Entities
C. Anticipated Effects
D. Implementation Costs
E. Program Savings
F. Effect on Beneficiaries
G. Effect on Suppliers
1. Affected Suppliers
2. Small Suppliers
H. Accounting Statement
I. Executive Order 12866
Regulation Text

I. Provisions of the May 1, 2006 Proposed Rule

A. Summary of the Proposed Rule

On May 1, 2006, we published in the **Federal Register** (71 FR 25654) a proposed rule to—

- Establish and implement competitive bidding programs for certain covered items of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) under sections 1847(a) and (b) of the Social Security Act (the Act), as amended by section 302(b)(1) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), Pub. L. 108–173.
- Implement requirements for independent accreditation organizations that will be applying quality standards to all DMEPOS suppliers as required by section 1834(a)(20) of the Act. (We note that, as explained later under section VII. of this final rule, we have finalized certain provisions of the May 1, 2006 proposed rule relating to accreditation in the DMEPOS provisions of a final rule entitled ''Inpatient Rehabilitation Facility Prospective Payment System for Federal FY 2007; Provisions Concerning Competitive Acquisition for Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS); Accreditation of DMEPOS Suppliers,'' which appeared in the **Federal Register** on August 18, 2006 (71 FR 48354) and is referred to throughout this final rule as the ''FY 2007 IRF final rule.'')
- Establish a new fee schedule for home dialysis supplies and equipment that continue to be paid on a reasonable charge basis. (We note that we will respond to comments on this proposal in a future final rule.)
- Establish a revised methodology for calculating fee schedule amounts for new DMEPOS items. (We note that we will respond to comments on this proposal in a future final rule.)
- Codify in our regulations that the statutorily imposed eyeglass coverage exclusion under Medicare Part B encompasses all devices that use lenses to aid vision or provide magnification of images for impaired vision. (We note that we will respond to comments on this proposal in a future final rule.)
- Codify in regulations that the Medicare fee schedule amount for therapeutic shoes, inserts, and shoe modifications are established in accordance with the methodology specified in sections 1833(o) and 1834(h) of the Act. (We note that we will respond to comments on this proposal in a future final rule.)

B. Public Comments Received

We received approximately 2,129 timely pieces of correspondence in response to the May 1, 2006 proposed rule. Except where indicated in section II.B. of this final rule, this final rule discusses the provisions of the May 1, 2006 proposed rule, summarizes the public comments received on each subject area, sets out our responses to those comments, and sets forth our final rules.

II. Issuance of Final Rules

A. Issuance of the FY 2007 IRF Final Rule Which Finalized Certain Provisions Relating to Competitive Acquisition for DMEPOS and the Accreditation of DMEPOS Suppliers

To ensure timely implementation of the Medicare DMEPOS Competitive Bidding Program, we responded to comments submitted on certain provisions of the May 1, 2006 proposed rule and finalized our proposals concerning the designation of competitive bidding implementation contractors (CBICs), competitive bidding education and outreach, and the accreditation of DMEPOS suppliers in the DMEPOS provisions of the FY 2007 IRF final rule (71 FR 48354). We also discussed in that final rule certain issues relating to the establishment of quality standards for DMEPOS suppliers that will be applied by independent accreditation organizations.

B. Future Issuance of a Final Rule on Certain Other Provisions Addressed in the May 1, 2006 Proposed Rule

We will respond to comments submitted on certain provisions of the May 1, 2006 proposed rule and finalize our proposals concerning the following provisions in a separate final rule that will be published at a later date in the **Federal Register:** (1) Establishment of a new fee schedule for home dialysis supplies and equipment that continue to be paid on a reasonable charge basis; (2) establishment of a revised methodology for calculating fee schedule amounts for new DMEPOS items; (3) codification in our regulations that the scope of the eyeglass coverage exclusion under Medicare Part B encompasses all devices that use lenses to aid vision or provide magnification of images for impaired vision; and (4) codification in our regulations that the Medicare fee schedule amounts for therapeutic shoes, inserts, and shoe modifications are established in accordance with the methodology specified in sections 1833(o) and 1834(h) of the Act.

III. Payment for DMEPOS Under Medicare Part B: Background

A. Payment for DMEPOS on the Basis of Reasonable Charges

Payment for most DMEPOS items, including supplies and equipment, furnished under Medicare Part B is made through contractors known as Durable Medical Equipment Medicare Administrative Contractors (DME MACs) (previously Durable Medical Equipment Regional Carriers (DMERCs), also known as Medicare carriers). Before January 1, 1989, payment for most of these items was made on a reasonable charge basis by Medicare carriers. Section 1842(b) of the Act sets forth the methodology for determining reasonable charges. Implementing regulations for section 1842(b) of the Act are located at 42 CFR Part 405, Subpart E.

Reasonable charge determinations are generally based on customary and prevailing charges derived from historic charge data, with the ''reasonable charge'' for an item being the lowest of the following factors:

- The supplier's actual charge for the item.
- The supplier's customary charge for the item.
- The prevailing charge in the locality for the item. The prevailing charge may not exceed the 75th percentile of the customary charges of suppliers in the locality.
- The inflation indexed charge (IIC). The IIC is defined in § 405.509(a) of the Medicare regulations as the lowest of the fee screens used to determine reasonable charges for services, including supplies, and equipment paid on a reasonable charge basis (excluding physicians' services), that is in effect on December 31 of the previous fee screen year, updated by the inflation adjustment factor. The inflation adjustment factor is based on the current change in the Consumer Price Index for All Urban Consumers (CPI–U), as compiled by the Bureau of Labor Statistics, for the 12-month period ending June 30 each year.

B. Payment for DMEPOS Under Fee Schedules

Section 1834 of the Act, as added by section 4062 of the Omnibus Budget Reconciliation Act of 1987 (OBRA '87), Public Law 100–203, provides for implementation of a fee schedule payment methodology for most durable medical equipment (DME), prosthetic devices, and orthotic devices furnished after January 1, 1989. Specifically, sections 1834(a)(1)(A) and (B) and 1834(h)(1)(A) of the Act provide that Medicare payment for these items is equal to 80 percent of the lesser of the actual charge for the item or the fee schedule amount for the item. We implemented this payment methodology at 42 CFR Part 414, Subpart D of our regulations. Sections 1834(a)(2) through (a)(5) and section 1834(a)(7) of the Act, and implementing regulations at § 414.200 through § 414.232 (with the exception of § 414.228), set forth separate payment categories of DME and describe how the fee schedule for each of the following categories is established:

- Inexpensive or other routinely purchased items (section 1834(a)(2) of the Act and § 414.220 of the regulations);
- Items requiring frequent and substantial servicing (section 1834(a)(3) of the Act and § 414.222 of the regulations);
- Customized items (section 1834(a)(4) of the Act and § 414.224 of the regulations);
- Oxygen and oxygen equipment (section 1834(a)(5) of the Act and § 414.226 of the regulations);
- Other items of DME (section 1834(a)(7) of the Act and § 414.229 of the regulations).

Each category has its own unique payment rules. With the exception of customized items, a fee schedule amount is calculated for each item or category of DME that is identified by a code in the Healthcare Common Procedure Coding System (HCPCS). The HCPCS is discussed in section III.C. of this final rule. The Medicare payment amount for a customized item of DME is based on the Medicare carrier's individual consideration of that item. The fee schedule amounts for oxygen and oxygen equipment are monthly payment amounts. Payment under the DME benefit is made for supplies necessary for the effective use of DME (for example, lancets used with blood glucose monitors). These supplies are paid for using the same methodology that we use to pay for the purchase of inexpensive or routinely purchased items.

The fee schedule amounts for DME are generally adjusted annually by the change in the CPI–U for the 12-month period ending June 30 of the preceding year. The fee schedule amounts are also generally limited by a ceiling (upper limit) and floor (lower limit) equal to 100 percent and 85 percent, respectively, of the median of the Statewide fee schedule amounts.

Since 1994, Medicare has paid for most surgical dressings in accordance with section 1834(i) of the Act and § 414.220(g) of the regulations, using the same methodology as is used for payment of purchased inexpensive or routinely purchased DME.

Under section 1834(h) of the Act and § 414.228 of the regulations, payment for prosthetic and orthotic devices is made on a lump sum basis and is equal to the lower of the fee schedule amount calculated for the item or the actual charge for the item, less any unmet deductible amount. The fee schedule amounts are calculated using a weighted average of Medicare payments made in the States in each of 10 CMS regions from July 1, 1986, through June 30,

1987, adjusted annually by the change in the CPI–U for the 12-month period ending June 30 of the preceding year. The regional fee schedule amounts are limited by a ceiling (upper limit) and floor (lower limit) equal to 120 percent and 90 percent, respectively, of the average of the regional fee schedule amounts for each State.

As authorized under section 1842(s) of the Act and 42 CFR Part 414, Subpart C of our regulations, Medicare pays for parenteral and enteral nutrition (PEN) nutrients, equipment, and supplies on the basis of 80 percent of the lesser of the actual charge for the item or the fee schedule amount for the item (§ 414.102(a)). The fee schedule amounts for PEN items are calculated on a nationwide basis and are the lesser of the reasonable charges for CY 1995 or the reasonable charges that would have been used in determining payment for these items in CY 2002 under the former reasonable charge payment methodology (§ 414.104(b)). The fee schedule amounts are generally adjusted annually by the percentage increase in the CPI–U for the 12-month period ending with June 30 of the preceding year (§ 414.102(c)). Under § 414.104(a), payment for PEN nutrients and supplies is made on a purchase basis, and payment for PEN equipment that is rented is made on a monthly basis. (We note that we proposed to revise § 414.1 in the May 1, 2006 proposed rule to specify that fee schedules were established for PEN items in accordance with our authority under section 1842(s) of Act. We will address this proposal in a final rule that will be published later in the **Federal Register**.)

Section 1833(o)(2) of the Act, as amended by section 627 of the MMA, requires implementation of fee schedule amounts, effective January 1, 2005, for the purpose of determining payment for custom molded shoes, extra-depth shoes, and inserts (collectively, ''therapeutic shoes''). We stated in the May 1, 2006 proposed rule that we believe this section of the MMA is largely self-implementing because it mandates use of the methodology set forth in section 1834(h) of the Act for prosthetic and orthotic devices in determining the fee schedule amounts for therapeutic shoes. We implemented the methodology for payment for prosthetic and orthotic devices in regulations at 42 CFR Part 414, Subpart D, and section 627 of the MMA provides that the same methodology shall apply to therapeutic shoes. We implemented section 627 of the MMA through program instructions, and on January 1, 2005, Medicare began paying for therapeutic shoes based on fee schedule amounts determined in accordance with section 1834(h) of the Act and Part 414, Subpart D of our regulations.

Section 5101(a) of the Deficit Reduction Act of 2005 (DRA), Public Law 109–171, amended section 1834(a)(7)(A) of the Act to change the way Medicare pays for capped rental items. As a result, section 1834(a)(7)(A)(i)(I) of the Act now states that payment for a capped rental item may not extend over a period of continuous use (as determined by the Secretary) of longer than 13 months, and section 1834(a)(7)(A)(i)(II) of the Act sets forth how the 13 monthly rental payment amounts are to be determined. In addition, section 1834(a)(7)(A)(ii) of the Act now provides that on the first day that begins after the 13th continuous month during which payment is made for a capped rental item, the supplier of the capped rental item must transfer title to the item to the Medicare beneficiary. Once the title has transferred, or once a purchase agreement for a power wheelchair has been entered into in accordance with section 1834(a)(7)(A)(iii) of the Act as amended, section 1834(a)(7)(A)(iv) of the Act provides that reasonable and necessary maintenance and servicing payments (for parts and labor not covered by the supplier's or the manufacturer's warranty, as determined by the Secretary to be appropriate for the particular item) will be made. These statutory changes apply only to capped rental items whose first rental month occurs on or after January 1, 2006. We implemented section 5101(a) of the DRA in a final rule, CMS–1304–F: Home Health Prospective Payment System Rate Update for Calendar Year 2007 and Deficit Reduction Act of 2005; Changes to Medicare Payment for Oxygen Equipment and Capped Rental Durable Medical Equipment, that was published in the **Federal Register** on November 9, 2006 (71 FR 65884).

Section 5101(b) of the DRA amended section 1834(a)(5) of the Act to limit monthly rental payments for oxygen equipment to a 36-month period of continuous use (as determined by the Secretary). On the first day that begins after the 36th continuous month during which payment is made for the oxygen equipment, new section 1834(a)(5)(F)(ii)(I) of the Act provides that the supplier must transfer title to the equipment to the Medicare beneficiary. Section 1834(a)(5)(F)(ii)(II)(aa) of the Act provides that Medicare will continue to make monthly payments for oxygen contents for beneficiary-owned oxygen equipment in the amounts recognized under section 1834(a)(9) of the Act for the period of medical need. However, under section 1834(a)(5)(F)(ii)(II)(bb) of the Act, maintenance and servicing payments for beneficiary-owned oxygen equipment (for parts and labor not covered by the supplier's or manufacturer's warranty) will be made only if they are reasonable and necessary. These statutory changes went into effect on January 1, 2006. For beneficiaries receiving Medicare-covered oxygen equipment as of December 31, 2005, the 36-month rental period began on January 1, 2006. We implemented section 5101(b) of the DRA in a final rule, entitled CMS–1304–F Home Health Prospective Payment System Rate Update for Calendar Year 2007 and Deficit Reduction Act of 2005; Changes to Medicare Payment for Oxygen Equipment and Capped Rental Durable Medical Equipment, that was published in the **Federal Register** on November 9, 2006 (71 FR 65884).

C. Use of the Healthcare Common Procedure Coding System (HCPCS)

The Healthcare Common Procedure Coding System (HCPCS) is a standardized coding system used to process claims submitted to Medicare, Medicaid, and other health insurance programs by providers, physicians, and other suppliers. The HCPCS code set is divided into the following two principal subsystems, referred to as Level I and Level II of the HCPCS:

- Level I of the HCPCS codes is comprised of Current Procedural Terminology (CPT) codes, which are copyrighted by the American Medical Association. CPT codes are a uniform coding system consisting of descriptive terms and identifying codes that are used primarily to identify medical services and procedures furnished by physicians and other health care professionals which are billed to public or private health insurance programs. CPT codes are developed, published, and maintained by the American Medical Association. CPT codes do not include codes needed to separately report medical items that are regularly billed by suppliers other than physicians.
- Level II of the HCPCS codes is a standardized coding system used primarily to identify products and supplies that are not included in the CPT codes, such as DMEPOS when used outside a physician's office.
- HCPCS Level II codes classify like items by category for the purpose of efficient claims processing. Assignment of a HCPCS code is not a coverage determination, and does not imply that any payer will cover the items in the code category. For some DMEPOS items,

such as wheelchairs and wheelchair cushions, minimum performance standards must be met before an item can be classified under a HCPCS code. In October 2003, the Secretary delegated authority under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) to CMS to maintain and distribute the HCPCS Level II codes. In the May 1, 2006 proposed rule, we proposed that the HCPCS Level II codes would be used to describe the DME, orthotic, and enteral nutrients, equipment, and supplies furnished under the Medicare DMEPOS Competitive Bidding Program, both for the purpose of requesting bids and for establishing payment amounts.

IV. Medicare Competitive Bidding Demonstrations

Prior to enactment of the MMA, section 4319 of the Balanced Budget Act of 1997 (BBA), Pub. L. 105–33, authorized implementation of up to five demonstration projects of competitive bidding for Medicare Part B items, except physician services. In accordance with section 4319 of the BBA, we planned and implemented the DMEPOS Competitive Bidding Demonstration to test the feasibility and program impacts of using competitive bidding to set prices for DMEPOS. The demonstration was implemented at two sites: Polk County, Florida, and in the San Antonio, Texas, Metropolitan Statistical Area (MSA). The competitive bidding demonstrations, authorized under the BBA, were implemented successfully in both demonstration sites from 1999 to 2002, resulted in a substantial savings to the program, and offered beneficiaries sufficient access and quality products.

At the first site, Polk County, Florida, we conducted the first of two rounds of bidding in 1999. Five categories of DMEPOS were put up for bidding: oxygen equipment and supplies (required by statute); hospital beds and accessories; enteral nutrition formulas and equipment; urological supplies; and surgical dressings. A total of 16 contract suppliers began providing demonstration products in Polk County on October 1, 1999, and continued for 2 years. The second and final round of bidding in Polk County was conducted in 2001 for the same product categories minus enteral nutrition. (Enteral nutrition was dropped to retain only product categories that are overwhelmingly used in private homes.) The second set of competitively bid payment amounts took effect in October 2001. As in round one, 16 suppliers were selected, of whom half had participated as winners previously. The new fee schedules developed from the bids in each round replaced the Statewide Medicare DMEPOS fees. The second round of the demonstration in Polk County ended in September 2002.

Texas was the second site for the demonstration. In Bexar, Comal, and Guadalupe counties in the San Antonio MSA, we conducted bidding in 2000 for five kinds of DMEPOS: oxygen equipment and supplies; hospital beds and accessories; wheelchairs and accessories; general orthotics; and nebulizer drugs. Fifty-one suppliers were selected and began serving Medicare beneficiaries under the new fees in February 2001. The San Antonio site ended operations in December 2002, the statutorily required termination date in the BBA.

In each area of evaluation, the data indicated mostly favorable results for the Medicare program. The demonstration led to lower Medicare fees for almost every item in almost every product category in each round of bidding. Fee reductions varied by product category and item, resulting in a nearly 20 percent overall savings at each site. Statistical and qualitative data indicate that beneficiary access and quality of services were essentially unchanged.

The DMEPOS Competitive Bidding Demonstration offered valuable information for understanding the impacts of competitive bidding for Medicare services. This information is especially important now because section 302(b) of the MMA mandates a larger role for competitive bidding within the Medicare program by requiring the Secretary to implement competitive bidding programs for the furnishing of certain DME and associated supplies, enteral nutrition and associated supplies, and off-the-shelf (OTS) orthotics. In addition, section 303(d) of the MMA required the Secretary to implement a competitive bidding program for certain Medicare Part B drugs not paid on a cost or prospective payment system basis, and section 302(b) of the MMA requires that competitive bidding demonstration projects be implemented for clinical laboratory services and managed care.

V. Discussion of the Provisions of This Final Rule

In this final rule we are adding new sections to 42 CFR Part 414, Subpart F that implement rules relating to the Medicare DMEPOS Competitive Bidding Program. A discussion of the specific provisions of the proposed rule, a summary of the public comments we received and our responses to those comments are presented in sections VI. through XVII. of this final rule. We present a regulatory impact analysis of the provisions of this final rule in section XVIII. of this final rule. The regulation text appears at the end of this final rule.

VI. Medicare DMEPOS Competitive Bidding Program

A. Legislative Authority and Program Advisory and Oversight Committee

1. Legislative Authority

Section 302(b)(1) of the MMA (Pub. L. 108–173) amended section 1847 of the Act to require the Secretary to establish and implement programs under which competitive bidding areas (CBAs) are established throughout the United States for contract award purposes for the furnishing of certain competitively priced items for which payment is made under Medicare Part B (the ''Medicare DMEPOS Competitive Bidding Program''). Section 1847(a)(2) of the Act provides that the items and services to which competitive bidding applies are certain durable medical equipment (DME) and medical supplies, which are covered items (as defined in section 1834(a)(13) of the Act) for which payment would otherwise be made under section 1834(a) of the Act, including items used in infusion and drugs, (other than inhalation drugs) and supplies used in conjunction with DME, but excluding class III devices under the Federal Food, Drug and Cosmetic Act; enteral nutrients, equipment and supplies (as described in section 1842(s)(2)(D) of the Act); and OTS orthotics (as described in section 1861(s)(9) of the Act) for which payment would otherwise be made under section 1834(h) of the Act and which require minimal self-adjustment. In addition, sections 1847(a) and (b) of the Act specify certain requirements and conditions for implementation of the Medicare DMEPOS Competitive Bidding Program.

Competitive bidding provides a way to harness marketplace dynamics to create incentives for suppliers to provide quality items in an efficient manner and at a reasonable cost to the program. In our view, the Medicare DMEPOS Competitive Bidding Program has five main objectives:

- To implement competitive bidding programs for certain DMEPOS items.
- To assure beneficiary access to quality DMEPOS as a result of the program.
- To reduce the amount Medicare pays for DMEPOS and create a payment structure under competitive bidding that is more reflective of a competitive market.

• To limit the financial burden on beneficiaries by reducing their out-of-pocket expenses for DMEPOS they obtain through the program.

• To contract with suppliers that conduct business in a manner that is beneficial for the program and for Medicare beneficiaries.

As discussed in section IV. of this final rule, the Medicare DMEPOS competitive bidding demonstration projects that were conducted prior to the enactment of the MMA offered valuable information for understanding the impacts of competitive bidding for Medicare services. This information, in part, led to the adoption of section 302(b) of the MMA, which requires that the Secretary implement competitive bidding programs for the furnishing of certain DMEPOS under the Medicare program.

2. Program Advisory and Oversight Committee

Section 1847(c) of the Act, as amended by section 302(b)(1) of the MMA, required the Secretary to establish a Program Advisory and Oversight Committee (PAOC) to provide advice to the Secretary with respect to the following functions:

• The implementation of the Medicare DMEPOS Competitive Bidding Program.

• The establishment of financial standards for entities seeking contracts under the Medicare DMEPOS Competitive Bidding Program, taking into account the needs of small providers.

• The establishment of requirements for collection of data for the efficient management of the Medicare DMEPOS Competitive Bidding Program.

• The development of proposals for efficient interaction among manufacturers, providers of services, suppliers (as defined in section 1861(d) of the Act), and individuals.

• The establishment of quality standards for DMEPOS suppliers under section 1834(a)(20) of the Act.

In addition, section 1847(c)(3)(B) of the Act authorizes the PAOC to perform such additional functions to assist the Secretary in carrying out the Medicare DMEPOS Competitive Bidding Program as the Secretary may specify.

As authorized under section 1847(c)(2) of the Act, the PAOC members were appointed by the Secretary and represent a broad mix of relevant industry, consumer, and government parties. Specifically, the membership roster includes two beneficiary/consumer representatives, four manufacturer representatives, five supplier representatives, three certification/standards representatives, six Federal and State program representatives, one physician, and one pharmacist. The representatives have expertise in a variety of subject matter areas, including DMEPOS, competitive bidding methodologies and processes, and rural and urban marketplace dynamics.

We held the first PAOC meeting, which was announced in a **Federal Register** notice (69 FR 31125), at the CMS Headquarters on October 6, 2004. We held the second meeting on December 6 and 7, 2004. We have held two additional PAOC meetings in 2005 and 2006 during which we, along with our contractor, RTI International, presented material to both the PAOC and the public relating to the provisions that are outlined in the proposed rule and in this final rule. The topics that we presented included—

• Medicare's timeline for implementation of the Medicare DMEPOS Competitive Bidding Program;

• Results of the Medicare competitive bidding demonstration projects authorized by section 4319 of the BBA;

• Structure of the Medicare DMEPOS Competitive Bidding Program;

• Existing non-Medicare competitive bidding programs for DMEPOS;

• Program design options for the Medicare DMEPOS Competitive Bidding Program;

• Criteria for selecting Metropolitan Statistical Areas (MSAs) in which competition under the Medicare DMEPOS Competitive Bidding Program will occur in both CYs 2007 and 2009;

• Criteria for selecting items for competitive bidding;

• Bidding process overview;

• Methodology for setting single payment amounts for competitively bid items;

• Capacity of DMEPOS suppliers and beneficiary utilization of DMEPOS;

• Financial capabilities of bidding suppliers;

• Exception authority under section 1847(a)(3) of the Act for rural areas and areas with low population density within urban areas that are not competitive; and

• Quality standards and accreditation procedures applicable to DMEPOS suppliers.

In addition to the PAOC meetings, we have designed and implemented a CMS Web site at *http://cms.hhs.gov/CompetitiveAcqforDMEPOS/PAOCMI/list.asp* specifically for the public to have access to all PAOC presentations, minutes, and updates for the Medicare DMEPOS Competitive Bidding Program. In accordance with section 1847(c)(5) of the Act, the PAOC will continue to operate until December 31, 2009. Future PAOC meeting dates, as well as other information pertinent to the Medicare DMEPOS Competitive Bidding Program, can be found on the CMS Web site.

B. Purpose and Definitions (§§ 414.400 and 414.402)

In the May 1, 2006 proposed rule, we proposed in § 414.400 to state that the purpose of 42 CFR Part 414, Subpart F would be to implement the Medicare DMEPOS Competitive Bidding Program for certain DMEPOS items as required by sections 1847(a) and (b) of the Act.

As set forth in proposed § 414.402, we proposed to define certain frequently occurring terms that would be used in competitive bidding. Specifically, we proposed to define the following terms:

Bid means an offer to furnish an item for a particular price and time period that includes, where appropriate, any services that are directly related to the furnishing of the item.

Competitive bidding area (CBA) means an area established by the Secretary under this subpart [42 CFR Part 414, Subpart F]. (We note that the definition language included in the preamble of the proposed rule was inconsistent with the definition language in the proposed regulation text, which was correct.)

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.

Competitive bidding program means a program established under this subpart [42 CFR Part 414, Subpart F]. (We note that the definition language included in the preamble of the proposed rule was inconsistent with the definition language in the proposed regulation text, which was correct.)

Contract supplier means an entity that is awarded a contract by CMS to furnish items under a competitive bidding program.

DMEPOS stands for durable medical equipment, prosthetics, orthotics and supplies.

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 under this subpart [42 CFR Part 414, Subpart F]:

(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.

(4) A capped rental item described in § 414.229.

Grandfathered supplier means a noncontract supplier that furnishes a grandfathered item.

Item means one of the following products identified by a HCPCS code, other than class III devices under the Federal Food, Drug and Cosmetic Act and inhalation drugs, and includes the services directly related to the furnishing of that product to the beneficiary:

(1) Durable medical equipment (DME), as defined in § 414.202 and further classified into the following categories:

(i) Inexpensive or routinely purchased items, as specified in § 414.220(a);

(ii) Items requiring frequent and substantial servicing, as specified in § 414.222(a);

(iii) Oxygen and oxygen equipment, as specified in § 414.226(b).

(iv) Other DME (capped rental items), as specified in § 414.229.

(2) Supplies necessary for the effective use of DME.

(3) Enteral nutrients, equipment, and supplies.

(4) Off-the-shelf orthotics, which are orthotics described in section 1861(s)(9) of the Act that require minimal self-adjustment for appropriate use and do not require expertise in trimming, bending, molding, assembling, or customizing to fit a beneficiary.

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.

Metropolitan Statistical Area (MSA) has the same meaning as that given by the Office of Management and Budget.

Nationwide competitive bidding area means a competitive bidding area that includes the United States and its territories.

Noncontract supplier means a supplier that is located in a competitive bidding area or that furnishes items through the mail to beneficiaries in a competitive bidding area but that is not awarded a contract by CMS to furnish items included in a competitive bidding program for that area.

Physician has the same meaning as in section 1861(r)(1) of the Act.

Pivotal bid means the highest composite bid based on bids submitted by a suppliers for a product category that will include 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 included in a competitive bidding program.

Single payment amount means the allowed payment for an item furnished under a competitive bidding program.

Supplier means an entity with a valid Medicare supplier number, including an entity that furnishes an item through the mail.

Treating practitioner means a physician assistant, nurse practitioner, or clinical nurse specialist, as those terms are defined in section 1861(aa)(5) of the Act.

Weighted bid means the item weight multiplied by the bid price submitted for that item.

Comment: Several commenters supported the definitions of ''bid'' and ''item'' because these definitions acknowledge that services are involved in the delivery of products to Medicare beneficiaries. One commenter suggested that Medicare competitively bid class III devices, which appear to be excluded under the proposed definition of ''item.''

Response: We appreciate the commenters' support. Section 1847(a)(2)(A) of the Act specifically excludes class III devices under the Federal Food, Drug, and Cosmetic Act from the Medicare DMEPOS Competitive Bidding Program. Therefore, we do not have the authority to conduct competitive bidding for these items. We are clarifying in the definition of ''item'' that the DME excludes class III devices under the Federal Food, Drug and Cosmetic Act as defined in § 414.402 and that inhalation drugs are not included in the term ''supplies necessary for the effective use of DME.'' We are also revising the regulatory cross-reference for ''oxygen and oxygen equipment.''

We agree with the commenters that the definition of an item should acknowledge what is included in an item for which bids are being submitted. Therefore, in this final rule, we are revising the definition of ''item'' to indicate that although we will always identify the product by its HCPCS code, we may combine several codes to form one competitively bid item or specify a particular method by which the item is furnished. For example, if we were to include diabetic test strips in a mail-order competitive bidding program, we would identify the item by its HCPCS code and indicate that the product is to be furnished only by mail. We are making this change because we need to be able to modify HCPCS codes or combine HCPCS codes to identify the items for which we will be conducting competitive bidding because HCPCS codes, by themselves, do not always fully define the items for which we wish to solicit competitive bids. We further discuss this revision in section VI.B. of this final rule. Therefore, in this final rule, we have revised the definition of ''item'' to specify that an item for purposes of competitive bidding may be comprised of two or more products identified by different HCPCS codes and/or modifiers and that these codes may be defined based on how a product is furnished (for example, by mail).

Comment: One commenter stated that the definitions for the ''composite bid'' and the ''single payment amount'' for the individual items should include all the costs associated with training the beneficiary and properly putting equipment in place to ensure the safe administration of a piece of DMEPOS in a beneficiary's home.

Response: We are not changing the definitions of ''composite bid'' and ''single payment amount'' because these definitions are based upon the bids, which, by definition, include any services that are directly related to the furnishing of the item to the beneficiary. In addition, to the extent that the service component is included in the definitions of ''bid'' and ''item,'' the ''composite bid'' and the ''single payment amount'' calculated for each item would reflect the costs of services associated with furnishing that item to a beneficiary.

Comment: Several commenters suggested that the proposed definition of ''noncontract supplier'' does not address suppliers that are physically located outside of a CBA, yet provide services to beneficiaries whose permanent address is inside a CBA. One commenter suggested that the definition read: ''A supplier that furnishes items to beneficiaries in a competitive bidding area, but that is not awarded a contract by Medicare to furnish items included in the competitive bidding program for that area.''

Response: Our proposed definition of the term ''noncontract supplier'' only included suppliers located in a CBA or that mailed items to beneficiaries in a CBA. However, we recognize the commenter's concerns that this definition would not capture suppliers that are located outside the CBA but that furnish items to beneficiaries who maintain a permanent residence in a CBA. Therefore, we are revising the definition of the term ''noncontract supplier'' in this final rule to mean: ''a supplier that is not awarded a contract by CMS to furnish items included in a competitive bidding program.''

Comment: Many commenters suggested that the definition of ''physician'' be expanded to allow podiatrists, optometrists and dentists to prescribe a particular brand or mode of

delivery of DMEPOS, along with physician assistants, nurse practitioners, and clinical nurse specialists. The commenters asserted that this expansion would allow a variety of qualified practitioners, in addition to physicians, to prescribe particular brands or modes of delivery where appropriate. The commenters requested that the definition of physician be changed from that specified in section 1861(r)(1) of the Act to that specified in section 1861(r) of the Act.

Response: We agree with the commenters and are revising the definition of ''physician'' applicable in this final rule to have the same meaning as in section 1861(r) of the Act. We believe that this revision is consistent with the intent of the 1847(a)(5)(A) as it reflects which professionals would be ordering Medicare-covered items under the Medicare DMEPOS Competitive Bidding Program. In addition, we are finalizing the definition that we had proposed that a treating practitioner means a physician assistant, nurse practitioner, or clinical nurse specialist, as defined in section 1861(aa)(5) of the Act. In ordering DMEPOS under the Medicare program, these treating practitioners can specify a particular brand or mode of delivery for an item, which would be paid at the single payment amount.

After consideration of the public comments received, we are finalizing proposed § 414.400 with only a technical change to the heading of the section (changing the heading from ''Basis'' to ''Purpose and Basis''). In addition, we are revising the definitions of ''item,'' ''noncontract supplier,'' and ''physician'' in § 414.402 as discussed above. We are also revising the definitions of several other terms in § 414.402, as well as adding new definitions. Below we state the revised and new definitions and indicate where a full discussion of each change can be found in this final rule:

- Revising the regulatory reference to the oxygen payment classes in the definition of ''item'' so that the definition now references § 414.226(c)(1) instead of § 414.225(b). We discuss this revision in section VI.G.6 of this final rule.
- Revising the definition of ''item weight'' by removing the phrase ''in a competitive bidding area'' and adding the phrase ''using national data'' in referencing the beneficiary utilization rate. We discuss this revision in section VI.D.2. (Evaluation of Bids) of this final rule.
- Adding a definition of ''mail order contract supplier'' to mean a contract supplier that furnishes items through the mail to beneficiaries who maintain a permanent residence in a competitive bidding area.'' This new definition is discussed in section V.I.E.5. of this final rule.
- Adding a definition of ''minimal self-adjustment'' to mean ''an adjustment that the beneficiary, caretaker for the beneficiary, or supplier of the device can perform and does not require the services of a certified orthotist (that is, an individual certified by either the American Board for Certification in Orthotics and Prosthetics, Inc., or the Board for Orthotist/Prosthetist Certification) or an individual who has specialized training. This new definition is discussed in section VI.F. of this final rule.
- Adding a definition of ''nationwide mail order contract supplier'' to mean a mail order contract supplier that furnishes items in a nationwide competitive bidding area, and a definition of ''regional mail order contract supplier'' to mean 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, as discussed in section VI.E.5. of this final rule.
- Adding a definition of ''network'' to mean 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. This change is discussed in section XII. of this final rule.
- Revising the definition of ''pivotal bid'' to mean 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.'' We consider this revision to be a clarification that the pivotal bid is the lowest composite bid in terms of the bid amounts submitted by the suppliers rather than the highest composite bid that includes sufficient number of suppliers to meet demand, as discussed in section VII.D.3. of this final rule.
- Revising the definition of ''product category'' to mean ''a grouping of related items that are used to treat a similar medical condition'', as discussed in section VI.G.5. of this final rule.
- Adding a definition of ''regional competitive bidding area ''to mean'' a CBA that consists of a region of the United States, its Territories, and/or the District of Columbia''as discussed in section VI.E.5. of this final rule.
- Adding a definition of ''small supplier'' to mean the ''a supplier that generates gross revenue of $3.5 million or less in annual receipts including Medicare and non-Medicare revenue,'' as discussed in section XII. of this final rule.

We are also making the following technical changes to proposed § 414.402:

- Revising the definition of ''competitive bidding program'' to clarify that such a program established under 42 CFR Part 414, Subpart F occurs ''within a designated CBA.''
- Clarifying the introductory language of the definition of ''grandfathered item'' to read: ''any one of the following items for which payment is made on a rental basis prior to the implementation of a competitive bidding program and for which payment is made after implementation of a competitive bidding program to a grandfathered supplier that continues to furnish items in accordance with § 414.408(j).''
- Revising the definition of ''grandfathered supplier'' to mean a noncontract supplier ''that chooses to continue to furnish grandfathered items to a beneficiary in a CBA.''
- Revising the definition of a ''nationwide competitive bidding area'' to mean a CBA that includes the United States, its Territories, and the District of Columbia.''

We are finalizing all of the other definitions in proposed § 414.402 without modification.

C. Competitive Bidding Implementation Contractors (CBICs) (§§ 414.406(a) and (e))

Section 1847(b)(9) of the Act provides that the Secretary may contract with appropriate entities to implement the Medicare DMEPOS Competitive Bidding Program. Section 1847(a)(1)(C) of the Act also authorizes the Secretary to waive such provisions of the Federal Acquisition Regulation (FAR) as are necessary for the efficient implementation of this section, other than provisions relating to confidentiality of information and such other provisions as the Secretary determines appropriate.

In the May 1, 2006 proposed rule (71 FR 25661), we proposed to designate one or more competitive bidding implementation contractors (CBICs) for the purpose of implementing the Medicare DMEPOS Competitive Bidding Program (proposed § 414.406(a)). We also stated that we envisioned the program would have six primary functions, including overall oversight and decision making, operation design functions (including the design of both bidding and outreach material templates, as well as program processes), bidding and evaluation,

access and quality monitoring, outreach and education, and claims processing.

As we stated earlier, under the DMEPOS provisions of the FY 2007 IRF final rule (71 FR 48354), we addressed the public comments we received on the proposed provisions relating to implementation contractors under the Medicare DMEPOS Competitive Bidding Program and finalized regulations at § 414.406(a), which allows us to designate one or more CBICs for the purpose of implementing the program, and at § 414.406(e), which codifies our proposal to have the regional carrier (now referred to as a Durable Medical Equipment Medicare Administrative Contractor, or DME MAC) that would otherwise be processing claims for a particular geographic region also process claims for items furnished under a competitive bidding program in the same geographic region. In the same final rule, we also finalized our policy regarding the elements of performance that will be included in a contract we enter into with a CBIC.

D. Payment under the Medicare DMEPOS Competitive Bidding Program

1. Payment Basis (§§ 414.408(a), (c), and (d))

Section 1847(b)(5) of the Act mandates that a single payment amount be established for each item in each CBA based on the bids submitted and accepted for that item. Medicare payment for the item is then made on an assignment-related basis equal to 80 percent of the applicable single payment amount, less any unmet Part B deductible described in section 1833(b) of the Act. Section 1847(a)(6) of the Act requires that this payment basis be substituted for the payment basis otherwise applied under section 1834(a) of the Act for DME, section 1834(h) of the Act for OTS orthotics, or section 1842(s) of the Act for enteral nutrients, equipment, and supplies, as appropriate.

As discussed in detail in section II.C. of the May 1, 2006 proposed rule (71 FR 25662), we proposed that payment to the contract supplier would be based on the single payment amount for the item in the CBA where the beneficiary maintains a permanent residence (proposed § 414.408(a)(1)). If an item that is included in a competitive bidding program is furnished to a beneficiary who does not maintain a permanent residence in a CBA, 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 (proposed § 414.408(a)(2)). We also proposed that implementation of a competitive bidding program would not preclude the use of an advanced beneficiary notice (ABN) to allow beneficiaries to make informed consumer choices regarding whether to obtain items for which Medicare might not make payment (proposed § 414.408(d)). Finally, as required under section 1847(b)(5)(C) of the Act, we proposed in § 414.408(c) that payment for an item furnished under a competitive bidding program would be made on an assignment-related basis.

Comment: Several commenters stated that basing payment amounts on the CBA where the beneficiary maintains a permanent residence, and not on the location where the item is furnished, may cause suppliers to be paid less than the single payment amount in their area. They recommended that CMS allow payment to be made at the payment amount for the area where the item is furnished. The commenters pointed out that it will also be difficult for contract suppliers to determine what the single payment amount is for beneficiaries who reside outside their CBA.

Response: Medicare currently pays for all DMEPOS items based on the payment amount applicable for the primary residence of the beneficiary, regardless of where the item is furnished. The Medicare payment system is set up to base payment amounts on the beneficiary's primary residence. We proposed to adopt this longstanding rule for the Medicare DMEPOS Competitive Bidding Program because it is an effective way to ensure that suppliers do not organize their businesses to obtain higher payment amounts that apply to certain geographic areas of the country. We do not believe it will be difficult for contract suppliers to determine how much they will be paid for an item furnished to a beneficiary who does not reside in the contract supplier's CBA because we will make the single payment amounts for each item in each CBA, along with the fee schedule amounts that will continue to be paid in areas that are not CBAs, publicly available to all suppliers.

Comment: Several commenters suggested that CMS not conduct competitive bidding, but simply lower the payment amounts for DMEPOS until the only suppliers left to provide these items are the minimum number necessary to furnish items needed by Medicare beneficiaries.

Response: Section 302(b) of the MMA mandated that the Secretary establish and implement competitive bidding programs for certain items of DMEPOS, and we have a legal obligation to comply with this legislative mandate.

After consideration of the public comments we received, we are finalizing, without substantive revisions, proposed § 414.408(a) that governs the payment basis under the Medicare DMEPOS Competitive Bidding Program. We did not receive comments on proposed §§ 414.408(c) and (d) and are finalizing those sections. We have made an editorial revision to § 414.408, using the acronym CBA instead of the terms ''area'' or ''competitive bidding area.''

2. General Payment Rules

Section 1834(a) of the Act and implementing regulations at 42 CFR § 414.200 through § 414.232 (with the exception of § 414.228) set forth the Medicare Part B payment methodology we currently use to pay for the rental or purchase of new and used DME. Each item of DME that is paid for under these sections is classified into a payment category, and each category has its own unique payment rules. Section 1842(s) of the Act provides authority for establishing a statewide or areawide fee schedule to be used for the payment of items described in section 1842(s)(2) of the Act. Under this authority, we implemented fee schedules for payment for the purchase and rental of enteral nutrients, equipment, and supplies (§ 414.100 through § 414.104). Section 1834(h) of the Act and § 414.228 of our regulations set forth the Medicare Part B payment methodology we currently use to pay for orthotics and prosthetics.

Other than the rules governing calculation of the single payment amount and other modifications to existing rules that are addressed in this final rule, we proposed that the current requirements regarding the rental or purchase of DMEPOS items would continue to apply under the Medicare DMEPOS Competitive Bidding Program. While we believe that we have discretion under section 1847(a)(6) of the Act to adopt new rules that would govern these requirements, we proposed only to change the payment basis for these items and to make a few modifications to existing rules.

3. Special Rules for Certain Rented Items of DME and Oxygen (Grandfathering of Suppliers) (§ 414.408(j))

a. Process for Grandfathering Suppliers

Section 1847(a)(4) of the Act requires that in the case of covered DME items for which payment is made on a rental basis under section 1834(a) of the Act, and in the case of oxygen for which

payment is made under section 1834(a)(5) of the Act, the Secretary shall establish a ''grandfathering'' process by which rental agreements for those covered items and supply arrangements with oxygen suppliers entered into before the start of a competitive bidding program may be continued. DME paid on a rental basis under section 1834(a) of the Act includes inexpensive or routinely purchased items furnished on a rental basis (as described in § 414.220 of the regulations), items requiring frequent and substantial servicing (as described in § 414.222 of the regulations), and capped rental items (as described in § 414.229 of the regulations). Section 1834(a)(5) of the Act and § 414.226 of our regulations provide that payment be made on the basis of monthly payment amounts for oxygen and oxygen equipment (other than portable oxygen equipment) with separate add-on payments for portable oxygen equipment. In cases where the beneficiary owns stationary and/or portable gaseous or liquid oxygen equipment, payment is made on the basis of monthly payment amounts for oxygen contents.

In the May 1, 2006 proposed rule (71 FR 25662), in proposed § 414.408(k) (redesignated as § 414.408(j) in this final rule), we proposed to establish the grandfathering process described below for rented DME and oxygen and oxygen equipment when these items are included under the Medicare DMEPOS Competitive Bidding Program. We proposed that this process would apply only to suppliers that began furnishing the items described above to Medicare beneficiaries who maintain a permanent residence in an area prior to the implementation of the competitive bidding program in that area that includes the same items.

In the case of the specific items identified in this section, we proposed in § 414.408(k)(4) to give Medicare beneficiaries the choice of deciding whether they would like to continue receiving the item from the grandfathered supplier or a contract supplier, unless the grandfathered supplier is not willing to continue furnishing the item under the terms we have specified below. If the grandfathered supplier is not willing to continue furnishing the item under these terms, a contract supplier would assume responsibility for continuing to furnish the item and be paid based on the single payment amount determined for that item under the Medicare DMEPOS Competitive Bidding Program. In addition, the beneficiary could elect, at any time, to transition to a contract supplier and the contract supplier would be required to accept the beneficiary as a customer. Suppliers that 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.

Comment: One commenter supported our grandfathering proposal. The commenter stated that our proposal would allow some beneficiaries to maintain an established relationship with a current supplier and that this was important to minimize disruption for beneficiaries.

Response: We appreciate the comment and agree that minimizing disruption of service for beneficiaries is an important principle that underlies our grandfathering rules.

b. Payment Amounts to Grandfathered Suppliers

(1) Grandfathering of Suppliers Furnishing Items Prior to the First Competitive Bidding Program in a CBA

For items requiring frequent and substantial servicing, as well as oxygen and oxygen equipment, we proposed that a grandfathered supplier may continue furnishing these items to beneficiaries in accordance with existing rental agreements or supply arrangements. However, we proposed that, as long as the items remain medically necessary, the grandfathered supplier would be paid the single payment amounts determined for those items under the competitive bidding program because beneficiaries rent these items for extended time periods (proposed §§ 414.408(k)(2)(iii) and (iv)); redesignated as §§ 414.408(j)(2)(iii) and (iv) in this final rule). We believe that this payment proposal is consistent with section 1847(a)(4) of the Act, which requires us to establish a ''process'' under which rental agreements and supply arrangements ''may be continued,'' but is silent regarding the terms of that process. Because the rental payments for these items are not calculated based on, or limited to, the purchase fee for that item as is the case for other rented DME items, we do not believe that it is reasonable to continue paying the fee schedule amounts for these items and believe that payment at the competitively determined rates (that is, the single payment amounts) will comport with an overarching goal of competitive bidding to achieve savings for the Medicare program.

Unlike other items requiring frequent and substantial servicing, the duration of the rental payments for capped rental items and inexpensive or routinely purchased items is limited. In addition, unlike oxygen equipment, the payment amounts made for capped rental items and inexpensive or routinely purchased items are limited to the approximate purchase fee for the item.

Therefore, for items that are furnished on a rental basis under § 414.220 or § 414.229, we proposed in §§ 414.408(k)(2)(i) and (k)(2)(ii) (redesignated as §§ 414.408(j)(2)(i) and (ii) in this final rule) that the grandfathered supplier could continue furnishing the items in accordance with existing rental agreements and continue to be paid in accordance with section 1834(a) of the Act. We believe that continuing to pay for these grandfathered items at the fee schedule rates is authorized under section 1862(a)(17) of the Act, which allows the Secretary to specify ''other circumstances'' in which Medicare will make payment where the expenses for a competitively bid item furnished in a CBA were incurred by a supplier other than a contract supplier. In our view, the limited duration of the rental agreements for capped rental items and inexpensive or routinely purchased items furnished on a rental basis, in addition to the fact that payments for these items are based on or limited to the purchase fees for the items, constitute appropriate circumstances under which we would allow these rental agreements, including their payment terms, to continue until their conclusion. The rental fee schedule amounts that we would pay for grandfathered items in the capped rental or inexpensive or routinely purchased categories would be those fee schedule amounts established for the State in which the beneficiary maintains a permanent residence.

Comment: Some commenters stated that the grandfathering and transition policies are both unworkable and unfair to contract suppliers that will be required to continue to furnish capped rental or oxygen equipment to beneficiaries in the CBA regardless of the number of rental payments that have already been made to other suppliers for the equipment. They added that a contract supplier could inherit an unknown number of beneficiaries who have been renting oxygen equipment for 20 to 30 months of continuous use. In these cases, the contract supplier would receive a minimal number of rental payments that would be insufficient to cover the cost of oxygen equipment for which title will transfer to the beneficiary after 36 months of continuous use. The commenters stated that if a contract supplier has to supply a capped rental item for the last 6 months of the rental cycle, the supplier

would only receive 45 percent of the single payment amount, which is not enough to cover costs. They recommended that Medicare initiate a new period of continuous use if a beneficiary decides to switch from a grandfathered supplier to a contract supplier.

One commenter suggested that CMS establish a defined timeframe within which a beneficiary can transfer to a new contract supplier. The commenter also suggested that CMS not require contract suppliers to accept, as customers, beneficiaries who are already currently using capped rental equipment furnished by another supplier. Another commenter stated that CMS should mandate grandfathering by requiring the supplier that furnished oxygen or a capped rental item to a beneficiary before the implementation of a competitive bidding program to continue to furnish that item to the beneficiary for the remainder of the rental period. Some commenters also questioned how section 5101 of the DRA, which imposes new requirements regarding the rental of oxygen, oxygen equipment, and capped rental items, will affect competitive bidding. Several commenters suggested that the information in the proposed rule is inadequate to serve as a basis for public comments, especially with respect to the impact that the implementation of the DRA will have on competitive bidding. Several commenters noted that until CMS establishes the scope of the DRA provisions and how they dovetail with competitive bidding, they cannot provide meaningful comments or make recommendations. For example, the commenters questioned how CMS intended to apply the DRA oxygen provisions to grandfathered suppliers and beneficiaries and whether the grandfathered relationship would terminate at the conclusion of 36 months.

Response: Section 5101 of the DRA (discussed in detail in section III.B. of this final rule) caps the number of rental payments that may be made for oxygen equipment and capped rental DME items and requires that title to these items transfer to the beneficiary at the conclusion of the rental period. We proposed in the May 1, 2006 proposed rule (71 FR 25662) that current requirements regarding the rental or purchase of DMEPOS items would continue to apply under the Medicare DMEPOS Competitive Bidding Program. These requirements include the changes we recently made to 42 CFR Part 414, Subpart D of our regulations that implemented section 5101 of the DRA, new supplier requirements that protect beneficiary access to oxygen, oxygen equipment and capped rental items, and new payment classes for oxygen and oxygen equipment (see 71 FR 65884 for a full discussion of these provisions). We recognize that the title transfer provisions that are part of these new requirements, when read together with proposed § 414.408(k)(1) (allowing a supplier to elect to be a grandfathered supplier) and proposed § 414.408(k)(4) (allowing a beneficiary the choice of receiving a grandfathered item from a grandfathered supplier or a contract supplier), might place a contract supplier in the position of being required to furnish oxygen equipment or a capped rental item to a beneficiary who previously rented the item from another supplier (either a supplier that does not elect to become a grandfathered supplier or a grandfathered supplier) and then transfer title to that item without being paid a sufficient amount to cover its costs. We also recognize that contract suppliers will not be able to predict how many beneficiaries will obtain capped rental items or oxygen equipment from them, rather than from a supplier that does not elect to become a grandfathered supplier.

In response to the commenters' concerns, we are implementing two new payment rules to ensure that contract suppliers that must begin furnishing oxygen equipment and/or capped rental items to which the grandfathering process would otherwise apply receive a sufficient number of monthly rental payments to recover their costs. We believe that these changes are consistent with our statutory mandate under sections 1847(a) and (b) of the Act, which give us broad authority regarding how to structure the Medicare DMEPOS Competitive Bidding Program, and more specifically with section 1847(b)(3)(A) of the Act, which allows us to specify the terms and conditions of contracts we enter into with contract suppliers.

Capped Rental: For capped rental items furnished on a rental basis, we are providing in a new § 414.408(h)(2) that a contract supplier 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. This will ensure that the contract supplier can recover its costs because, as discussed in section VI.G.5. of this final rule, 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, as described in section 1847(a)(4) of the Act, only apply to those situations in which a beneficiary had been previously receiving the item from a noncontract supplier. In this case, the new contract supplier would be paid the single payment amount for the duration of the rental period.

Oxygen Equipment: For oxygen equipment, we provide in a new § 414.408(i)(2) that a contract supplier 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, we would make payment 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, we would make 10 rental payments assuming the equipment remains medically necessary. We believe this is a reasonable solution because our 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, we believe 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.

We note that the DRA does not apply to inexpensive or routinely purchased items when they are furnished on a rental basis. Therefore, we do not see a need to make these special payment provisions applicable to those items.

Comment: Several commenters suggested that CMS establish a transition period that would allow beneficiaries who reside in a CBA to continue to receive items from a noncontract supplier. They indicated that suppliers should be paid the current fee schedule amounts for these items during this transition period. They further suggested that CMS could use this period of time to educate beneficiaries and suppliers about the Medicare DMEPOS Competitive Bidding Program. Other commenters stated that the payment amount to grandfathered suppliers should always be the fee schedule amount (not just during a transition period) and never be the single payment amount.

Response: We proposed to establish a grandfathering process that would allow existing rental agreements for certain rented items to continue because we want to minimize the potential that these arrangements will be disruptive to the beneficiary due to the implementation of competitive bidding. We do not believe it is necessary to establish a transition process, however, as discussed in the proposed rule, we are requiring that a supplier that elects to be a grandfathered supplier for a specific item must serve as a grandfathered supplier to all beneficiaries who elect to receive that item from them. We plan to start educating suppliers, beneficiaries, and referral agents about competitive bidding as soon as this final rule is published and expect that these efforts will make the transition to this new program go as smoothly as possible. We do not, however, have authority to establish a grandfathering process that would allow beneficiaries to continue receiving from their current supplier items other than those specified in section 1847(a)(4) of the Act.

We proposed to pay grandfathered suppliers the single payment amount for items requiring frequent and substantial servicing and oxygen and oxygen equipment because the rental payments for these items are not calculated based on, or limited to, the purchase fees for these items. Therefore, we believe that it is reasonable to require suppliers that want to continue furnishing these items as grandfathered suppliers to accept the same payment that will be made for these items to contract suppliers. This achieves the goal of the program to achieve savings for the Medicare program.

However, the payment amounts made to grandfathered suppliers for furnishing capped rental and inexpensive or routinely purchased items will continue to be based on the fee schedule amounts that are paid for these items. Unlike items requiring frequent and substantial servicing and oxygen and oxygen equipment, the monthly rental payments for these items are made for a more limited period of time. In addition, the payment amounts for these items are based on the purchase fees for these items. Therefore, we believe that it is reasonable to continue paying for these items in accordance with existing rental agreements.

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

There may be instances when a supplier that was awarded a contract to furnish rental items or oxygen and oxygen equipment under a competitive bidding program is not awarded a contract to furnish the same items under a subsequent competitive bidding program in the same area. We are concerned that if this occurs, beneficiaries will need to switch suppliers in the middle of the rental period and could experience a disruption of service as a result. In order to minimize this possibility, we proposed to apply section 1847(a)(4) of the Act not only in a CBA where we implement a competitive bidding program for the first time, but also in the same area when we implement a subsequent competitive bidding program (proposed § 414.408(k)(3); redesignated § 414.408(j)(3) in this final rule). We believe our proposal is consistent with section 1847(a)(4) of the Act, which we interpret as applying to each competitive bidding ''program'' that we implement in an area because each program will be unique in terms of bidders, contract suppliers, items included in the program, and prices. Under the proposed rule, Medicare beneficiaries would be allowed to continue renting medically necessary 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, we proposed that Medicare make payment for the item in the amount established for that item under the new competitive bidding program for that area. We believe that section 1847(a)(4) of the Act gives us this discretion, since that section only requires us to establish a ''process'' under which these rental agreements or supply arrangements ''may continue'' but does not specify a payment methodology that must be used under that process. In addition, we do not believe that the alternative, which would be to make payment for the item under the fee schedule, is reasonable since the rental agreement or supply arrangement began under a competitive bidding program.

All rules that applied to grandfathered suppliers will apply in this situation when a supplier is a contact supplier in under one competitive bidding program *e.g.* in round one but is not a contract supplier in a subsequent competitive bidding program in the same CBA, *e.g.* in round two. However, the payment amounts will not revert back to the current fee schedule but rather the payment amounts will be the new competitive bid single payment amounts as determined under § 414.416.

We did not receive any specific comments on these proposals. Therefore, in this final rule, we are redesignating proposed § 414.408(k)(3) as § 414.408(j)(3), making editorial revisions, and finalizing that section.

c. Payment for Accessories for Items Subject to Grandfathering (§ 414.408(j)(5))

We proposed that accessories and supplies used in conjunction with an item which is furnished under a grandfathering process described above may also be furnished by the grandfathered supplier. Payment would be based on the single payment 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, we proposed that 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.

Our proposal is similar to the grandfathering approach that was used in the DMEPOS competitive bidding demonstrations under which we paid grandfathered suppliers the competitively bid amount for certain items and the fee schedule amounts for other items. We specifically solicited comments on our grandfathering proposals.

Comment: Several commenters supported our proposal to require that accessories and supplies used in conjunction with an item furnished under the grandfathering process be furnished by a grandfathered supplier.

Response: We appreciate the commenters' support and continue to believe that this approach is reasonable. To clarify the situations in which this may occur, we are revising proposed § 414.408(k) (redesignated § 414.408(j) in this final rule) by adding a new paragraph (j)(5) to specify that accessories and supplies that are necessary for the effective use of DME may also be furnished by the same grandfathered supplier that furnishes the grandfathered item. This approach will provide the beneficiary with continuity of service by requiring one supplier to provide all related items the beneficiary may need for the proper use of their equipment. This rule will not apply to accessories that are not an integral part of the base equipment. 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. We believe that the amount to be paid under the Medicare DMEPOS Competitive Bidding Program should be the single payment amount, regardless of which supplier furnishes the accessories or supplies. Payment for most accessories or supplies for DME is made on a purchase basis, and in those cases where a single payment amount has been established for the accessories or supplies, we believe it is reasonable to pay the single payment amount for the accessories or supplies to the grandfathered supplier for the base equipment. We believe this is reasonable, regardless of what payment category the base equipment falls under because the single payment amount reflects a reasonable payment amount determined by a competitive market. If the grandfathered supplier chooses not to furnish the accessories or supplies for the grandfathered base equipment, a contract supplier would be responsible for furnishing the accessories or supplies.

Comment: One commenter suggested that CMS needs to establish a transition plan for Medicare Advantage beneficiaries who disenroll from their MA plan and enroll in traditional fee-for-service Medicare Part B. The commenter pointed out that these beneficiaries may currently be using a noncontract supplier and should be given the option to remain with their existing supplier under the grandfathering provisions.

Response: All beneficiaries to whom the grandfathering process applies can elect to continue receiving certain rented items from a supplier that elects to become a grandfathered supplier. Therefore, if a supplier from whom a Medicare Advantage beneficiary previously rented one of these items is eligible, and elects, to become a grandfathered supplier, then the beneficiary could continue to receive the item from that supplier.

Comment: One commenter stated that the rule should apply grandfathering provisions to enteral equipment, nutrition, and supplies. The commenter stated that beneficiaries on enteral nutrition develop an ongoing relationship with their suppliers. The commenter pointed out that suppliers that furnish enteral equipment, nutrition, and supplies frequently service and maintain the enteral pumps. The commenter added that, under the proposed rule, contract suppliers would be responsible for servicing and maintaining enteral pumps that they did not provide to beneficiaries. The commenter recommended that the previous enteral supplier be able to continue to provide enteral equipment, nutrition, and supplies to the beneficiary until the 15-month rental period ends.

Another commenter stated that our grandfathering proposal did not include a process for grandfathering glucose testing supplies. The commenter indicated that competitive bidding could force many beneficiaries to switch their glucose monitoring system if the contract supplier does not offer the testing supplies for the monitor they currently use.

Another commenter suggested that Medicare allow grandfathering for all DMEPOS items. Another commenter suggested that Medicare only allow grandfathering for oxygen equipment because otherwise, competitive bidding for capped rental items, oxygen, and oxygen equipment will only affect beneficiaries who need to obtain these items after a competitive bidding program has been implemented in their area, which undermines a program goal to harness market place dynamics.

Response: Section 1847(a)(4) of the Act requires that we establish a process by which rental agreements for DME and supply arrangements for suppliers of oxygen and oxygen equipment entered into before the implementation of a competitive bidding program may be continued. We do not believe we have authority to allow grandfathering for other DMEPOS, such as glucose testing supplies and enteral nutrition, equipment, and supplies.

After consideration of the public comments received, we are redesignating proposed § 414.408 (k) as § 414.408 (j) and finalizing this section as discussed above and with additional technical modifications. We are also adding new § 414.408(h)(2) and § 414.408(i)(2), which provide for special payments to certain contract suppliers that furnish certain rented items.

4. Payment Adjustments

a. Adjustment to Account for Inflation (§ 414.408(b))

The fee schedule payment amounts for DMEPOS items are updated by annual update factors described in 42 CFR Part 414, Subparts C and D. In general, the update factors are established based on the percentage change in the CPI–U for the 12-month period ending June 30 of each year and preceding the calendar year to which the update applies. In accordance with section 1847(b)(3)(B) of the Act, the term of a competitive bidding contract may not exceed 3 years.

In the May 1, 2006 proposed rule (71 FR 25663), we proposed to apply an annual inflation update to the single payment amounts established for a competitive bidding program (proposed § 414.408(b)). Specifically, beginning with the second year of a contract entered into under a competitive bidding program, we proposed to

update the single payment amounts by the percentage increase in the CPI–U for the 12-month period ending with June 30 of the preceding calendar year. We stated that using the CPI–U index would be consistent with Medicare using this index to update the DME fee schedule. This would account for inflation in the cost of business for suppliers submitting bids for furnishing items under a multi-year contract.

Comment: One commenter suggested that CMS not finalize its proposal to make an annual inflation update to the single payment amounts. The commenter believed that this payment adjustment may make it possible for single payment amounts to rise faster than current fee schedule payment amounts, particularly in the event of a payment freeze or a payment reduction. The commenter recommended that CMS determine a single payment amount that will apply for the full term of the contract or allow each bidder to specify an annual adjustment in its bid.

Response: We agree with the commenter and will not finalize our proposal to make an annual inflation update to the single payment amounts. The single payment amounts will remain in effect for the duration of the contract. We believe it is more appropriate for suppliers to address the possible effects of inflation or price increases when they formulate their bids because automatic payment adjustments to competitively bid items may result in higher payment amounts than would occurred under the DMEPOS fee schedule payment amounts if these amounts are subject to Congressional freezes or payment reductions.

Comment: Several commenters stated that the proposal did not address situations where the manufacturers or distributors raise their prices, thereby requiring suppliers to pay more money to purchase their products. They believe that suppliers may be required to continue to furnish these items at the single payment amounts notwithstanding the fact that their costs have increased.

Response: While we recognize that increases in suppliers' costs for equipment and other costs can occur at any time, suppliers should be generally aware of how often these changes occur and how these changes affect their businesses. We expect suppliers to consider this factor when developing their bids, which represent bids for furnishing items during the entire period that the contract will be in effect.

Comment: Several commenters recommended that CMS continue to use the CPI–U to adjust fee schedule amounts for class III devices. The commenters indicated that the March 2006 GAO report was flawed because it did not provide a full assessment of changes over time in the costs of producing, supplying and servicing class III devices. The commenters also noted that the report does not specify a specific percentage update for CY 2007 or CY 2008. Another commenter stated that the GAO report examines class III devices in relation to only a very limited number of higher-technology class III items that may not be reflective of the general class III items. One commenter unfavorably compared the GAO report to the Medicare Payment Advisory Commission (MedPAC) reports which assess the adequacy of Medicare payments for hospital inpatient and outpatient services, physician services, outpatient dialysis services, skilled nursing facility services, home health services, long-term care hospital services and inpatient rehabilitation facility services. (Following each detailed assessment, MedPAC then recommends an update policy for each provider category for the coming year.) The commenter noted that the GAO report does not justify its alternative assessment methodology or its failure to take into account changes over time in manufacturer costs for class III devices. Another commenter recommended that the class III proposal be included in a separate rulemaking procedure because it is not related to competitive bidding.

Response: Pursuant to section 1834(a)(14)(H)(i) of the Act, in determining the appropriate fee schedule update percentages for class III medical devices prescribed in section 513(a)(1)(C) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 360(c)(1)(C)) for CY 2007, we must take into account recommendations contained in the report of the Comptroller General of the United States under section 302(c)(1)(B) of the MMA. We have not yet made a determination regarding the appropriate percentage change for CY 2007 in the fee schedule amounts for class III DME and, therefore, are not making that determination as part of this final rule. We will address this issue in a future rulemaking.

After consideration of the public comments received, in this final rule, we are revising proposed § 414.408(b) to specify that the single payment amount for each item that is determined under each competition will be in effect for the duration of the contract and will not be adjusted by an annual inflation update.

b. Adjustments to Single Payment Amounts to Reflect Changes in the HCPCS (§ 414.426)

We proposed under § 414.426 that revisions to HCPCS codes for items under a competitive bidding program that occur in the middle of a bidding cycle would be handled as follows:

- If a single HCPCS code for an item is divided into multiple codes for the components of that item, the sum of payments for these new codes would be equal to the payment for the original item. Suppliers selected through competitive bidding to provide the item would also provide the components of the item. During the subsequent competitive bidding cycle, suppliers would bid on each new code for the components of the item, and we would determine new single payment amounts for these 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. During the next cycle, suppliers would bid on the new separate and distinct 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. Suppliers that were selected through competitive bidding to supply the various components of the item would continue to supply the item using the new code. During the subsequent bidding cycle, suppliers would bid on the new code for the single item to determine a new single payment amount for this new code.
- 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 would also provide the item under the new single code. During the subsequent bidding cycle, suppliers would bid on the new single code and determine a new single payment amount for this code.

Comment: Several commenters stated that when multiple codes for similar items are merged to a new code, CMS should continue to use the former codes and single payment amounts for the remainder of the contract period. One commenter stated that the proposal that the payment amounts for new HCPCS codes continue to be the same payment

amounts until the next competitive bidding cycle is not an equitable proposal and a more appropriate procedure must be developed. Another commenter stated that CMS' only authority to adjust payment amounts for an item is through the inherent reasonableness authority under the Medicare statute. The commenter disagreed with the proposal for paying for new HCPCS codes that are established during a competitive bidding cycle. The commenter stated that CMS should rebid these items, assuming they are appropriate for inclusion in the program.

Response: After further consideration, we are clarifying that when multiple codes for different items are discontinued and the items are placed into a new single code, the payment for the new code will be based on the fee schedule methodology, even if we had previously established a single payment through competitive bidding for the items included in the new code. The old codes will be considered invalid and therefore will no longer be included in the competitive bidding program for the remainder of the contract term. During a subsequent competitive bidding program, suppliers would bid on the new single code and we will determine a new single payment amounts for this code based on the bids submitted and accepted. We are not finalizing this part of the proposed methodology because we do not believe the single payment amount in this case would be reflective of the bids submitted and accepted for these multiple items. However, unlike this proposal, our other three proposals will be finalized because they are reflective of the bids submitted and accepted for the items described by the new codes.

We note that we do not believe we have authority to use the inherent reasonableness authority to adjust the single payment amounts set through competitive bidding. We believe that the prices set by competitive bidding will be reasonable because they will be reflective of the market. When we split or merge HCPCS codes, we will ensure that the new payment amounts are reflective of the previously established payment amounts, and this does not require the use of the inherent reasonableness authority or the need to rebid the items.

After consideration of the public comments we received, we are finalizing §§ 414.426(a) through (c) and revising § 414.426(d) as discussed above and with additional technical changes.

5. Authority to Adjust Payments in Other Areas

Section 1834(a)(1)(F)(ii) of the Act provides authority, effective for covered items furnished on or after January 1, 2009, that are included in a competitive bidding program, for us to use the payment information determined under that competitive bidding program to adjust the payment amounts otherwise recognized under section 1834(a)(1)(B)(ii) of the Act for the same DME items in areas not included in a competitive bidding program. Sections 1834(h)(1)(H)(ii) and 1842(s)(3)(B) of the Act provide the same authority for orthotic and prosthetic devices, and enteral nutrition, respectively.

In the May 1, 2006 proposed rule (71 FR 25664), we proposed to use this authority but stated that we had not yet developed a detailed methodology for doing so. Therefore, we specifically invited comments and recommendations on this issue. We stated that we believed that our methodology would be influenced by our experience and information gained from the competitive bidding programs in CYs 2007 and 2009. When submitting recommendations on a methodology for using this authority, we asked commenters to keep in mind the following factors that are likely to be incorporated in the methodology:

- The threshold or amount or level of savings that the Medicare program must realize for an item or group of items before we would use payment information from a competitive bidding program to adjust payment amounts for those items in other areas.
- Whether adjustments of payment amounts in other areas would be on a local, regional, or national basis, depending on the extent to which the single payment amounts and price indexes (for example, local prices used in calculating the CPI–U) for an item or group of items varied across different areas of the country.
- Whether adjustments of payment amounts in other areas would be based on a certain percentage of the single payment amount(s) from the CBA(s).

Comment: Some commenters stated that CMS must issue a final rule to spell out a detailed plan for using the authority provided by sections 1834(a)(1)(F)(ii), 1834(h)(1)(H)(ii), and 1842(s)(3)(B) of the Act before it can implement these provisions.

Response: We agree with the commenters that a more detailed plan must be developed for using the authorities provided by sections 1834(a)(1)(F)(ii), 1834(h)(1)(H)(ii), and 1842(s)(3)(B) of the Act, and we plan to conduct subsequent rulemaking prior to implementing these provisions. Subsequent rulemaking would provide a more detailed plan for using these authorities. Therefore, we are not finalizing proposed § 414.408(e) until the subsequent rulemaking is completed.

6. Requirement to Obtain Competitively Bid Items From a Contract Supplier (§§ 411.15(s), 414.408(e))

Beneficiaries often travel, for example, to visit family members or to reside in a State with a warmer climate during the winter months. To prevent these beneficiaries from having to return home to obtain needed DMEPOS, in proposed § 414.408(f)(2)(ii) (redesignated § 414.408(e)(2)(iii) in this final rule), we proposed to allow beneficiaries who are traveling outside the CBA where they permanently reside to obtain items that they would ordinarily be required to obtain from a contract supplier for their CBA 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 CBA and the item is subject to the competitive bidding program in that area, the beneficiary would be required to obtain the item from a contract supplier for that area. If the area that the beneficiary is visiting is not a CBA, or if the area is a CBA but the item needed by the beneficiary is not included in the competitive bidding program for that area, the beneficiary would be required to obtain the item from a supplier that has a valid Medicare supplier number. In either case, payment to the supplier would be made based on the single payment amount for the item in the CBA where the beneficiary maintains a permanent residence.

In the May 1, 2006 proposed rule, we proposed 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 exemption to the general rule that beneficiaries who reside in a CBA must obtain DMEPOS covered by competitive bidding from contract suppliers in that area would not apply. We stated that we plan to monitor the programs closely 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.

We also proposed to base claims jurisdiction and the payment amount on the beneficiary's permanent residence as we have done since the early 1990s with the current DMEPOS program under § 421.210(e). Under this proposal, the

DME MAC responsible for the area where the beneficiary maintains a permanent residence would process all claims submitted for items furnished to that beneficiary, whether or not the beneficiary obtained the item in that area. If the beneficiary maintained a permanent residence in a CBA and obtained an item included in the competitive bidding program for that area, Medicare would pay the supplier the single payment amount for the item determined under the competitive bidding program for that area. If the beneficiary did not maintain a permanent residence in a CBA, Medicare would pay the supplier the fee schedule amount for the area in which the beneficiary maintains a permanent residence. We believe that this proposal is consistent with our current policy, under which suppliers across the country are paid the same amount for similar products obtained by beneficiaries who maintain their permanent residence within the same geographic area.

We proposed that Medicare beneficiaries who maintain their permanent residence in a CBA be required to obtain competitively bid items from a contract supplier for that area with the following two exceptions:

- A beneficiary may obtain an item from a supplier or a noncontract supplier in accordance with the competitive bidding program grandfathering provisions described in section VI.C.3. of this final rule.
- A beneficiary who is outside of the CBA where he or she maintains a permanent residence may obtain an item from a contract supplier, if he or she is in another CBA and the same item is included under a competitive bidding program for that area, or 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.

We proposed that unless one of the exceptions discussed above applies, Medicare would not pay for the item. We also proposed to add a new § 411.15(s) that would prohibit Medicare from making payment for an item that is included in a competitive bidding program if that item is furnished by a supplier other than a contract supplier, unless an exception applies.

Comment: Several commenters suggested that CMS exclude from competitive bidding beneficiaries who have Medicare as their secondary insurance. The commenters stated that claims for beneficiaries with Medicare as a secondary payer should be processed and paid under the standard fee schedule.

Response: We believe that the commenters' intent was to request that Medicare pay for an item that was furnished by a supplier that the beneficiary is required to use under his or her primary insurance policy even if that item is furnished by a supplier that is not a contract supplier. We agree with the commenters that an exception under the Medicare DMEPOS Competitive Bidding Program needs to be made for beneficiaries with Medicare as their secondary insurance. Section 1862(a)(17) of the Act allows the Secretary to specify circumstances under which it would be appropriate to pay for an item that is furnished by an entity other than a contract supplier. To address secondary payer concerns, we are adding an exception at § 414.408(e)(2)(ii) of the list of circumstances when Medicare will make payment where the expenses for a competitively bid DMEPOS item furnished in a CBA were incurred by a supplier other than a contract supplier. Under this exception Medicare may make a secondary payment for a DMEPOS item that is furnished by a noncontract supplier if the beneficiary, in order to comply with his or her primary insurance plan, does not have the option to use a contract supplier. In addition, Medicare will only make a secondary payment to a supplier that the beneficiary is required to use under his or her insurance plan if the supplier is eligible to submit claims to Medicare. These suppliers will need to have a valid Medicare billing number to be eligible to submit claims to Medicare. This regulation does not supersede the established Medicare secondary payer statutory and regulatory requirements, including the Medicare secondary payment rules found at 42 CFR 411.32 and 411.33, and payment will be calculated in accordance with those rules.

Comment: One commenter stated that the requirement to obtain competitively bid items from a contract supplier will be extremely confusing to the traveling beneficiary and will limit beneficiary access to DMEPOS while the beneficiary is away from his or her permanent residence. The commenter also proposed that the supplier outside of the beneficiary's CBA be reimbursed either (a) the regular fee schedule amount for the product if the area traveled to is not a CBA or (b) the higher single payment amount for the two CBAs, if the area where the beneficiary has traveled is in a CBA.

Some commenters were concerned that the difference between the fee schedule amount and the single payment amount may be substantial, thereby hindering beneficiary access to needed equipment. They recommended that CMS continue to pay for an item based on the fee schedule amount that corresponds with the beneficiary's permanent residence if the beneficiary obtains the item while visiting another area. The commenters were concerned about the impact that the requirement to obtain competitively bid items from a contract supplier would have on both suppliers and beneficiaries who travel to ''snowbird'' areas.

Response: The approach set out in the proposed rule is consistent with our long-standing rule under which Medicare payment for DMEPOS is based on the beneficiary's primary residence. If a beneficiary maintains a permanent residence in a CBA, payment for an item that the beneficiary obtains while visiting another area will be based on the payment amount for the item in the beneficiary's CBA. We note that, under our current rule, there are instances when a supplier is paid more or less than the fee schedule amount that the supplier would otherwise receive for an item because the payment amount has been determined based on where the beneficiary resides. The same will be true under the Medicare DMEPOS Competitive Bidding Program. For example, when a beneficiary who resides in an area that is not a CBA travels into a CBA and needs to obtain an item, the supplier that furnishes the item will be paid the current fee schedule amount for the item based on the beneficiary's residence, even if the fee schedule amount is greater than the single payment amount that the supplier would otherwise receive for furnishing the item. We believe that it is appropriate to adopt our current claims jurisdiction policy for the Medicare DMEPOS Competitive Bidding Program because it minimizes the possibility that suppliers will set up locations in certain geographic areas for the purpose of obtaining higher payment amounts.

We plan to conduct an extensive education campaign to minimize confusion on the part of both beneficiaries and suppliers regarding this provision and all other provisions of the Medicare DMEPOS Competitive Bidding Program.

Comment: Several commenters stated that suppliers need access to a beneficiary database that identifies the county in which a beneficiary resides at the zip code level, so they can determine if the beneficiary resides in a CBA.

Response: We do not believe that this is necessary for suppliers. Currently,

payment is based on beneficiary residence, and suppliers do not have access to beneficiary zip code information to bill for items. We will post all counties and zip codes where competitive bidding is conducted on our Web site. The Medicare claims form requires a beneficiary address. Therefore, the supplier will be able to ascertain if the beneficiary resides in a CBA. We currently post fee schedules on our Web site and the single payment amounts for each item in each CBA will also be posted. Therefore, suppliers can look to the postings to determine payment amounts in other areas. In addition, our claims processing systems are equipped to identify the appropriate payment amount so no calculations are necessary to determine the payment amount for an item.

Comment: Several commenters stated that beneficiaries will not have access to newer technology for competitively bid products.

Response: One of the main objectives of the Medicare DMEPOS Competitive Bidding Program is to ensure that beneficiaries have access to quality DMEPOS. Therefore, we have built safeguards into the competitive bidding program to ensure there is continued access to quality medical equipment and supplies, as well as to services necessary to maintain the equipment. As we discuss more fully in response to comments in section XV. Physician or Treating Practitioner Authorization and Consideration of Clinical Efficiency and Value of Items in Determining Categories for Bids of this final rule (§ 414.422(c)), we have proposed to include a nondiscrimination clause in each contract awarded under this program. We believe that the inclusion of this contract provision will ensure that beneficiaries who obtain items under a competitive bidding program have access to the same products as other Medicare customers and private pay individuals. In addition, we are taking other steps to ensure that high quality items are furnished to beneficiaries under this program. We plan to implement a complaint system so that beneficiaries, referral agents, providers, and suppliers can report problems and difficulties they encounter with the ordering and furnishing of DMEPOS in CBAs. In addition, we will not award a contract to a supplier unless that supplier meets our eligibility standards, is accredited, and meets our financial standards.

In addition, items that represent new technology and that receive a new HCPCS code to separately designate them, rather than updates to current technology will not be added to a contract supplier's contract. Instead, beneficiaries will be able to obtain these items from any supplier for the remainder of the contract period, and the supplier will be paid the fee schedule amount for those items.

Comment: One commenter stated that competitive bidding will limit full-time access to supplies that are crucial to beneficiaries with diabetes. The commenter stated that beneficiaries may find that they can no longer purchase their supplies from their current supplier and may be inconvenienced. The commenter recommended that CMS implement an aggressive education outreach program.

Response: We do not believe that competitive bidding will limit beneficiary access to any competitively bid items, including diabetic supplies. Although it is true that some beneficiaries will have to find a contract supplier to purchase their supplies, we do not believe this will result in an inconvenience to beneficiaries, because there will be a sufficient number of contract suppliers that furnish these items for each CBA. The process we have proposed for awarding contracts under the Medicare DMEPOS Competitive Bidding Program will ensure that there are a sufficient number of contract suppliers to furnish items to all beneficiaries located in a CBA. We plan to conduct an aggressive outreach program for all beneficiaries, suppliers, and referral agents. (We refer readers to the DMEPOS provisions of the FY 2007 IRF final rule (71 FR 48354) for a complete discussion of our planned education and outreach policy.)

Comment: One commenter expressed concern that in a State with multiple MSAs, there could be a different payment rate for the same item in each MSA. The commenter believed this would add confusion and would increase billing time and expenses, which will, in turn, increase the price of products.

Response: We agree that if we conducted competitive bidding in multiple CBAs within a State, there could be different prices in each CBA for the same item. However, we do not believe that this would be a problem for contract suppliers. Under the current program, suppliers may have a customer base that comes from areas with different fee schedule amounts because the fee schedules vary by State. Therefore, we believe that many suppliers are already equipped to handle price variations for an item. In addition, the fee schedule for each item in each State is published on our Web site, and we plan to also publish the single payment amounts for each item in each CBA on our Web site.

After consideration of the public comments we received, we are redesignating proposed § 414.408(f) as § 414.408(e) and adding a new § 414.408(e)(2)(ii) that specifies that Medicare may make a secondary payment for a DMEPOS item that is furnished by a supplier that is not awarded a contract under a competitive bidding program. We are also finalizing the remainder of proposed §§ 414.408(f)(1) and (f)(2)(i) and (f)(2)(ii) (redesignated as §§ 414.408(e)(2)(i) and (e)(2)(iii)) with only technical modifications. We are also finalizing § 411.15(s).

7. Limitation on Medicare Payment and Beneficiary Liability for Items Furnished by Noncontract Suppliers (§§ 414.408(e)(3) and (e)(4)

In the May 1, 2006 proposed rule (71 FR 25664), we proposed that 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 discussed in section VI.D.3. of this final rule applies (proposed § 414.408(f)(2)(iii); redesignated § 414.408(e)(3) in this final rule).

We proposed that this rule would not apply if the noncontract supplier furnished items that are not included in the competitive bidding program for the area. We proposed to specially designate the supplier numbers of all noncontract suppliers so that we will easily be able to identify whether a noncontract supplier has furnished a competitively bid item to a beneficiary who maintains a permanent residence in a CBA (proposed § 414.408(f)(3)) (redesignated in this final rule as § 414.408(e)(4)).

Comment: Several commenters suggested that proposed § 414.408(f)(2)(ii) be clarified to include a limitation on beneficiary liability unless the noncontract supplier has obtained a signed ABN, which indicates that the beneficiary was informed prior to receiving service that there would be no coverage due to the supplier's noncontract status and that the beneficiary still desired to receive the service from the noncontract supplier.

Response: We are revising the regulation to add § 414.408(e)(3)(ii) and § 414.408(c) to reflect that there is a limitation on beneficiary liability unless the noncontract 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 noncontract 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.

We are also revising proposed § 414.408(f)(2)(iii) (redesignated in this final rule as § 414.408(e)(3)(ii) to delete the phrase ''who maintains a permanent residence in a CBA.'' We believe this change clarifies our final policy that beneficiaries will not be financially responsible for making payment to a noncontract supplier that furnishes a competitively bid item in violation of the Medicare DMEPOS competitive bidding program.

After consideration of the public comments we received, we are redesignating proposed §§ 414.408(f)(2)(iii) and (f)(3) as final §§ 414.408(e)(3)(ii) and (e)(4), respectively, and finalizing these sections as discussed above and with additional technical changes.

8. Payment for Repair and Replacement of Beneficiary-Owned Items (§ 414.408(k))

In the proposed rule (71 FR 25681), we proposed that repair or replacement of beneficiary-owned DME, enteral nutrition equipment, or OTS orthotics that are subject to the Medicare DMEPOS Competitive Bidding Program must be furnished by a contract supplier because only winning suppliers can provide these items in a CBA (proposed § 414.422(c)). The contract supplier could not refuse to repair or replace beneficiary-owned items subject to competitive bidding. We indicated that this proposed provision would help ensure that the beneficiaries will get the items from qualified suppliers, and is consistent with the competitive bidding program in that it directs business to contract suppliers.

Therefore, we proposed that repair or replacement of beneficiary-owned items subject to a competitive bidding program must be furnished by a contract supplier. We indicated that this proposed requirement would not apply to Medicare beneficiaries who are outside of a CBA.

Comment: Some commenters objected to the requirements that repair of beneficiary-owned equipment that is subject to a competitive bidding program must be furnished by a contract supplier and that a contract supplier must agree to service all items included in its contract. The commenters remarked that a limited number of suppliers have repair facilities. In addition, the commenters noted that contract suppliers may not have access to the parts necessary to repair equipment sold by another contract supplier, and this provision would allow manufacturers to inflate the price for parts that must be obtained by contract suppliers that do not regularly furnish their products. The commenters also suggested that, in cases where the manufacturer is the sole distributor of an item, the repair parts and accessories for the item might not be interchangeable and the use of parts that are not provided by the manufacturer may void the manufacturer's warranty. The commenters also suggested that if there are warranties that must be honored on previously rented or purchased equipment, the cost of service should be borne by the contract supplier that received reimbursement for the malfunctioning item. Several commenters expressed concern about assuming the liability for modifying a splint if they were not the contract supplier that originally furnished it. In addition, the commenters suggested that this proposal could restrict Medicare beneficiary access to a choice of suppliers that can repair their equipment. Several commenters noted that contract suppliers may not have the training and expertise required for repairs. One commenter asked how the repair proposal might be affected by the DRA provisions that impose new requirements regarding capped rental items, oxygen, and oxygen equipment.

Another commenter recommended that repairs should be treated as a separate bid on the RFB, rather than as a cost of furnishing an item in an overall product category.

Response: After consideration of the commenters' concerns, we are revising our proposal on payment for repairs and replacement of beneficiary-owned items. We will not require that repairs of beneficiary-owned competitively bid items be performed by contract suppliers because we recognize that contract suppliers may not have the training and expertise to repair every make and model of equipment that could be provided to a Medicare beneficiary. This policy will also apply to maintenance services required by the DRA. We 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 (§ 414.408(k)). Payment will generally be made for parts and labor consistent with the methodology we currently use to make these payments, which can be found in 42 CFR 414.210(e)(1) of our regulations for durable medical equipment, and prosthetic and orthotic devices. 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, we will pay the supplier the single payment amount for the part because we do 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. For example, if a beneficiary needs to obtain a new battery for his or her wheelchair, and the battery is itself a competitively bid item for the applicable CBA, we will pay the supplier that performs the repair the reasonable and necessary charges for the labor needed to service the wheelchair and the single payment amount for the battery. We believe that allowing any supplier to furnish a part when performing a repair, even though the part is itself a competitively bid item, is a reasonable accommodation that will enable the supplier to complete the repair properly, and an appropriate circumstance under which we can make payment to the supplier under our authority in section 1862(a)(17) of the Act.

In addition, under final § 414.408(k)(2) to be consistent with our current maintenance and servicing rules for oxygen equipment, we will make general maintenance and servicing payments to suppliers that service oxygen equipment (other than liquid and gaseous equipment) in accordance with § 414.210(e)(2) 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, as provided under § 414.210(e)(3).

We note that we do not have authority under § 1847(a)(2) to include splints in the Medicare DMEPOS Competitive Bidding Program.

Comment: Numerous commenters raised concerns regarding the requirement that replacement of beneficiary-owned equipment that is subject to the Medicare DMEPOS Competitive Bidding Program must be furnished by a contract supplier. The commenters suggested that CMS allow contract suppliers to replace items even if they do not ordinarily furnish these items. The commenters believed that implementing the replacement

provision may be difficult as a replacement may relate to a warranty claim or require that the same product be furnished to ensure continuity of care. The commenters also noted that, under the proposed provision, contract suppliers would be required to replace products that have been damaged despite the fact that they did not sell the item initially. The commenters asserted that if a beneficiary purchased a product from a noncontract supplier prior to competitive bidding, the noncontract supplier should be responsible for repairs or replacement and be paid accordingly. The commenters also stressed that payment rates should be generous enough to ensure that beneficiaries receive an appropriate level of response or service, and contract suppliers should be reimbursed for the service and replacement items they provide. The commenters remarked that the proposed rule assumes that replacement equipment will be provided and paid for in an amount equal to the single payment amount. Several commenters suggested that CMS eliminate the requirement that beneficiary-owned equipment subject to competitive bidding must be replaced by a contract supplier. Other commenters requested that CMS revise proposed § 414.422(c) to limit the scope of this requirement so that contract suppliers that are FDA-approved manufacturers and that only furnish their own products to beneficiaries in the CBA are exempt and would only be required to replace their own products. One commenter asked how the replacement proposal might be affected by DRA provisions that imposed new requirements regarding capped rental items, oxygen, and oxygen equipment.

Response: As we stated above, we have decided to modify our proposal regarding the maintenance and servicing of beneficiary-owned items to allow any supplier to perform this service, provided that the supplier has a valid Medicare billing number. However, we do not believe that this modification should extend to situations where an item must be replaced in its entirety because the concern expressed by the commenters, namely that suppliers cannot be expected to have the expertise to repair every make and model of equipment, would not be a factor in the event that an item must be replaced. Accordingly, we continue to believe that beneficiaries should be required to obtain a replacement of an entire item, as apposed to replacement of a part for repair purposes, from a contract supplier. As we stated in the May 1, 2006 proposed rule (71 FR 25681), this rule will help ensure that beneficiaries obtain replacement items from qualified suppliers, and it is consistent with one of the competitive bidding program's goals, that is, to direct business to contract suppliers that conduct business in a manner that is beneficial for the Medicare program and for beneficiaries. Therefore, in final § 414.408(k)(3) we have retained this requirement.

Medicare regulations at 42 CFR 414.210(f) provide that if an item of DME or a prosthetic or orthotic device paid for by Medicare has been in continuous use by the patient for the equipment's reasonable useful lifetime or if the carrier determines that the item is lost, stolen, or irreparably damaged, the patient may elect to obtain a new piece of equipment. If these requirements are met, the Medicare beneficiary would be required to go to a contract supplier to obtain a complete replacement of beneficiary-owned equipment. However, as we stated above, if a beneficiary needs to obtain a replacement part for his or her beneficiary-owned equipment, or needs to obtain maintenance or servicing of the equipment, the beneficiary may obtain the part or service from any supplier that has a valid Medicare billing number. If the replacement part is itself a competitively bid item in the CBA where the beneficiary maintains a permanent residence, the supplier that performs the repair would generally be paid for the labor associated with the repair in accordance with the methodology described in § 414.210(e)(1), and the single payment amount for the part.

We do not agree with the commenters that our replacement rules would generally require a contract supplier replace an entire competitively bid item with the same make or model to ensure continuity of care. Rather, as we discuss in § 414.420 of this final rule, this would only be required if a physician or treating practitioner prescribed a particular brand or mode of delivery for an item. If a beneficiary needs a replacement item, a manufacturer that only furnishes its own brand would generally be able to furnish that brand to the beneficiary. In addition, we expect that a manufacturer's warranty would be honored by the manufacturer, regardless of which supplier from which the Medicare beneficiary obtains the replacement.

In summary, after consideration of the public comments we received, in this final rule, we are redesignating proposed § 414.422(c) as new § 414.408(k) and revising this section as discussed above.

E. Competitive Bidding Areas (§§ 414.402, 414.406(b)–(c), 414.410, 414.412(f) and (g)

1. Background

Section 1847(a)(1)(A) of the Act requires that competitive bidding programs be established and implemented in areas throughout the United States. We are interpreting the term ''United States'' to include all States, Territories, and, as discussed in section VI.B. of this final rule, the District of Columbia. Section 1847(a)(1)(B) of the Act provides us with the authority to phase in competitive bidding programs so that the competition under the programs occurs in—

- 10 of the largest MSAs in CY 2007;
- 80 of the largest MSAs in CY 2009; and
- Additional areas after CY 2009.

We proposed to implement this statutory provision in § 414.406(b)–(c), and in § 414.410.

Section 1847(a)(1)(B) of the Act also authorizes us to phase in competitive bidding programs first among the highest cost and volume items or those items that we determine have the largest savings potential. As we proposed, we describe our methodologies for selecting the MSAs for CYs 2007 and 2009 below. Once the MSAs have been selected for CYs 2007 and 2009, we proposed to define the CBAs for CYs 2007 and 2009. The process we proposed for establishing CBAs in future years, which we are finalizing in this final rule, is also discussed below.

2. Methodology for MSA Selection for CYs 2007 and 2009 Competitive Bidding Programs (§§ 414.410(a) and (b))

Based on sections 1847(a)(1)(B)(i)(I) and (II) of the Act, we have the authority to select from among the largest MSAs during the first two implementation phases in order to phase in the programs in the most successful way, thereby achieving the greatest savings while maintaining quality and beneficiary access to care. In phasing in the competitive bidding programs, we proposed to adopt a definition of the term ''Metropolitan Statistical Area'' (MSA) consistent with that issued by the Office of Management and Budget (OMB) and applicable for CYs 2007 and 2009 (§ 414.402). OMB is the Federal agency responsible for establishing the standards for defining MSAs for the purpose of providing nationally consistent definitions for collecting, tabulating, and publishing Federal statistics for a set of geographic areas. OMB most recently revised its standards for defining MSAs in CY 2000 (65 FR

82228 through 82238). Under these standards, an MSA is defined as a core-based statistical area (CBSA) (a statistical geographic area consisting of the county or counties associated with at least one core (urbanized area or urban cluster) of at least 10,000 population, plus adjacent counties having a high degree of social and economic integration as measured through commuting ties with the counties containing the core) associated with at least one urbanized area that has a population of at least 50,000, and is comprised of the central county or counties containing the core, plus adjacent outlying counties having a high degree of social and economic integration with the central county as measured through commuting. OMB issues periodic updates of the MSAs between decennial censuses based on United States Census Bureau estimates, but other than identifying certain MSAs having a population core of at least 2.5 million, does not rank MSAs based on population size. However, the U.S. Census Bureau periodically publishes a Statistical Abstract of the United States, which contains a table listing large MSAs, or MSAs having a population of 250,000 and over. For the purpose of this rule, we proposed to use these data to identify the largest MSAs.

In the May 1, 2006 proposed rule (71 FR 25665), we proposed a formula driven methodology for selecting the MSAs for competitive bidding in CYs 2007 and 2009. After we select the MSAs, we would define the CBAs. For the purpose of our proposal, DMEPOS allowed charges would be the Medicare fee-for-service (FFS) allowed charge data for DMEPOS items that we have authority to include in a competitive bidding program. These data do not include Medicare expenditures for DMEPOS items under the Medicare Advantage Program.

a. MSAs for CY 2007

We proposed to use a multiple step process in selecting the MSAs for CY 2007. First, we proposed to identify the 50 largest MSAs in terms of total population in CY 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, 25 MSAs out of the 50 MSAs identified in step one would be eliminated from consideration based on our determination that they have the lowest totals of DMEPOS allowed charges for items furnished in CY 2004. This step would allow us to focus on the 25 MSAs that have the highest totals of DMEPOS allowed charges which, we believe, would produce a greater chance of savings as a result of competitive bidding than MSAs with lower total DMEPOS allowed charges. Table 1 of the proposed rule (71 FR 25665 and 25666), which is republished below, illustrated the DMEPOS allowed charge data for items furnished in CY 2003 and Census Bureau population estimates as of July 1, 2003.

TABLE 1.—TOP 25 MSAS BASED ON TOTAL DMEPOS MEDICARE ALLOWED CHARGES FOR CY 2003

MSA	Allowed charges
New York-Northern New Jersey-Long Island, NY-NJ-PA (New York)	$312,124,291
Los Angeles-Long Beach-Santa Ana, CA (Los Angeles)	253,382,483
Miami-Fort Lauderdale-Miami Beach, FL (Miami)	221,660,443
Chicago-Naperville-Joliet, IL-IN-WI (Chicago)	173,922,952
Houston-Baytown-Sugar Land, TX (Houston)	149,060,607
Dallas-Fort Worth-Arlington, TX (Dallas)	139,910,862
Detroit-Warren-Livonia, MI (Detroit)	121,444,298
San Juan, PR	108,478,208
Philadelphia-Camden-Wilmington, PA-NJ-DE-MD (Philadelphia)	97,487,063
Atlanta-Sandy Springs-Marietta, GA (Atlanta)	75,860,276
Tampa-St. Petersburg-Clearwater, FL (Tampa)	71,309,635
Boston-Cambridge-Quincy, MA-NH (Boston)	62,467,094
Washington-Arlington-Alexandria, DC-VA-MD-WV (DC)	61,416,109
Baltimore-Towson, MD (Baltimore)	59,714,310
Pittsburgh, PA	56,612,095
St. Louis, MO-IL	55,931,373
Riverside-San Bernardino-Ontario, CA (Riverside)	52,910,209
Cleveland-Elyria-Mentor, OH (Cleveland)	52,237,312
Orlando, FL	51,982,164
San Francisco-Oakland-Fremont, CA (San Francisco)	45,565,320
San Antonio, TX	44,113,886
Cincinnati-Middletown, OH-KY-IN (Cincinnati)	41,582,961
Kansas City, MO-KS	41,310,326
Virginia Beach-Norfolk-Newport News, VA-NC (Virginia Beach)	41,016,726
Charlotte-Gastonia-Concord, NC-SC (Charlotte)	37,874,144

Table 1 showed the 25 MSAs that would be left for consideration after step two is completed. However, we proposed to select the actual MSAs for CY 2007 using U.S. Census Bureau population data published as of July 1, 2005, and DMEPOS allowed charge data for items furnished in CY 2004. We proposed using population data for CY 2005 and DMEPOS allowed charge data for CY 2004 because we believed these data would be the most recently available data at the time that the MSAs are selected for CY 2007 implementation. We now have more current utilization data (that is, from CY 2005); we will use these data in selecting the MSAs for the first round of competitive bidding.

Third, we proposed to score the MSAs based on combined rankings of DMEPOS allowed charges per FFS beneficiary (charges per beneficiary) and the number of DMEPOS suppliers per number of beneficiaries receiving DMEPOS items (suppliers per beneficiary) in CY 2004, with equal weight (50 percent) being given to each factor. The MSAs would be ranked from 1 to 25 in terms of DMEPOS allowed charges per FFS beneficiary (for example, the MSA with the highest DMEPOS allowed charges per FFS beneficiary would be ranked number 1). Similarly, areas having more suppliers per beneficiary are more likely to be

competitive and would be ranked higher than MSAs having fewer suppliers per beneficiary. Based on our experience from the DMEPOS competitive bidding demonstrations, the number of suppliers would be based on suppliers with at least $10,000 in allowed charges attributed to them for DMEPOS items furnished in the MSA in CY 2004. The number of beneficiaries would be based on the number of beneficiaries receiving DMEPOS items in the MSA in CY 2004. If more than one MSA receives the same score, we proposed to use total DMEPOS allowed charges for items that we have authority to include in a competitive bidding program in each MSA as the tiebreaker because this would be an indicator of where more program funds would be spent on DMEPOS items subject to competitive bidding. Table 2 in the proposed rule (71 FR 25666), which is republished below, illustrated how the 25 MSAs from Table 1 in the proposed rule would be scored, based on data for CY 2003.

TABLE 2.—SCORING OF TOP 25 MSAS BASED ON DATA FOR CY 2003

[Scoring based on combined rank from columns 3 and 4]

MSA	Score	Charges per beneficiary	Suppliers per beneficiary	Allowed charges
Miami	3	$428.44 (1)	0.01121 (2)	$221,660,443
Houston	6	348.83 (2)	0.00864 (4)	149,060,607
Dallas	8	297.33 (3)	0.00749 (5)	139,910,862
Riverside	9	220.93 (8)	0.01144 (1)	52,910,209
San Antonio	9	243.03 (6)	0.00897 (3)	44,113,886
Los Angeles	11	277.16 (5)	0.00692 (6)	253,382,483
Charlotte	14	226.09 (7)	0.00661 (7)	37,874,144
Orlando	18	212.57 (9)	0.00569 (9)	51,982,164
San Juan	25	291.97 (4)	0.00388 (21)	108,478,208
Atlanta	25	185.80 (15)	0.00569 (10)	75,860,276
Tampa	25	190.30 (13)	0.00529 (12)	71,309,635
Kansas City	25	186.39 (14)	0.00555 (11)	41,310,326
Pittsburgh	26	197.95 (11)	0.00484 (15)	56,612,095
Virginia Beach	26	207.28 (10)	0.00477 (16)	41,016,726
St. Louis	32	169.81 (18)	0.00488 (14)	55,931,373
San Francisco	32	127.56 (24)	0.00632 (8)	45,565,320
Cincinnati	32	167.06 (19)	0.00528 (13)	41,582,961
Cleveland	33	182.01 (16)	0.00470 (17)	52,237,312
Detroit	37	195.99 (12)	0.00290 (25)	121,444,298
Baltimore	37	174.38 (17)	0.00396 (20)	59,714,310
Philadelphia	40	152.38 (21)	0.00443 (19)	97,487,063
DC	41	128.97 (23)	0.00449 (18)	61,416,109
Chicago	44	160.26 (20)	0.00327 (24)	173,922,952
New York	45	139.81 (22)	0.00342 (23)	312,124,291
Boston	47	113.99 (25)	0.00371 (22)	62,467,094

We proposed that the final scoring be based on utilization data for CY 2004 and population data for CY 2005 because we believed these data would be the most recently available data at the time that the MSAs are selected for CY 2007 implementation. However, we will use utilization data for CY 2005 when we perform the final scoring for the third step because this is the most current utilization data that we have.

For purposes of phasing in the programs, we proposed to exclude from consideration for competitive bidding until CY 2009 the three largest MSAs in terms of population, as well as any MSA that is geographically located in an area served by two DME MACs. The three largest MSAs based on total population (based on CY 2003 data) are New York, Los Angeles, and Chicago. We believe that these MSAs should not be phased in until CY 2009 because of the logistics associated with the start-up of this new and complex program. As of 2000, each of these three MSAs had a total population of over 9 million. By comparison, the largest area in which the demonstrations were conducted was San Antonio (total population of 1.7 million in 2000). We want to gain experience with the competitive bidding process in MSAs larger than San Antonio before moving onto the three largest MSAs. After we have gained experience operating competitive bidding programs in CBAs that encompass smaller MSAs in CYs 2007 and 2008, we plan to implement programs that include New York, Los Angeles, and Chicago in CY 2009.

In the May 1, 2006 proposed rule, we indicated that we were considering an alternative under which we would establish CBAs that include portions of one or more of these MSAs (for example, by county). We believe that this alternative is authorized by section 1847(a)(1)(B)(II) of the Act, which states that competition under the programs shall occur in 80 of the largest MSAs in CY 2009 but does not require the competition to occur in the entire MSA. In addition, section 1847 of the Act does not prohibit us from implementing a competitive bidding program in an area that is larger than a MSA. In the proposed rule, we solicited specific comments on these alternatives.

Comment: Several commenters stated that CMS does not have the authority to extend or decrease the size of the MSA boundaries and that this proposal is inconsistent with the statute. They noted that section 1847(a)(1)(B) of the Act requires that competitive acquisition occur in MSAs in CY 2007 and CY 2009, and only authorizes competitive acquisition in ''other areas'' after CY 2009.

Response: Section 1847(a)(1)(B) of the Act requires that competition under the programs occur in CY 2007 and CY 2009 in a minimum number of MSAs. We did not propose to extend or decrease any MSA boundaries. Rather, we stated that section 1847(a)(1)(B) of the Act does not require us to define the boundaries of a CBA congruently with the boundaries of an MSA, as long as 10 MSAs are involved in CY 2007 and 80 MSAs are involved in CY 2009. We also proposed to consider an area for inclusion in a CBA in CY 2007 or CY 2009, or both,

if (1) The area is not part of the MSA but adjoins an MSA in which a competitive bidding program will be operating; (2) the area is competitive (meaning that it has high DMEPOS utilization, significant expenditures, and/or a large number of suppliers that furnish items that will be included in the competitive bidding program for the adjoining MSA); and (3) the area is part of the normal service area or market for suppliers that also serve the MSA market or areas within the boundaries for an MSA in which a competitive bidding program will be operating. We continue to believe this approach is reasonable because if an area meets these criteria, we believe that we could properly characterize the area as being integrated with the MSA in terms of the DMEPOS market.

Comment: One commenter recommended that, when picking the first 10 MSAs, CMS should pick the smallest of the 10 largest MSAs.

Response: Section 1847(a)(1)(B) of the Act requires us to phase-in the competitive bidding programs so that the competition occurs in 10 of the largest MSAs in 2007. The process that we proposed and are finalizing in this final rule is a formula driven approach that bases the decision on the total population of an MSA, the Medicare allowed charges for DMEPOS items per FFS beneficiary in an MSA, the total number of DMEPOS suppliers per FFS beneficiary who received DMEPOS items in an MSA, and the MSA's geographic location, for example, in the first round, to ensure that there is at least one CBA in each DME MAC region. We believe that this approach will result in the selection of MSAs that have more potential to produce savings for the Medicare program than we might otherwise achieve if we selected MSAs based on their size alone. However, we also recognize that implementing the Medicare DMEPOS Competitive Bidding Program will involve many challenges, and we want to gain sufficient experience in administering the program before we implement competitive bidding programs in the three largest MSAs in terms of population size. Therefore, we proposed to exclude the MSAs that include New York City, Los Angeles, and Chicago from the competition that will occur in CY 2007.

Comment: One commenter recommended excluding Miami from the first round of bidding. The commenter noted that Miami has the largest MSA market based charges per beneficiary, suppliers per beneficiary, and total DMEPOS allowed charges. The commenter stated that there is a big difference between the Medicare DMEPOS market in an MSA and the total population of an MSA. The commenter also recommended that CMS exclude, until CY 2009, or once further experience has been accumulated and cultural competency has been accounted for, culturally diverse MSAs such as Miami and those located in Puerto Rico from competitive bidding. A number of other commenters also recommended excluding MSAs located in Puerto Rico.

Response: We believe our methodology results in the selection of top priority areas in terms of potential savings for the program. Cultural diversity is not one of the factors we considered when developing a formula driven approach because our goal in implementing the program is to select areas that provide the greatest opportunity for savings.

We proposed not to include CBAs that cross DME MAC regions because this could complicate implementation by having two DME MACs processing claims from one CBA.

The next step that we proposed entails ensuring that there is at least one CBA in each DME MAC region by first selecting the highest scoring MSA in each DME MAC region (other than New York, Los Angeles, Chicago, or MSAs that cross DME MAC boundaries). This would ensure that each DME MAC gains some experience with competitive bidding prior to CY 2009, when competitive bidding would be implemented in CBAs that include 80 MSAs.

Comment: One commenter recommended that one MSA be selected from each DME MAC region for CY 2007.

Response: Section 1847(a)(1)(B) requires us to implement competitive bidding in 10 of the largest MSAs in CY 2007. We are adopting as final the approach outlined in our proposed rule (71 FR 25667) which ensures that there is a least one CBA in each DME MAC region. This would ensure that each DME MAC region gains experience with the competitive bidding program prior to CY 2009 when we phase in 70 additional CBAs.

We also proposed to select no more than two MSAs per State among the initial CBAs selected for CY 2007 in order to learn how competitive bidding works in more States and regions of the country. In summary, we proposed to select the 10 MSAs in which competition under the programs would occur in CY 2007 using the following steps:

- 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 DME MAC boundaries.
- Select the lowest scoring MSA from each DME MAC region.
- Select the next six lowest scoring MSAs regardless of DME MAC 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.

In the proposed rule, we indicated that we considered a number of alternative methods for selecting the MSAs for CY 2007. We indicated that the MSAs could be selected based on a combination of one or more variables or measures including, but not limited to—

- General population;
- Medicare FFS beneficiary population;
- Number of beneficiaries receiving DMEPOS items that we have authority to include in a competitive bidding program;
- Total Medicare allowed charges for DMEPOS items subject to competitive bidding; and
- Number of suppliers of DMEPOS items that we have authority to include in a competitive bidding program.

In evaluating these alternatives, we defined the general population as all individuals residing in an MSA, whether or not they were enrolled in Medicare. One advantage of this variable would have been that total population is a widely accepted measure of gauging MSA size and the data are readily accessible to the general public through the U.S. Census Bureau Web site. Another advantage of using this variable would be that total population takes into account the demand for DMEPOS items and other supplies from population groups other than the Medicare population. DMEPOS demand from non-Medicare individuals might make it less likely that a supplier not selected as a contract supplier would exit the market. This could help increase the likelihood of competition in future rounds of competitive bidding within that MSA. However, we recognize that the MSAs with the largest total populations might not have the

most Medicare beneficiaries or the greatest potential for savings. One reason is that the age distribution is not uniform across MSAs. MSAs located in States that have either large immigrant populations or have experienced rapid recent growth often have younger than average age profiles. Another reason is that DMEPOS utilization and potential profits are not uniform across MSAs. It is quite possible that some of the smaller population MSAs may have a greater potential for savings than MSAs with much larger populations. We believe that the disadvantages of selecting MSAs based on general population are greater than the advantages of using this method and, therefore, did not propose using general population as the sole variable in selecting the MSAs for CY 2007.

An advantage of selecting MSAs based on the Medicare FFS population would have been that this population represents the number of individuals who could potentially be affected by competitive bidding. A disadvantage of selecting MSAs based solely on this variable is that it does not reflect actual DMEPOS utilization. Therefore, we did not propose using the FFS population as the sole variable in selecting the MSAs for CY 2007. Per capita DMEPOS utilization rates vary across MSAs. As a result, MSAs with fewer Medicare beneficiaries could have a greater potential for savings from competitive bidding. The advantage of using the number of Medicare beneficiaries receiving DMEPOS items to select the MSAs is that MSAs would be selected based on the number of individual beneficiaries who are most likely to be directly affected by competitive bidding because they already have a need for these items. A disadvantage of this variable is that the number of specific beneficiaries receiving DMEPOS items is only a static measure. The number of beneficiaries who would be receiving DMEPOS products in the future could be substantially different from the current number. Treatment patterns within the MSA could change or the number of beneficiaries receiving DMEPOS items could fluctuate if beneficiaries switch from FFS benefits to a Medicare Advantage plan. For these reasons, we did not propose using the number of beneficiaries receiving DMEPOS items as the sole variable in selecting the MSAs for CY 2007.

Selecting the MSAs using the steps we proposed utilizes a variety of variables that we believe would help us predict which MSAs will offer the largest savings potential under a competitive bidding program. In step 2 above, we would focus on a subset of large MSAs with higher allowed charges for DMEPOS items, which is consistent with section 1847(a)(1)(B)(ii) of the Act and which would allow us to phase in the Medicare DMEPOS Competitive Bidding Program first for those items that have the highest cost and highest volume, or those items that have the largest savings potential. This step would directly address the question of which MSAs have the highest costs. In step 3 above, we proposed to use allowed DMEPOS charges per beneficiary and the number of suppliers per beneficiary to further measure the savings potential for each MSA. Allowed DMEPOS charges per beneficiary is a measure of per capita DMEPOS utilization in terms of the overall DMEPOS cost per beneficiary. We believe that areas with higher utilization rates and costs would have a greater potential for savings under the programs, which will rely on competition among suppliers to lower costs in the area. Competition among suppliers is necessary for competitive bidding to be successful. Without sufficient competition among suppliers, suppliers have little incentive to submit low bids in response to the RFBs for DMEPOS products. In addition, we believe that competition for market share among winning suppliers will act as a market force to maintain a high level of quality products. The number of suppliers per beneficiary is a direct measure of how many suppliers are competing for each beneficiary's business. We expect that the higher the number of suppliers per beneficiary, the higher the degree of competition will be.

In the proposed rule, we invited specific comments about the selection method for the original 10 MSAs in CY 2007. We welcomed recommendations of other options and criteria for consideration. We indicated that, after further consideration of comments received, in the final rule, we may adopt other criteria regarding issues described above or other criteria and options brought to our attention through the comment process.

Comment: Several commenters recommended that CMS identify the initial 10 MSAs in the final regulation.

Response: We plan to announce the first 10 MSAs, which will be based on 10 of the largest MSAs, at the same time we publish this final rule.

Comment: Several commenters recommended that CMS stagger the implementation of the initial 10 MSAs to identify and correct problems encountered early in the implementation process.

Response: Section 1847(a)(1)(B)(i)(I) of the Act requires that the competition take place in 10 of the largest MSAs in CY 2007. In implementing competitive bidding programs in 10 CBAs that include these MSAs, we do not believe it is necessary or practical to use the staggered approach recommended by the commenters, as we believe that this would likely result in confusion for beneficiaries and suppliers and make the phase-in process too administratively complicated.

Comment: Several commenters suggested that CMS use an area selection methodology that initially results in a limited number of small CBAs. The commenters also stated that this is an experimental program. They noted that there is little geographic diversity in the CBAs identified in Table 2 of the proposed rule (republished as Table 2 in this final rule), and that based on this table, the CBAs would be disproportionately concentrated in DME MAC Region C. The commenters suggested that the geographic diversity should be expanded to provide more useful information that CMS can consider when implementing the program in more areas in the future.

Response: We believe that our proposed methodology for selecting MSAs will result in the selection of the most appropriate MSAs (and therefore CBAs) in terms of achieving one of the most critical goals of the program to reduce Medicare expenditures for DMEPOS. As we explained above, several aspects of our methodology, including in the first round of competitive bidding selecting at least one MSA in each DME MAC region, and selecting not more than two MSAs per State, allow for geographic diversity.

b. MSAs for CY 2009

In selecting the 70 additional MSAs in which competition will occur in CY 2009, we proposed using generally the same criteria used to select the MSAs for CY 2007 (proposed § 414.410(b)). Because the number of MSAs in which competition must occur in CY 2009 is much higher than the number for CY 2007, we proposed that the steps in the selection process would change as follows:

- We would 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.
- We would use the same criteria to score the MSAs as we would use in selecting the MSAs for CY 2007, but use data from CY 2006.

In the proposed rule, we indicated that one option we were considering and on which we requested comments is whether we should modify the

ranking of MSAs based on allowed DMEPOS charges per beneficiary so that it focuses on charges in each MSA for the items that experienced the largest payment reductions or savings under the initial round of competitive bidding in CY 2007.

In selecting the MSAs for CY 2009, we did not propose excluding the 3 largest MSAs in terms of population size or MSAs that cross DME MAC boundaries from the 80 largest MSAs to be included in the CBAs. In addition, we did not propose limiting the number of MSAs that could be selected from any one State.

Comment: One commenter suggested that New York, Los Angeles, and Chicago be top priorities in the CY 2009 phase of implementation due to the potential for significant cost savings to the Medicare program.

Response: These MSAs are only being excluded from consideration during the first phase of competitive bidding and will be included in the selection methodology for the second phase.

After consideration of the public comments we received, we are finalizing our rules under proposed §§ 414.410(a) and (b) regarding the methodology for MSA selection with only technical changes.

3. Establishing Competitive Bidding Areas and Exemption of Rural Areas and Areas With Low Population Density Within Urban Areas (§ 414.410(c))

Section 1847(a)(1) of the Act requires that we phase in competitive bidding programs and establish CBAs throughout the United States over several years beginning in CY 2007. Section 1847(a)(3)(A) of the Act gives us the authority to exempt ''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 or service.''

In the May 1, 2006 proposed rule, we proposed to use the authority in section 1847(a)(3) of the Act to exempt areas from competitive bidding if data for the areas indicate that they are not competitive based on one or more of the following indicators:

- Low utilization of items in terms of the 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.
- Low number of Medicare beneficiaries receiving FFS benefits in the area relative to other similar geographic areas.

We proposed to make decisions regarding what constitutes low (noncompetitive) levels of utilization, suppliers, and beneficiaries on the basis of our analysis of the data for allowed charges, allowed services for items that may be subject to competitive bidding, and the number of Medicare beneficiaries receiving FFS benefits and DMEPOS suppliers in specific geographic areas. In defining urban and rural areas, we proposed to use the definitions currently in § 412.64(b)(1)(ii) of our regulations. We proposed to incorporate these provisions in proposed § 414.410(c).

We invited comments on the methodologies we proposed for determining whether an area within an urban area that has a low population density is not competitive. We indicated that we would be reviewing the total allowed charges, the number of beneficiaries, and the number of suppliers to determine whether a rural area should be exempted from competitive bidding. In addition, we invited comments on standards for exempting particular rural areas from competitive bidding.

Comment: Several commenters believed that competitive bidding should not be implemented in MSAs with less than 500,000 people. They indicated that this will help keep small business owners in rural communities open and, therefore, beneficiary access in these areas will not be compromised.

Response: Section 1847(a)(1) of the Act requires that we establish competitive bidding programs throughout the United States. We have the authority under section 1847(a)(3) of the Act to exempt rural areas and areas with low population density within urban areas that are not competitive unless there is a significant mail order market for a particular item. When we implement the program, we will only include areas in CBAs that are competitive and that we believe will produce savings for the program. In addition, we have revised our rules regarding small suppliers in response to public comments and believe that the revised rules will help to ensure that small suppliers have an opportunity to participate in the Medicare DMEPOS Competitive Bidding Program. A full discussion of these modifications can be found in section XI. of this final rule.

After consideration of the public comments we received, we are finalizing, with only technical changes, proposed § 414.410(c) regarding the exclusion of rural areas or areas with low population density from a CBA.

4. Establishing Competitive Bidding Areas for CYs 2007 and 2009 (§§ 414.406(b) and (c))

Section 1847(a)(1)(B) of the Act requires that the competition ''occurs in'' 10 of the largest MSAs in CY 2007, and in 80 of the largest MSAs in CY 2009, but does not require us to define the competition boundaries concurrently with the MSA boundaries, as long as 10 MSAs are involved in CY 2007 and 80 MSAs are involved in CY 2009. Therefore, we do not believe that section 1847(a)(1)(B) of the Act prohibits us from extending individual competition areas beyond the MSA boundaries in CYs 2007 or 2009.

In the May 1, 2006 proposed rule, we proposed in § 414.406(b) to designate through program instructions each CBA in which a competitive bidding program will take place, and we proposed in § 414.406(c) that we could revise the CBAs if necessary. We also proposed (71 FR 25668) that an area (for example, a county, parish, or zip code) outside the boundaries of an MSA be considered for inclusion in a CBA for CY 2007 or CY 2009, or both if all of the following apply:

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

As explained in section VI.E.2. of this final rule, we proposed to define an MSA as a Core Based Statistical Area associated with at least one urbanized area that has a population of at least 50,000, and comprised of the central county or counties containing the core, plus adjacent outlying counties having a high degree of social and economic integration with the central county as measured through commuting. However, when using this definition to establish the boundaries of an MSA, OMB would not consider whether an area or areas adjoining an MSA are served by the same DMEPOS suppliers that furnish items to beneficiaries residing in the MSA. If an area has a high level of utilization, significant expenditures, and/or a large number of suppliers of DMEPOS items included in the competitive bidding program for the

adjoining MSA, we stated that we believe that it would be practical and beneficial to include this area in the CBA. The savings to the program associated with adding the area to the CBA would likely offset any incremental administrative costs incurred by the CBIC associated with including the area in the competitive bidding program for the MSA.

Finally, we did not propose to consider counties that do not adjoin an MSA for inclusion in a CBA for CY 2007 or CY 2009 because we believe that these outlying counties are too far removed from the areas that OMB has determined to be economically integrated. We stated that we have the discretion to define a CBA to be either concurrent with an MSA, larger than an MSA, or smaller than an MSA. We also stated that we would detail in the RFBs the exact boundaries of each CBA. We invited comments on the criteria to be used in considering whether to include counties outside MSAs in a CBA in CY 2007 or CY 2009.

Comment: Several commenters recommended that the maximum number of CBAs in a State should be one instead of two. They stated that the methodology should be changed to distribute the CBAs so that there are three areas in each of two of the DME MAC regions, and two in each of the remaining two DME MAC regions to ensure geographic distribution.

Response: We believe that our proposed methodology for selecting MSAs and designating CBAs will not only produce large savings for the Medicare program, but that it will also ensure that the work involved with administering the program and processing claims is evenly distributed among our contractors. We also note that one of the factors we proposed to consider when selecting MSAs is their geographic location.

Comment: Several commenters urged CMS to adopt CBAs that are somewhat smaller than the MSAs to help minimize the risk of a CBA crossing a state line or areas shared by more than one DMERC and to ensure adequate geographic distribution of suppliers within a CBA in order to maintain beneficiary access to competitively bid items.

Response: We proposed to designate CBAs whose boundaries are concurrent with, larger than, or smaller than the associated MSA because we believe that it is practical and beneficial to implement competitive bidding programs in areas that are integrated in terms of DMEPOS utilization, expenditures, and suppliers. We believe that these factors, as well as the other factors that we proposed to consider when designating CBAs, will help ensure that the CBAs are geographically distributed in a way that does not limit beneficiary access to competitively bid items. We also note that, as specified in § 414.412 of this final rule, each contract supplier will be required to furnish items to every beneficiary who maintains a permanent residence in the contract supplier's CBA. We believe that this requirement will further ensure that beneficiary access to competitively bid items is maintained.

Comment: Several commenters suggested that CMS not rely heavily on DMEPOS allowed charges per beneficiary and suppliers per beneficiary.

Response: We disagree. We believe that our methodology properly identifies large MSAs with a significant savings potential by considering DMEPOS allowed charges per FFS beneficiary and suppliers per FFS beneficiary, as these data would indicate that these MSAs have the largest number of suppliers available for competition and the most expenditures/utilization per Medicare beneficiary.

Comment: One commenter suggested that CMS divide the MSAs by some easily recognized boundaries as proposed as an alternative proposal in the proposed rule.

Response: We will establish the CBAs based on the most current data and use our authority to adjust the areas to exclude rural areas and areas with low population density within urban areas that are not competitive. We will set easily recognizable boundaries by using county lines and zip codes to identify the CBAs we select.

Comment: One commenter supported the criteria for MSA selection that would consider MSAs based on their total population, total DMEPOS charges, charges per beneficiary, and the number of DMEPOS suppliers per DMEPOS users. The commenter also suggested considering the numbers of suppliers of constituent categories of DMEPOS, for example, oxygen and supplies or hospital beds. The commenter believed that, if there are enough suppliers to conduct a competition for each of the constituent categories within a CBA, the constituent categories should be included in the competitive bidding program.

Response: We believe our methodology, which concentrates on allowed charges per beneficiary and suppliers per beneficiary, will result in the selection of areas with the most potential for savings under the programs. This methodology relies on average expenditures per beneficiary and the availability of competing suppliers. We believe that the criteria that we will be using are sufficiently representative to select the appropriate MSAs for competitive bidding because they will identify those MSAs that have high beneficiary allowed charges and a high number of DMEPOS suppliers per DMEPOS users. We acknowledge the value of more specific item data for the purposes of selecting items for competitive bidding. Therefore, we will be looking at utilization of items when we select the items for competitive bidding.

Comment: One commenter suggested that we identify the top 80 MSAs for competitive bidding using the methodology as proposed. However, for the initial competitive bidding program, the commenter proposed that the agency use only the allowed DMEPOS charges per beneficiary metric when selecting the 10 MSAs from the set of 80. The commenter believed that this selection methodology will provide us with a range of valuable data regarding areas that have many suppliers per beneficiary and areas that have fewer suppliers per beneficiary.

Response: We believe that selecting the initial 10 MSAs based on combined rankings of both DMEPOS allowed charges per FFS beneficiary and the number of DMEPOS suppliers per number of beneficiaries receiving DMEPOS items, as well as based on the MSA's total population and geographic area, is important and necessary for designating CBAs that will produce savings for the Medicare program. In addition, we believe that these factors are appropriate indicators of how robust competition is likely to be in an area which will ultimately result in lower prices and increased savings for the program.

Comment: One commenter questioned CMS' decision to exclude the top three MSAs from consideration for competition prior to CY 2009. The commenter stated that the decision was arbitrary and discriminatory.

Response: As stated in the proposed rule, because of the logistics associated with the startup of this new and complex program, we would like to gain experience in the first phase of competitive bidding prior to implementing programs in CBAs that include the three largest MSAs (New York, Los Angeles, and Chicago). However, we will include these MSAs when we consider which MSAs to select for the CY 2009 competition.

Comment: One commenter requested that implementation of competitive bidding be delayed indefinitely to

permit thoughtful review and revisions to the program.

Response: Section 1847(a)(1) of the Act requires that competition under the competitive bidding program occurs in 10 of the largest MSAs in CY 2007. Therefore, the Act does not permit us to delay indefinitely implementation of the program.

Comment: One commenter recommended that CMS count all suppliers that have submitted Medicare DMEPOS claims in the past year in determining the number of suppliers per beneficiary. The commenter asked if CMS will only calculate suppliers with physical locations inside of the CBA or if it will base its number of suppliers on those that have submitted Medicare claims for DMEPOS for a specific time period. Another commenter believed that the proposed dollar amount, $10,000, for suppliers with allowed charges attributed to them for DMEPOS items furnished in the MSA in CY 2004 is too low. In addition, the commenter added that the $10,000 threshold may be too small for some items of DME. The commenter further stated that for higher cost items, $10,000 in allowed charges would not indicate that the supplier has an adequate level of experience with a product to appropriately meet the needs of Medicare beneficiaries. The commenter suggested that CMS look at total allowed charges and allowed charges for the items being bid. In addition, the commenter recommended that the supplier set an appropriate dollar threshold for each product category that would demonstrate that the supplier has adequate experience with the product category before counting that supplier for MSA selection purposes.

Response: We believe that the $10,000 threshold will give us an assurance that there will be a sufficient number of suppliers that have the capability to serve the area regardless of the experience with the particular product category. For suppliers with less than $10,000 in allowed charges, we do not have the assurance that the majority of them because of the cost of participating in the competitive bidding program and accreditation will be interested in participating in the competitive bidding program. By including in our calculations only those suppliers with allowed charges of at least $10,000, we are ensuring that we select MSAs that have a large number of suppliers that are interested and able to participate in the competitive bidding program considering those suppliers.

Comment: One commenter recommended that CMS adjust data on DMEPOS allowed charges and on the number of beneficiaries and suppliers in ''snowbird'' locations before selecting CBAs.

Response: We believe that our methodology provides us with the most appropriate CBA selection and greatest savings for the program. As part of our evaluation of Medicare allowed charges for items per fee-for-service beneficiary and the total number of suppliers per fee-for-service beneficiary, we will consider how these data might be affected in areas where beneficiaries reside for only part of the year.

Comment: One commenter recommended that CMS exclude areas that have a high probability of experiencing a natural disaster until CY 2009 and consult with both the Federal Emergency Management Agency (FEMA) and the Department of Homeland Security before implementing competitive bidding in these areas.

Response: The statute provides us with a geographic exception authority only for rural areas and areas with low population density within urban areas that are not competitive, unless there is a significant nationwide market through mail order for a particular item or service. We do not have authority to exclude areas that might experience a natural disaster.

Comment: One commenter recommended that CMS initially implement competitive bidding programs in three CBAs in October 2007; in three CBAs in February 2008, and in four CBAs in June 2008. The commenter also recommended excluding St. Louis, Kansas City, Baltimore, and Washington, D.C. from the MSA selection process because these MSAs overlap with multiple DME MAC regions or recent transition to a new DME MAC. In addition, the commenter recommended excluding Orlando and San Antonio from the MSA selection process because these areas were part of the demonstration projects.

Response: We believe that our approach to conduct the competition in all 10 CBAs at once is appropriate and will ensure that the CBAs are geographically dispersed. In addition, as stated above, we believe that this approach will alleviate the confusion that could otherwise result if we conducted the competition in the manner suggested by the commenter. The statute provides us with a geographic exception authority only for rural areas and areas with low population density within urban areas that are not competitive, unless there is a significant nationwide market through mail order for a particular item or service.

Comment: One commenter recommended initially implementing competitive bidding programs in 3 MSAs, Miami, Houston, and Dallas, then 120 days later, implementing programs in the next 3 MSAs in February, and finally implementing programs in the last 4 MSAs. The commenter indicated that this will allow CMS to monitor and proactively make changes before it fully implements programs in the 10 MSAs.

Response: The statute requires that the competition occur in 10 of the largest MSAs in CY 2007. As we explained above, we believe that our methodology provides us with the most appropriate CBA selection methodology and greatest savings potential for the program and that initially implementing programs in all 10 CBAs at once will reduce the potential for confusion that could otherwise result if we conducted the competition in the sequence suggested by the commenter.

Comment: One commenter requested that CMS define ''combined rankings.'' The commenter asked whether this term means the allowed charges that suppliers have submitted to Medicare or the allowed payments.

Response: ''Combined rankings'' means a combined score for the DMEPOS allowed charges per beneficiary in an MSA and the number of DMEPOS suppliers per beneficiary in the same MSA with equal weight given to each. The term ''allowed charges'' includes both Medicare's approved payment amount and the beneficiary's coinsurance amount.

Comment: One commenter recommended that, in the situation where more than one MSA receives the same score, instead of using the total DMEPOS allowed charges for items that CMS has the authority to include in competitive bidding in each MSA as the tiebreaker, CMS use the FFS charges for the items proposed for bidding in each MSA and the total number of accredited suppliers in each MSA to break ties.

Response: We chose to use the total DMEPOS allowed charges because this number indicates the size of the overall business that is conducted in an MSA for items subjected to the competitive bidding program. We believe that using total DMEPOS allowed charges is a better indication of savings than the total number of suppliers in an area for the purpose of having a tie breaker because this measure indicates how many items are actually being furnished in an area.

Comment: One commenter agreed with our proposal to exclude the three largest MSAs from inclusion in competitive bidding until CY 2009.

Response: The three largest MSAs will be included in the list of potential MSA candidates for the CY 2009 competitive bidding program.

5. Nationwide or Regional Mail Order Competitive Bidding Program (§§ 414.410(d)(2) and 414.412(f) and (g))

Our data show that a significant percentage of certain items such as diabetic testing supplies (blood glucose test strips and lancets) are furnished to beneficiaries by nationwide mail order suppliers. Therefore, in the May 1, 2006 proposed rule (71 FR 25669), we proposed in § 414.410(d)(2) and §§ 414.412(f) and (g) to 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 these items across the nation or region to beneficiaries who elect to obtain them through the mail. We proposed that the national or regional CBAs under the Medicare DMEPOS Competitive Bidding Program would be phased in after CY 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.

We proposed that, prior to the establishment of a nationwide or regional competitive bidding program in CY 2010, mail order suppliers would be eligible to submit bids for furnishing items in one or more of the CBAs we establish for purposes of the CYs 2007 and 2009 implementation phases. In addition, beginning with programs implemented in CY 2010, we proposed that mail order suppliers would be eligible to submit bids in one or more CBAs to furnish items that are not included in a nationwide or regional competitive bidding program. Nationwide or regional mail order suppliers would be required to submit bids and be selected as contract suppliers for each CBA in which they seek to furnish these items. However, we proposed that they would have the choice of either submitting the same bid amounts for each CBA or submitting separate bids.

For items that are subject to a nationwide or regional mail order competitive bidding program, we proposed that suppliers that furnish these same items in the local market and do not furnish them via mail order would not be required to participate in the nationwide or regional mail order competitive bidding program. However, we would only allow these suppliers to continue furnishing the items in CBAs if they were selected as contract suppliers.

We proposed to allow these nonmail order suppliers to continue furnishing these items in areas subject to a competitive bidding program if the supplier has been selected as a contract supplier. When furnishing items to beneficiaries who do not maintain a permanent residence in a CBA, nonmail order suppliers would be paid based on the payment amount applicable to the area where the beneficiary maintains his or her permanent residence.

In a September 2004 report (GAO–04–765), GAO recommended that we consider using mail delivery for items that can be provided directly to beneficiaries in the home as a way to implement a DMEPOS competitive bidding strategy. In the proposed rule, we solicited comments on our proposal to implement this recommendation and on the types of items that would be suitable for a mail order competitive bidding program.

In addition, we requested public comment on an alternative that would require that replacement of all supplies such as test strips and lancets for Medicare beneficiaries be furnished by mail order suppliers under a nationwide or regional mail order program. For example, there are services paid under the Medicare Physician Fee Schedule (MPFS) that are associated with the furnishing of blood glucose testing equipment (for example, home blood glucose monitors) such as training, education, assistance with product selection, maintenance, and servicing, that do not relate to the furnishing of replacement supplies used with the equipment. Once the brand of monitor has been selected by the beneficiary, the services associated with furnishing the supplies must be provided on a timely basis and the beneficiary must receive the brand of test strips needed for his or her monitor. We invited public comment on whether the service of furnishing replacement test strips, lancets or other supplies can easily, effectively, and conveniently be performed by nationwide mail order suppliers.

Comment: Several commenters suggested that a separate program for mail order is unnecessary for CY 2010. They also noted that mail order supplies are not excluded for CYs 2007 and 2009.

Response: Our data indicate that over 60 percent of Medicare expenditures for diabetic supplies are for items furnished by nationwide mail order suppliers. We believe that the implementation of a separate mail order competitive bidding program would result in significant savings because it would focus on suppliers that can obtain discounts from manufacturers because they furnish a large volume of items to beneficiaries through the mail. Therefore, we envision that large savings for the Medicare program would result from the implementation of a separate mail order program.

Comment: Several commenters noted that there is no definition of a ''mail order supplier'' or description of a nationwide or regional mail order company in the proposed rule.

Response: In the proposed rule, we provided a definition of a ''supplier'' that includes an entity that furnishes items through the mail. However, to further prevent confusion, as discussed in section VI.A. we have added definitions of ''mail order contract suppler,'' ''nationwide mail order contract supplier,'' ''regional competitive bidding area,'' and ''regional mail order contract supplier'' in § 414.402. For purposes of competitive bidding a ''mail order contract supplier'' will be a contract supplier that furnishes items through the mail to beneficiaries who maintain a permanent residence in a competitive bidding area.

Comment: One commenter asked whether a supplier would qualify to participate in a mail order competitive bidding program if the supplier furnishes items both through the mail and through a storefront location to beneficiaries.

Response: Any national or regional mail order competitive bidding program that we might choose to implement starting in CY 2010 would be limited to the furnishing of items through the mail. Therefore, if a supplier wants to participate in a mail order program, it will have to submit a separate mail order program bid. Only a designated mail order contract supplier may furnish items under a mail order competitive bidding program. To participate in a program for providing items from a local storefront, a separate bid would have to be submitted.

Comment: One commenter noted that mail order is an appropriate and cost effective vehicle for delivery of some replacement supplies (test strips and lancets). Several commenters opposed the requirement for beneficiaries to use the mail order suppliers and suggested that the mail order program be voluntary for beneficiaries. Several commenters noted that beneficiaries

must have the option to get the supplies from their local suppliers.

Response: We continue to believe that a national or regional mail order program will be cost effective for the Medicare program, and did not propose that it would be mandatory for beneficiaries. Such a mail order program will be voluntary and beneficiaries will have the option to receive their items through the mail or from a local contract supplier.

Comment: One commenter suggested that CMS specifically ensure that all suppliers in a mail order competitive bidding program are in compliance with the DMEPOS quality standard that requires that ''mail services are not used for the initial delivery, set-up, and beneficiary education/training'' for DME equipment and supplies.

Response: The DMEPOS quality standard that the commenter is referring to was included in the draft quality standards that were released for public comments on September 25, 2005. Although the final quality standards do not preclude suppliers from furnishing certain DMEPOS through the mail, they also require suppliers to verify that a beneficiary has received an item and to provide clear instructions to the beneficiary related to the use, maintenance, and potential hazards of the item. A supplier cannot be accredited unless a CMS-approved accreditation organization has determined that the supplier is complying with the quality standards, and accreditation is a prerequisite to a supplier being eligible to participate in the Medicare DMEPOS Competitive Bidding Program. Therefore, our goal is to award contracts only to suppliers that conduct business in a manner that is beneficial to beneficiaries under the program. The final Quality Standards document can be found under the basic standards and the consumer services section at the Medicare DMEPOS Competitive Bidding Program Web site: *http://www.cms.hhs.gov/CompetitiveAcqforDMEPOS/04_New_Quality_Standards.asp#TopofPage.*

Comment: One commenter suggested that CMS not implement a mail order competitive bidding program for diabetes testing supplies until the effects of such a program on beneficiaries with diabetes have been carefully studied, perhaps through a pilot program.

Response: We do not believe a pilot program is necessary. Our data show that 60 percent of beneficiaries currently receive supplies from mail order suppliers. Under the competitive bidding programs, beneficiaries will continue to have the option of receiving their supplies through the mail or from a local supplier.

Comment: One commenter suggested that CMS create a national supplier designation for which suppliers, mail-order or retail, can apply.

Response: As we discussed above, we will separately designate the supplier numbers of all noncontract suppliers to monitor whether they are complying with the rules regarding the limited circumstances under which they can furnish a competitively bid item. To address the commenter's concern, in addition to differentiating between contract suppliers and noncontract suppliers, we will also differentiate between mail order contract suppliers and mail order noncontract suppliers. We will be making those designations with the award of contracts.

Comment: One commenter recommended that, if CMS decides to create a nationwide or regional mail order competitive bidding program, CMS include a program oversight provision related to refilling of supplies. The commenter suggested that CMS prohibit contract suppliers from automatically refilling and sending replacement supplies without receiving a refill request from the beneficiary.

Response: Section 200, Chapter 20 of the Medicare Claims Processing Manual (Publication 100–4), prohibits suppliers/manufacturers from automatically delivering replacement supplies to beneficiaries unless the beneficiary, or their caregiver has requested them. The reason for this prohibition is to ensure that the beneficiary actually needs the replacement supplies. This requirement will apply to the Medicare DMEPOS Competitive Bidding Program.

Comment: One commenter opposed mail order/drop shipping for oxygen and related equipment because this might actually encourage contract suppliers to ship oxygen cylinders or other similar devices than deliver directly to the beneficiary.

Response: Pursuant to our DMEPOS supplier standards at 42 CFR 424.57(c), a supplier must operate its business and furnish Medicare covered items in compliance with all applicable Federal and State licensure and regulatory requirements. Therefore, suppliers are required to furnish oxygen cylinders and other similar devices in accordance with these requirements.

6. Additional Competitive Bidding Areas After CY 2009 (§ 414.410(d)(1))

Section 1847(a)(1)(B)(III) of the Act requires that competition under the Medicare DMEPOS Competitive Bidding Program occur in additional areas after CY 2009. Beginning in CY 2010, we proposed in § 414.410(d)(1) to designate through program instructions additional CBAs based on our 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.

We did not receive any comments on this specific.

Therefore, after considering the comments we received on Section II. D. of the proposed rule, we are finalizing §§ 414.406(b)–(c) and § 414.410 as discussed above and with additional technical changes, which include specifying in § 414.406(b) that we may designate CBAs through program instructions or by other means. We are also adding a several definitions, including a of ''mail order contract supplier'' under § 414.402. Finally, we are finalizing §§ 414.412(f) and (g) as discussed above and with technical changes.

F. Criteria for Item Selection (§§ 414.402 and 414.406(d))

Section 1847(a)(2) of the Act describes the DMEPOS items that are subject to competitive bidding. They include:

- Durable medical equipment and medical supplies: Covered items (as defined in section 1834(a)(13) of the Act) for which payment would otherwise be made under section 1834(a) of the Act, including items used in infusion and drugs (other than inhalation drugs) and supplies used in conjunction with DME, but excluding class III devices under the Federal Food, Drug, and Cosmetic Act.
- Other equipment and supplies (enteral nutrition, equipment, and supplies)—Items described in section 1842(s)(2)(D) of the Act, other than parenteral nutrients, equipment, and supplies.
- OTS orthotics: Orthotics described in section 1861(s)(9) of the Act for which payment would otherwise be made under section 1834(h) of the Act, which require minimal self-adjustment for appropriate use and do not require expertise in trimming, bending, molding, assembling, or customizing to fit the individual.

In the May 1, 2006 proposed rule, we proposed in § 414.406(d) to designate the items that would be included in each competitive bidding program through program instructions. We also proposed (71 FR 25669) to define ''minimal self-adjustment'' to mean an adjustment that the beneficiary, caretaker for the beneficiary, or supplier of the device can perform without the assistance of a certified orthotist (that is, an individual certified by either the American Board for Certification in

Orthotics and Prosthetics, Inc., or the Board for Orthotist/Prosthetist Certification). We also proposed to consider any adjustments that can only be made by a certified orthotist to be adjustments that require expertise in trimming, bending, molding, assembling, or customizing to fit the individual. We proposed to consult with a variety of individuals, including experts in orthotics, to determine which items and/or HCPCS codes would be classified as OTS orthotics. We invited comments on a process for identifying OTS orthotics subject to competitive bidding.

Section 1847(a)(1)(B)(ii) of the Act gives us the authority to phase in competitive bidding ''first among the highest cost and highest volume items or those items that the Secretary determines have the largest savings potential.'' In addition, section 1847(a)(3)(B) of the Act grants us the authority to exempt items for which the application of competitive bidding is not likely to result in significant savings. In exercising this authority, we proposed to exempt items outright or on an area-by-area basis using area-specific utilization data. For example, if we found that utilization (that is, allowed services or allowed charges) for commode chairs was low (or the number of commode chair suppliers was low) in a given area compared to other areas, we might choose to exempt commode chairs from the competitive bidding programs in the CBA where significant savings would not be likely while including commode chairs in the competitive bidding programs for other CBAs. This decision would be based on area-specific utilization data.

We proposed to use the authority provided by section 1847(a)(1)(B)(ii) of the Act to phase in only those items that we determine are among the highest cost and highest volume items during each phase of the Medicare DMEPOS Competitive Bidding Programs. In section II.F. of the proposed rule, we proposed to conduct competitive bidding for product categories that would be described in each RFB. Suppliers would submit a separate bid for each item under a defined product category, unless specifically excluded in the RFB. We proposed to include a ''core'' set of product categories in each CBA. We indicated that we might elect to phase in some individual product categories in a limited number of CBAs in order to test and learn about their suitability for competitive bidding.

Because we had not yet identified the product categories for competitive bidding at the time we issued the proposed rule, we used policy groups developed by the statistical analysis durable medical equipment regional carrier (SADMERC) for purposes of illustration. The SADMERC has defined a set of 64 DMERC [DME MAC] policy groups for analytical purposes in its role as the statistical analysis contractor for DMEPOS. A policy group is a set of HCPCS codes that describe related items that are addressed in a DME MAC medical review policy. For example, the policy group ''oxygen and supplies'' consists of approximately 20 HCPCS codes. Although the product categories subject to competitive bidding will not necessarily correspond to these policy groups, we presented data for these policy groups and items contained in these policy groups for the purpose of identifying the highest cost and highest volume DMEPOS items that may be subject to competitive bidding. In other words, we proposed using SADMERC data for ''policy groups'' to identify groups of items we will consider phasing in first under the competitive bidding programs, but the actual ''product categories'' for which we would request bids could be a subset of items from a ''policy group'' or a combination of items from different ''policy groups.'' The highest volume items (HCPCS codes) fall into a relatively small number of policy groups as illustrated in Table 3.

TABLE 3.—CY 2003 HIGH VOLUME ITEMS (HCPCS CODES)

HCPCS code	Allowed charges	Product description	Policy group
E1390	$2,033,123,147	Oxygen concentrator	Oxygen.
K0011*	1,176,277,899	Power wheelchair with programmable features	Wheelchairs.
A4253	779,756,243	Blood glucose/reagent strips, box of 50	Diabetic Supplies & Equipment.
E0260	331,457,962	Semi-electric hospital bed	Hospital Beds/Accessories.
E0431	228,066,037	Portable gaseous oxygen equipment	Oxygen.
B4150*	206,396,813	Enteral formula, category I	Enteral Nutrition.
B4035	197,057,150	Enteral feeding supply kit, pump fed, per day	Enteral Nutrition.
E0277	156,762,241	Powered air mattress	Support Surfaces.
E0439	141,268,474	Stationary liquid oxygen	Oxygen.
E0601	123,865,463	Continuous positive airway pressure device (CPAP)	CPAP Devices.
K0001	103,217,209	Standard manual wheelchair	Wheelchairs.
K0004	87,208,486	High strength lightweight manual wheelchair	Wheelchairs.
A4259	79,575,166	Lancets, box of 100	Diabetic Supplies & Equipment.
E0570	76,588,088	Nebulizer with compressor	Nebulizers.
B4154*	76,326,903	Enteral formula, category IV	Enteral Nutrition.
E0143	75,950,410	Folding wheeled walker w/o seat	Walkers.
K0533*	75,136,517	Respiratory assist device with backup rate feature	Respiratory Assist Devices.
K0538*	65,603,531	Negative pressure wound therapy electrical pump	Negative Pressure Wound Therapy (NPWT) Devices.
K0532*	56,046,930	Respiratory assist device without backup rate feature	Respiratory Assist Devices.
K0003	55,318,959	Lightweight manual wheelchair	Wheelchairs.
K0108	52,139,979	Miscellaneous wheelchair accessory	Wheelchairs.
E0192*	48,413,938	Wheelchair cushion	Support Surfaces.
E0163	48,216,855	Stationary commode chair with fixed arms	Commodes.
B4034	42,277,968	Enteral feeding supply kit syringe, per day	Enteral Nutrition.

*Due to HCPCS coding changes made since 1993, the descriptions or code numbers for these codes have been modified. The power wheelchair codes became effective November 15, 2006 and will be billed under several new HCPCS codes.

Because we proposed that we would conduct competitive bidding for items grouped into product categories, we indicated that we would consider DMEPOS allowed charges and volume at the product category level for the

purpose of selecting which items to phase in first under the competitive bidding programs. The table below provides data for the top 20 policy groups based on Medicare allowed charges for the items within each policy group that we may choose to include in the competitive bidding programs. Data from the SADMERC for claims received in CY 2003 are used for all policy groups except those for nebulizers and OTS orthotics. For the nebulizer and OTS orthotics groups, data are included from the CMS BESS (Part B Extract and Summary System) database for items furnished in CY 2003. The percentage of total allowed Medicare charges for DMEPOS that each policy group makes up is included in Table 4.

TABLE 4.—CY 2003 DMEPOS ALLOWED CHARGES BY POLICY GROUP

Rank	Policy group	CY 2003	Percent of DMEPOS
1	Oxygen Supplies/Equipment	$2,433,713,269	21.3
2	Wheelchairs/Power Operated Vehicle (POVs) **	1,926,210,675	16.9
3	Diabetic Supplies & Equipment	1,110,934,736	9.7
4	Enteral Nutrition	676,122,703	5.9
5	Hospital Beds/Accessories	373,973,207	3.3
6	CPAP Devices	204,774,837	1.8
7	Support Surfaces	193,659,248	1.7
8	Infusion Pumps & Related Drugs	149,208,088	1.3
9	Respiratory Assist Devices	133,645,918	1.2
10	Lower Limb Orthoses *	122,813,555	1.1
11	Nebulizers *	98,951,212	0.9
12	Walkers	96,654,035	0.8
13	Negative Pressure wound therapy (NPWT) Devices	88,530,828	0.8
14	Commodes/Bed Pans/Urinals	51,372,352	0.5
15	Ventilators	42,890,761	0.4
16	Spinal Orthoses *	40,731,646	0.4
17	Upper Limb Orthoses *	29,069,027	0.3
18	Patient Lifts	26,551,310	0.2
19	Seat Lift Mechanisms	15,318,552	0.1
20	TENS Devices **	15,258,579	0.1
Total for 20 Groups		7,830,384,538	68.6
Total for DMEPOS		11,410,019,351	

* Data are from the CMS BESS (Date of Service). Data for orthoses policy groups exclude data for custom fabricated orthotics, but may include data for other items that will not be considered OTS orthotics.
** POVs are power-operated vehicles (scooters), and TENS devices are transcutaneous electrical nerve stimulation devices.

Section 1847(a)(1)(B)(ii) of the Act provides that the items we phase in first under competitive bidding may include products having the greatest potential for savings. In the May 1, 2006 proposed rule, we proposed 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 competitive bidding demonstrations.
- Reports and studies.

We proposed that items with high allowed charges or rapidly increasing allowed charges would be our highest priority in selecting items for competitive bidding.

The number of suppliers furnishing a particular item or group of items would also be an important variable in identifying items with high savings potential. We believe that a relatively large number of suppliers for a particular group of items would likely increase the degree of competition among suppliers and increase the probability that suppliers would compete on quality for business and market share. We saw evidence in the competitive bidding demonstrations that products furnished by a large number of suppliers had large savings rates and fewer problems with quality. We understand that having a large number of suppliers is not always a necessary condition for competition. A CBA could be more concentrated and less competitive than the number of suppliers would predict if the market is dominated by only a few suppliers and the remaining suppliers have only minimal charges.

The DMEPOS competitive bidding demonstrations took place from 1999 to 2002 in two MSAs: Polk County, Florida and San Antonio, Texas. Five product categories containing items we might include in the Medicare DMEPOS Competitive Bidding Programs were included in at least one round of these demonstrations: oxygen equipment and supplies; hospital beds and accessories; enteral nutrition; wheelchairs and accessories; and general orthotics.

The results of the demonstrations provide useful information because they are based on actual Medicare competitive bidding and the amounts suppliers actually were willing to accept as payment from Medicare. However, we recognize that these results should be used with caution. The demonstrations occurred more than 3 years ago and the fee schedule has changed as a result of certain provisions in the MMA (for example, section 302(c)(2) of the MMA (codified at section 1834(a)(21) of the Act), which requires that CMS adjust the fee schedules for certain items based on a comparison to other payers such as the Federal Employees Health Plan (FEHP)).

The HHS Office of the Inspector General (OIG) and GAO frequently conduct studies that analyze the extent to which Medicare overpays for specific items, and we believe that these studies could assist with determining the saving potential for an item if it were included in competitive bidding. Examples of relevant OIG studies include the following:

- Medicare Allowed Charges for Orthotic Body Jackets, March 2000 (OEI–04–97–00391);

• Medicare Payments for Enteral Nutrition, February 2004 (OEI–03–02–00700); and

• A Comparison of Prices for Power Wheelchairs in the Medicare Program, April 2004 (OEI–03–03–00460).

In addition, CMS and the DME MACs obtain retail pricing information for items in the course of establishing fee schedule amounts and considering whether payment adjustments are warranted for items using the inherent reasonableness authority in section 1842(b)(8) of the Act. In the proposed rule, we indicated that we could use these studies to identify products where CMS pays excessively and where we could potentially achieve savings.

Excessive payments are only one factor to consider when evaluating whether savings will be realized by the application of competitive bidding to an item. However, these studies offer us a guide regarding which items may have the greatest potential for savings. We also recognize that some studies are older than others and that recent MMA and FEHP reductions in fees may affect whether the results of these studies are still relevant.

Comment: Many commenters objected to the proposed definition for OTS orthotics that would be subject to competitive bidding in accordance with section 1847(a)(2)(C) of the Act. They specifically objected to the discussion in the proposed rule that states that the expertise required to trim, bend, assemble, mold, or custom fit an orthotic device for an individual would be that of a certified orthotist. They pointed out that occupational therapists, physical therapists, and physicians are licensed and trained to trim, bend, mold, assemble, and customize some orthotics to fit a beneficiary. They indicated that under the Act, occupational and physical therapists are recognized as Medicare practitioners who furnish orthotics to Medicare beneficiaries pursuant to a written plan of care. The commenters added that the Act recognizes orthotists as suppliers of DMEPOS only and not as practitioners. They recommended revising the language to read: '' 'Minimal self-adjustment' means an adjustment that the beneficiary, caretaker for the beneficiary, or supplier of the device can perform without the assistance of a physician, physical therapist, occupational therapist, orthotist, or other professional designated by the Secretary.''

In addition, many commenters stated that there is no Federal definition of orthotists or their scope of practice and that a limited number of States have licensure or certification laws for orthotists. They added that, for those States that have such laws, the scope of practice varies considerably. The commenters recommended including the statutory definition of ''qualified practitioner'' located in section 1834(h)(1)(F)(iii) of the Act to identify those individuals with expertise in custom fitting orthotics. They believed that linking OTS orthotics to the work of a certified orthotist would dramatically expand the list of products that are considered OTS orthotics that would be subject to competitive bidding. They further noted that the list of OTS orthotics has yet to be published.

Response: We appreciate the comments. Section 1847(a)(2) of the Act describes OTS orthotics as those orthotics described in section 1861(s)(9) of the Act for which payment would otherwise be made under section 1834(h) of the Act, which require minimal self-adjustment for appropriate use and do not require expertise in trimming, bending, molding, assembling, or customizing to fit to the individual. Orthotics that are currently paid under section 1834(h) of the Act and are described in section 1861(s)(9) of the Act are leg, arm, back, and neck braces. The Medicare Benefit Policy Manual, Chapter 15, Section 130 provides the longstanding Medicare definition of ''braces.'' Braces are defined in this section as ''rigid or semi-rigid devices which are used for the purpose of supporting a weak or deformed body member or restricting or eliminating motion in a diseased or injured part of the body.'' To clarify the definition of OTS orthotics for purposes of competitive bidding, in this final rule we are defining the term ''minimal self-adjustment'' to mean an adjustment that the beneficiary, caretaker for the beneficiary, or supplier of the device can perform and that does not require the services of a certified orthotist (that is, an individual who is certified by the American Board for Certification in Orthotics and Prosthetics, Inc., or by the Board for Orthotist/Prosthetist Certification) or an individual who possesses specialized training. These individuals possess specialized skills and knowledge used to custom fit braces for individual beneficiaries so that they function appropriately. Therefore, if an adjustment to an OTS orthotic that requires expertise in trimming, bending, molding, assembling, or customizing to fit the individual such that it must be performed by a certified orthotist (that is, an individual who is certified by the American Board for Certification in Orthotics and Prosthetics, Inc. or by the Board for Orthotist/Prosthetist Certification) or someone who possesses specialized training, it would not be an OTS orthotic that is eligible to be included in a competitive bidding program.

As we proposed, we will identify specific OTS orthotics that will be included in specific competitive bidding programs through program instructions.

Comment: Several commenters requested exemption of OTS orthotics that have the HCPCS codes L3908–L3954 (wrist, hand, and finger orthoses) and L3980–L3985 (upper extremity fracture orthoses). They believed that these codes should be exempted because clinicians and practitioners use them for short-term protection and stabilization of a joint or limb. They further indicated that practitioners do not dispense these items as a product or supply item but rather as part of the evaluation and treatment of beneficiaries.

Response: Section 1847(a)(2) of the Act provides that OTS orthotics described in section 1861(s)(9) of the Act, for which payment would otherwise be made under section 1834(h) of the Act, are to be included in the Medicare DMEPOS Competitive Bidding Program if they require minimal self-adjustment for appropriate use and do not require expertise in trimming, bending, molding, assembling, or customizing to fit the individual. Although the items identified by the commenters are orthotics as described in section 1861(s)(9) of the Act for which payment is made under section 1834(h) of the Act, we have not yet determined whether they require minimal self-adjustment. We have also not yet determined whether one or more of these items might not be appropriate for inclusion in the Medicare DMEPOS Competitive Bidding Program because it is not likely to produce significant savings. We will consider the commenters' suggestions and designate the items that will be included in each competitive bidding program through program instructions or by other means, such as the RFB or our Web site.

Comment: Several commenters believed that the selection of items for competitive bidding is being driven by allowed charges and utilization only. They believed that this poses a risk and allows competitive bidding to become a substitute for appropriate coverage policies as a way of controlling expenditures. The commenters believed that consideration of clinical and service factors specific to the product should be part of the selection criteria.

Response: We do not have data on which we could evaluate clinical and service factors specific to individual items nor were any data submitted through the public comment process. In addition to allowed charges and utilization, we identified in the proposed rule the following variables that we will use to select items for competitive bidding: Annual growth in expenditures; number of suppliers; savings in the DMEPOS competitive bidding demonstrations; and reports and studies. We stated that we would use all of these variables to make determinations about an item's potential to reduce costs for the Medicare program. We note that the Medicare DMEPOS Competitive Bidding Program is not a coverage program, and that this final rule does not supersede in any way Medicare coverage laws, regulations, or policies.

Comment: Several commenters believed that ostomy products and supplies do not meet the definition of DME and, therefore, are not part of the items and services subject to the competitive bidding programs described in section 1847(a)(2)(A) of the Act.

Response: We believe that section 1847(a)(2)(A) of the Act is ambiguous regarding whether ostomy products and supplies are to be included in the Medicare DMEPOS Competitive Bidding Program because the term ''medical supplies'' in the section heading could be interpreted either to modify the term ''durable medical equipment'' (meaning that the medical supplies would have to be associated with the DME to be included), or to be a separate category of items that are not associated with DME. In addition, although the definition of ''covered item'' in section 1834(a)(13) of the Act means ''durable medical equipment (as defined in section 1861(n) [of the Act]), including such equipment described in section 1861(m)(5) [of the Act] * * *,'' the term ''such equipment'' in section 1861(m)(5) of the Act could be interpreted to refer either to the term ''durable medical equipment'' or to the term ''medical supplies'' (which would include ostomy supplies) in that section. In light of these ambiguities, we believe we have discretion to interpret section 1847(a)(2)(A) of the Act to include or exclude ostomy products and supplies in the competitive bidding programs. We are not planning to exercise our authority to include these items at this time and will continue to review this issue.

Comment: Many commenters believed that the following items that are integral to beneficiary care should be exempted from competitive bidding: diabetic supplies; diabetic shoes; diabetic inlays; prosthetics for the foot; crutches; walkers; fracture ankle-foot orthoses; braces; splints; and surgical dressings. A few commenters requested exemption of products commonly provided directly by manufacturers. They believed that the products are available from relatively few suppliers and would not produce Medicare savings.

A few commenters requested the exemption of oxygen, continuous positive airway pressure devices, and invasive and noninvasive ventilation devices. They believed that these items are technologically complex devices. Several commenters recommended exempting negative pressure wound therapy (NPWT) devices from the first round of competitive bidding. They reported that in October 2000, a new HCPCS code (E2402) was established for NPWT. Since 2003, more than 3,000 physicians have ordered NPWT devices more than 36,000 times. They reported that new products have been added to HCPCS code E2402 despite the fact that these new products are clinically different from the original NPWT product. The commenters believed that the newer items are not yet well-understood or well-established and physician choice in selecting an item must be respected.

Many commenters requested exemption of power wheelchairs, including complex rehabilitative and assistive technology devices, for the first round of competitive bidding. They believed that competitively bidding these devices would result in a negative impact on the clinical outcome for the beneficiary. They described these items as being uniquely prescribed for the beneficiary. The commenters recommended exempting wheelchair cushions, adaptive seating, and positioning products. They indicated beneficiaries who require complex rehabilitative or assistive technology require a complete system to meet their functional and medical needs. The commenters pointed out that a complete system requires several pieces of equipment, each meeting a specific medical or functional need and determined to be compatible technologies. They believe that the recent changes in HCPCS codes for power mobility devices, a new local coverage determination policy, and new fee schedules will significantly impact the utilization and allowed charges for these items. They believe that, in light of these changes, there will be a lack of allowed charges and volume data that will make it difficult to determine which codes have the highest allowed charges and highest volume or potential for savings.

Many commenters requested the exemption of manual wheelchairs because as early as CY 2007, the HCPCS codes will be subjected to a recoding process that is similar to the recoding process that CMS recently undertook for power mobility devices. Under the proposed rule, a supplier that bids on the category of manual wheelchairs must be prepared to provide all types of manual wheelchairs including standard, ultra lightweight, bariatric, or manual tilt-in-space. They believed that the current HCPCS codes are too broad, encompassing items that represent vastly different technologies.

Several commenters requested the exemption of speech generating devices (SGDs). They stated the functional, physical, operational, and support characteristics of a specific SGD model are selected based on the individual needs of the beneficiary. The commenters reported that Medicare has purchased fewer than 5,000 SGDs since 2001. They indicated that, on average, 1,211 SGDs are purchased per year, and that in 2004, Medicare spent only $4,562 on SGDs (code E2511), less than $220,000 on mounting systems (code E2512), and less than $280,000 on all SGD accessories.

Some commenters requested that CMS not create a product category that consists of ''infusion pumps and related drugs.'' They pointed out that infusion drugs are covered under the DMEPOS benefit because they go through the pump, which is DME. They added that managed care plans include home infusion therapy coverage under either their major medical benefit or their prescription drug benefit and that Medicare Part D covers hundreds of home intravenous drugs. The commenters believed that there is confusion among beneficiaries who require Medicare Part B and Part D drugs, and that adding infusion pumps that are used for drug administration to competitive bidding will confuse both beneficiaries and referral agents further. They also indicated that these devices vary in drug therapy, technology, length of treatment, and site of care, and that the devices range from critical acute care to chronic infusion.

Some commenters requested the exemption of enteral nutrition equipment and supplies. They believed that the use of competitive bidding to set prices under Medicare has not been tested sufficiently or successfully. The commenters indicated that Medicare allowed charges for enteral nutrition decreased by approximately 5 percent from CY 2003 to CY 2004. They

reported that there is confusion among beneficiaries who require Medicare Part B and Part D drugs, and believed that adding competitive bidding will only confuse beneficiaries and referral agents further.

A few commenters requested the exemption of transcutaneous electrical nerve stimulator (TENS) devices from competitive bidding. They believed that these devices constitute a miniscule percentage of Medicare charges, and that including these devices in one product category will induce beneficiaries to purchase inferior services. They reported that some manufacturers include a post-sale periodic monitoring service, whereas others do not.

Some commenters requested the exemption of support surfaces until the completion of the Support Surface Standards Initiative. They indicated that data from the Agency for Healthcare Research and Quality showed an increase in hospitalizations for beneficiaries with pressure ulcers up to 63 percent during the period 1993 through 2003. The commenters recommended that if support surfaces are selected for competitive bidding, CMS subdivide the codes and evaluate separate bids for each subcategory. They also recommended that stakeholders be consulted regarding the subcategories.

Several commenters stated that Medicare should not subject vision-related DMEPOS commonly dispensed by optometrists to competitive bidding. They believed that optometrists should not be required to submit a bid.

Many commenters recommended the following sources for gathering information about various homecare services and allowed charges: American Society for Parenteral and Enteral Nutrition (ASPEN), American Association for Respiratory Care (AARC), American Nurses Association (ANA), American Dietetic Association (ADA), National Home Oxygen Patients Association (NHOPA), American Lung Association (ALA), American Diabetes Association (ADA), Joint Commission on the Accreditation of Healthcare Organizations (JCAHO), and other accrediting organizations.

Response: Section 1847(a)(3)(B) of the Act grants us the authority to exempt items and services for which the application of competitive bidding is not likely to result in significant savings. Section 1847(a)(1)(B)(ii) of the Act gives us the authority to phase in competitive bidding ''first among the highest cost and highest volume items and services or those items and services that the Secretary determines have the largest savings potential.'' As we stated in the May 1, 2006 proposed rule, we will consider annual Medicare allowed charges, annual growth in expenditures, the number of suppliers furnishing the item, reports and studies, and data showing whether we realized savings by including the item in the competitive bidding demonstrations to determine whether including an item(s) under the competitive bidding programs is likely to result in significant savings. As we evaluate specific items for inclusion in competitive bidding programs, we will also consider the recommendations offered by these commenters. We note that diabetic shoes and inserts, prosthetics for the foot, splints and casts, prosthetic devices that aid vision, and surgical dressings are not among the items and services described in section 1847(a)(2) of the Act and, therefore, cannot be included in the competitive bidding programs.

Comment: Some commenters recommended that CMS publish the items that will be included in the initial competitive bidding programs in an interim final rule. They also believed that a meeting should be scheduled with the PAOC to solicit additional public comment after product selections are announced.

Response: We intend to announce the product categories for competitive bidding on or shortly after the date of issuance of this final rule, and we will designate the items to be included in each competitive bidding program through program instructions or by other means, such as the RFB, and post them on our Web site. We do not believe that we need to publish the list of items in the form of an interim final rule in the **Federal Register**. We also note that the PAOC provided feedback on the criteria for item selection that we proposed in the May 1, 2006 proposed rule. Further, the public had the opportunity to comment on our proposed methodology for item selection through the public notice and comment rulemaking process, and the opportunity to participate in PAOC meetings that dealt with this subject. We will take under consideration the commenters' suggestion to hold future PAOC meetings on item selection.

Comment: Several commenters requested an explanation of the specific measure that will be used to identify an item's true potential savings after accounting for any recent policy changes and rate cuts. They asked if any thresholds would be used to measure the actual savings. They reported that changes in payment policy significantly decreased CY 2003 allowed charges for oxygen equipment, nebulizers, and inhalation drugs. The commenters also reported that payment for glucose meters, test strips, and lancets were previously frozen in CYs 1998, 1999, and 2000 and again in CY 2002. They indicated that these payment freezes call into question the feasibility of achieving significant additional Medicare savings through competitive acquisition. The commenters believed that the annual growth in expenditures for the above items could be attributed to other factors such as an increase in the number of new beneficiaries or the elimination of Medicare Advantage Plans in various markets. Many commenters recommended establishing a savings threshold that would use ongoing administrative allowed charges to assess the appropriateness of competitive bidding for each product category. They recommended using a threshold of a 10-percent margin to determine the net savings after excluding administrative costs associated with the ongoing support of the competitive bidding programs from the total savings incurred.

Response: We will determine which items offer the best savings potential. We disagree that an exact dollar threshold is appropriate for determining if significant savings will be achieved for an item under a competitive bidding program because it would be logistically difficult to set an exact number for what the savings will be for a particular item until we receive the bids. Once we receive the bids, we can estimate the dollar savings amount to determine whether that represents an appropriate savings. In addition to allowed charges and utilization, we identified in the proposed rule the following variables that we will use to select items for competitive bidding: annual growth in expenditures; number of suppliers; savings in the DMEPOS competitive bidding demonstrations; and reports and studies. We stated that we would use all of these variables to make determinations about an item's potential to reduce costs for the Medicare program. We will also assure savings because we will not accept a bid to furnish an item unless the submitted bid price is at or below the fee schedule amount for the item.

Comment: Some commenters suggested that the greatest potential for savings to the Medicare program could be achieved by eliminating coverage of specific DME items or entire product categories.

Response: We appreciate the comment. However, competitive bidding is a program for determining Medicare payment for covered items and services and does not supersede any

Medicare rules, policies, or procedures relating to coverage.

Comment: Some commenters reported that the proposed rule indicates Medicare expenditures for DME infusion pumps and related drugs in CY 2003 were approximately $149 million. They indicated that this number appears to include expenditures made for insulin and insulin pumps for beneficiaries with diabetes, which are not provided by infusion pharmacies and largely serve a different beneficiary market than infusion pumps and related drugs used by beneficiaries for other medical conditions. They believe that the more accurate amount of Medicare expenditures for CY 2003 for DME infusion pumps and related drugs was approximately $87 million.

Response: Insulin pumps are a type of infusion pump used by beneficiaries with diabetes and currently are included in the SADMERC policy group for external infusion pumps and related drugs. Although we will be using the SADMERC policy groups to identify groups of items that we will consider including in one or more competitive bidding programs, the actual product categories that we develop might be a subset of items from a SADMERC policy group or a combination of items from different SADMERC policy groups. In determining which items are appropriate to include in a product category, we will also evaluate its savings potential, as discussed above.

Comment: Many commenters believed that the OIG and GAO reports and studies focus largely on a narrow issue or a small subset of issues, and as a result, the reports often reflect a skewed perspective of the particular problem and the suggested solution to that problem. They believed that none of the historical OIG studies reflects the cost of accreditation or complying with the quality standards that are the bases of accreditation. They believed that the OIG studies do not focus on the services and functions required of suppliers, the allowed charges associated with these services and functions, or whether payment rates are limited to the allowed charges of items and equipment. In addition, they indicated that the OIG reports generally collect information from across the United States, while competitive bidding is market-specific. In light of these discrepancies, they recommended that our decisions should not rely heavily on OIG reports when we select items for inclusion in the competitive bidding programs.

Response: We believe that the OIG and GAO reports and studies provide useful information for identifying items with high expenditures. However, we will not rely solely on these reports. As we indicated in the proposed rule, we would rely on several variables in determining the savings potential for specific items or categories of items. Those variables include annual allowed charges, annual growth in expenditures, number of suppliers, savings under the demonstrations, and various reports and studies conducted by CMS and other Federal agencies.

After consideration of the public comments we received, we are adding a definition of the term ''minimal self-adjustment'' under § 414.402. We are also finalizing § 414.406(d), with a technical change. We are specifying that when we designate the items that will be included in each competitive bidding program, we will do so by program instructions or by other means, such as the RFB or our Web site.

G. Submission of Bids for Competitively Bid DMEPOS (§§ 414.404, 414.408, 414.412, and 414.422)

Sections 1847(b)(6)(A)(i) and (b)(6)(A)(ii) of the Act provide that payment will not be made under Medicare Part B for items furnished under a competitive bidding program unless the supplier has submitted a bid to furnish those items and has been selected as a contract supplier. Therefore, in order for a supplier that furnishes competitively bid items in a CBA to receive payment for those items, the supplier must have submitted a bid to furnish those particular items and must have been awarded a contract to do so by CMS (proposed § 414.412). In section II.C.6. of the May 1, 2006 proposed rule (71 FR 25664), we proposed that there would be limited exceptions to this requirement for items required by beneficiaries who reside in a CBA but are out of the area and need items (proposed § 414.408(f(2)(ii))). We also proposed that there would be an exception for suppliers that are grandfathered to continue to provide and service certain items (§ 414.408(f)(2)(i), as discussed in section VI.D.3. of this final rule.

1. Furnishing of Items (§§ 414.412(c) and 414.422(e))

In the May 1, 2006 proposed rule, under proposed § 414.422(e) we proposed that a contract supplier must agree to furnish the items included in its contract to all beneficiaries who maintain a permanent residence in, or who visit, the CBA and who request these items from the contract supplier. However, as we explained in the proposed rule (71 FR 25672 and 25681), we proposed that a skilled nursing facility (SNF) as defined in section 1819 of the Act that is also a contract supplier must only agree to furnish the items included in the contract to patients to whom it would otherwise provide Medicare Part B services (proposed § 414.422(e)(2)(i)). In addition, we proposed that a physician who is also a contract supplier must only agree to furnish the items included in the contract to his or her patients (proposed § 414.422(e)(2)(ii)). Because suppliers will have to factor this requirement into their responses to the RFBs, we have chosen to discuss this requirement in this section of the final rule.

a. Furnishing of Items to Medicare Beneficiaries Who Maintain a Permanent Residence in a CBA

In the May 1, 2006 proposed rule (71 FR 25681), we proposed that 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 (proposed § 414.422(e)(1)). We indicated that this rule would prohibit a contract supplier from refusing to furnish items to beneficiaries because they are not in close proximity to that supplier. In order to ensure beneficiary access to competitively bid items that are rented, we proposed that 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. This is particularly important in those cases where a supplier or noncontract supplier does not elect to continue furnishing the item in accordance with the grandfathering provisions discussed in section VI.D.3. of this final rule. Suppliers must factor the cost of furnishing items in these situations into their bid submissions.

In addition, in order to ensure beneficiary access to the competitively bid items in the inexpensive or routinely purchased DME payment category, or to a competitively bid power wheelchair, we proposed that 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.

Comment: One commenter requested that CMS clarify that a contract supplier can limit the number of items it provides in each category to its contracted capacity.

Response: As part of a supplier's response to the RFB, a supplier will be

expected to state its projected capacity to furnish the items in each product category for which it is submitting a bid. The projected capacity submitted by a supplier would not become a binding term of the contract because contract suppliers will be required to furnish the items in their contract to all beneficiaries who maintain a permanent residence in the CBA, or who visit the CBA, and who request the items from them unless one of the exceptions discussed in this final rule applies.

b. Furnishing of Items to Medicare Beneficiaries Whose Permanent Residence Is Outside a CBA

In the May 1, 2006 proposed rule (71 FR 25681), we proposed that in order to obtain medically necessary DMEPOS items, a Medicare 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 CBA that he or she visits. We considered allowing beneficiaries whose residence is outside of a CBA to obtain these items from noncontract suppliers when coming into a CBA. However, consistent with section 1847(b)(6) of the Act, we proposed that beneficiaries would be required to use a contract supplier because we believe that new business for competitively bid items should be directed only to contract suppliers. Noncontract suppliers would be allowed to continue servicing current beneficiaries who maintain a permanent residence in a CBA if they qualified for the grandfathering program discussed in section VI.D.3. of this final rule.

Comment: One commenter stated that CMS should indicate how the provision to furnish competitively bid items to Medicare beneficiaries whose permanent residence is outside a CBA will be communicated to beneficiaries who are visiting a CBA.

Response: Noncontract suppliers located in a CBA will be informed that they are not eligible to furnish competitively bid items to beneficiaries visiting the CBA and as we discussed earlier in this final rule, beneficiaries will not be held liable to make a payment for an item furnished in contravention of this rule, unless the beneficiary signs an ABN indicating the beneficiary's knowledge and understanding that Medicare will not pay for that item. Noncontract suppliers will be educated to refer beneficiaries to contract suppliers in these situations. We are also planning an extensive educational campaign to inform the public of the requirement that an item must be obtained from a contract supplier when a beneficiary is visiting a CBA, if the item that the beneficiary needs is included in the competitive bidding program for the CBA that the beneficiary is visiting. A list of all contract suppliers along with other competitive bidding information will be on the CMS and CBIC Web sites. This information will also be available to beneficiaries through the toll-free telephone number 1–800 Medicare.

Comment: One commenter stated that it was confused as to whether certain products might be drop-shipped into the area where the beneficiary is visiting. The commenter requested clarification on this because the commenter believed there are many types of equipment such as oxygen equipment that should not be drop-shipped. Another commenter stated that a beneficiary visiting in the CBA should not be required to use a contract supplier because such a requirement would confuse beneficiaries. The commenter recommended that CMS not adopt the proposed rule or modify it so that it only applies to beneficiaries who have resided in the CBA for 3 or more months. Two commenters stated that there will be an undue impact on ''snowbirds'' as a result of the requirement that contract suppliers furnish items to Medicare beneficiaries whose permanent address is outside the CBA and that this provision should not be adopted.

Response: The proposed requirement would establish a process whereby beneficiaries visiting a CBA must get a competitively bid item for that CBA from a contract supplier that furnishes the item in the CBA. If, however, the beneficiary needs an item that is included in the competitive bidding program for the CBA that the beneficiary is visiting (even if the item is not included in the competitive bidding program for the CBA where the beneficiary maintains a permanent residence), the beneficiary would be required to obtain the item from a contract supplier in the CBA where the beneficiary is visiting. Therefore, if a beneficiary is visiting a CBA, he or she may obtain the item from a contract supplier, and there would be no reason to drop-ship a product. As we explained in our response to the previous comment, we plan to implement a process by which beneficiaries will be able to locate contract suppliers in a CBA where they are visiting. We believe that a beneficiary who visits a CBA should be required to obtain competitively bid items for that CBA only from contract suppliers for that CBA because we believe that new business for these items should only be directed to contract suppliers. The purpose of competitive bidding is to award contracts to certain suppliers based upon their winning bids and to ensure the beneficiaries receive items from these suppliers.

Comment: One commenter suggested that CMS establish a system to ensure that all beneficiaries will continue to have access to their DMEPOS supplies, even while visiting an area that is not the beneficiary's CBA. The commenter stated that CMS should require that suppliers aggressively educate beneficiaries on the proper procedures for obtaining their supplies while away from home, and should allow beneficiaries to purchase extra supplies for extended vacations or temporary changes of residence. The commenter also urged CMS to allow beneficiaries to purchase their supplies from noncontract suppliers in the event of an emergency.

Response: As we discussed above, we will conduct an extensive education campaign to educate beneficiaries, suppliers, and referral agents on how beneficiaries who are away from home can obtain medically necessary items. As we proposed, our contract supplier selection methodology will ensure there are enough contract suppliers in each CBA to ensure beneficiary access to needed items and services. In addition, beneficiaries on vacation or who have temporary changes of residence will be able to obtain competitively bid items that are included in the competitive bidding program for the CBA that they are visiting from contract suppliers for that CBA. Contract suppliers will be listed on the Internet in order for beneficiaries to determine who the contract suppliers are in the CBA they are visiting. As we explained above, we will require that contract suppliers assist Medicare beneficiaries in locating contract suppliers while visiting other CBAs. We do not believe an exception is needed in the event of an emergency because we will ensure that there will be a sufficient number of contract suppliers in a CBA to meet the access needs of beneficiaries.

2. Requirements for Providers to Submit Bids (§§ 414.404(a) and 414.422(e)(2))

In the May 1, 2006 proposed rule (71 FR 25672), we proposed in § 414.404(a) that the Medicare DMEPOS Competitive Bidding Program would apply to suppliers, and in proposed § 414.404(b) that the program would apply to providers that furnish items under Medicare Part B as suppliers. Accordingly, providers that furnish Medicare Part B items are located in a competitive bidding area, and that are also DMEPOS suppliers would be

required to submit bids in order to furnish competitively bid items to Medicare beneficiaries. We also proposed that providers that are not awarded contracts must use a contract supplier to furnish these items to Medicare beneficiaries to whom they provide services. However, we proposed in new proposed § 414.422(e)(2)(i) that a SNF, as defined in section 1819(a) of the Act, would not be required to furnish competitively bid items to beneficiaries outside of the SNF if it elected not to function as a commercial supplier. We stated that this rule is consistent with the current practice of some SNFs to furnish Medicare Part B services only to their own residents.

Comment: Several commenters recommended that CMS exclude institutional providers, such as SNFs and other long-term care facilities, from competitive bidding or exempt products that are primarily used in institutional settings from competitive bidding. They stated that because the residents of these institutions are often among the most frail and critically ill the level of care required for these patients should not be threatened or compromised by rules whose impact, although well-intended, are not conducive to the long-term care environment. The commenters believed that competitive bidding may distort current institutional purchasing patterns and result in higher prices. Several commenters also suggested that CMS postpone bidding in long-term care settings until CMS convenes a working group of key stakeholders to examine how the requirements for competitive bidding impact these facilities. They further stated that CMS should phase in the program over at least 4 years. Others suggested delaying implementation of the program.

Response: Congress specifically provided that certain categories of items and services, specifically certain DME, medical supplies, enteral nutrients, equipment, and supplies, and OTS orthotics are subject to the Medicare DMEPOS Competitive Bidding Program and established phase-in implementation rules. Items and services may only be excepted from the program if we determine that they are not likely to result in significant savings if they are included. A large volume of enteral nutrients, equipment, and supplies are furnished to patients in SNFs and nursing facilities (NFs along with some OTS orthotics. Currently, we allow SNFs and nursing facilities (NFs) to choose whether to provide these services directly or under contract with an outside supplier. To avoid disruption of this practice, we will continue to provide SNFs and NFs with this choice.

We continue to believe that Medicare DMEPOS Competitive Bidding Program should apply to institutional providers to the extent they furnish items under Part B because section 1847 of the Act does not distinguish these providers from other types of Part B suppliers. However, we believe that SNFs and NFs should be treated differently from other providers in terms of who they must furnish items to because they generally do not use a commercial model of providing services throughout the community. Instead, they generally provide items only to patients that reside in their facility. We do not believe it would be in the best interest of the program to exempt institutional providers from participating or delay implementation in these settings because these providers furnish items subject to competitive bidding to their residents, and the category of enteral nutrition, as a whole, is made up of high-cost, high-volume items.

Therefore, we are finalizing our proposal under § 414.422(e)(2) to permit SNFs as defined in section 1819(a) of the Act, to furnish competitively bid items only to their own residents. We are extending this provision to NFs, as defined in section 1919(a) of the Act, because we believe the services they furnish, the customers they serve, and their business model are parallel to SNFs. A SNF or NF will still be required to submit a bid and have a bid in the winning range and the SNF or NF must indicate in its response to the RFB it intends to elect this option. If the SNF or NF is not selected as a contract supplier, it will have to use a contract supplier within the CBA to furnish competitively bid items to its residents. In addition, should a SNF or NF indicate in its response to the RFB that it plans to furnish items to beneficiaries who are not residents of its facility, this special rule will not apply and the SNF or NF will be required to furnish items to all beneficiaries who maintain a permanent residence in, or who visit, the CBA where the SNF or NF is located.

Comment: One commenter stated that section 1847 of the Act was never intended to apply to institutional providers and that the phrase ''items and services'' means those that are purchased directly by individuals and not by institutions on behalf of individuals. The commenter further stated that section 1847(b)(4)(A) of the Act requires that CMS ''take into account the ability of bidding entities to furnish items and services in sufficient quantities to meet the anticipated needs * * * in the geographical area covered under the contract on a timely basis.'' The commenter believed that this sentence could be interpreted to mean that institutional providers are outside the scope of the competitive bidding program. The commenter indicated that institutions already purchase items for their patients through arrangements made in a variety of ways and that requiring them to participate in the Medicare DMEPOS Competitive Bidding Program could result in actually raising prices of items purchased by institutions.

Response: We do not agree that sections 1847(a) and (b) of the Act only apply to items and services directly purchased by Medicare beneficiaries and does not apply to institutions that purchase on behalf of beneficiaries. Indeed, these sections identify the items and services subject to competitive bidding and provide that the program applies when these items are furnished under Medicare Part B. Therefore, to the extent that institutional providers are furnishing items as Part B suppliers, we believe that the Medicare DMEPOS Competitive Bidding Program should apply to them. However, as we explained above, we are allowing SNFs and NFs to elect to only furnish competitively bid items to residents in their facilities if they are selected as contract suppliers.

Comment: Several commenters stated that hospital-based suppliers should not have to bid, as hospital-based suppliers are not structured to compete for all beneficiaries in the region. Some commenters stated that hospital-based suppliers should be eligible to participate in the competitive bidding program, if they are willing to accept the single payment amount. Other commenters stated that CMS should exclude hospital-based suppliers from having to serve all beneficiaries in a CBA.

Response: Hospital-based suppliers provide the same ranges of items and services as other commercial suppliers. We believe hospital-based suppliers are different than SNFs and NFs because they do use a commercial model and do provide items to patients who do not reside in a hospital. Therefore, the hospital-based suppliers are competing with other commercial suppliers in the same area and should be considered as part of the same competitive bidding program for this reason.

Comment: One commenter stated that CMS should not combine SNFs and physicians in the same competition with commercial DMEPOS suppliers. The commenter believed that including all of these provider/supplier types in the same bidding will distort the bid evaluation and selection because SNFs

and physicians will have significantly lower operating costs arising from the fact that because they do not have to serve all beneficiaries and they do not have to accept beneficiaries from noncontract suppliers, regardless of rental month.

Response: We are establishing provisions that treat SNFs, NFs, physicians, and certain other nonphysician practitioners differently from other suppliers. As we discussed above, we are allowing SNFs and NFs that are selected as contract suppliers to furnish items only to their own patients. In addition, as we discuss more fully below, we will permit physicians and certain nonphysician practitioners to furnish certain competitively bid items to their own patients without submitting a bid and being selected as a contract supplier. We believe that it is appropriate to allow SNFs (and, as discussed above, NFs) to compete to serve their own patients, but we believe it is appropriate to include them in the same bidding process as other suppliers because the statute requires us to conduct bidding for items in which we expect savings.

Comment: One commenter stated that the requirement that suppliers that are not awarded contracts must use a contract supplier to furnish competitively bid items to Medicare beneficiaries to whom they do provide services conflicts with current Medicare policies. The commenter asked how such a supplier would be able to subcontract to use a contract supplier to furnish supplies without violating current policies.

Response: We do not believe that this requirement conflicts with current policy. Specifically, SNFs are currently allowed to have arrangements under which outside suppliers come to their facilities to provide enteral nutrients, equipment, and supplies. SNFs routinely engage in this practice. Under competitive bidding, SNFs that are not winning contractors must make arrangements to use a contract supplier in the community to furnish competitively bid items to residents of the facility.

Accordingly, we are revising § 414.404(a) to specify that the Medicare DMEPOS Competitive Bidding Program applies to providers that furnish items under Part B. In addition, we are redesignating proposed § 414.422(e)(2)(i) as § 414.422(e)(2) and finalizing that section with the modifications discussed above. Finally, as we discuss below, we are deleting § 414.422(e)(2)(ii) because we have modified our proposal regarding the applicability of the Medicare DMEPOS Competitive Bidding Program to physicians, and, as discussed below, placing the new provisions in § 414.404(b).

3. Physicians and Certain Nonphysician Practitioners (§§ 414.404(a) and (b))

In the May 1, 2006 proposed rule (71 FR 25672), we proposed in proposed § 414.404(c) that the Medicare DMEPOS Competitive Bidding Program would apply to physicians who furnish items under Medicare Part B as suppliers. Accordingly, physicians who are also DMEPOS suppliers would be required to submit bids and be awarded contracts in order to furnish items included in the competitive biding program for the area in which they provide medical services. We proposed that physicians who do not become contract suppliers must use a contract supplier to furnish competitively bid items to Medicare beneficiaries. However, in proposed § 414.422(e)(2)(ii), we proposed that these physicians would not be required to furnish these items to Medicare beneficiaries who are not their patients. In proposing this policy for physicians who are also DMEPOS suppliers, we recognized that the physician self-referral law (section 1877 of the Act, also known as the Stark law) generally prohibits physicians from furnishing to their office patients a variety of common DMEPOS items. Therefore, we proposed that physicians 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.

Comment: Several commenters suggested that CMS not require physicians, including podiatric physicians, to participate in the competitive acquisition program for certain DMEPOS. The commenters noted that under the physician self-referral (''Stark'') provisions under section 1877 of the Act, a physician in a group practice may not refer Medicare beneficiaries to the group practice, and the group practice may not bill for any DME except crutches, canes, walkers, folding manual wheelchairs, and blood glucose monitors. The commenters also requested that CMS not require physician assistants, physical therapists, or occupational therapists to participate in the Medicare DMEPOS Competitive Bidding Program because those health care professionals are licensed by State boards. According to the commenters, if a physician or non-physician practitioner does not participate in the competitive bidding program, he or she should be reimbursed at the single payment amount for any DME items that are furnished to his or her own patients. In addition, the commenters requested that CMS clarify how the requirement for physicians to submit bids and provide all items within a product category does not violate the physician self-referral law.

Response: After considering the comments, in this final rule, we are deleting proposed § 414.404(c) and revising § 414.404(b) to give physicians (as defined at section 1861(r) of the Act, which includes podiatric physicians) and treating practitioners (defined in § 414.404 as physician assistants, clinical nurse specialists, and nurse practitioners) the option to furnish certain types of competitively bid items without participating in the Medicare DMEPOS Competitive Bidding Program, provided that certain conditions are satisfied. First, the items that may be furnished are limited to crutches, canes, walkers, folding manual wheelchairs, blood glucose monitors, and infusion pumps that are DME. Second, the items must be furnished by the physician or treating practitioner to his or her own patients as part of his or her professional service. Third, the items must be billed using 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. We are adding a new § 414.404(b)(3) providing that the items furnished and billed in this manner will be paid at the single payment amount, which is the rate at which these items would otherwise be paid if this exception did not apply. We believe that physicians engaged in the practice of medicine (and their medical practices) should have the option not to participate in the competitive bidding program because, to comply with the physician self-referral prohibition, they generally provide to their own patients only the DMEPOS items noted above. Because physician assistants, clinical nurse specialists, and certified nurse practitioners furnish services under the supervision of, or in collaboration with, a physician, we believe they (and the group practices that may bill for their services) should similarly have the option to not become a contract supplier.

We are also modifying the regulation by adding § 414.404(b)(2) to give physical therapists in private practice and occupational therapists in private practice the option to furnish certain

types of competitively bid items without participating in the Medicare DMEPOS Competitive Bidding Program, provided that certain conditions are satisfied. First, the items that they may furnish without becoming a contract supplier are limited to OTS orthotics. Second, the items must be furnished only to their own patients as part of their professional service. OTS orthotics furnished in accordance with § 414.404(b) by physical and occupational therapists who are not contract suppliers will be paid at the single payment amount. We are limiting this exception to the bidding requirement to OTS orthotics because we have determined that these are the items that would ordinarily be furnished as an integral part of occupational therapy or physical therapy services.

We note that if a physician, treating practitioner, physical therapist in private practice, or occupational therapist in private practice wishes to furnish in a CBA a competitively bid item not specifically authorized by this rule, and can otherwise legally do so, the physician, treating practitioner, physical therapist in private practice, or occupational therapist in private practice would have to submit a bid and be awarded a contract to do so.

The Medicare DMEPOS Competitive Bidding Program does not affect the applicability of the physician self-referral provisions in section 1877 of the Act. All provisions of the physician self-referral law remain fully in effect. In other words, notwithstanding the requirement that a contract supplier must furnish all items in a product category, a contract supplier cannot furnish an item as a result of a referral prohibited under section 1877 of the Act. We are revising proposed § 414.422(e) to provide that a contract supplier must furnish all items in each product category to which the contract applies, ''except as otherwise prohibited under section 1877 of the Act or any other applicable law or regulation.''

Comment: Several commenters stated that there is no reason to treat occupational therapists and physical therapists differently from physicians. They stated that occupational therapists are not like ''commercial suppliers'' and should only have to furnish competitively bid items to their own patients. Several commenters requested that CMS exempt physical therapists in private practice from competitive bidding or give them special consideration under the competitive bidding program. They stated that physical therapists should be exempt from having to provide every item in a product category and CMS should allow them to participate even if they do not submit exactly the same type of bid required of large suppliers. Several commenters suggested that CMS exclude all occupational and physical therapists and hand therapists that provide pre-fabricated splints to Medicare beneficiaries from the competitive bidding program. They stated that CMS should ensure that occupational and physical therapists can continue to furnish orthotics to their patients. The commenters added that if they cannot dispense OTS orthotics to patients during visits, beneficiaries will need to make other arrangements to obtain the items.

Response: As we stated above, we are revising § 414.404(b) to give occupational therapists in private practice and physical therapists in private practice the option to furnish OTS orthotics to their own patients as part of their professional practice without participating in the Medicare DMEPOS Competitive Bidding Program. We agree with these comments, but only as they relate to furnishing of OTS orthotics by occupational and physical therapists that provide these items in the course of therapy. There is a specific statutory benefit to pay for the services of occupational therapists and physical therapists. However, there is no comparable benefit that only pertains to hand therapists. We are limiting this exception to the bidding requirement to OTS orthotics because we have determined that these are the items that would ordinarily be furnished as part of occupational therapy or physical therapy professional services. In addition, physical and occupational therapists in private practice who elect to operate under this special exception may not furnish these items and services to beneficiaries outside of their normal practice without submitting a bid and being awarded a contract to do so.

After consideration of the public comments, we are revising § 414.404(a) to specify that the Medicare DMEPOS Competitive Bidding Program generally applies to physicians, treating practitioners, physical therapists, and occupational therapists that furnish items under Part B. However, we are revising proposed § 414.404(b) to specify the terms and conditions under which physicians, treating practitioners, physical therapists, and occupational therapists do not have to participate in the program. Finally, to be consistent with our changes to § 414.404(b), we are not finalizing proposed § 414.422(e)(2)(ii).

4. Product Categories for Bidding Purposes (§§ 414.402 and 414.412(b)(1),(c) Through (e))

In the May 1, 2006 proposed rule (71 FR 25672), we proposed in §§ 414.412(b) through (d) to conduct bidding for items that are grouped into product categories. We proposed to require suppliers to submit a separate bid for all items that we specify in a product category. The submitted bid must include all costs related to the furnishing of each item such as delivery, set-up, training, and proper maintenance for rental items. However, we proposed to require suppliers to only submit bids for the product categories that they are seeking to furnish under the program. All items that would be included in a product category for bidding purposes would be detailed in the RFBs. We proposed to define the term ''product category'' (proposed § 414.402) as a group of similar items used in the treatment of a related medical condition (for example, hospital beds and accessories). We explained that we believe the use of product categories will allow Medicare beneficiaries to receive all of their related products (for example, hospital beds and accessories) from one supplier, which will minimize disruption to the beneficiary.

We also discussed in the proposed rule other design options that we considered but did not propose. One option was to require suppliers to submit a bid for all items in every defined product category. Another option was for suppliers to bid at the HCPCS level and submit a bid only for the individual items that they were seeking to furnish under the program.

There are currently approximately 55 separate policy groups already established by the DME MACs. However, these policy groups were not established for the purpose of competitive bidding. We proposed to specifically develop product categories for the purpose of competitive bidding. Each group would be defined and comprised of individual HCPCS codes.

Section 1847(a)(3)(B) of the Act gives us the authority to exempt items for which the application of competitive bidding is unlikely to result in significant savings. We proposed not to include items in a product category if they are rarely used or billed to the program. In addition, we did not propose to include items within a product category if we believed that these were items for which we might not realize savings. Therefore, under this approach, we proposed to establish product categories to identify those

items included in competitive bidding and stated that we might choose to establish different product categories from one CBA to another, as well as in different rounds of competitive bidding in the same CBA.

We proposed to allow suppliers to submit bids only for the product categories they are seeking to furnish under a competitive bidding program because this option accommodates DMEPOS suppliers that want to specialize in one or a few product categories. For example, if a supplier wanted to specialize in the treatment of respiratory conditions, the supplier could choose to bid on all items that fall within the oxygen product category, the continuous positive airway pressure product category, or the respiratory assist device product category. We believe that specialization at the product category level will make it easier for referral agents (entities that refer beneficiaries to health care practitioners or suppliers to obtain DMEPOS items) and other practitioners to order related products from the same supplier.

Establishing a bidding process that promotes specialization would allow suppliers to realize economies of scope within a product category, which means that a supplier may be able to furnish a bundle of items at a lower cost than it can produce each individual item. In our view, this approach would also be more favorable to small suppliers because they could choose to specialize in only one product category. It would be more difficult for a small supplier, as opposed to a large supplier, to furnish all product categories. This approach would also be more convenient for Medicare beneficiaries, as they could choose to receive all their related supplies from one supplier and would not have to deal with multiple suppliers to obtain the proper items for a single condition. We recognized the importance of the relationship between a DMEPOS supplier and the Medicare beneficiary. The supplier delivers the item to the beneficiary, sets up the equipment, and also educates the beneficiary on the proper use of the equipment. The use of product categories would facilitate the transition for those beneficiaries who have to change suppliers. We stated in the proposed rule that it was our goal to establish a productive relationship between the supplier and the beneficiary, and we believe we can accomplish this goal by designing the Medicare DMEPOS Competitive Bidding Program in a manner that would give the beneficiary the option of selecting one supplier that would be responsible for the delivery of all medically necessary items that fall within a product category.

Comment: Some commenters recommended revising proposed § 414.412(c) to read, ''Product categories include items that are used to treat a related medical condition. The list of product categories, and the items included in each product category are identified in the RFBs document. The product categories should be consistent with the policy groups of the SADMERC, unless there is good cause to align items differently for a particular competitive bidding program.'' The commenters also recommended revising § 414.412(d) to read, ''Suppliers must submit a separate bid for every item included in each product category that they are seeking to furnish under a competitive bidding program unless a bid is determined for a sub-category for bidding purposes.'' Many commenters believed it will cause confusion if new product categories are developed. They reported that the CMS Web site is organized by policy groups and accessed by suppliers frequently for information. The commenters believed that keeping track of old categories and new categories in a single market or State would be next to impossible. Many commenters believed combining medical policies may affect beneficiary access or quality of services. They believed the only providers and suppliers that are eligible to bid are those that carry the broadest product offerings, and sometimes these are not the providers or suppliers with the strongest expertise in a specific product or HCPCS code. One commenter suggested that CMS include subcategories within a product category.

Response: We have revised our proposed definition of ''product category'' to provide that product category is a grouping of related items that are used to treat a similar medical condition. The list of product categories and the items included in each product category that is included in each competitive bidding program will be identified in the request for bids document for that competitive bidding program and by other means. The DME MACs establish policy groups for the purposes of developing Medical review policies and for data analysis, and these policy groups will serve as the starting point for establishing product categories. Product categories will generally be consistent with these policy groups unless CMS determines that a policy group should be redefined for the purposes of competitive bidding because there may be items in the policy group that are either not subject to competitive bidding or that we would want to exempt from competitive bidding using our authority to exempt items. For this reason, the product categories for which we would request bids could also be a subset of items from a DME MAC policy group or a combination of items from different policy groups.

In response to the suggestion that we create subcategories within a product category, we do not believe this approach is necessary because if we believed that we needed to separate items in a policy group, we would create a new product category for each set of items instead of a product category with subcategories.

Comment: A few commenters believed that a product category such as ''oxygen equipment and related supplies'' is likely to contain different oxygen delivery modalities such as stationary oxygen concentrators and liquid oxygen systems. They indicated that, while this may appear logical on the surface, the groupings are, in fact, incompatible with accurate bidding. The commenters added that the costs of acquisition, beneficiary support, and equipment maintenance and servicing are different for modalities.

Response: We appreciate the comments and recognize that there are different costs associated with the different type of equipment that are used to furnish oxygen therapy. The standard payment methodology and monthly payment amount for oxygen and oxygen equipment have been modality neutral since 1989. It is our intention at this time to maintain the policy of modality neutral payments under the competitive bidding programs because this guards against suppliers attempting to furnish only the most expensive modalities that result in higher profits. For example, suppliers that submit bids for stationary oxygen and oxygen equipment will need to factor in the costs of furnishing all of the different modalities or delivering stationary oxygen to beneficiaries in the CBA because physicians may specify a specific oxygen modality when ordering the equipment.

Comment: One commenter stated that the majority of its clients do not purchase items from just one policy group but rather from several groups. The commenter believed that bidding per product category sends clients from one supplier to another as their needs change and is not favorable to beneficiaries.

Response: As stated above, we are revising § 414.402 to define a product category as a grouping of related items that are used to treat a similar medical

condition, for example, hospital beds and accessories. It is our goal to give beneficiaries an opportunity to receive all competitively bid items used to treat an individual medical condition from the same contract supplier, which will make the program convenient for them. This will be accomplished by requiring a supplier that chooses to bid on a particular product category to bid on every item within that category and to furnish every item within a product category for which it is awarded a contract. Suppliers currently specialize in particular products, and we do not see this process being interrupted by competitive bidding. In addition, suppliers will be able to choose which product categories for which they want to submit a bid.

Comment: Several commenters raised concerns regarding the development of product categories. The commenters believed that product categories should be defined narrowly, to make sure they are consistent and representative of the products that a supplier might actually furnish. One commenter suggested, for example, a broad category for wheelchairs or power wheelchairs could be problematic. The commenter added that suppliers that do not specialize in rehabilitation may not carry every brand name of power wheelchairs that fall under a particular code. The commenters stated that CMS should not combine products from multiple medical review policies into one product category because it adds complexity and risks to the beneficiary because it may not allow suppliers to specialize in certain products. The commenters further stated that bidding by specific medical policies ensures that suppliers that specialize can address the needs of individuals with specific disease states/conditions. Several commenters requested that CMS not establish broad product categories. They further stated that many suppliers structure their business around specific disease states and conditions. The commenters noted that CMS should identify the quantities of each item within the product category that CMS expects will be required by Medicare in the respective CBA. Several commenters indicated that the core product categories should have codes that include sufficiently similar items in terms of capability, function, and other relevant characteristics. Some commenters believed that having broad product categories will restrict a specialty practitioner's ability to submit a bid.

Response: As we stated above, we will generally make the product categories consistent with the policy groups that have been defined by our contractors and, in the future, will be established by our contractors. We do not plan to make product categories overly broad, and we do not intend to combine products from various policy groups into a single product category unless the product already falls in several policy groups. However, the use of product categories instead of policy groups will allow us to exclude from a product category low-volume items or items that we believe will not result in significant savings, and to add items that we believe are appropriate for inclusion because we believe that they are related items used to treat a similar medical condition. As we explain below, we will identify in the RFB and by other means such as our Web site or program instruction, the product categories for each competitive bidding programs, the items within each product category, the historic beneficiary demand for each item in the applicable CBA, and the item weight for each item within each product category.

Comment: One commenter noted that the requirement to bid on all HCPCS codes in a product category would be a major problem for manufacturers that also serve as suppliers. The commenter also recommended that CMS adopt special rules for manufacturers wishing to bid, permitting them to only bid on products they manufacture.

Response: The goal of product categories is to minimize the disruption to beneficiaries by allowing them to receive all related competitively bid items for a similar medical condition from one contract supplier. Therefore, we believe it would be in the best interest of beneficiaries if we require a contract supplier that is also a manufacturer to furnish all items within a product category. We also believe it would not be equitable to adopt special rules for manufacturers while requiring all other suppliers that are not physicians or certain nonphysician practitioners to furnish all items in a product category as defined for purposes of competitive bidding.

Comment: Several commenters were concerned that a supplier that wins a bid in the wheelchair category may lose the bid for the associated cushions that are necessary for wheelchairs. They believed this would cause the patient to need to deal with two or more suppliers for a single rehabilitation wheelchair.

Response: As explained above, product categories will be comprised of related items used to treat a similar medical condition. Our goal is to minimize beneficiary disruption. Therefore, product categories will generally be established so that beneficiaries can receive related items from the same contract supplier.

Comment: Some commenters stated that complex rehabilitation products such as wheelchairs should not be competitively bid. They indicated that the accessory codes are the same for the accessories whether they are provided for a standard wheelchair or a complex mobility system. Therefore, they believed that the same HCPCS code may fall into several categories.

Response: We recognize that certain accessories that can be used on manual wheelchairs can also be used with complex mobility systems. Under our revised definition of ''item'' a product might be identified by a HCPCS code that has been specified for competitive bidding (such as when the product is furnished through the mail). One way that we might choose to specify a product identified by a HCPCS code for competitive bidding is when an accessory such as the one identified by the commenters is needed for use with a particular item. When we announce the product categories and the items included in each product category, we will identify any items specified for purposes of competitive bidding, such as accessories used with certain base equipment in a specific product category. In this way, we will be able to ensure that each product category properly includes all the related items that are used to treat a similar medical condition.

Comment: One commenter argued that CMS should limit bids to one bid per supplier. The commenter expressed concerns regarding national chains with multiple supplier numbers and indicated that these chains could potentially submit multiple bids in a CBA and compromise competition. The commenter suggested that CMS require that a single entity that has multiple supplier numbers only be allowed to submit one bid in each CBA. Under the commenter's suggestion, affiliated entities that do not have their own Medicare supplier number, but that are part of a national supplier and operate under the national supplier's 6-digit supplier number, would not be allowed to bid separately in a CBA. The commenter further suggested that CMS include a requirement in the regulations that suppliers with common ownership of 5 percent may only submit a single bid for each product category in a given CBA.

Response: We agree with the commenter that commonly-owned suppliers or a supplier that has a controlling interest in another supplier should not be allowed to submit different bids for the same product

category in the same CBA. Therefore, we are requiring under revised § 414.412(e) that all bidding suppliers must disclose as part of their bid whether they have an ownership or controlling interest in one or more other suppliers or if one or more other suppliers has an ownership or controlling interest in it, CMS will reject multiple bids submitted by commonly-owned or controlled suppliers for the same product category in the same CBA because we believe that allowing these suppliers to bid against themselves will undermine the integrity of the bidding process. For purposes of this disclosure requirement, two or more suppliers are commonly-owned if one or more of them has an ownership interest totaling at least 5 percent in the other(s). We are defining the term ''ownership interest'' as ''the possession of equity in the capital, the stock, or the profits of another supplier.'' This is consistent with how the term ''ownership interest'' is defined in 42 CFR § 420.201 of our regulations, which contains terms relevant to what certain entities, including DMEPOS suppliers, must currently disclose regarding ownership and control information. We believe it is a logical and appropriate approach to adapt definitions that apply to disclosure requirements in other parts of the Medicare program. In addition, the 5 percent requirement is consistent with what constitutes a ''person with an ownership or control interest'' in § 420.201. Finally , a supplier controls another supplier for purposes of these disclosure requirements if one or more of its owners is an officer, director, or partner in the other. This is also consistent with the definition of a ''person with an ownership or control interest'' in § 420.201.

Commonly-owned or controlled suppliers with multiple locations in the same CBA will be required to submit a single bid on behalf of all the locations and must indicate the combined capacity for all those locations. The bid must also include any locations outside the CBA that would be furnishing items in the CBA if a contract is awarded. Therefore, if we award a contract based on the single bid submitted by the commonly-owned or controlled suppliers, all of these suppliers would become contract suppliers. As stated above, we believe that these rules are necessary to prevent commonly-owned or controlled suppliers from bidding against themselves and undermining the integrity of the bidding process. In addition, contracting with all or none of the suppliers that are commonly-owned or controlled as described above will make it easier for beneficiaries to be informed regarding who is or who is not a contract supplier for their CBA.

We are also revising our definition of ''product category'' in § 414.402. We have combined proposed § 414.412(e) and proposed § 414.412(c) into a new § 414.412(c), but deleted the first sentence of proposed § 414.412(c) as redundant because we include the definition of ''product category'' in § 414.402, specified that the bid must include all costs related to furnishing an item to any beneficiary who maintains a permanent residence in, or who visits, the CBA where those items will be furnished and made additional technical changes. We are renumbering proposed § 414.412(b) a final § 414.412(b)(1), and finalizing § 414.412(d) with technical changes. Finally, we are finalizing § 414.412(e), which set forth our ownership rules, as discussed above.

We are redesignating proposed § 414.412(e) as final §§ 414.412(d) and adding a new § 414.412(e) to require that all bidding suppliers must disclose as part of their bid whether they have an ownership interest in one or more other suppliers that would be considered as contract supplier for the same CBA.

5. Bidding for Specific Types of Items and Associated Payment Rules (§§ 414.408(f) Through (j))

In the May 1, 2006 proposed rule (71 FR 25673 and 25674), we proposed that, in preparing a bid in response to the RFBs, suppliers would use our existing regulations at 42 CFR Part 414, Subparts C and Subpart D to determine whether a rental or purchase payment would be made for the item and whether other requirements would apply to the furnishing of that item, as further explained below.

a. Inexpensive or Other Routinely Purchased DME Items (§§ 414.408(f) and (h)(6))

The current fee schedule amounts for inexpensive or other routinely purchased DME items are based on average reasonable charges for the purchase of new items, purchase of used items, and rental of items from July 1, 1986, through June 30, 1987. In those cases where reasonable charge data from 1986/1987 are not available, the fee schedule amounts for the purchase of new items are currently based on retail purchase prices deflated to the 1986/1987 base period by the percentage change in the CPI-U, the fee schedule amounts for the purchase of used items are generally based on 75 percent of the fee schedule amounts for the purchase of new items, and the fee schedule amounts for the monthly rental of items are generally based on 10 percent of the fee schedule amounts for purchase of new items. This method of establishing fee schedule amounts in the absence of reasonable charge data has been in use since 1989. Under the Medicare DMEPOS Competitive Bidding Program, we proposed that bids be submitted only for the furnishing of new items in this category that are included in a competitive bidding program. Based on the bids submitted and accepted for these new items, we proposed to also calculate a single payment amount for used items based on 75 percent of the single payment amount for new items. In addition, we proposed to calculate a single payment amount for the rental of these items based on 10 percent of the single payment amount for new items. We stated our belief that calculating single payment amounts for used items and items rented on a monthly basis based on bids submitted and accepted for new items will simplify the bidding process and will not create problems with access to used items or rented items in this category.

Comment: One commenter stated that inexpensive and routinely purchased DME items included in competitive bidding should be purchased items only. The commenter believed that the additional expense for contract suppliers to bill for rental items is prohibitive. The commenter added that, for inexpensive and routinely purchased items, the cost of billing and collection must be done numerous times at a substantial cost to the supplier.

Response: There are certain items, such as pneumatic compression devices, that are routinely purchased but very expensive and may only be needed on a short-term basis. We believe that the option for renting these items is necessary in order to enable beneficiaries to save money, and we will allow beneficiaries to continue to do so under the competitive bidding programs.

b. DME Items Requiring Frequent and Substantial Servicing (§ 414.408(h)(7))

In the May 1, 2006 proposed rule (71 FR 25673), we proposed that bids be submitted for the monthly rental of items in this payment category with the exception of continuous passive motion exercise devices. We proposed that bids be submitted for the daily rental of continuous passive motion exercise devices. For items in this category other than continuous passive motion exercise devices, we stated that this proposal would be consistent with § 414.222(b) of our existing regulations.

Coverage of continuous passive motion exercise devices is limited to 21 days of use in the home following knee replacement surgery. Therefore, payment can only be made on a daily basis as opposed to a monthly basis for this item.

Based on the bids submitted and accepted for these items, we would calculate single payment amounts for the furnishing of these items on a rental basis.

c. Oxygen and Oxygen Equipment (§ 414.408(i))

If included under a competitive bidding program, we proposed that the single payment amounts for oxygen and oxygen equipment would 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 described in § 414.226(b)(1)(i) through (b)(1)(iv).

Subsequent to the publication of the May 1, 2006 proposed rule, we issued a final rule that implemented new payment classes for oxygen and oxygen equipment furnished for years after 2006 (CMS–1304–F: Home Health Prospective Payment System Rate Update for Calendar Year 2007 and Deficit Reduction Act of 2005; Changes to Medicare Payment for Oxygen Equipment and Capped Rental Durable Medical equipment (71 FR 65884)). In accordance with these new rules, we will now calculate the single payment amounts for oxygen and oxygen equipment based on the separate bids submitted and accepted for the furnishing on a monthly basis of each of the oxygen and oxygen equipment payment classes described in §§ 414.226(c)(1)(i)–(v).

We refer the reader to section VI.D.1. of this final rule where we discuss a new provision at § 414.408(i)(2) relating to additional payments to 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.

d. Capped Rental Items (§ 414.408(h))

With the exception of power wheelchairs, payment for items that fall into this payment category is currently made on a rental basis only. The rental fee schedule payments for months 1 through 3 are based on 10 percent of the purchase price for the item as determined under § 414.229(c) of our existing regulations. The rental fee schedule payments for months 4 through 15 are based on 7.5 percent of the purchase price for the item as determined under § 414.229(c) of our existing regulations. Section 5101(a) of the DRA of 2005 amended section 1834(a) of the Act to require that on the first day that begins after the 13th continuous month during which payment is made for a capped rental item, the supplier of the item must transfer title to the item to the individual. Since this change does not apply to beneficiaries using a capped rental item prior to January 1, 2006, these beneficiaries may still elect either to take ownership of the item after 13 months of continuous use or to continue renting the item beyond 13 months of continuous use. In addition, the DRA leaves intact the rule under which a supplier must offer the beneficiary the option to purchase a power wheelchair at the time the supplier initially furnishes the item (in which case payment would be made for the item on a lump-sum basis). However, with regard to all other capped rental items for which the rental period begins after January 1, 2006, the DRA requires the supplier to transfer title to the item to the beneficiary after 13 months of continuous use.

We proposed that the lump sum purchase option for power wheelchairs be retained under the Medicare DMEPOS Competitive Bidding Program. At the time we issued the May 1, 2006 proposed rule, this purchase option could be found in § 414.229(d) of our regulations. In accordance with a final rule that we subsequently published in the **Federal Register** on November 9, 2006 (71 FR 65884), the purchase option for power wheelchairs furnished beginning on or after January 1, 2006, can be found in § 414.229(h). We also proposed that separate payment for reasonable and necessary maintenance and servicing only be made for beneficiary-owned DME and that payment for maintenance and servicing of rented items would be included in the single payment amount for rental of the item.

We also proposed in the May 1, 2006 proposed rule that ''purchase'' bids be submitted for the furnishing of new items in the capped rental 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. In cases where 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. We stated our belief that calculating single payment amounts for used items and items rented on a monthly basis based on bids submitted and accepted for new items will simplify the bidding process and will not result in problems with access to used items or rented items in this category.

Comment: One commenter believed that the rule does not address situations when a supplier has to rent an item to a beneficiary and the item is defined by the manufacturer as ''single patient use only.'' The commenter also believed that the rule does not address what happens to those products should the patient die. The commenter also questioned how CMS will handle the rental of products that have limited manufacturer warranties.

Response: If a beneficiary dies during the period in which he or she is renting an item, the contract supplier would retain ownership of the item. As is the case today, if the item is designated by the manufacturer for a ''single patient use only,'' meaning that it cannot be used by other beneficiaries, the contract supplier may not furnish it to a new beneficiary. Medicare currently does not pay for costs that are covered by manufacturers' warranties and this policy will not change under competitive bidding.

Comment: One commenter suggested that CMS limit to discrete situations a requirement that contract suppliers of power wheelchairs offer rental items. The commenter was concerned that this rule would require suppliers to float a large volume of loans to subsidize rentals. The commenter further believed that most beneficiaries requiring power mobility have chronic progressive conditions that require them to keep the equipment for a long period of time.

Response: We disagree with the commenter. Power wheelchairs are very expensive and may only be needed on a short-term basis. The option for renting these items is necessary to enable beneficiaries to save money, and

for this reason, we will allow them to be rented under the competitive bidding programs.

We refer readers to section VI.D.1. of this final rule where we discuss additional payments to contract suppliers for capped rental DME when a contract supplier 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.

e. Enteral Nutrients, Equipment, and Supplies (§§ 414.408(f), (g)(2)–(3), and (h)(4))

Enteral nutrients, equipment, and supplies are currently paid under Medicare Part B on a purchase or rental basis. Section 6112(b)(2)(A) of the OBRA '89 limits the rental payments to 15 months. To be generally consistent with the bidding requirements discussed above for capped rental DME, in the May 1, 2006 proposed rule (71 FR 25674), we proposed that bids be submitted for the purchase of new items in this category. Based on the bids submitted and accepted for new items, we 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. The single payment amount for rented items for months 4 through 15 would be based on 7.5 percent of the single payment amount for new items. In cases where the beneficiary elects to purchase enteral nutrients, equipment, and supplies the single payment amount for new enteral nutrients, equipment, and supplies would be based on the bids submitted and accepted for new enteral nutrients, equipment, and supplies, and the single payment amount for used enteral equipment would be based on 75 percent of the single payment amount for the purchase of new enteral equipment.

Based on the bids submitted and accepted for new items, we would calculate a single payment amount for purchase of enteral nutrients, equipment, and supplies.

Comment: One commenter noted that intravenous medication and enteral nutrients, equipment, and supplies should not be included in competitive bidding. The commenter did not believe it is appropriate to revise the payment methodology in this rule. The commenter suggested that CMS should not revise the enteral nutrients, equipment, and supplies fee schedule without formal comments from the industry.

The commenter stated that because parenteral nutrients, equipment, and supplies were never intended to be included in competitive bidding, it is unclear why CMS proposed to revise this payment methodology at this time when some beneficiaries are attempting to coordinate their intravenous therapy needs between Medicare Part B and Part D.

Several commenters stated that, under the proposed rule, payment for enteral pumps would be determined as if enteral pumps were a capped rental item. They stated that enteral pumps fall under the prosthetic device benefit and are paid under a specific fee schedule. These commenters added that there is no basis for the change in payment methodology for enteral nutrients, equipment, and supplies. Another commenter noted that CMS should modify the proposed payment structure for enteral pumps consistent with current fee schedule policy.

Response: In accordance with section 1847(a)(2)(B) of the Act, parenteral nutrients, equipment, and supplies cannot be part of the Medicare DMEPOS Competitive Bidding Program. However, the same section directs that enteral nutrients, equipment, and supplies be included in the program. In accordance with section 1847(a)(6) of the Act, the payment basis determined under the Medicare DMEPOS Competitive Bidding Program for enteral nutrients, equipment, and supplies replaces the payment basis that would otherwise apply under section 1842(s)(1) of the Act and 42 CFR Part 414, Subpart C of our regulations. Therefore, the payment methodology we establish for enteral nutrients, equipment, and supplies furnished under this program will replace the fee schedule methodology for those items. We proposed to retain many of the same rules that currently govern the rental or purchase of enteral nutrients, equipment, and supplies to make the transition to competitive bidding easier for both suppliers and beneficiaries. However, under § 414.408(f), we are establishing a process for a supplier to bid on the purchase price for a new enteral pump. However, payments will be made on a rental basis if the beneficiary chooses to obtain the item on a rental basis or a purchase basis if the beneficiary chooses to obtain the item on a purchase basis. We also note that this rule does not supersede any laws for rules that govern whether a particular drug is covered under Medicare Part B or Part D.

f. Maintenance and Servicing of Enteral Nutrition Equipment (§ 414.408(h)(5))

Section 6112(b)(2)(B) of OBRA '89 requires that we pay for maintenance and servicing of enteral nutrition equipment after monthly rental payments have been made for 15 months. The maintenance and servicing payments are to be made in amounts that we determine are reasonable and necessary to ensure the proper operation of the equipment. Since October 1, 1990, program instructions have specified when and how these payments are made. These program instructions are currently found at section 40.3 of Chapter 20 of the Medicare Claims Processing Manual (Pub. 100–04). These instructions provide that maintenance and servicing payments may be made beginning 6 months after the last rental payment for the equipment and no more often than once every 6 months for actual incidents of maintenance where the equipment requires repairs and/or extensive maintenance. Extensive maintenance involves the breaking down of sealed components or performance of tests that requires specialized testing equipment not available to the beneficiary or nursing facility. The program instructions also state that the maintenance and servicing payments cannot exceed one-half of the rental payment amounts for the equipment.

Under the Medicare DMEPOS Competitive Bidding Program, we proposed at § 414.408(i)(3) (redesignated as § 414.408(h)(4) in this final rule) that the monthly rental payments for enteral nutrition equipment for months 1 through 3 be equal to 10 percent of the single payment amounts for the purchase of the new enteral nutrition equipment. We proposed that 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. We proposed 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. In addition, we proposed to establish the maintenance and service payments under proposed § 414.408(i)(4) (redesignated as § 414.408(h)(5) in this final rule) 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. This would limit the payment rate for maintenance and service to one-half of the rental payment amount for the first

month of rental, which is similar to the program instructions mentioned above. The provisions of the proposed rule are similar to current Medicare payment rules in section 40.3 of Chapter 20 of the Claims Processing Manual.

g. Supplies Used in Conjunction With DME (§ 414.408(g)(1))

We proposed under proposed § 414.408(h)(1) that bids be submitted for the purchase of supplies necessary for the effective use of DME, including drugs (other than inhalation drugs). Based on the bids submitted and accepted for these items, we would calculate single payment amounts for the furnishing of these items on a purchase basis.

h. Off-the-Shelf (OTS) Orthotics (§ 414.408(g)(4))

We proposed under proposed § 414.408(h)(4) that bids be submitted for the purchase of OTS orthotics. Based on the bids submitted and accepted for these items, we would calculate single payment amounts for the furnishing of these items on a purchase basis.

Comment: One commenter agreed with the proposed distinction for prosthetics and orthotics.

Response: We agree with the commenter because the statute distinguishes between prosthetics and orthotics.

In summary, after consideration of all of the public comments received on the bidding requirements and associate payment rules described above, we are renumbering proposed §§ 414.408((g) through (j) as §§ 414.408(f) through (i), respectively, and finalizing these sections (with the exception of § 414.408(h)(2) and (i)(2)), which have been added and finalized as described above, and with additional changes.

VII. Conditions for Awarding Contracts for Competitive Bids

In proposed § 414.414, we set forth a series of proposals regarding how we would evaluate and select suppliers for contract award purposes under the Medicare DMEPOS Competitive Bidding Program. Proposed § 414.414(a) provides generally that the rules in § 414.414 govern the evaluation and selection of suppliers under the program. The specifics of our other proposals are discussed below:

A. Quality Standards and Accreditation

Section 1847(b)(2)(A)(i) of the Act specifies that a contract may not be awarded to any entity unless the entity meets applicable quality standards specified by the Secretary under section 1834(a)(20) of the Act. Section 1834(a)(20) of the Act instructs the Secretary to establish and implement quality standards for all DMEPOS suppliers in the Medicare program, not just for suppliers subject to competitive bidding or in CBAs. All suppliers must meet these quality standards to be eligible to submit claims to the Medicare program, irrespective of the Medicare DMEPOS Competitive Bidding Program. The quality standards are to be applied by recognized independent accreditation organizations that have been designated by the Secretary under section 1834(a)(20)(B) of the Act. Section 1834(a)(20)(E) of the Act explicitly authorizes the Secretary to establish the quality standards by program instruction or otherwise after consultation with representatives of relevant parties. We proposed that 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, we 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.

In the May 1, 2006 proposed rule, we indicated that we had consulted with the PAOC and determined that it is in the best interest of the industry and beneficiaries to select the accreditation organizations and publish the quality standards through program instructions in order to ensure that suppliers that wish to participate in competitive bidding will know what standards they must meet in order to be awarded a contract. We proposed in § 414.414(c)(1) that all bidding suppliers must satisfy the quality standards in order to be eligible to participate in the Medicare DMEPOS Competitive Bidding Program. In proposed § 414.414(c)(2), we proposed that all bidding suppliers must be accredited by a CMS-approved accreditation organization, as defined under 42 CFR 424.57(a), but stated that a supplier would be considered to be grandfathered if it had received a valid accreditation before the CMS-approved accreditation organizations were designated and the accreditation was granted by an organization that CMS designates as a CMS-approved accreditation organization under 42 CFR 424.58.

To expedite the accreditation process for contract suppliers under the Medicare DMEPOS Competitive Bidding Program, we finalized the requirements for accreditation organizations as a new § 424.58 as part of the DMEPOS provisions in the FY 2007 IRF final rule (71 FR 48354). We published the list of the selected accreditation organizations and the final quality standards through program instructions and posted the response to comments document on the quality standards. The names of the accreditation organizations and the final quality standards and our responses to public comments on the quality standards and on the portion of the proposed rule pertaining to the quality standards are posted on the CMS Web site at: *http://www.cms.hhs.gov/competitiveAcqforDMEPOS*.

B. Eligibility (§ 414.414(a) Through (c))

In the May 1, 2006 proposed rule (71 FR 25675), we proposed in § 414.414(b)(1) that all bidders must meet enrollment standards to be considered for selection as a contract supplier under the Medicare DMEPOS Competitive Bidding Program. These standards are included in the supplier standards regulation at § 424.57. In addition, we proposed § 414.414(b)(2), that each bidder must certify in its bid that its high level employees, chief corporate officers, members of board of directors, affiliated companies and subcontractors are not now and have not been sanctioned by any governmental agency or accreditation or licensing organization. In the alternative, the bidding supplier must disclose information about any prior or current legal actions, sanctions, or debarments by any Federal, State or local program, including actions against any members of the board of directors, chief corporate officers, high-level employees, affiliated companies, and subcontractors.

In the preamble to the May 1, 2006 proposed rule (71 FR 25675) we stated that sanctions would include, but are not limited to, debarment from any Federal program, OIG sanctions, or sanctions issued at the State or local level. In addition, we proposed that the bidder must have all State and local licenses required to furnish the items that are being bid (proposed § 414.414(b)(3)). Finally, we proposed that the supplier must agree to all of the terms in the contract outlined in the RFBs (proposed § 414.414(b)(4)). We stated in the preamble to the May 1, 2006 proposed rule (71 FR 25675) that we would suspend or terminate a contract if a supplier loses its good standing with us or any other government agency.

Comment: Several commenters suggested that CMS require all contract suppliers to be physically located in the CBA for which they were awarded a

contract. Other commenters believed that relying on physical location would prevent participation of many suppliers, including several suppliers with capacity to operate on a national scale. The commenters believed that relying on physical location could cause product supply issues. Other commenters requested that CMS clarify whether a supplier can submit a bid if the supplier is not physically located in the CBA, but can show that it has a presence within the CBA. They asked whether CMS would quantify this for evaluation purposes.

Response: We continue to believe that it is appropriate to allow suppliers that do not maintain a physical location in a CBA to submit a bid to furnish items in that CBA. One of the purposes of the program is to create a competitive bidding payment structure that is more reflective of a competitive market. By accepting bids from all suppliers that can meet the requirements of the program, regardless of their physical location, we believe that we will encourage a more robust competition that will result in the best possible prices for beneficiaries without compromising their access to DMEPOS. It is our intent to review each bidder to determine whether it can meet the requirements of the competitive bidding program for which they submit a bid. One of these requirements will be that the supplier must be able to demonstrate that it maintains a presence in the CBA. In other words, the supplier must be able to furnish items to all beneficiaries who maintain a permanent residence in the CBA, regardless of where that beneficiary is located, including delivering items and providing necessary training and ensuring that items are appropriately set-up in the beneficiary's home. Thus, a supplier's ability to furnish items to all beneficiaries in the CBA, and not its physical location, will be evaluated to determine whether the supplier meets this requirement. We would reject a bid if we determined that the bidding supplier did not meet this bidding requirement, or any other bidding requirement.

Comment: Several commenters stated that CMS should apply an appropriate screening process to determine which bidder qualifies for consideration. They recommended that the bidding process include a 3-step elimination process in this order: Accreditation; financial standards; capacity assessment. The commenter suggested that only after this 3-step screening is applied should CMS accept a bid.

One commenter asserted that a supplier's financial stability and accreditation must take place before bid prices are arrayed and the pivotal bid selected. Otherwise, the commenter believed the bidding pool will be tainted by bids from suppliers that are not qualified. The commenter suggested that bids from suppliers that have not satisfied the quality standards, are not accredited, and/or that do not meet CMS' financial and eligibility standards should not be considered in selecting winning bids and setting payment amounts. The commenter also suggested that the rule should clarify that the establishment of a composite bid should only be completed for suppliers that meet the bidding requirements.

Response: We will not award a contract to any supplier that does not meet our bidding requirements. Those requirements include complying with our eligibility standards, including compliance with the enrollment standards in § 424.57(c) of our regulations and disclosure of certain compliance-related issues, financial standards, quality standards, and accreditation standards unless a grace period for obtaining accreditation applies. We may allow a grace period for suppliers that have not yet been accredited at the time they submit their bid. To qualify for this grace period, a supplier must have submitted its application for accreditation to a CMS-approved accreditation organization and be waiting for the accreditation process to be completed by that organization. We expect that suppliers will have obtained their accreditation before they are awarded a contract under the Medicare DMEPOS Competitive Bidding Program. We will evaluate a supplier's compliance with our bidding requirements before we finalize the pivotal bids as well as the single payment amounts. We will reject a bid that does not demonstrate that the supplier has met our bidding requirements. As a result, only bids from eligible, qualified, and financially sound suppliers will be used to determine the single payment amounts and select contract suppliers.

We note that although we will be considering each supplier's projected capacity as part of our determination of where to set the pivotal bid.

Comment: One commenter stated that the proposed rule indicated that suppliers would have to disclose information on debarments, sanctions, or other legal actions affecting them. However, Form A, the application section of the RFB, requires suppliers to disclose information about pending or prior investigations. The commenter noted that investigations are merely fact-finding tools that do not presume guilt and should not be used to negatively impact a supplier's bid evaluation. Another commenter stated that the term ''sanctioned'' is subject to being interpreted differently by each supplier. The commenter suggested that CMS detail what specific types of ''sanctions'' should be included in the disclosure. In addition, the commenter suggested that CMS more clearly define what it meant when it stated that bidding suppliers would have to ''certify'' in their bids that they, their high-level employees, chief corporate officers, members of the board of directors, affiliated companies, and subcontractors are not, and have not been, sanctioned by any governmental agency or accreditation or licensing organization. The commenter also wanted to know if CMS intends for the certification to take the form of a simple attestation or whether CMS would require suppliers to sign a prescribed legal statement testifying to the veracity of the disclosures or lack of disclosures.

Response: We agree with this comment that investigations are not in themselves evidence of guilt. We did not propose in the May 1, 2006 proposed rule to require a bidding supplier to disclose information in its bid about pending and prior investigations, and this final rule likewise does not require such disclosures. The RFB will conform to this final rule. We are revising proposed § 414.414(b)(2)(ii) so that it clarifies what disclosures a supplier must make in its response to the RFB. Specifically, we will require that each bidding supplier must disclose information regarding—(1) Any revocations of a supplier number; and (2) sanctions, program-related convictions as defined in section 1128(a)(1) through (a)(4) of the Act, exclusions, or debarments imposed against the supplier, its high-level employees, chief corporate officers, members of the board of directors, affiliated companies, and subcontractors by any Federal, State, or local agency. We are finalizing proposed § 414.414(b)(2)(i) to require a supplier to certify in its bid that this information is complete and accurate. We might reject a bid based on these disclosures. As discussed more fully below, we might conclude that a contract supplier has breached its contract if we discover that the contract supplier did not fully comply with these disclosure requirements, or if it is sanctioned or debarred, has legal action taken against it, or falls out of compliance with the Medicare program requirements (compliance with which we characterized in the proposed rule as

the supplier being in ''good standing'' with CMS), including enrollment requirements set forth at §§ 424.500 et seq., during the contract term.

We have added a cross-reference to final § 414.414(b) to indicate that networks (discussed more fully in section XII. of this final rule) must also meet the network requirements found in final § 414.418.

After consideration of public comments, we are finalizing § 414.414(a) without modification. We are finalizing §§ 414.414(b)(1)–(3) with the changes discussed above and with additional technical changes.

C. Financial Standards (§ 414.414(d))

Section 1847(b)(2)(A)(ii) of the Act specifies that we may not award a contract to an entity unless the entity meets applicable financial standards specified by the Secretary, taking into account the needs of small providers. Applying financial standards to suppliers assists us in assessing the expected quality of suppliers, estimating the total potential capacity of selected suppliers, and ensuring that selected suppliers are able to continue to serve market demand for the duration of their contracts. Ultimately, we believe that financial standards for suppliers will help maintain beneficiary access to quality services.

Therefore, as part of the bid selection process, we proposed that the RFBs would identify the specific information we will require to evaluate suppliers (proposed § 414.414(d)). We noted that this information may include: a supplier's bank reference that reports general financial condition, credit history, insurance documentation, business capacity and line of credit to fulfill the contract successfully, net worth, and solvency. We welcomed comments on the financial standards, in particular the most appropriate documents that would support these standards. We found that, in the demonstration, general financial condition, adequate financial ratios, positive credit history, adequate insurance documentation, adequate business capacity and line of credit, net worth, and solvency were important considerations for evaluating financial stability.

Comment: Several comments argued that the financial standards were too strict for certain suppliers and should be flexible enough to regulate mail order suppliers, small local suppliers, SNFs, departments of hospitals, retail pharmacies, and publicly-traded and privately-held family firms. The commenters stated that if financial standards are too restrictive, qualified suppliers might not be able to participate in the Medicare DMEPOS Competitive Bidding Program. They added that, conversely, if financial standards are too lax, suppliers may be financially unable to meet the challenges of a competitive market.

Response: We have revised proposed § 414.414(d) to indicate that the RFB form will specify the documents required as part of the bid application and that each supplier must submit this documentation along with its bid. We agree with the commenters that it is important to have financial standards that ensure suppliers are able to meet the challenges of competitive bidding and can fulfill their contract obligations. However, we also agree that our financial standards should not be so burdensome that suppliers, and especially small suppliers, cannot satisfy them. After further consideration and in response to comments, we believe that the proposed financial documentation discussed in the preamble to the proposed rule (71 FR 25675) would be too burdensome, particularly for small suppliers. Therefore, in order to obtain a sufficient amount of information about each supplier while minimizing the burden on both bidding suppliers and the bid evaluation process, we will require that for the initial round of competition, suppliers must submit certain schedules from their tax returns, a copy of the 10K filing report from the immediate 3 years immediately prior to the date on which the bid is submitted (if the supplier is publicly traded) certain specified financial statement reports, such as cash flow statements, and a copy of their current credit report, which must have been completed within 90 days prior to the date in which the supplier submits its bid and must have been prepared by one of the following: Experian; Equifax; or TransUnion. All documents that are not prepared as part of a tax return must be certified as accurate by the supplier and must be prepared on an accrual or cash basis of accounting. This financial information will allow us to determine financial ratios, such as a supplier's debt-to-equity ratio, and credit worthiness, which will allow us to assess a supplier's financial viability.

We will generally require that suppliers submit the same types of information for subsequent competitions, but we might choose to add or delete specific document requests as we gather experience on what financial information most accurately predicts whether a suppler is financially stable enough to participate in the Medicare DMEPOS Competitive Bidding Program.

Comment: One commenter suggested that CMS also publish the criteria it will use to assess supplier's financial stability and how it will rank suppliers based on these criteria. The commenter stated that bank statements should only be requested when we need to resolve doubts about the supplier's other submissions. The commenter believed that if we maintain the requirement for bank statements, the statements need to be defined for the period for which we are requesting the financial information.

Response: As we explained above, we recognize that our collection of financial information must be comprehensive enough to allow us to assess a supplier's financial soundness, but not so burdensome as to encumber the bidding process (especially for small suppliers) and the bid evaluation process. Therefore, as stated above, we will require that for the initial round of competition, suppliers must submit certain schedules from their tax returns, a copy of their 10K filing report from the 3 years immediately prior to the date on which the bid is submitted (if the supplier is publicly traded), certain specified financial statement reports, such as cash flow statements, and a copy of their current credit report, which must have been completed within 90 days prior to the date in which the supplier submits its bid and must have been prepared by one of the following: Experian; Equifax; or TransUnion.

We will generally require that suppliers submit the same types of information for subsequent competitions, but we might choose to add or delete specific document requests as we gather experience on what financial information most accurately predicts whether a suppler is financially stable enough to participate in the Medicare DMEPOS Competitive Bidding Program.

Comment: Several commenters stated that CMS should consider the supplier's debt-to-equity ratio (long-term debt divided by shareholders' equity). They indicated that this is a measurement of a supplier's capacity to borrow and expand. One commenter indicated, however, that this measurement will be problematic when applied to private firms. The commenters suggested that an alternative would be to require the EBITDA (earnings before interest, taxes, depreciation and amortization)-to-debt ratio because this is more difficult to manipulate. The commenter suggested that CMS could also use the quick ratio (current assets minus inventory divided by current liabilities) because this measurement is favored by lending institutions. Some commenters

indicated that CMS should also define the accounts receivable as the quick ratio (less than 180 days sales outstanding). They indicated that this ratio shows how long it takes the supplier to collect money owed and measures a supplier's liquidity and ability to meet short-term operating needs. Some commenters also suggested that CMS inquire as to how long a supplier has been in business.

Commenters also suggested that the information that CMS collects should include 2 years of financial statements prepared in accordance with generally accepted accounting principles. Some commenters recommended the financial statements be accompanied by a compilation, review, or audit report from an independent certified public accountant, a certificate of insurance verifying a minimum of $1 million of liability coverage, and a letter from a primary institutional lender verifying current lending relationship and the potential borrowing capacity of the supplier. Commenters also recommended that CMS receive a credit report from a recognized credit rating organization. One commenter wanted CMS to define a set ratio, for example, asset ratio should be not be higher than (X percent) and the asset to liability ratio should be no lower than (X percent).

Response: We will use appropriate financial ratios to evaluate suppliers. If suppliers do not meet certain ratios, they could be disqualified from the competition. Examples of ratios we might consider include a supplier's debt-to-equity ratio and a financial credit worthiness score from a reputable financial services company. The supplier standards in § 424.57(c)(10) require that the supplier carry a $300,000 comprehensive liability policy. We believe that imposing an additional cost for maintaining $1 million in liability coverage is not necessary. We will be reviewing all financial information in the aggregate and will not be basing our decision on one ratio but rather overall financial soundness.

As we noted above, we will require for CY 2007 competition that suppliers submit a credit report from one of three credit bureaus identified above to assist in determining a supplier's financial soundness. For all competition rounds, we will specify in the RFB what financial information must be submitted.

Comment: Several commenters recommended that CMS consider using Dunn and Bradstreet accounts payable ratings (paydex score) which measures how quickly a company pays its accounts payable. The commenters indicated that this information provides an additional measure of whether the supplier is, in fact, able to meet its current obligations.

Response: We will require suppliers to provide us with information which is included on a supplier's credit report when they submit their bids to assist us in determining their financial soundness.

Comment: One commenter argued that CMS must recognize that publicly traded companies are different from privately held community pharmacies, as they have fiduciary obligations to shareholders. Other commenters argued that the financial standards proposed are too burdensome and discourage small suppliers from participating. They recommended that CMS define different standards for small suppliers and pharmacies. The commenters suggested that the standards be limited to credit report, lien searches, credit references and 3 years' worth of tax returns.

Response: We are committed to ensuring the financial soundness of contract suppliers in the competitive bidding program. In previous responses, we have described the financial documentation that will generally be required for the competitions. We have determined that we can obtain the necessary information through collection of a limited number of financial documents and believe that the submission of this information will be less burdensome for all suppliers, including small suppliers. We believe we have balanced the needs of small suppliers and the needs of the beneficiaries in requesting documentation that will provide us with sufficient information to determine the financial soundness of a supplier.

After consideration of the public comments received, we are revising discussed proposed § 414.414(d) so that it now specifies that a supplier must submit the financial information specified in the RFB. For purposes of the CY 2007 competition, the financial documents discussed in this section will be those that the RFB will require. These requirements are as follows:

- Suppliers that file individual tax returns that include business taxes are required to submit the Schedule C (the Profit and Loss Statement) from their 1040 Tax Return for the 3 years immediately prior to the date on which the bid is submitted. In addition to the tax return information, these suppliers are also required to submit a Compiled Balance Sheet (Statement of Financial Position), a Statement of Cash Flow (Statement of changes in Financial Position) and a Statement of Operations (Income Statement) for the three years immediately prior to the date on which the bid is submitted. Suppliers are also required to submit a copy of their current credit report, which must have been completed within 90 days prior to the date on which the bid is submitted. The credit report must be prepared by one of the following: Experian; Equifax; or TransUnion.
- Limited partnerships and partnerships must submit their Schedule L from their 1065, U.S. Return of Partnership Income for the 3 years immediately prior to the date on which the bid is submitted, along with all other financial documentation that must be submitted by a supplier that files an individual tax return.
- Suppliers that file corporate tax returns are required to submit the Schedule L (Balance Sheet) from their tax return for the 3 years immediately prior to the date on which the bid is submitted. In addition to the tax return information, these suppliers are also required to submit a Statement of Cash Flow (Statement of Changes in Financial Position), and a Statement of Operations (Income Statement) for the 3 years immediately prior to the date on which the bid is submitted. Suppliers are also required to submit a copy of their current credit report, which must have been completed within 90 days prior to the date on which the supplier submits its bid. The credit report must be prepared by one of the following: Experian; Equifax; or TransUnion.
- All documents that are not prepared as part of a tax return must be certified as accurate by the supplier and must be prepared on an accrual or cash basis of accounting.
- Suppliers that are publicly traded companies must additionally submit a copy of their 10–K Filing Reports filed with the Securities Exchange Commission for the 3 years immediately prior to the date on which the bid is submitted. If a supplier is a wholly owned subsidiary of a publicly traded company, it must submit the parent company's 10-K reports.
- If a supplier does not have financial documentation for one or more of the 3 years immediately prior to the date on which the bid is submitted, then in addition to submitting the financial documentation for the years in which it is available, the supplier must also submit projected financial statements. The projected financial statements must show what is likely to occur in the future based on key financial and business assumptions of the present, and must include a description of the financial and business assumptions.

• For networks, the legal entity that submits the bid must submit financial statements on behalf of each network member in one complete package.

• If a supplier is submitting an individual bid and is also part of a network, the supplier must submit financial statements along with both the individual bid and the network bid.

D. Evaluation of Bids (§ 414.414(e))

In the May 1, 2006 proposed rule (71 FR 25675), we proposed to select the product categories that include individual items for which we will require competitive bidding. We stated that individual products would be identified by the HCPCS codes and would be further described in the RFBs. We proposed that suppliers would be required to submit bids for each individual item within each product category they are seeking to furnish under the program, but would not be required to bid for every product category.

1. Market Demand and Supplier Capacity (§§ 414.414(e)(1) and (e)(2))

Section 1847(b)(4)(A) of the Act requires that in awarding competitive bidding contracts, the Secretary may limit the number of contract suppliers in a CBA to the number necessary to furnish items to meet the projected demand for items covered under the contract for the CBA. Therefore, we proposed in proposed § 414.414(e)(1) to calculate expected beneficiary demand in a CBA for items in a product category. We stated that in order to fulfill this statutory mandate, the first step would be to determine the expected demand for an item in a CBA. We proposed to calculate expected demand in each CBA in a relatively straightforward way using existing Medicare claims. We proposed to examine claims data to determine the number of units of each item supplied to Medicare beneficiaries during the past 2 years, and then to determine the number of new beneficiaries who have entered the market during the last 2 years. We believed that 2 years' worth of data would be sufficient to allow us to identify trend analyses and utilization measurements. We also indicated that we would gather data on the number of new FFS Medicare enrollees coming into a CBA and use this number to project the number of new enrollees.

We discussed in the preamble to the May 1, 2006 proposed rule (71 FR 25675) how we proposed to calculate 2 years of claims on a monthly basis to determine beneficiary demand. We stated that we would take into consideration the expected demand over the total duration of the contract and the seasonal effects (for example, an increase in beneficiary population in Florida during the winter), and proposed to use 2 years of data to identify any time trends. If there were no seasonal effects or time trends, we proposed to use the average monthly total and new patient figures as the market demand measures. However, if there were seasonal effects or changes identified only during certain months, we proposed that the maximum monthly total and new patient figures would be used as the market demand measures. If trends showed that there was noticeable growth or reduction in beneficiary demand for products in an area, we proposed to take these factors into consideration when developing estimates of beneficiary demand for competitively bid items.

We proposed to adopt the following approach to estimate supplier capacity to meet the projected demand in a CBA. First, we proposed to analyze Medicare claims to determine how many items a supplier was currently providing in the CBA, as well as in total. Second, as part of the bid, we would ask suppliers to indicate how many units they were willing and capable of supplying at the bid price in the CBA. We would compare this information to what the supplier has dispensed to Medicare beneficiaries in the past and what it specified in its response to the RFB as its projected capacity. We proposed to require evidence of financial resources to support market expansion, such as letters from investors or lending agents. We would use this information to evaluate the capacity of the bidder. Third, we proposed to compare expected capacity and Medicare volume to determine how many suppliers we would need in an area. For new suppliers, we would ask them for their expected capacity, look at trend data for new suppliers in that area, and examine the capacity of other suppliers in that area. We would need to use these data to make estimates about capacity because we believe that suppliers might have more capacity potential than they are currently exhibiting.

During the DMEPOS competitive bidding demonstrations, demonstration suppliers were able to expand their output to meet market demand and replace market share previously provided by nondemonstration suppliers; indeed, some demonstration suppliers were disappointed that they did not gain more market share during the demonstration. We presented numerous issues to the PAOC where we requested advice on issues such as market capacity and demands. During the February 28, 2005 PAOC meeting, we asked the panel to discuss the issue of demand and capacity. Several members of the committee, based upon their expertise and knowledge of the industry, suggested 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.

We welcomed comments on our proposed approach for calculating market demand and estimating supplier capacity. We were especially interested in any information that would help us compare current Medicare volume with potential capacity, including potential formulas we could apply to determine capacity.

Comment: Several commenters argued that there was insufficient information given as to how CMS will determine a supplier's capacity. The commenters wanted to know if the projected capacity that suppliers must identify in their responses to the RFB form was a bid commitment or estimation. The commenters also noted that CMS did not describe what criteria it will use to compare bidders (aside from bid price) and how these criteria will be applied. They further suggested that CMS look at a supplier's history and allow a 20-percent growth rate to determine the supplier's capacity.

Response: We proposed that suppliers would have to estimate in their response to the RFB how many items they would be able to furnish in the CBA for the bid price. We also proposed that suppliers would be required to submit documentation evidencing any planned business expansion, such as letters from investors or lending agents. We will look at this documentation, as well as the supplier's other financial documentation to determine the ability of that supplier to furnish its projected capacity. The capacity identified in the supplier's response to the RFB form should represent the supplier's best estimation of the number of items it can provide to Medicare beneficiaries in a given CBA. We might, however, make two types of adjustments to a supplier's projected capacity for purposes of finalizing the pivotal bid. First, if a supplier estimates that it can furnish more than 20 percent of what we determine to be the expected beneficiary demand for the product category in the CBA, we will lower that supplier's capacity estimate to 20 percent. We believe that this capacity adjustment is necessary to ensure that at least 5 suppliers have composite bids at or

below the pivotal bid for the product category, which will then enable us to award contracts to at least those 5 suppliers. By awarding contracts to at least 5 suppliers per product category, we expect that there will be sufficient contract suppliers in the CBA to provide beneficiaries with more variety and choice. However, we are confident that, due to the nature of supplies that can be furnished via mail order (for example, diabetic supplies) national or regional mail order suppliers will easily be able to expand to meet very large demands. Therefore, we do not believe it is necessary to ensure that there are at least five national or regional mail order suppliers. If we were to require at least five such suppliers, we believe it would dilute our savings.

Second, we might further adjust a supplier's capacity if, after making the initial adjustment discussed above, we conclude that the supplier's financial and business expansion documentation do not support the projected capacity stated in its bid. In determining whether this further adjustment is necessary, we will give consideration to the suggestion of the PAOC that a supplier's capacity could easily be increased by up to 20 percent. We believe, however, that this further adjustment may be necessary to limit the potential that we would award contracts to an inadequate number of suppliers based on inflated capacity projections that the suppliers would not be able to actually meet. If we believe that this further adjustment is necessary, we will lower the supplier's projected capacity to its historical capacity, as evidenced by its financial documentation and past claims data.

We note that after making these adjustments, if we are still unable to award five contracts in a CBA because there are not enough qualified suppliers, we will award at least 2 contracts to qualified suppliers for the furnishing of that product category under a competitive bidding program.

We also note that the adjustments we might make to a supplier's projected capacity would not impact the supplier's ability to actually furnish items if it is awarded a contract. In other words, a contract supplier will be able to furnish items to all beneficiaries who wish to receive them from it.

Comment: Some commenters stated that CMS must consider how changes in coding, utilization, and documentation may affect the utilization data for the last 2 years. They cited, for example, that changes in wheelchair cushions and respiratory coding may affect the utilization data.

Response: We proposed that we would calculate the expected beneficiary demand for a product category in a CBA by using two years of existing Medicare claims data, which we believe is sufficient to allow us to identify changing trends in utilization. In calculating the expected beneficiary demand for a product category in a CBA, we might also evaluate data showing beneficiary demand for key high volume items in the product category.

After consideration of the comments received, we are adopting as final § 414.414(e)(1), which provides that we will calculate the expected beneficiary demand for items within a product category in each CBA as part of the bid evaluation process. In addition, we are adding a new § 414.414(e)(2) to finalize our proposal to evaluate the total supplier capacity that would be sufficient to meet beneficiary demand for items in the CBA for the items in a product category.

2. Composite Bids (§§ 414.402, 414.414(e)(3) and (4))

Because suppliers will be bidding for multiple items in a product category, the lowest bid for each item will not always be submitted by the same supplier. In this case, looking at the bids for individual items would not tell us which suppliers should be selected since different suppliers may submit the lowest bids for different items. Therefore, in proposed §§ 414.414(e)(2) and (e)(3) (redesignated as § 414.414(e)(3) and (e)(4) in this final rule), we proposed to use a composite bid to compare all of the suppliers' bids submitted for an entire product category in a CBA. We stated that using a composite bid would be a way to aggregate a supplier's bids for individual items within a product category into a single bid for the whole product category. This would allow us to determine which suppliers can offer the lowest expected costs to Medicare for all items in a product category. To compute the composite bid for a product category, we would 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 would be based on the utilization of the individual item compared to other items within that product category based on historic Medicare claims. Item weights would be used to reflect the relative market importance of each item in the product category. We would select item weights that ensure that the composite bid is directly comparable to the costs that Medicare would 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 would become the supplier's composite bid for that product category.

We sought comment on the best method of weighting individual items within a product category to determine the composite bid. We indicated that one approach we were considering would be to set the weight for each item based on the volume of the individual item's share compared to the total utilization of the product category. Under this weighting system, the composite bid would be exactly proportional to the expected cost of furnishing the entire bundle of items. Therefore, if supplier 1 had a lower composite bid than supplier 2, it would also have a lower expected cost of furnishing the entire product bundle that makes up the product category. Another approach we considered was to set 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. We stated that this approach might better reflect the relative value of each item because it is based on how much we actually pay for an item, and that this was the approach that we used in the first round of bidding in Polk County under the competitive bidding demonstration program. However, we stated that we also found that this approach could result in too much weight being placed on low-volume and high-priced items. The first year evaluation report also found that using the allowed charges as the weights could result in a supplier that offered lower bids having a higher composite bid than a supplier that offered a higher bid for individual items.

In the May 1, 2006 proposed rule, we used the volume of items or units displayed in Table 5 of that rule (and as republished below) as the basis of our examples, but we requested comments on which weighting method should be used in calculating the composite. We also requested comments on other methods of weighting that could be applied to individual items.

TABLE 5.—ITEM WEIGHTS

Item	A	B	C	All
Units	5	3	2	10
Item Weight	0.5	0.3	0.2	1

The example above shows how our proposed weight-setting methodology would work. The expected volume for Items A, B, and C are 5, 3, and 2 units, respectively, for a total volume of 10 units. The item weight for Item A is 0.5

(5/10), the weight for Item B is 0.3 (3/10), etc.

As explained above, the composite bid for a supplier would equal the item weight times the item bid amount summed across all items in the product category. The item weights would be the same for bidders for the same product categories. In our example, supplier 1 bid $1.00 for item A, $4.00 for item B, and $1.00 for item C. The composite bid for Supplier 1 = (0.5 * $1.00) + (0.3 * $4.00) + (0.2 * $1.00) = $1.90. Table 6 shows the expected cost of the bundle based on each supplier's bids. The expected costs are directly proportional to the composite bids; the factor of proportionality is equal to the total number of units (10) in the product category. We used the composite bid to determine the expected costs for all of the items in the product category based upon expected volume.

TABLE 6.—COMPOSITE BIDS

Item	A	B	C	Composite bid	Expected cost of bundle
Units	5	3	2		
Item weight	0.5	0.3	0.2		
Supplier 1 bid	$1.00	$4.00	$1.00	$1.90	$19.00
Supplier 2 bid	$3.00	$3.00	$2.00	$2.80	$28.00
Supplier 3 bid	$2.00	$2.00	$2.00	$2.00	$20.00
Supplier 4 bid	$1.00	$2.00	$2.00	$1.50	$15.00

Under the proposed methodology, bid selection would proceed by ranking the composite bids from lowest to highest (Table 6). In order to ensure that we would pay less under competitive bidding than we would under the current fee schedule, as is required under section 1847(b)(2)(A)(iii) of the Act, we would compute the expected cost of the bundle of goods for comparison purposes. This would require us to calculate the bid amount times the expected number of units that we expect suppliers will furnish based on the most current Medicare claims data and sum across each item by supplier. For example, if supplier 1 bid $1.00 for item A and we expected to purchase 5 units—$1.00 × 5 units = $5.00, item B—$4.00 × 3 units = $12.00, item C—$1.00 × 2 units = $2.00, the sum for these 3 items would be $19.00. As previously noted, prior to selecting a supplier for a contract, we would ensure that suppliers meet quality and financial standards.

Comment: One commenter stated that the bidding should not be so complex. The commenter stated that the use of a weighted composite bid is confusing and cumbersome. The commenter also stated that the weights should be provided to each supplier prior to bidding. Other commenters indicated that if the median methodology is used, bids should be weighted by proposed capacity so that payment rates more accurately represent the market of successful bidders.

Response: We understand the commenters' concern and believe we have simplified the methodology as much as possible. We plan to provide the weights for each item prior to bidding, so that bidders will be aware of the weight given to each item. We stated in the proposed rule that using a composite bid would be a way to aggregate a supplier's bids for individual items within a product category into a single bid for the whole product category. This would allow us to determine which suppliers can offer the lowest expected costs to Medicare for all items in a product category. To compute the composite bid for a product category, we would multiply a supplier's bid for each item in a product category by the item's weight and sum these numbers across items. In the proposed rule, we defined the term ''item weight'' as 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.'' We are revising this definition to indicate that we will use national beneficiary utilization data to determine the item weights for the CBA because we believe that it results in a more representative number that reflects the utilization rate for the item. We believe that this weighting methodology will best reflect the relative market importance of each item in the product category.

After consideration of the comments received, we are redesignating proposed § 414.414(e)(2) and (e)(3) as § 414.414(e)(3) and (e)(4) and adopting them as final with a technical change to paragraph (e)(4) to clarify that we will array the composite bids from the lowest ''composite bid price'' to the highest ''composite bid price.'' We are also revising the definition of ''item weight'' in § 414.402.

3. Determining the Pivotal Bid (§§ 414.414(e)(5) and (e)(6))

We proposed that the pivotal bid would be the point where expected combined capacity of the bidders would be sufficient to meet expected demands of beneficiaries for items in a product category. In the example below, the projected demand would be for 1,000 units. Therefore, the supplier 10's composite bid would represent the pivotal bid, because that supplier's cumulative capacity of 1,100 would exceed the projected demand of 1,000. The statute requires multiple winners, so in all cases where we award contracts, we stated that we would need to accept at least two winning bidders. All bidders that were eligible for selection and whose composite bid for the product category was less than or equal to the pivotal bid would be selected as winning bidders. In the Table 7 below, for example, $135.00 would be the pivotal bid. Suppliers 2, 3, 1, and 10 would then be selected as winning bidders with supplier 10's composite bid becoming the pivotal bid. We acknowledged that this approach may leave out other suppliers with very close, but slightly higher bids.

TABLE 7.—DETERMINING THE PIVOTAL BID

[Point where beneficiary demand is met by supplier capacity—For this example, beneficiary expected demand is 1,000 units—Supplier 10's bid is the pivotal bid]

Supplier No.	Eligible for selection	Composite bid	Supplier capacity	Cumulative capacity
2	Yes	$100	100	100
3	Yes	115	300	400
1	Yes	120	400	800
10	Yes	135	300	1100
4	Yes	140	500	1600
7	Yes	150	100	1700
No longer being considered				
5	No	120	n.c.	n.c.
6	No	130	n.c.	n.c.
8	No	175	n.c.	n.c.
9	No	200	n.c.	n.c.

n.c. = not calculated.

We also noted that we had considered the use of a competitive range to determine the contract suppliers. In this approach, we would determine a competitive range for the composite bid. We would array all suppliers by their bids and eliminate all suppliers whose composite bid is greater than the competitive range. We would then evaluate the quality and financial standards only for those remaining suppliers.

During the demonstration, evaluating quality and financial standards was time-consuming for the bid evaluation panel and required bidders to provide extensive information on quality and finances. The last two rounds of the demonstration used a competitive range to reduce the burden on the bid evaluation panel and bidders. After evaluating basic eligibility requirements, the composite bids were calculated and arrayed, and a competitive range was selected with more than enough suppliers to serve the market. Suppliers whose composite bids were clearly outside of this range were not required to provide detailed financial information, and the bid panel was not required to evaluate the eligibility of these suppliers to participate. Suppliers within the competitive range provided detailed financial information and had their quality rigorously evaluated. The remaining suppliers were only selected as contract suppliers if they met the quality and financial standards and their composite bids were at or below the pivotal bid.

We also discussed in the proposed rule other options that we considered to determine the pivotal bid. One of these options would have been to make the pivotal bid depend on one of the summary statistics (for example, mean, median, 45th percentile) associated with the distribution of bids from eligible suppliers. For example, the pivotal bid could have been set equal to the median bid submitted by eligible suppliers. We stated that the advantage of this option would have been that the pivotal bid could be set near the central distribution of bids. We also considered including additional suppliers whose bids were close to the central distribution as being eligible to become a contract supplier. Both options would likely have affected the number of contract suppliers. Finally, we noted that the exact summary statistic or percentile could have been increased or decreased to reflect the trade-off between the number of winners and program costs. One negative aspect of this approach would have been that winners might have insufficient capacity. In addition, with a given percentile cutoff, the pivotal bid might have included an excessive number of winning bidders. As the number of eligible bidders increased, so would the number of winners. If additional bidders had higher costs, and their bids fell into the upper half of the distribution, the pivotal bid would increase, resulting in greater payments by the Medicare program and a loss of savings.

Another option we discussed would have been to base the pivotal bid on a target number of winners. For example, we might have decided to select five winners in each product category. Suppliers might have responded to this approach by bidding aggressively, knowing that only a fixed number of winners would be guaranteed to be selected. A negative aspect of this approach would have been that there is no assurance that a predetermined target number of winners would have had sufficient capacity to meet projected market demand. In addition, the target number of winners must somehow be selected and this could have resulted in selecting an arbitrary number. If too high, suppliers might have had little incentive to bid aggressively.

We also considered an option to base the pivotal bid on a target composite bid; for example, we could have chosen a target that was 20 percent below the DMEPOS fee schedule amount for that product category. A possible advantage of this approach would have been that the target composite bid could be set to ensure savings for the program. On the other hand, we believed that suppliers might perceive this approach to be anticompetitive. Rather than letting bidding and the market forces determine the pivotal bid and fee schedule, we might have been viewed as pre-ordaining the outcome. In addition, suppliers that bid below the target composite bid might have had insufficient capacity to meet projected market demand.

Comment: One commenter requested additional explanation as to what cumulative capacity is and how it is calculated in the competitive bidding program.

Response: The cumulative capacity is determined by arraying the composite bids from the lowest to the highest, then calculating the pivotal bid for the product category by ensuring that the number of suppliers selected to furnish items for that product category in a CBA have sufficient cumulative capacity to do so. We will determine the cumulative capacity of bidding suppliers for the product category by adding each supplier's projected or adjusted capacity. For example, if supplier 1 states it can provide 15 units, supplier 2 states it can provide 40 units, and supplier 3 states it can provide 35

units, the cumulative capacity of those suppliers is 90 units.

After consideration of the public comments we received, we are redesignating proposed § 414.414(e)(4) as § 414.414(e)(5), and finalizing newly redesignated § 414.414(e)(5) with the changes discussed above. We also are redesignating proposed § 414.414(e)(5) as § 414.414(e)(6) and revising newly redesignated § 414.414(e)(6) so that it now provides that the only suppliers we will select for contract award purposes will be those suppliers that have satisfied our eligibility, quality, accreditation (unless a grace period applies), and financial requirements.

4. Assurance of Savings (§ 414.414(b)(2), 414.414(f))

Section 1847(b)(2)(A)(iii) of the Act prohibits awarding contracts to any entity for furnishing items unless the total amounts to be paid to contractors in a CBA are expected to be less than the total amounts that would otherwise be paid. Under proposed § 414.414(f), we proposed to interpret this requirement to mean that contracts will not be awarded to any entity unless the amounts to be paid to contract suppliers in a CBA are expected to be less for a competitively bid item than would have otherwise been paid. Therefore, we stated that we would not accept any bid for an item that is higher than the current fee schedule amount for that item. This approach would ensure that the single payment amount for each item in a product category is equal to or less than our current fee schedule amount for that item.

We acknowledged that an alternative interpretation of ''less than the total amounts that would otherwise be paid'' could mean contracts would not be awarded to an entity unless the amounts paid to contract suppliers in a CBA for the product category are expected to be less than what would have otherwise been paid for the entire product category. During the demonstration, several product categories received overall savings, whereas payment amounts increased for a few individual items within those product categories. One concern we had with this approach was that there might be a greater potential for shifting of utilizations from one item to another higher priced item. We stated that this approach might not result in adequate savings, and that we believed a reasonable interpretation of the Act would be one in which ''the total amounts'' mean payment at the item level.

We specifically requested comments on the various methods for assuring savings under the Medicare DMEPOS Competitive Bidding Program.

Comment: Numerous commenters disagreed with the proposed requirement that bids must be at or below the current fee schedule for an item. The commenters believed that this places artificial constraints on a process that is designed to harness market forces. They indicated that, if bids are submitted higher than the current fee schedule, CMS should choose not to include that particular item in the bidding product category.

Response: Section 1847(b)(2)(A)(iii) of the Act prohibits CMS from awarding a contract to a supplier under a competitive bidding program unless the total amounts to be paid to contractors in a CBA are expected to be less than the total amounts that would otherwise be paid. In order to ensure that the requirement is met and to guarantee savings for the Medicare program, we must require the bids for each item to be at or below the current fee schedule amount for the item in order to preclude increases that may occur due to shifting to items priced above the fee schedule. Without this safeguard, we are concerned that suppliers might simply start furnishing the items priced above the fee schedule rather than those that would normally be furnished because of the potential for higher profits. In addition to increased expenditures, because of a shift to items with higher payment amounts, we might exceed the total amounts that we had been paying for particular products as a group within a product category. This could also result in less appropriate products being furnished to Medicare beneficiaries. We believe that this requirement is necessary to structure a competitive bidding program that reflects the requirements of the statute.

Accordingly, we are adding a new § 414.412(b)(2), which provides that the bid for an item cannot exceed the payment amount that would otherwise apply if the item was not included in the competitive bidding program. In addition, we are finalizing proposed § 414.414(f) with only technical changes.

5. Assurance of Multiple Contractors (§ 414.414(h))

Section 1847(b)(4)(B) of the Act specifies that the Secretary will award contracts to multiple entities submitting bids in each area for an item. In addition, section 1847(b)(2)(A)(iv) of the Act specifies that contracts may not be awarded unless access of individuals to a choice of multiple suppliers is maintained. As a result, we proposed under proposed § 414.414(g) (redesignated as § 414.414(h) in this final rule) that we would have multiple contract suppliers in each CBA for each product category if at least two suppliers met all requirements for participation, and the single payment amounts to be paid to those suppliers did not exceed the fee schedule amounts for the items that were bid. We acknowledged that offering choices to beneficiaries, referral agents, and treating practitioners that order DMEPOS for Medicare beneficiaries is important to maintain competition among suppliers based on the quality of items. We stated that we had to weigh that advantage against the disincentive for a supplier to submit its best bid if we select too many suppliers to service a CBA. We believe we will be able to have multiple suppliers servicing one product category in a CBA and still accomplish the goals of competitive bidding.

Comment: Several commenters recommended that CMS select more suppliers than necessary to meet minimum demand. The commenters believed that this will ensure a sufficient number of suppliers to address contingency or emergency situations, such as a natural disaster. Several commenters recommended that CMS use 130 percent of anticipated capacity. A few commenters requested that CMS cap estimated capacity per supplier when selecting winning bidders to preserve competition and beneficiary choice. Some commenters recommended that CMS cap each supplier's capacity at 20 percent, or 25 percent, of anticipated demand to ensure that a small number of very large suppliers do not become the only winning bidders.

Response: We anticipate that we will select a sufficient number of suppliers to ensure beneficiary access. As we have explained above, we may make adjustments to a supplier's projected capacity in order to ensure that we award contracts to a sufficient number of suppliers. As explained below, we are also modifying our proposed rule for participation by small suppliers to set a small supplier target which will be calculated by multiplying 30 percent times the number of winning suppliers at or below the pivotal bid for each product category. As a result, we will be able to ensure that small suppliers have an opportunity to participate in the programs.

Comment: Several commenters observed that the proposed rule does not mention whether CMS will consider the geographic distribution of suppliers when determining the number of contract suppliers for each product

category in each CBA. They believed that geographic distribution is important to maintain local presence and for beneficiary convenience. They suggested that CMS analyze capacity at the zip code level to ensure that each zip code is served by several contract suppliers. They also stated that there is precedent for determining geographic distribution, citing that the TRICARE standard and the Medicare Part D program have established guidelines for the required number of retail pharmacies, depending on the type of area. One commenter also suggested that any competitive bidding program for diabetic testing supplies include a requirement that a minimum number of community-based suppliers be included and those suppliers be geographically dispersed within the CBA to provide convenient access for Medicare beneficiaries.

Response: We believe that we have created a contract supplier selection methodology that will ensure that beneficiaries have convenient access to competitively bid items. Contract suppliers will also be required to furnish all items to all beneficiaries who maintain a permanent residence in a CBA (or who visit a CBA) unless an exception set forth in this final rule applies. If a beneficiary is unable to come to the storefront of the contract supplier, we would expect that the contract supplier would deliver the item to the beneficiary and, if necessary, set up the item in the beneficiary's residence and train the beneficiary how to use the item. This will ensure beneficiary convenience and access to competitively bid items. We reviewed the TRICARE access standards and believe the standards are not appropriate for meeting the purposes of the Medicare DMEPOS Competitive Bidding Program. The retail pharmacy industry is different from the DMEPOS supplier industry. The retail pharmacy industry provides access through storefront presence where they provide a variety of consumer products. In contrast, most DMEPOS suppliers deliver medical products to the beneficiaries' homes.

After consideration of the public comments we received, we are redesignating proposed § 414.414(g) as § 414.414(h)(1) and revising it to provide that CMS will award at least five contracts for the furnishing of a product category under a competitive bidding program if the requirements in §§ 414.414(b) through (f) are met by at least 5 suppliers. We are also adding a new § 414.414(h)(2), which provides that if the requirements in §§ 414.414(b) through (f) are not by at least 5 suppliers, we will award contracts to at least 2 qualified suppliers. Finally, we are adding a new § 414.414(h)(3), which provides an exception for mail order suppliers to the requirement that if there are at least 5 qualified suppliers, we will award contracts to at least 5 qualified suppliers.

6. Selection of New Suppliers After Bidding (§ 414.414(i))

In the May 1, 2006 proposed rule (71 FR 25678), we proposed to select only as many suppliers as necessary to ensure we have enough capacity to meet projected demand. However, we noted that we might have to suspend or terminate a contract supplier's contract if that supplier falls out of compliance with any of the requirements identified in the regulation and in the bidding contract. Alternatively, we recognized that we could later determine that the number of contract suppliers we selected to furnish a product category under a competitive bidding program was insufficient to meet beneficiary demand for those items. In situations where CMS determines that there is an unmet demand for items, for example, if CMS terminates a contract supplier's contract, we proposed to 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, we proposed to refer to the list of suppliers that submitted bids for that product category in that round of competitive bidding in that CBA, use the list of composite bids that we arrayed from lowest to highest, and proceed to the next supplier on the list. We would contact that supplier to determine if it would be interested in becoming a contract supplier. If the supplier was interested, we proposed to require the supplier to provide updated information to ensure its continued eligibility for participation. A condition for acceptance of a contract would be that the supplier must agree to accept the already determined single payment amounts for the individual items within the product category in the CBA. We would continue to go down the list until we were satisfied that the expected demand would be met and beneficiary access to the items in the product category would not be a problem. After consultation with the DMEPOS industry and PAOC, we were informed that additional capacity should not be a problem as suppliers would be willing and able to handle the expected demand.

Another option that we considered, but did not propose, was to conduct a new round of bidding to select additional suppliers. However, we did not choose this option because it would delay the resolution of an access problem and place an additional administrative burden on the program.

Comment: One commenter argued that it would be a violation of the statute to award contracts to a new supplier after contracts have been awarded without conducting a new competition. The commenter stated that the law requires that CMS conduct a competition for the award of any contracts for a competitively bid item. Therefore, the commenter believed an award to the bidder next-in-line when a contract supplier leaves the program or CMS find that it needs additional suppliers would not constitute a competitive acquisition.

Response: We agree that contracts cannot be awarded to a supplier that did not compete. We disagree that this regulation requirement results in awarding a contract to a supplier that did not submit a bid. These suppliers have competed and met all applicable eligibility, quality, financial, and accreditation requirements to be awarded a contract. We intend to only use this methodology when we find that there is a need for additional contract suppliers because a contract supplier's contract is suspended or terminated or when CMS finds it needs additional contract suppliers to meet beneficiary demand for a particular product category in a CBA. It would not be in the best interest of beneficiaries to delay awarding the additional contracts when we need to ensure sufficient capacity because a contract supplier's contract has been suspended or terminated or there is greater need in an area than we anticipated.

Comment: One commenter stated that CMS should have a process identified if there are no suppliers located in a CBA willing to accept the single payment amount and enter into a competitive bidding contract.

Response: We would not be able to have competitive bid pricing in a CBA in which no suppliers could accept the single payment amount.

In summary, after consideration of the public comments received, we are redesignating proposed § 414.414(h) as § 414.414(i) and adopting it as final with only technical changes.

VIII. Determining Single Payment Amounts for Individual Items

A. Setting Single Payment Amounts for Individual Items (§§ 414.416(a) and (b))

Section 1847(b)(5)(A) of the Act requires that the Secretary determine a

single payment amount for each item in each CBA based on the bids submitted and accepted for that item, and we proposed in § 414.416(a) and (b) to implement this statutory requirement. Once contract suppliers are selected for a product category based on their composite bid and the pivotal bid, single payment amounts for individual items in the product category must be determined. We considered several different methodologies for determining the single payment amounts. Each of the options we considered is discussed in detail in this section. After careful consideration of these options, we proposed to adopt 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

We must expect to pay less for each individual item than we would have otherwise paid for that item under the current fee schedule. Single payment amounts cannot be higher than our current fee schedule amounts for individual items within a product category.

To satisfy these principles, we evaluated several different approaches to setting payment amounts. As a result of our review, we decided on a preferred approach that 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. The individual items would be identified by the appropriate HCPCS codes. The median of the bids submitted by the contract suppliers for a particular item would be the single payment amount that we would 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, we would employ the average (mean) of the two bid prices in the middle of the array to set the single payment amount. In addition, we proposed that the single payment amount for each item must be less than the current fee schedule amount for that item.

We believe that setting the single payment amount based on the median of the contract suppliers' bids satisfies the statutory requirement that single payment amounts are to be based on bids submitted and accepted. This will result in a single payment for an item under a competitive bidding program that is representative of all acceptable bids, not just the highest or the lowest of the winning bids for that item.

TABLE 8.—MEDIAN OF THE WINNING BIDS

Item	A	B	C	Actual composite bid
Supplier 4 bid	$1.00	$2.00	$2.00	$1.50
Supplier 1 bid	1.00	4.00	1.00	1.90
Supplier 3 bid	2.00	2.00	2.00	2.00
Median of winning bids—Single payment amount	1.00	2.00	2.00	

While this was our proposed approach, we solicited comments on other methodologies for setting the single payment amount, including using an adjustment factor as part of the methodology for setting the single payment amount. This was the methodology we used for the competitive bidding demonstrations, and it would have required the following steps. The first step of this methodology would have been to calculate the average of the winning bids per individual item. The second step would have been to calculate the average of the composite bids by taking the sum of the composite bids for all contract suppliers in the applicable CBA and dividing that number by the number of contract suppliers. The third step would have been to determine an adjustment factor, the purpose of which would be to bring every winner's overall bids for a product category up to the pivotal bidder's composite bid. Once we determined the adjustment factor, we would have taken the average of the winning bids per item and multiplied that by the adjustment factor to adjust all bids up to the point of the pivotal bid, so that all winners would be paid by Medicare as much for the total product category as the pivotal bidder. This amount would have become the single payment amount for the individual item. This is the price that all contract suppliers within a CBA would have been paid for that product as illustrated in Table 9. ?≤

TABLE 9.—ADJUSTING THE AVERAGE WINNING BIDS

Item	A	B	C	Average composite bid	Actual composite bid
Supplier 4 bid	$1.00	$2.00	$2.00		$1.50
Supplier 1 bid	1.00	4.00	1.00		1.90
Supplier 3 bid	2.00	2.00	2.00		2.00
Supplier 2 bid	N/A	N/A	N/A		N/A
Average of winning bids	1.33	2.67	1.67	1.80	
Adjustment factor = (Pivotal Composite Bid)/(Average Composite Bid)	1.11	1.11	1.11		
Adjusted average bids-single payment amount per item	1.48	2.96	1.85		

This approach would have ensured that the overall payment amounts that contract suppliers received were at least as much as their bids. As a result, this may have guarded against suppliers leaving the Medicare program because the payment amounts are not sufficient. However, we did not favor this alternative because, in general, most payment amounts would have been higher than the actual bids as a result of the adjustment factor being greater than

zero. This would have been true because the purpose of the adjustment factor would have been to make the composite bid of all winning suppliers equivalent to the composite bid of the pivotal supplier. We chose not to propose this approach because we believe that this approach is not reflective of all of the winning bids accepted. In addition, we stated that we were concerned that this methodology might be confusing and overly complicated.

We also considered taking the minimum winning bid for each item in a CBA and not applying an adjustment factor. We did not favor this alternative because we also did not consider it as being reflective of the actual bids accepted because it is only reflective of the lowest bid. The lowest bid would not be reflective of what suppliers would sell the item for as most of them bid higher.

Finally, we considered taking the maximum winning bid for each item. However, this approach would have led to program payment amounts that were higher than necessary because some suppliers were willing to provide these items to beneficiaries at a lower cost.

In the proposed rule, we indicated that we were still in the process of determining the appropriate approach for setting payment amounts, as well as the alternatives considered and outlined above, and invited comments on our proposed methodology.

Comment: Several commenters expressed concerns that the proposed method to determine the single payment amount would result in suppliers submitting low bids and only offering the lowest cost devices. They believed that quality and access would be impacted by the use of the median bid. They further indicated that requiring savings on each item rather than in the aggregate encourages suppliers to bid on the oldest, lowest priced product within each HCPCS code. The commenters suggested that CMS base savings at the product category level and not for each individual code.

Response: We disagree with these commenters. We recognize the necessity for a process to identify and eliminate irrational, infeasible bids. As required in § 414.414(b)(4), each supplier must submit a bona fide bid that is complies with all the terms and conditions contained in the RFB. Also, as discussed in section XIV of this final rule, we will establish a formal complaint and monitoring system for each CBA. Specifically, we will direct the CBIC to establish a monitoring program that includes beneficiary satisfaction indicators and supplier performance indicators.

The Medicare DMEPOS Competitive Bidding Program is designed to ensure that the Medicare payment amounts are appropriate and reasonable. In addition, competitive bidding will harness market forces and create competition among suppliers. We believe that this competition will prevent suppliers from offering the lowest cost devices, as suppliers will be interested in increasing their market share by offering appropriate services and high quality products to maintain and increase their customer base.

In addition, and as discussed more fully in section IX. of this final rule, we will include a nondiscrimination clause in the contracts we enter into with contract suppliers. Under that provision, contract suppliers will be obligated to make the same items available to beneficiaries under the Medicare DMEPOS Competitive Bidding Program that they make available to other customers. We believe that the inclusion of this clause will help to ensure that Medicare beneficiaries have access to the highest quality DMEPOS items. Section 1847(b)(2)(A)(iii) of the Act states that the total amounts to be paid to contractors in a competitive acquisition area are expected to be less that the total amounts that would otherwise be paid. In order to guarantee that we implement this section to ensure that we achieve savings for the Medicare program, we must require bids to be at or below the current fee schedule for the item. This will preclude our setting single payment amounts for certain items above the fee schedule and causing contract suppliers to attempt to shift utilization to these items because of the higher payment amounts. Without this safeguard, we are concerned that suppliers might simply start furnishing an alternative item, because the physician's order may not be item specific, within the same product category because the item may have a greater potential for higher profits. In addition to increased expenditures, this could also result in less appropriate items being furnished to Medicare beneficiaries.

In addition, we believe that basing product savings at the item level will guarantee assurance of savings for the Medicare DMEPOS Competitive Bidding Program because accepting bids above the fee schedule for certain products may result in these items being furnished as an alternative to other items within the product category, which would increase their utilization and expenditures compared to the current levels.

Comment: Several commenters argued that the use of the median bid to set the single payment amount is flawed because the median bid could be vulnerable to a variety of gaming strategies. They noted that, when using the median, 50 percent of winning bidders would have to accept less than their bids to participate. They indicated that if a contract supplier is not able to provide the items at the median, demand would not be met and access would be impaired. The commenters raised concerns that all bids would have the same weight, and bids from small suppliers, which only serve a few Part B beneficiaries, would have the same impact on the calculation as bids from suppliers responsible for a large number of beneficiaries, which would give too much weight to small suppliers. Other commenters suggested that the use of the median bid favors large chain suppliers that deliver large volume of items. Other commenters suggested that CMS include a mechanism to ''rationalize'' bids to ensure there are no unreasonably low bids. They added that CMS should have a mechanism to eliminate outlier bids. One commenter suggested that CMS calculate the single payment amount only from among those bids that are ''reasonable.'' Numerous commenters suggested that CMS use the Adjustment Factor Method (AFM) that was used during the demonstration. Because suppliers were paid at least as much as they bid in aggregate, commenters believed that the AFM would provide sufficient protections to encourage small suppliers to bid. One commenter suggested setting the payment amount at the 90th percentile of winning bids or not lower than 5 percent below the highest winning bid. Another commenter recommended calculation of the single payment amount only from those bids that lie within one standard deviation of the mean of the bids. One commenter supported the use of a median calculation as a statistically valid method for determining the single payment amount. Lastly, some commenters recommended that CMS pay contract suppliers their bid amounts or the single payment amount, whichever is lower. These commenters believed that this would be consistent with the statutory payment basis of the fee schedule or the actual charge, whichever is less.

Response: We disagree with the concerns raised by commenters regarding the use of median bid to set the single payment amount. We believe that the use of the median takes into consideration all bids submitted and accepted and not just the high and low bids. We further believe that the median

is not influenced by outliers at the extremes of the data set. For this reason, the median is often used when there are a few extreme values that could greatly influence the mean and distort what might be considered typical. We believe the median of the accepted bids would represent a reasonable payment amount and does not favor large or small suppliers, and we believe this approach is more equitable than other approaches suggested in the comments. Regarding access, if a winning supplier does not enter into a contract because it is not able to furnish the items at the median, we believe that access will not be adversely affected because we will be selecting a sufficient number of contract suppliers to ensure that demand is met in the CBA. In addition, we believe that most, if not all, of the winning suppliers will be willing to furnish items in the product category at the single payment amounts.

In addition, section 1847(b)(5)(A) of the Act states that payment shall be based on bids submitted and accepted. The single payment amount will be determined from only those bids that are considered ''acceptable,'' meaning that the supplier meets all quality, financial, and eligibility standards and that the bid is in the wining range. For this reason, we believe that the single payment amount should be representative of all of the accepted bids and not just the highest or the lowest bids. We further believe that using the adjustment factor is not reflective of the actual bids accepted because it is only reflective of the pivotal bid. We do not believe that the adjustment factor is necessary to ensure that small suppliers have the opportunity to be considered for participation in the competitive bidding program because the median represents a reasonable payment based on accepted bids from suppliers that are at or below the pivotal bid. We note that we discuss special provisions for small suppliers in section XI. of this final rule. We will only be entering into contracts with those suppliers that agree to accept the single payment amount. Moreover, as we explain above, we believe that using the median bid would not result in an insufficient payment, and we also believe that our contract supplier selection methodology will ensure that we have a sufficient number of contract suppliers to meet the demand for competitively bid items in each product category in each CBA.

Further, we disagree with the commenters' suggestion that we would have the authority under the Act to pay suppliers the lower of their bid amounts or the single payment amount. Section 1847(b)(5)(A) of the Act requires the Secretary to determine a single payment amount for each item in each CBA based on the bids submitted and accepted for that item. A ''single payment amount'' is one amount, and does not lend itself to an interpretation that would allow us to pay the lesser of the two amounts.

We recognize the necessity for a process to identify and eliminate irrational, infeasible bids. Accordingly, we will be evaluating bids to ensure that they are bona fide, and we may request that a supplier submit additional financial information, such as manufacturer invoices, so that we can verify that the supplier can provide the product to the beneficiary for the bid amount. If we conclude that a bid is not bona fide, we will eliminate the bid from consideration.

Comment: Several commenters suggested that a flaw in using the median methodology is that it is highly dependent on whether there are an even or odd number of suppliers in the final array.

Response: As included in our discussion in the preamble of the proposed rule regarding the use of the median, in cases where there is an even number of winning bidders for an item, we would employ the average (mean) for the two bid prices in the middle of the array to set the single payment amount. We are adding this rule to the final regulations at § 414.416(b)(1). As noted in the response to the previous comment, we believe that the use of the median is not a flawed methodology.

Comment: One commenter suggested that CMS follow defined procedural rules to select winning suppliers and determine the single payment amount, similar to the process that it has developed for the National Coverage Determination (NCD) process. For example, the commenter suggested that CMS ensures that the public is informed at the time it initiates the process, provides for public input, and arranges for all of these processes to occur during a defined time period.

Response: This final rule outlines a defined process that we will follow to select contract suppliers and determine the single payment amounts for each item in each product category in each CBA. In addition, we are developing an extensive educational program that will educate and inform the public about the processes that will be used to conduct the bidding and to determine the winning suppliers. Our plans for education are described in more detail in the DMEPOS section of the FY 2007 IRF final rule (71 FR 48354).

After consideration of the public comments we received, we are finalizing our methodology for setting the single payment amount in §§ 414.416(a) and (b), by adopting paragraph (a) in final (with technical revisions), revising paragraph (b)(1) to address how the single payment will be computed when there is an even number of winning bids. We are also adding new § 414.414(b)(4), which provides that each supplier must submit a bona fide bid that complies with all of the terms and conditions in the RFB.

B. Rebate Program

In the May 1, 2006 proposed rule (71 FR 25680), we proposed to allow contract suppliers that submitted bids for an individual item below the single payment amount to provide the beneficiary with a rebate (proposed § 414.416(c)). We stated in the preamble of the proposed rule that the rebate would be equal to the difference between their actual bid amount and the single payment amount. The following example illustrates how the rebates would be applied under this proposed approach:

If, based on the bids received and accepted for an item, we determined that the single payment amount for the item was $100, Medicare payment for the item would be 80 percent of that amount, or $80, and the coinsurance amount for the item would be 20 percent, or $20. However, if a contract supplier submitted a bid of $90 for this item and chose to offer a rebate, the rebate amount would be equal to the difference between the single payment amount ($100) and the contract supplier's actual bid ($90), or $10. Therefore, after the contract supplier received the Medicare payment of $80 and the $20 coinsurance, the contract supplier would be responsible for providing the beneficiary with a $10 rebate. We solicited comments on how to handle those cases in which the rebates would exceed the copayment amount.

Before deciding to propose this methodology, we considered whether to make the rebates mandatory or voluntary. We proposed that the rebates be voluntary but that contract suppliers could not implement them on a case-by-case basis. If a contract supplier submitted a bid below the single payment amount and chooses to offer a rebate, it must offer the rebate to all Medicare beneficiaries receiving the competitively bid item to which the rebate applies. This commitment would be incorporated into the contract supplier's contract. Stated another way, while the decision to offer rebates might be voluntary, 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. Moreover, the contract supplier could not amend or otherwise alter the provision of rebates during the term of the contract. Contract suppliers would also 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.

We proposed that only contract suppliers that submitted bids below the single payment amount for a competitively bid item would have the choice to offer rebates. Contract suppliers that submitted bids above the single payment amount would not be allowed to issue rebates because their actual bids for an individual item would be above this amount.

Our reason for proposing to allow these contract suppliers to offer rebates was to allow beneficiaries the ability to realize additional savings and the full benefits of the Medicare DMEPOS Competitive Bidding Program.

We solicited comments concerning the rebate process outlined in the proposed rule. We indicated that we would continue to evaluate the fraud and abuse risks of the proposed rebate program, and we specifically solicited comments on such risks.

Following is a summary of the public comments received.

Comments: Several commenters expressed concern over the proposed rebate program. They argued that the rebate program would be illegal and violate the antikickback statute, the beneficiary inducement statute, and the Medicare provisions of the Social Security Act governing the waiver of copayments. They argued that the rebate program would promote fraud and abuse by encouraging beneficiaries to purchase unnecessary supplies and the program will entice suppliers to ''game'' the program. They further stated that the OIG has issued numerous opinions that emphasize ''that providing things of value to beneficiaries in exchange for referrals is unlawful.'' The commenters believed that rebates also create tension with the Federal Anti-Kickback safe harbor statute. They pointed out that, to qualify for a safe harbor, a rebate must be disclosed in writing prior to the initial purchase. They added that the proposed rule expressly prohibits a supplier from advertising either directly or indirectly to beneficiaries. One commenter supported the inclusion of the rebate provision in the program as an innovative means to control beneficiary's out-of-pocket expenses and to reward bidders that submit good faith, competitive bids.

Several commenters suggested that rebates encourage suppliers to offer lower cost, less innovative products, particularly from large manufacturers. Several commenters suggested that the use of rebates leads to beneficiaries selecting suppliers based solely on availability of rebates, rather than quality of care. The commenters indicated that this could lead to poorer patient outcomes. They added that large manufacturers can spread the cost of discounts across many products, but small manufacturers may have only one or two products that would not support rebates. The commenters asserted that OIG states that the use of giveaways also favors large providers with greater financial resources for such activities, disadvantaging smaller providers and businesses. They further added that the rebate program may provide an incentive to large suppliers to ''lowball'' their bids, resulting in reduced marketplace competition by small suppliers.

One commenter suggested that if CMS offers a rebate, it should not be voluntary. Requiring suppliers to supply a rebate would assure that the suppliers are not bidding low just to be selected and then have their payments raised to the median level automatically. The commenter believed that this would prevent deliberate low-ball bidding.

Several commenters questioned whether rebates should become a binding contractual commitment when an express contractual provision would not exist.

Several commenters suggested that a rebate would be logistically impossible for a supplier to implement in its information system, branch operation, and accounts receivable processes. They added that physicians would have no way of keeping the rebate logistics straight. The commenters believed that CMS would also experience difficulties in monitoring the program. Another commenter inquired in what form CMS would require the rebate to be distributed, that is, gift certificate to family store, a money order, check, cash, among others. The commenter also asked if claims are denied and a rebate already paid, who would be responsible for collecting from the patient.

Several commenters suggested that suppliers that pay rebates are less likely to provide service in those areas where the supplier has bid above the contract price and will focus on those items where the payment amount is greater than the supplier's bid amount.

Several commenters suggested that logistical challenges would exist with implementation of rebates. The commenters stated that one supplier serving beneficiaries within the CBA and outside the CBA would have two different sets of rules because only CMS may inform the beneficiaries which suppliers offer a rebate. They asked how a supplier should answer a direct question about rebates when posed by a referral source or patient. They added that often the cost to issue a rebate check exceeds the value of the check issued and asked how suppliers will integrate a rebate with the patient's Part B supplemental insurance plan where the plan pays 100 percent of the copayment or when the copayment is waived because of financial hardship.

One commenter suggested that the rebate provision violates the single payment amount provision of the Act by permitting different payment amounts for different contract suppliers.

One commenter suggested that the rebate proposal may also have the effect of allowing retail store DMEPOS suppliers to ''cherry pick'' that portion of the DMEPOS business that is least costly to provide, driving up the costs of providing full-line services without any comparable savings to the program.

Several commenters suggested that rebates should not exceed the copayment amount in order to reduce risks of overutilization. They believed that the current proposal could eliminate all copayments in some cases and lower the copayment below the amount that would otherwise typically apply in every case. Several commenters suggested that the rebate runs counter to a fundamental principle of the Medicare program that requires beneficiary coinsurance. They pointed out that the purpose behind the 20-percent copayment is to discourage excessive or unnecessary utilization and stated that CMS is not authorized to change the Medicare Part B plan design by using rebates that would reduce or eliminate copayments.

Although we proposed that the rebate program be voluntary, one commenter suggested that our proposal to disseminate information about suppliers that participate in the rebate program would create an unfair marketing advantage to those suppliers.

Response: After considering the comments we received, we have decided that rebates will not be authorized under the Medicare DMEPOS Competitive Bidding Program and the provisions of proposed § 414.416(c) are not included in this final rule. We believe that competition will drive suppliers to compete for beneficiaries based on value and quality. We also recognize that requiring

rebates might raise fraud and abuse concerns. In addition, we have concerns that rebates may provide incentives to beneficiaries to obtain unnecessary items.

In summary, we are not adopting in this final rule the provisions of proposed § 414.416(c).

IX. Terms of Contracts

Section 1847(b)(3)(A) of the Act gives the Secretary the authority to specify the terms and conditions of the contracts used for competitive bidding and we proposed in § 414.422(a) to implement this provision. Section 1847(b)(3)(B) of the Act requires the Secretary to recompete contracts under the Medicare DMEPOS Competitive Bidding Program at least every 3 years and we proposed in § 414.422(b) to implement this provision. The length of the contracts may be different for different product categories, and we proposed to specify the length of each contract in the RFBs.

A. Terms and Conditions of Contracts (§§ 414.422(a) Through (c))

In the May 1, 2006 proposed rule (71 FR 25680), we proposed 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.
- Our discretion not to proceed if we find 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.
- Nondiscrimination against beneficiaries in a CBA (so that all Medicare beneficiaries inside and outside of a CBA 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.
- Other terms as CMS may specify.

Comment: One commenter asked if a supplier that is a subcontractor to another supplier can submit a bid to furnish items in one product category in a CBA and also be a subcontractor to another supplier that submits a bid to furnish items under another product category. Another commenter also asked if a losing bidder can become a subcontractor to a contract supplier. One commenter asked about the ramifications to a subcontractor if the contract supplier violates its contract with CMS. One commenter stated that the requirements for subcontractors need to be clearly defined. The commenter asked if subcontractors would need to satisfy the same accreditation and financial standards required of contract suppliers and, if so, how CMS would enforce this.

Response: Our rules would not preclude a supplier from submitting an individual bid for a product category in a CBA and also becoming a subcontractor to another supplier that submits a bid in the same CBA for the same product category. As an example, a supplier can bid to become an oxygen contract supplier and be awarded a contract and still be a subcontractor for another oxygen contract supplier. In addition, a supplier that submits a bid and loses can become a subcontractor to a contract supplier. We will not evaluate subcontractors to determine if they meet the accreditation, quality, financial, and eligibility standards because a subcontractor to a contract supplier cannot itself be a contract supplier and cannot submit claims under the Medicare DMEPOS Competitive Bidding Program. However, a supplier may not subcontract with any supplier that has been excluded from the Medicare program, any State health program or any other government executive branch procurement or nonprocurement activity. In addition, the subcontractor will not have to submit a bid to be a subcontractor. However, the contract supplier will be responsible for fulfilling all of the terms of its contract, even if it uses one or more subcontractors. In other words, if a contract supplier breaches its contract due to its subcontractor's failure to perform, the contract supplier will be held liable for the breach. Therefore, the contract supplier needs to ensure that the subcontractor is performing its duties appropriately. In their response to the RFB, bidders must submit any plans for subcontracting.

Comment: One commenter stated that a number of different proposed contract terms were not listed in the proposed rule. The commenter presumed that the actual contract provisions will be subject to a separate notice of proposed rulemaking in order to permit suppliers to offer more productive comments. One commenter suggested that CMS clearly define contract requirements so that suppliers can ensure that they meet Medicare guidelines.

Response: In the proposed rule, we discussed the details of the Medicare DMEPOS Competitive Bidding Program and identified a number of provisions that will be included in the contract. We also stated that we might specify other terms in the contracts themselves. We do not believe that an additional rulemaking is required in order to specify other terms and conditions that might be included in the contracts. In addition, we believe that our discretion to specify the contract terms and conditions would allow us to specify the terms and conditions for each new competition.

Comment: One commenter stated that some bidders are likely to be large nationwide or regional entities that are publicly traded companies. The commenter encouraged CMS to limit information concerning ownership to those owners required to be disclosed in regular filings with the Securities and Exchange Commission.

Response: Our purpose for requesting information about key personnel is not the same as that for the Securities and Exchange Commission. We need to obtain information about key personnel, both corporate and local, in order to determine the appropriateness of the bid submission and to ensure no key personnel have been the subject of legal actions, or have been sanctioned or convicted of a crime. This information will also be useful in determining common ownership to ensure that companies are not bidding against themselves to furnish the same product categories in the same CBA by submitting different bids for commonly owned separate locations.

Comment: Numerous commenters urged that the contract length be the same for all products in a CBA to minimize confusion among beneficiaries, referring physicians, and suppliers. The commenters stated that, because there are many variables that stakeholders will have to understand (such as which products are part of competitive bidding, boundaries of CBAs, among others), contracts of different lengths of time within a CBA will be time consuming, costly, and confusing for all involved. One commenter stated that the length of each contract should be specified in the RFB. Another commenter recommended that CMS recompete the contracts more frequently in the early stages of the competitive bidding program, in order to capitalize on what it learns during this initial period.

Response: We agree that it is important that we capitalize on what we learn during the early stages of competitive bidding. However, we want to retain the option for staggering the contract period for different product categories to allow for any changes in

coding or in technology and to facilitate use of the authority to phase in items under the programs. We would not have different contract lengths for items within the same product category within the same CBA. The length of each contract will be specified in the RFB; however, no contract will be longer than 3 years because section 1847(b)(3)(B) of the Act requires us to recompete the competitive bid contracts no less often than every 3 years.

Comment: One commenter proposed that CMS require all suppliers in a single CBA to be accredited in the same year and then to place the contracts for all product categories in that CBA on the same 3-year cycle as the accreditation requirement.

Response: We believe that this commenter's suggestion would be too difficult to implement from a logistical standpoint and too regimented an approach to adopt. Suppliers have the option of pursuing accreditation at any time. However, they must be accredited before we can award contracts under the Medicare DMEPOS Competitive Bidding Program, unless a grace period applies. As we explained above, in the first round of bidding, a supplier's accreditation must at least be pending before a bid can be submitted. In addition, a contract supplier that obtains its accreditation must maintain that accreditation for the remainder of the contract period.

Comment: One commenter recommended that no new products should be added during a contract term. The commenter stated that suppliers may or may not have access to the new products and, as a result, may not be able to furnish them.

Response: We agree with this comment. If a new product does not fit under a code for which we have conducted competitive bidding a single payment amount will not be applied until we conduct another round of bidding A further discussion of our rules regarding HCPCS codes changes can be found in section VI.D.4 of this final rule Under section 1847(b)(3)(B) of the Act, we are required to recompete the contracts no less often than every 3 years. For purposes of competitive bidding, we cannot add additional codes for items for which we have not done bidding because we need to conduct bidding before we can determine the single payment amount for these items. We would pay for these codes under the DMEPOS fee schedule.

Comment: Several commenters stated that our proposal to include in each contract a nondiscrimination provision, which would require that the competitively bid items furnished by a contract supplier to Medicare beneficiaries be the same items that the contract supplier furnishes to other customers is unrealistic. The commenters argued that this provision would impair beneficiary access to DMEPOS and would limit the savings that otherwise would be achieved through competitive bidding. Another commenter stated that the proposed rule provided very little detail about what would be expected or how CMS would ensure that the nondiscrimination contract provision is being met and urged CMS to discuss the nondiscrimination clause in more detail so that suppliers and beneficiaries will be able to understand what CMS has in mind, and know what protections are being afforded to beneficiaries by this provision.

Response: We believe that Medicare beneficiaries should receive the same items that the contract supplier would furnish to other customers and, therefore, we proposed to include a nondiscrimination provision in the contracts. One of the main objectives of the Medicare DMEPOS Competitive Bidding Program is to ensure that beneficiaries have access to quality DMEPOS. Therefore, we have built safeguards into the competitive bidding program to ensure there is continued access to quality medical equipment and supplies. We believe the nondiscrimination clause will ensure that Medicare beneficiaries have access to the same items as other individuals. One mechanism that we would use to enforce the nondiscrimination clause is the complaint and monitoring system that we plan to implement. Under this system, which is discussed more fully in section XIV. of this final rule, beneficiaries, referral agents, providers, and suppliers can assure us that the supplier conducts business in a manner that is beneficial to Medicare and beneficiaries. We have added this proposed requirement to the final regulation at § 414.422(c).

Comment: One commenter noted that CMS should consider nonprice variables, such as a supplier's compliance with Medicare program requirements when awarding contracts for certain DMEPOS. The commenter also recommended that CMS revise § 414.422(a) of the proposed regulations so that it would require a contract supplier to comply with the accreditation requirements specified in § 414.414(c) for the duration of the contract period. One commenter suggested that CMS retain the discretion to determine the likely value a particular supplier's compliance program brings Medicare and consider its value as an individual variable in determining whether the supplier is eligible to receive a contract award.

Response: As proposed in § 414.422(a), contract suppliers must comply with all the terms of their contracts, including any option exercised by CMS, for the full duration of the contract period. Once accredited, contract suppliers will be required to retain that accreditation throughout the duration of the contract. Accreditation requirements are mandatory and an important step forward to make sure we have quality suppliers. Compliance plans may be helpful to suppliers in meeting Medicare requirements; nevertheless, all suppliers have to meet our applicable standards and accreditation requirements. Therefore, we do not consider it appropriate to give extra weight in the selection process to suppliers with compliance programs.

Comment: One commenter suggested that CMS require contractors to subcontract portions of contracts to minority or female-owned businesses to comply with Federal contracting requirements.

Response: Due to size, complexity and nature of this program, we do not believe it would be feasible to require subcontracting with minority or female owned businesses and still meet our other goals. We also note that these contracts are not procurement contracts and, therefore, are not subject to the SBA or FAR requirements. Pursuant to section 1847(b)(6)(D) of the Act, we are only required to give small suppliers certain considerations.

Comment: One commenter urged CMS not to prohibit contract suppliers from turning away beneficiaries, since there will be more than one contract supplier per CBA. The commenter stated that there may be circumstances in which a contract supplier is already operating beyond capacity and would not be able to furnish items to additional beneficiaries. In addition, the commenter noted that a contract supplier may not believe that a requested item is appropriate for the beneficiary.

Response: We continue to believe that contract suppliers should not be able to turn away beneficiaries because we do not want to create an opportunity for contract suppliers to turn away beneficiaries who have the most difficult medical conditions or are otherwise difficult to serve. We note that we proposed that there would be a limited exception to this requirement if there is a particular item that a physician or treating practitioner has ordered to avoid an adverse medical outcome, but is an item that the contract

supplier does not normally furnish. In this case, if the contract supplier could not furnish the item, the requirements at § 414.420(b) of this final rule would apply.

Comment: One commenter suggested there be some mechanism in place to prevent the awarding of contracts to suppliers that do not provide at least some percentage of the services themselves. The commenter believed that quality will be lost if winning bidders are allowed to subcontract the entire or a large portion of the product category, and that beneficiaries will receive lower quality items because the winning bidder will make a profit on items that it does not actually furnish. Another commenter suggested that in order to prevent abuse of the bidding process, the competitive bidding contracts should allow a winning supplier to subcontract a portion of its services only if the subcontractor entities satisfy the same quality and accreditation standards that must be satisfied by the winning suppliers.

Response: As explained above, we will request information on the RFBs about the use of subcontractors. We believe that the eligibility standards, applicable accreditation standards and financial standards will ensure that contract suppliers are reputable, viable businesses and not just companies that subcontract their work. In addition, we will hold the contract supplier responsible for meeting all the terms and conditions of its contract, whether or not one of those terms is actually performed by a subcontractor.

Comment: One commenter stated that lack of timely DMEPOS access would be harmful for beneficiaries who are clinically ready to return to home or to the community from the hospital. The commenter also noted that delaying the discharge of Medicare beneficiaries due to restricted and untimely availability of specific DMEPOS would produce serious problems for beneficiaries' continuity of care and also for the hospital. The commenter stated that, from a hospital perspective, it is essential for CMS to ensure that DMEPOS be available on a timely basis and to sanction providers for untimely service. The commenter recommended that CMS take additional steps to prevent these problems, including imposing specific sanctions on contract suppliers that fail to timely furnish DMEPOS to these hospital patients, because such delays would delay discharge and jeopardize a patient's clinical progress. Another commenter stated that beneficiaries should be guaranteed prompt receipt of items, if in stock, within a specified period of time after the order is received. The commenter stated that delays could lead to adverse events for beneficiaries.

Response: We do not believe it is appropriate to establish a general timeframe within which all competitively bid items must be delivered to beneficiaries. Due to the individual characteristics of the products and beneficiary circumstances, the items will vary widely in terms of whether they are in stock and must be customized. However, a contract supplier should furnish items to beneficiaries in accordance with timeframes that meet the ordering physician's, or treating practitioner's, prescription. We also note that under the final quality standards (under Consumer Services) that we issued, in August 2006, and with which suppliers must comply in order to participate in the Medicare DMEPOS Competitive Bidding Program, the supplier must ensure it provides beneficiaries with information regarding expected timeframes for receipt of delivered items and the supplier must verify that beneficiaries have received the items. In addition, under § 424.57(c)(12) of our regulations, which suppliers must also satisfy in order to participate in the program, suppliers are responsible for the delivery of Medicare-covered items to beneficiaries and must maintain proof of delivery. The quality standards also require the supplier to ensure that it provides beneficiaries with the necessary information and instructions on how to use Medicare-covered items safely and effectively.

Comment: One commenter stated that FDA regulations require manufacturers, not suppliers, to evaluate product complaints and inform the FDA if the problems are considered to be reportable events. The commenter noted that CMS should require suppliers to inform the relevant DMEPOS manufacturer of any problem with equipment or supplies, including any adverse effects involving Medicare beneficiaries, so that the manufacturers will be in a position to address the problem, report to the FDA, or take other corrective action if needed. The commenter also noted that CMS should in no way imply that a product warranty is the supplier's legal obligation, as opposed to that of the product manufacturer.

Response: The Medicare Claims Processing Manual, Chapter 20-Section 40.1 provides that suppliers are prohibited from submitting a claim for a payment for items and services that are covered by manufacturer or supplier warranties. The supplier on record is responsible for ensuring that a claim is not submitted for items covered under a manufacturer's product warranty. To be eligible to submit a bid, DMEPOS suppliers must meet the supplier standard found in 42 CFR 424.57(c)(1), which require them to comply with applicable Federal and State licensure and regulatory requirements. FDA regulations and requirements are applicable to items paid for under the competitive bidding program just as they currently apply to items paid for under the fee schedule methodology.

Comment: One commenter noted that the proposed rule would require suppliers to provide information as requested regarding the integrity of each product sold and billed under the Medicare DMEPOS Competitive Bidding Program, as well as information on the integrity of the suppliers' businesses as a whole. The commenter believed that suppliers should not be required to provide information on product integrity as long as there is a SADMERC coding verification that the product has been approved for billing under a particular HCPCS code. The commenter also believed that a rule that would require suppliers to provide information on their business integrity was inappropriate because it would duplicate information provided during certification and accreditation.

Several commenters requested that CMS clarify whether it intends for all suppliers to have a corporate compliance program, a mission statement and operating principles, and/or other ethical aspects of their business; or clearly defined organizational conflicts of interest. One commenter recommended that the definition of ''affiliate'' be simplified for public companies with multiple locations tied to a single tax identification number so that suppliers do not have to provide the names or supplier numbers of all locations on an application for a single CBA. The commenters requested that CMS provide additional detail regarding the level of employee information it expects to be specified, for example, the highest ranking local manager and title or the chief executive officer or chief operating officer of a public company; and that CMS define the term ''customer service protocol'' because different companies define the customer service process differently.

Several commenters recommended that CMS also require each supplier to provide: a description of its corporate compliance program; its procedure for ensuring that it does not knowingly employ any individuals who have been debarred from participating in government programs; its procedure for

conducting background checks on employees who will have direct contact with beneficiaries; awards, honors, or other distinctions issued to the company; a description of its credentialing program if a subcontractor will be used to furnish items to beneficiaries; a description of its emergency preparedness plan; and a description of its process for selecting products. These commenters also recommended that CMS independently verify each supplier's disclosure by using objective measures. Two commenters suggested that CMS explain and define the requirements and terms that would be included in the RFBs, including the conflicts of interest and affiliated companies of the supplier. One commenter suggested that CMS consider requesting complete disclosure on corporate integrity agreements, entered into by the supplier as well as OIG convictions against the supplier, and that CMS conduct criminal background checks.

Response: We appreciate these comments. After consideration of the comments, we believe that the most appropriate place to list the specific information that we will need from each supplier is in the RFB. Our purpose in collecting such information is to evaluate suppliers' bids, and we have attempted to minimize the burden on bidders as much as possible. Therefore, the specific information to be collected will be detailed in the RFB. We 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

We believe that many of these items are best addressed in the quality standards and accreditation standards. We are using the RFB notice and comment period to finalize the list of items that we are going to require.

We are adding a clause to § 414.422(a) which provides that we will specify the terms and conditions in the competitive bidding contacts, and finalizing the remainder of § 414.422(a) which provides that a contract supplier must comply with all terms of its contract, including any option exercised by CMS for the full duration of the contract period and adopting revised § 414.422(a) as final.

We are adopting as final, without modifications, § 414.422(b), which provides that we will recompete the competitive bidding contacts at least once every 3 years.

We are finalizing § 414.422(c) which provides that a nondiscrimination provision will be included in each contract we enter into with a supplier under the Medicare DMEPOS competitive bidding program.

B. Change in Ownership (§ 414.422(d))

In the May 1, 2006 proposed rule, under proposed § 414.422(d), we proposed to evaluate a supplier's ownership information, its compliance with appropriate quality standards, its financial status, and its compliance status with government programs before we determine that a supplier can qualify as a contract supplier if there is a change of ownership. For this reason, we proposed that suppliers would not be granted winning status by merely merging with or acquiring a contract supplier's business. We do not want to allow suppliers to 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 anticompetition prohibitions. Therefore, we proposed that contract suppliers must notify CMS in writing 60 days prior to any changes of ownership, mergers, or acquisitions being finalized.

We proposed that we would have the discretion to allow a successor entity, after a merger with or acquisition of a contract supplier, to function as contract supplier when—

- 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; and
- We determine that the successor entity meets all the requirements applicable to contract suppliers.

We proposed that the successor entity must agree 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 is legally liable for the nonfulfillment of obligations of the original contract supplier.

In addition, we proposed to only allow the successor entity to function as a contract supplier if it executed a novation agreement with CMS.

Comment: Numerous commenters objected to the proposed provision that would require contract suppliers to notify CMS in writing 60 days prior to any changes of ownership, mergers, or acquisitions being finalized and recommended that the 60-day prior notice provision be modified to a notice period of no more than 30 days. The commenters also recommended that if the transaction is set to close within less than 30 days, the parties should have an obligation to provide notice as soon as the parties sign a letter of intent to change ownership. One commenter suggested that notification regarding change of ownership be required within 30 days after change has occurred. The commenters believed that the proposed rule fails to take into consideration the short time period in which acquisitions/mergers occur. The commenters added that the 60-day requirement is a burdensome restraint on legitimate corporate transactions, and that acquisitions and mergers frequently occur in a much more compressed timeframe. They believed that our proposed timeframes are unrealistic, and as a result, CMS could be notified of numerous acquisitions that are not consummated. They emphasized that it is important that the prior notice requirement be optional and that notice promptly after transaction would be appropriate to protect the Medicare program and beneficiaries.

The commenters pointed out that there generally is no advance notice requirement prior to completing an acquisition and/or merger. They requested clarification that any such notices furnished to Medicare will remain confidential until the successor entity notifies CMS that the transaction has been completed. To the extent notice is required they recommended that the final rule should make it clear that notice will be confidential and exempt from disclosure under Exemption 4 of the Freedom of Information Act (FOIA) and implementing HHS regulations as trade secrets. The commenters also recommended that commercial or financial information obtained from a person should be privileged or confidential and that this is necessary so that public companies can appropriately maintain sensitive nonpublic information and at the same time ensure that disclosure is made appropriately when that disclosure is timely under applicable securities regulations that protect shareholders.

Response: We continue to believe that sufficient advance notice is necessary to allow us to evaluate whether a new owner will meet all of the requirements to be a contract supplier under the Medicare DMEPOS Competitive Bidding Program. However, we are revising the language under § 414.422(d)(1) to clarify what a contract supplier's obligations are in the event of a change of ownership. Specifically, § 414.422(d)(1) now provides that 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. Under § 414.422(d)(2), if the supplier that acquires or merges with the

contract supplier wishes to itself become a contract supplier, it must meet all of our requirements, including compliance with applicable quality standards, accreditation, eligibility standards, and financial standards, and must submit the documentation required in § 414.414. 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. We have clarified in § 414.422(d) that if a new entity will be formed as a result of the merger or acquisition, the existing contract supplier submits to CMS, at least 30 days before the anticipated effective date of the change of ownership, its final draft of a novation agreement for CMS review. The successor entity shall submit to CMS within 30 days after the effective date of the change of ownership an executed novation agreement acceptable to CMS. We understand that the change of ownership information is highly confidential, and will make every effort to protect it as required by law.

Comment: Numerous commenters recommended that CMS retain the authority to disallow a successor entity to participate as a contract supplier only if CMS determines that allowing the successor entity to participate as a contract supplier would have significant anticompetitive effects. The commenters indicated that CMS should not unreasonably withhold its approval of a change of ownership and that CMS does not have the authority to, and, in any event, should not deny winning supplier status to a new owner on the basis that its capacity is not necessary within the CBA. They added that contract suppliers in CBAs will most likely experience an increase in the value of their business and, therefore, should be able to take advantage of the marketplace without interference from government agencies if they wish to lawfully transfer ownership.

Several commenters agreed that CMS should not allow a supplier to circumvent the bidding process through mergers or acquisitions, but suggested that the proposed rule creates a restraint of trade situation and/or devalues the business of a supplier that decides to sell the company.

In addition, several commenters recommended that CMS revise the proposed change in ownership rules so that they are consistent with existing requirements for DMEPOS suppliers. Other commenters suggested that CMS apply the change of ownership rules found in 42 CFR 489.18(a), which provides that a change of ownership for a corporation occurs when the merger or provider corporation merges into another corporation or the consolidation of two or more corporations, results in the creation of a new corporation, and states that the transfer of corporate stock or the merger of another corporation into the provider corporation does not constitute change of ownership.

Response: We want to evaluate whether a supplier that acquires or merges with a contract supplier and that wants to become a contract supplier itself meets our standards for being a contract supplier under the Medicare DMEPOS Competitive Bidding Program. These requirements serve the needs of the program because we do not want to encourage suppliers to adopt a strategy of circumventing the regular bidding process by gaining winning status through acquisitions of or mergers with contract suppliers not to violate any anticompetitive prohibitions.

We disagree with the commenter that suggested that we apply the change of ownership rules found in 42 CFR 489.18(a) because this section of our regulation applies only to Medicare Part A providers, such as hospitals, SNFs, and HHAs, but competitive bidding applies to Medicare Part B suppliers.

Comment: One commenter stated that the change of ownership provision should not apply when a contract supplier, as opposed to a noncontract supplier, purchases or acquires another supplier. The commenter noted that if a supplier that purchases or acquires a contract supplier does not intend to be a contract supplier, there is no reason for this requirement to apply, and if the acquiring supplier is already a contract supplier, there is no reason to require an additional review as to its qualifications. The commenter stated that while it understands the need to conduct oversight and diligence if the acquiring supplier is not a contract supplier, it requested that CMS clearly specify requirements for approval of the acquisition if the acquiring party is a contract supplier but does not intend for the supplier it acquires to be a contract supplier.

The commenter also urged that the final rule clarify that the requirements for an acquirer would be no more burdensome than the requirements to be a contract supplier because such requirements could result in an unequal burden on entities that acquire contract suppliers. The commenter stated that, if additional requirements are to be imposed, CMS should state what they are explicitly so that the public understands and can comply with them in advance of incurring substantial transaction costs.

Response: As stated in response to the previous set of comments, we plan to evaluate the same information required to be submitted by a bidding supplier if a contract supplier purchases a noncontract supplier or if a noncontract supplier purchases a contract supplier. However, if a contract supplier purchases another contract supplier, we will not ask the contract supplier to duplicate information we already have on file.

Comment: One commenter stated that CMS should be able to assure itself that the acquired supplier continues to meet all obligations and requirements for contract suppliers, and its review should be limited to a consideration of whether, post acquisition, the acquired supplier: (1) Meets all the requirements of a contract supplier; (2) is willing to assume all obligations under the contract; and (3) has executed a novation agreement. The commenter stressed that if CMS desires to encourage all suppliers to bid, the contract supplier's status as the winning bidder should be preserved as a valuable asset for consideration in any commercial transaction.

Other commenters were concerned about the following issues: the successor's liability for potentially fraudulent activities that could have occurred on the previous company's watch; instances where the new contract supplier determines a revised Certificate of Medical Necessity (CMN) is needed and the physician or treating practitioner is no longer in practice or refuses to execute a new CMN; and the tax implications of restricting change of ownership transactions to only stock transactions. The commenter observed that there may be instances where the sale of a supplier because of the death of the owner would be prohibitively expensive if executed as a stock transaction, leaving the widow with little money and no recourse to dispose of the business.

Response: As we stated earlier, our requirements regarding change of ownership are intended to provide us with assurance that the successor entity meets all of our requirements before we can consider it to be eligible to assume the previous contract supplier's contract. A new contract supplier will be responsible for meeting all CMS program requirements.

After consideration of the public comments received, in this final rule we are finalizing § 414.422(d) as discussed above.

C. Suspension or Termination of a Contract (§§ 414.422(f) and (g))

In the May 1, 2006, proposed rule (71 FR 25682), we specified that contract suppliers would be held to all the terms of their contracts for the full length of the contract period (proposed § 414.422(f)). Any deviation from contract requirements, including a failure to comply with governmental agency or licensing organization requirements, would constitute a breach of contract. We indicated that, if we conclude that the contract supplier has breached its contract, the actions we 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 (which might include reprocurement costs), precluding the supplier from participating in the competitive bidding program, or availing ourselves of other remedies permitted by law. We indicated that we also would have the right to terminate the contract for convenience (proposed § 414.422(g)).

Comment: Several commenters believed that CMS must include additional procedural safeguards for contract suppliers before terminating their contracts. The commenters suggested that CMS give a contract supplier notice that it believes the supplier has breached its contract, an opportunity and adequate timeframe for the contract supplier to cure the breach, and a review or appeal mechanism if the contract supplier's contract is terminated. One commenter stated that contract suppliers should only be terminated for ''material breach'' of their contracts.

Another commenter noted that the proposed rule grants CMS the unilateral right to terminate a contract without cause which eliminates a principal advantage for contract suppliers. The commenter stressed that without modification of the proposed rule, suppliers would be dissuaded from submitting the lowest bid possible because they would have to calculate the financial risk of termination and compensate for this uncertainty in their bid prices.

Another commenter stated that it is reasonable for CMS to expect that contract suppliers will be held to all the terms of their contracts for the full length of the contract period. Two commenters objected to the provision stating that CMS may include reprocurement costs if a contract supplier's contract is terminated because the contract supplier cannot know Medicare's reprocurement cost structure. One commenter asked whether the provision stating that CMS could preclude a contract supplier that breached its contract from participating in the competitive bidding program referred only to the program in the supplier's CBA or the entire Medicare DMEPOS Competitive Bidding Program.

Response: We believe that defining a breach of contract as any deviation from contract requirements, including a failure to comply with governmental agency or licensing organization requirements, will help ensure that contract suppliers do not breach their contract requirements. We have set out a variety of potential actions of varying levels of severity that we could take in the event of a breach of contract, such as requiring that contract supplier submit a plan to correct the deficiency that created the breach of contract, suspending the contract, precluding the contract supplier from participating in the competitive bidding program in the future, revoking the supplier number of the contract supplier, and/or availing ourselves of other remedies allowed by law. In deciding which course of action to take, we will consider the nature of the breach, including whether the breach is indicative of a substantial failure to comply with the terms of the supplier's contract, and the extent to which the efficient and effective administration of the Medicare program has been compromised by the breach.

We are making several changes to the proposed rule. In response to the comments which addressed the potential problems that might stem from our proposal to permit CMS to require terminated suppliers to reimburse CMS for reprocurement costs, proposed at § 414.422(f)(2)(iii), we are deleting that proposal. We are also making several revisions to our proposal to permit CMS to terminate a contract with a contract supplier in the event of a breach of contract or to take other action against a supplier after a breach of contract has occurred. We have eliminated the phrase ''for default'' from § 414.422(f)(iii). We have revised the wording to state that CMS may ''[t]erminate the contract.'' We believe that this is consistent with CMS' approach to contracts and agreements with providers, suppliers and other contracted entities in other areas of the Medicare program. CMS will have the authority to terminate a contract with a contract supplier where a breach of contract has occurred.

CMS is making several other minor clarifications to the language at § 414.422(f). Specifically, at § 414.422(f)(2)(i), we proposed that CMS could require a contract supplier to ''correct the breach condition'' where a breach of contract had occurred. We are revising this language to state that CMS may ''[r]equire the contract supplier to submit a corrective action plan.'' Also, at § 414.422(f)(2)(ii), we proposed that in the event of a breach of contract, CMS could ''[s]uspend performance under the contract.'' We are revising this language to state that in the event of a breach of contract, CMS can ''suspend the contract supplier's contract.''

CMS agrees with the need for procedural safeguards where CMS is taking action to terminate a contract supplier's contract. 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.

Comment: One commenter requested greater clarification of the phrase ''for convenience'' used in the preamble to the proposed rule (71 FR 25682) to describe a basis for CMS to terminate a contract. The commenter stated that at a minimum there should be an explicit notice period required prior to termination. Another commenter recommended deleting this provision.

Response: In response to comments, CMS has decided to delete this provision.

Comment: One commenter stated that the proposed rule does not explicitly prohibit the Secretary from unilaterally changing the price of an item in a CBA during the term of the competitive bidding contract. Several commenters also stated that there should be a provision that allows suppliers to terminate, without being in breach of contract, in cases of hardship or material change in circumstances that are not the fault of or within the control of the supplier if unexpected circumstances arise that hinder its ability to render performance. Another commenter stated that the lack of parity in the ability of the contracting parties to terminate may serve as an impediment to many potential bidders' submission of the lowest possible bid.

Response: Each supplier contract under each competitive bidding program will identify the product categories, items, and single payment amounts for items furnished under that program. The single payment amount for each item in each contract will not change for the duration of the contract, with the only exception being in limited cases where a HCPCS code is divided or merged as provided in § 414.426. However, even where § 414.426 applies, the total single payment amounts for the sum of the item components, the newly

separated item(s), or the newly combined item will be equal to the single payment amounts that were originally listed in the contract. Contract suppliers will be held to all of the terms of their contracts for the length of the contract period and we will not allow them to suspend their performance under their contracts without consequences because of the potential hardship that the Medicare program and beneficiaries could suffer if there were no longer enough contract suppliers to furnish one or more product categories in a CBA. If a supplier breaches its contract with CMS, we have the right to ask the contract supplier to correct the breach, suspend the contract, terminate the contract, or preclude the supplier from participating in the Medicare Competitive Bidding Program. We do, however, recognize the hardships may arise for contract suppliers and we will take this into consideration as we decide what appropriate actions should be taken in the event of a breach.

Comment: One commenter suggested that contract suppliers should have the ability to exit the program with a 90-day notice. The commenter stated that this will allow the bidders that may have failed to meet quality standards and reach their market expectations to exit in a business-like manner.

Response: As we explained above, we are selecting a sufficient number of contract suppliers to furnish each product category in each CBA, and allowing contract suppliers to terminate their contracts may impede beneficiary access to competitively bid items and otherwise result in a hardship for the Medicare program. Contract suppliers are expected to comply with their contracts for their entire duration.

After consideration of the public comments received, in this final rule, we are finalizing the breach of contract and termination provisions in §§ 414.422(f) and (g) with the changes described above.

X. Administrative or Judicial Review of Determinations Made Under the Medicare DMEPOS Competitive Bidding Program (§ 414.424)

Section 1847(b)(10) of the Act provides that there will be no administrative or judicial review of determinations made under section 1869, section 1878, or any other section of the Act, for the—

- Establishment of payment amounts under a competitive bidding program;
- Awarding of contracts under a competitive bidding program;
- Designation of CBAs 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.
- Bidding structure and number of contract suppliers selected under a competitive bidding program.

In the May 1, 2006, proposed rule (71 FR 25682), we proposed to incorporate in a new proposed § 414.424 the provisions for no administrative or judicial review of the determinations specified in section 1847(b)(10) of the Act listed above. We indicated that the proposed regulation would have no impact on the 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 CBA in a manner not authorized by this rule.

Comment: A number of commenters agreed that the proposed rule tracked the provisions of the Act, which does not provide for administrative or judicial review under the Medicare DMEPOS Competitive Bidding Program. However, many of the commenters believed that CMS should establish some type of grievance and review process to provide contract suppliers an opportunity to review the competitive bidding process and to challenge the outcome of the bid evaluation process and the selection of contract suppliers. One commenter added that because Medicare is required to make available to the public the final process documentation under the Freedom of Information Act requirements, it is only fair that CMS also provide an opportunity for suppliers to challenge any decisions in this documentation.

Two commenters asserted that the statutory limitations on administrative and judicial review do not preclude the establishment of a process that would give suppliers an opportunity to communicate with CMS regarding grievances and seek redress. They asserted that the implementation of such a process would be consistent with Constitutional due process rights. One commenter recommended that CMS establish some type of expedited review process specific to contract award decisions and urged full transparency of factors influencing contract award decisions in order to support the highest level of integrity in the process. One commenter recommended that CMS keep in place all current mechanisms to defend the supplier's rights, including the Administrative Law Judge review.

One commenter believed that the nonavailability of administrative review violates not only the Administrative Procedure Act but also individual and corporate rights to due process and to redress grievances. The commenter recommended that appeal rights be restored as these rights exist elsewhere in the Medicare program.

Response: We understand the commenters' concerns. However, we believe that Congress enacted section 1847(b)(10) of the Act to avoid any delay or disruption in the implementation of the program caused by challenges and appeals regarding specified aspects of the Medicare DMEPOS Competitive Bidding Program. We intend to conduct an extensive education and outreach program to ensure that the suppliers are educated about the rules and provisions of the program and understand the contract selection process and what is required of bidding suppliers. In addition, we will be providing the suppliers with a 60-day open bidding period during which they can change, update, or correct their bid packages before certifying their final submissions.

Comment: Numerous commenters recommended that CMS include a procedure for debriefing suppliers that were not selected as contract suppliers and provide an opportunity for a review to determine, at a minimum, whether an error on the part of CMS or its contractors was the reason that the supplier lost the bid.

Several commenters recommended that CMS put appropriate procedures in place for bidders to ensure that calculations related to their bids are reviewed for accuracy and that these procedures provide suppliers an opportunity to redress issues such as simple calculation errors. One commenter pointed out that because the review and award of contracts under the competitive bidding program will be labor intensive, it is likely that there will be many inadvertent human and computer errors and/or indisputably arbitrary decisions. The commenter pointed out that while the statute grants CMS discretion in making determinations under the competitive bidding program, Congress has not granted CMS the authority to render moot the authority of published regulations by using known improper or erroneous information to implement those regulations. Therefore, the commenter recommended a ''reconsideration process'' with regard to the award of contracts only, and delegation of authority to the Provider Reimbursement Review Board or some similar body within the Medicare program to hear such requests for reconsideration. The commenter acknowledged that under this process,

the agency's decisions would not be administratively or judicially appealed. However, the commenter pointed out that the establishment of a reconsideration process would, at least, enable errors to be corrected.

Response: In accordance with section 1847(b)(10) of the Act, we proposed that there will be no administrative or judicial review for the awarding of contracts or the establishment of payment amounts under a competitive bidding program. We believe that Congress enacted section 1847(b)(10) of the Act to avoid any delay or disruption in the implementation of the program that could arise if we had to defend numerous challenges and appeals brought by losing bidders. We intend to conduct an extensive education and outreach program to ensure that suppliers are educated about the rules and provisions for the program. In addition, we are developing a quality assurance system to ensure that bids submitted to us are correctly identified and recorded. We intend 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. We will also be notifying all losing bidders, but believe it would not be administratively feasible to provide debriefings for all losing bidders, due to logistics, volume of bidders, and time constraints.

Comment: One commenter strongly objected to the lack of administrative or judicial oversight of the process. The commenter stated that the Medicare DMEPOS Competitive Bidding Program is a procurement program by which CMS seeks to acquire the same types of commercial items that it acquires for itself in accordance with the FAR. The commenter firmly believed that considering the number of procurements that are set aside each year by GAO and the United States Court of Federal Claims based on government error, CMS should allow administrative or judicial review. The commenter believed that the proposal could lead to arbitrary and erroneous awards, if not fraud. The commenter suggested that CMS clarify that all contract awards and invitations to participate will be subject to the traditional review of procurements conducted by the Government. The commenter added that regardless of whether CMS possesses the right to waive the FAR and avoid judicial or administrative oversight, prudence and the obligation to maintain integrity in the procurement process that it is developing require that CMS open the process up to protect review.

Response: We disagree with these comments. The Medicare DMEPOS Competitive Bidding Program is a unique program that differs in many ways from traditional government procurement. We are bound to implement this program in accordance with the statute, which as noted earlier in this section, provides that there will be no administrative or judicial review of certain functions. In the proposed rule we provided notice to the public of how we intend to implement the Medicare DMEPOS Competitive Bidding Program, and this final rule responds to the public's comments.

Comment: A number of commenters pointed out that even though CMS acknowledged in the preamble of the proposed rule that the existing rights of beneficiaries and suppliers to appeal denied claims are undisturbed by competitive bidding, the proposed regulatory language of § 414.424 as written does not make clear that these existing rights are unaffected. The commenters suggested the addition of language in § 414.424 to clarify that these rights would be preserved. Three commenters also indicated that the statement in the regulation that ''[a] denied claim is not appealable if CMS determines that a competitively bid item was furnished in a CBA in a manner not authorized by this subpart'' is vague as written and suggested that the statement be rewritten for clarification or removed. One commenter suggested that CMS add language to state that ''A claim is not appealable if the denial is based on a determination by CMS that a competitively bid item was furnished in a CBA in a manner not authorized by this subpart.''

Response: In this final rule, we have revised the language in § 414.424(b) to clarify that there are no appeal rights for claim denials if the denial is based on our determination that a competitively bid item was furnished in a CBA in a manner not authorized by 42 CFR Part 414 Subpart F.

After consideration of the public comments we received, we are adopting as final, with technical clarifications, the provisions of proposed § 414.424.

XI. Opportunity for Participation by Small Suppliers (§§ 414.402, 414.414(g))

Section 1847(b)(6)(D) of the Act requires us, in developing bidding and contract award procedures, to take appropriate steps to ensure that small suppliers of items have an opportunity to be considered for participation in the Medicare DMEPOS Competitive Bidding Program. Section 1847(b)(2)(A)(ii) of the Act also states that the needs of small suppliers must be taken into account when evaluating whether an entity meets applicable financial standards.

Size definitions for small businesses are, for some purposes, developed by the Small Business Administration (SBA) based on annual receipts or employees, using the North American Industry Classification System (NAICS). Based on the advice from the SBA, we expect that most DME suppliers will fall either into NAICS Code 532291, Home Health Equipment Rental, or NAICS Code 446110, Pharmacies, since the SBA defines these small businesses as businesses having less than $6.5 million in annual receipts.

In the May 1, 2006 proposed rule (71 FR 25682), we proposed using the SBA's small business definition when evaluating whether a DMEPOS supplier is a small supplier. We relied on the expertise of the SBA to determine what constitutes the appropriate definition of a small supplier. We proposed that all contract suppliers would be expected to service the whole CBA. However, we considered allowing a small supplier that has fewer than 10 full-time equivalent (FTE) employees to designate a geographic service area that is smaller than the entire CBA. We did not propose this approach because we want to ensure that beneficiaries have the choice of going to any contract supplier in their respective CBA. Carved-out areas could lead to confusion for beneficiaries faced with multiple competitive bidding subareas. Further, we believe such an approach would allow selection of more favorable market areas by smaller businesses potentially leading to an unfair market advantage. We sought comments on this issue.

Information available to us 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. Our 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.

Although section 1847(b)(6)(D) of the Act focuses on ensuring participation in the bidding, and not on bidding outcomes, we believe that it is worth

noting how small suppliers fared in the bidding in the Medicare competitive bidding demonstration projects. Both small and large suppliers were selected as demonstration suppliers. Some small suppliers that were selected as demonstration suppliers were able to increase their market share substantially during the demonstration. Others experienced little change in market share.

We recognize the importance, benefits, and convenience offered by the local presence of small suppliers. In the May 1, 2006 proposed rule, we proposed to take the following steps to ensure that small suppliers have the opportunity to be considered for participation in the program.

First, as required by section 1847(b)(4)(B) of the Act, we will select multiple winners in each CBA. If a single winner was selected in an area, a small supplier would have difficulty participating in the competition because the supplier, as a minimum, would have to demonstrate that it could rapidly expand to serve the entire projected demand in the area. Selecting multiple suppliers should make it easier for small suppliers to participate in the program.

Second, we proposed to conduct separate bidding competitions for product categories, allowing suppliers to decide how many product categories for which they want to submit bids, rather than conduct a single bidding competition for all DMEPOS items and other equipment. We believe that separate competitions for product categories will encourage participation by small suppliers that specialize in one or a few product categories. If a single competition was held for all DMEPOS items and other equipment, small, specialized suppliers would have to either significantly expand their product and service offerings or submit bids for items they currently do not provide.

We stated that we recognize the importance of small suppliers in the DMEPOS industry, and we welcomed comments on the options identified in the proposed rule. We also expressed interest in other ways to ensure that small suppliers have opportunities to be considered for participation in the program.

To collect additional information on this issue, we contracted with RTI International to conduct focus groups with small suppliers. The purpose of the focus groups was to gather input on ways to facilitate participation by small suppliers in the program. The focus groups also discussed the impact of the requirement for the quality standards and accreditation, which will affect all small suppliers, regardless of whether they seek to participate in a competitive bidding program. As we indicated in the proposed rule, we reviewed our efforts to ensure participation by small suppliers in the Medicare DMEPOS Competitive Bidding Program after we reviewed public comments on the proposed rule and the results of the focus groups. We also considered the findings of the focus groups, along with the additional options and comments presented on the proposed rule, in developing this final rule.

Comment: Several commenters requested that CMS share the findings of the focus groups.

Response: Nine focus groups were conducted, during April and May 2005, with DMEPOS suppliers that had less than $3 million in gross revenue and employed up to 10 FTE employees. The purpose of the focus groups was to explore small DMEPOS suppliers' thoughts and opinions on the potential impact of quality standards, accreditation, competitive bidding, and financial standards requirements on their businesses. We presented an overview and results of the focus groups related to quality standards and accreditation to the PAOC on September 26, 2005. This PowerPoint Presentation can be accessed at http*://www.cms.hhs.gov/CompetitiveAcqforDMEPOS/PAOCMI/list.asp#TopOfPage*.

The results of the focus groups related to competitive bidding and financial standards were presented to the PAOC on May 23, 2006. Several focus group participants remarked that the competitive bidding process would force many small suppliers out of business. The participants suggested alternatives to competitive bidding, including: (1) CMS should determine product prices and allow all willing suppliers to provide products at the set price; and (2) CMS should reserve a percentage of winning bids for small suppliers. Many participants believed that lower payment rates for suppliers would inevitably lead to lower quality goods and services. Participants were particularly emphatic in their belief that CMS continues to neglect the valuable service component that small suppliers provide to their customers. They believed that it is their commitment to service that sets them apart from the national companies. A number of participants were concerned about the possibility of requiring small supplier bid winners to furnish items in the entire MSA, given the fact that some MSAs cross State boundaries. There was also a consensus among these small suppliers that the impact of competitive bidding would differ by product line. They believed that items involving high-end technology equipment, respiratory equipment, and customized products are more service intensive than other products, such as standard wheelchairs, that involve fewer repairs, set-up time, and patient education.

Inclusion of mail order businesses in competitive bidding was also a controversial issue for many participants. Because mail order businesses often do not have a physical storefront and do not provide patient education, small suppliers argued that such businesses are in violation of the 21 Medicare supplier standards.

Finally, many participants in the focus groups believed that tax returns, quarterly standard financial statements, and Dun & Bradstreet were helpful sources of information about a business's credit history and cash flow. The participants noted that suppliers that grossed over $3 million in revenue used audited financial statements, whereas suppliers that grossed less than $3 million in revenue used cash basis accounting principles. A summary of the PAOC discussion related to the focus group results can be accessed at http*://www.cms.hhs.gov/CompetitiveAcqforDMEPOS/downloads/PAOC_summary.pdf*. We have used the comments from the focus groups and the public comment process in developing our final policies for the Medicare DMEPOS Competitive Bidding Program.

Comment: Several commenters noted that section 1847(b)(6)(D) of the Act is entitled ''protection'' of small suppliers and not the mere identification of small suppliers. They reported that there are currently 40,000 practitioners, providers and suppliers enrolled as Medicare suppliers, including approximately 1,078 physical therapists. They agreed with the option to define small supplier as fewer than 10 FTE employees. The commenters stated that health care practitioners who provide DMEPOS as an integral part of their professional services specialize in providing items for specific conditions. They added that these suppliers offer considerable expertise in evaluating both the patient and the item in order to provide the patient with the best possible outcome. They also believe that small suppliers serve rural and underserved urban communities where larger suppliers may not operate.

The commenters proposed the following alternative policies: (1) At least 50 percent of suppliers that receive a contract should be small suppliers (based on $3 million or less in revenue or less than 10 FTE employees); (2) CMS should allow suppliers with less than 10 FTE employees to furnish items to less

than the entire CBA; (3) CMS should award contracts to small suppliers with the lowest bids that exceed the pivotal bid; (4) CMS should allow truly small suppliers to promise to accept the single payment amount; and (5) CMS should establish a certain volume of items in each geographic area that will be ''set-aside'' for small suppliers.

Response: We agree that section 1847(b)(6)(D) of the Act is entitled ''Protection of Small Suppliers.'' We recognize the concerns raised by the commenters and have considered the suggested alternatives provided during the small supplier focus groups and through the public comment process. We also recognize the importance of maintaining storefront capabilities to meet the needs of beneficiaries. In this final rule, we are revising our proposed policies to ensure that small suppliers have an opportunity to be considered for participation in the Medicare DMEPOS Competitive Bidding Program. As of January 2006, the SBA defines a small business as generating less than $6.5 million in annual receipts. The SBA definition refers to small businesses rather than ''small suppliers.'' We believe that $6.5 million is not representative of small suppliers that provide DMEPOS items to Medicare beneficiaries, as it would encompass too many suppliers. In coordination with the SBA, we are defining a small supplier as a supplier that generates gross revenue of $3.5 million or less in annual receipts and we are revising § 414.402 to include this definition. We would accept relevant documentation from a supplier that shows its sales volume, including information that would qualify as a ''receipt'' under 13 CFR 121.104 to determine if the supplier meets this definition. Before we receive supplier bids, we would not have information on each supplier's total revenue. We only have information on suppliers' Medicare revenues. As a result, we had to make an assumption about what percent of a supplier's revenues come from Medicare. We looked at filings by public DMEPOS companies and, based on that information, we assume one-half of the average supplier's revenues come from Medicare DMEPOS.

To ensure the participation of multiple suppliers and storefront locations, beneficiary access, and increased participation by small suppliers, we have revised our rules as noted below:

- 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, we have also established a target number for DMEPOS small supplier participation in each competitive bidding program. Our target number for small supplier participation will be determined by multiplying 30 percent times the number of suppliers that have met our 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 our goal for small supplier participation for that product category. We 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, we 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, we 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 we reach the target number or there are no additional small suppliers that submitted a bid for the product category. We are codifying this methodology in final § 414.414(g)(1).

Comment: Many commenters disagreed with using the definition of the SBA for a ''small business'' (less than $6 million in annual receipts) because the CY 2003 Medicare data showed that at least 90 percent of suppliers had less than $1 million in allowed charges. They recommended defining a small supplier as a supplier that generates less than $3 million in annual receipts. The commenters believed that a lack of small supplier participation would negatively impact patient care. They added that small businesses would have to endure large expenses in order to participate in the Medicare DMEPOS Competitive Bidding Program.

Response: We agree with the commenters and, as we explained above, we have modified our definition of a small supplier so that it now means a supplier that generates gross revenue $3.5 million or less in annual receipts.

Comment: A few commenters indicated that conducting separate bidding processes for individual product categories is administratively burdensome. They stated that CMS' assumption that large suppliers could expand their products by offering supplies and equipment easier or more quickly than small suppliers is a false view of a company's ability to expand. They also reported that large organizations must seek approval from their boards or other stakeholders before they can undertake certain business expansion activities.

Response: We appreciate the comment but believe that conducting separate bidding processes for individual product categories will encourage the participation of small suppliers that specialize in one or a few product categories. It is our goal to allow Medicare beneficiaries an opportunity to receive all related equipment from the same supplier, thereby minimizing disruption to the beneficiary. Suppliers currently specialize in particular products, and we do not see this process being interrupted by competitive bidding.

After consideration of the public comments received, in this final rule, we are adding a definition of ''small supplier'' at § 414.402 and finalizing § 414.414(g), with revisions sets forth our methodology for ensuring that a sufficient number of small suppliers have an opportunity to participate in the Medicare DMEPOS Competitive Bidding Program.

XII. Opportunity for Networks (§§ 414.402, 414.418)

In the May 1, 2006 proposed rule (71 FR 25683), we proposed to allow suppliers the option to form networks for bidding purposes (proposed § 414.418). In the proposed rule, we refer to networks as several companies joined together through some type of legal contractual relationship to submit bids for a product category under competitive bidding. This option would allow suppliers to band together to lower bidding costs, expand service options, or attain more favorable purchasing terms. We recognize that forming a network may be challenging for suppliers, and it also poses challenges for bid evaluation and program monitoring. Networking was included as an option in the Medicare competitive bidding demonstration project, but no networks submitted bids. Still, we believe that networking may be a useful option for suppliers in some cases. Therefore, we proposed to offer it as an option. If suppliers decide to form

networks, we proposed that 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. We specifically requested comments regarding other types of suitable arrangements that would not require suppliers to form a new legal entity but would allow them to form a network for purposes of submitting bids. For example, one supplier could be designated as a primary contractor and the other suppliers in the group would function as subcontractors. In this example, if the contract with the primary contractor was terminated, the contracts with the subcontractors would also be terminated, thus nullifying the entire contract.

• All legal contracts must be in place and signed before the network entity can submit a bid for the Medicare DMEPOS Competitive Bidding Program.

• Each member of the network must be independently eligible to bid. If a member of the network is determined to be ineligible to bid, the network would be notified and given 10 business days to resubmit its application.

• Each member must meet any accreditation and quality standards that are required. Each member is equally responsible for the quality of care, service, and items that it delivers to Medicare beneficiaries. If any member of the network falls out of compliance with this requirement, CMS would have the option of terminating the network contract.

• The network cannot be anticompetitive. We proposed that the network members' market shares for competitively bid item(s), when added together, cannot exceed 20 percent of the Medicare market within a CBA. We believe that, by setting the maximum size of the network's market shares at 20 percent of the marketplace, firms will be able to gain the potential efficiencies of networking while at the same time ensure that there would continue to be competition in the area. If the 20-percent rule were adopted and suppliers joined networks, there would still be at least 5 networks competing in a DMEPOS competitive bidding program, which we believe would allow for sufficient competition among suppliers. In particular, we requested comments about what percentage of the marketplace would be appropriate for networks for suppliers.

• A supplier may only join one network and cannot submit individual bids if it is part of a network. The network must identify itself as a network and identify all members in the network.

• The legal entity would be responsible for billing Medicare and receiving payment on behalf of the network suppliers. The legal entity would also be responsible for appropriately distributing payments to the other network members.

Comment: Many commenters expressed concern about potential violations of Federal antitrust laws that could arise under the proposed network provisions. For example, they expressed concern that forming a network could violate the Federal antitrust laws because those laws do not permit suppliers to reach a mutual consensus on pricing. They also stated that the proposed rule would require suppliers to agree on proposed prices for all items within a competitive bidding product category. A commenter expressed concern that networks consisting of a large number of suppliers would not be legitimate under the antitrust laws. The commenter also expressed concern that the proposed network policy could be falsely interpreted as providing a safe harbor from the antitrust laws.

Many commenters believed that the option to form a network is not a realistic solution for ensuring that small suppliers participate in the competitive bidding program. They further believed the proposed rule is complex, and that suppliers would not have sufficient time to form a network and comply with all the requirements to meet the competitive bidding implementation timelines. A commenter indicated that the network option would reduce potential burdens on small suppliers and specifically recommended limiting the network option to small suppliers.

Response: We strongly agree that networks must not violate antitrust laws and that networks must take steps to ensure that they are not in violation of Federal antitrust laws. We emphasize that suppliers that pursue the network option must comply with all applicable Federal antitrust laws, and we will reject a network bid if we believe it has been prepared in violation of those laws. We will also refer any suspected cases of Federal antitrust violations to the Department of Justice for further review. In response to comments voicing concern that the network formation process could implicate the Federal antitrust laws, we 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 inclusion of this certification from all network members will help assure us that each network member joined the network for a legitimate, legal purpose (that is, it cannot otherwise compete because it is unable to furnish the product category throughout the entire geographic area of the CBA).

The network option is a key piece of our efforts to ensure that small suppliers have an opportunity to be considered for participation in the Medicare DMEPOS Competitive Bidding Program. In response to comments requesting that networks be limited to small suppliers, we will limit network participation to small suppliers which, as we explained previously, will now be defined as suppliers that generate gross revenue of $3.5 million or less in annual receipts. We have revised § 414.418 to add this provision. We believe that this modification to our proposal will help ensure that the competition in each CBA is actually a competition between suppliers of all sizes and that it is not dominated by a limited number of networks comprised only of large suppliers that, in our estimation, should be able to compete independently. In addition, in response to concerns that networks would be anti-competitive if they had excessively large number of members, 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. We believe that this limit would protect against excessively large, anti-competitive networks while allowing small suppliers to have an opportunity to be considered for participation under the Medicare DMEPOS Competitive Bidding Program.

Finally, to further implement networking rules that promote a robust competition and protect the Medicare DMEPOS Competitive Bidding Program against anticompetitive behavior, we are deleting the provision at proposed § 414.418(b)(2) that would have allowed networks 10 business days to resubmit bids that CMS rejected because we determined that a network member was ineligible to bid. In order not to allow networks with an unnecessary advantage over other suppliers, we are deleting this provision because we do not allow other suppliers not in a network this opportunity. Also, we are finalizing our proposal that at the time of bidding, the network's total market share for each product category that is the subject of the network's bid cannot

exceed 20 percent of the Medicare demand for that product category in that CBA.

Once again, we stress that these rules are intended to assist us in evaluating network bids and to protect the Medicare program against anticompetitive behavior, and they should not be interpreted as superseding any Federal laws or regulations that protect against anticompetitive behavior.

We acknowledge that forming a network may pose some challenges. However, we believe that networks are a realistic solution for small suppliers because we recognize that it may be difficult for small suppliers to service the entire CBA independently. We continue to believe that networks are an appropriate option for small suppliers that cannot independently service the entire CBA to be able to participate in the Medicare DMEPOS Competitive Bidding Program and to promote competition and efficiencies that could improve services to beneficiaries. The proposed rule was published May 1, 2006. We believe sufficient notice has been given for these suppliers to consider network options and plan accordingly. Forming a network is a business decision, and we believe that our network policy is constructed in a way that will help ensure that small suppliers have an opportunity to be considered for participation in the Medicare DMEPOS Competitive Bidding Program.

Comment: A few commenters agreed with our proposal to require that suppliers participating in a network form a discrete legal entity and stated that this would prevent the commingling of Medicare funds, as well as violations of the Federal anti-kickback statute, self-referral rules and regulations, and allegations of unfair business practices among the participating network suppliers. Other commenters believed that requiring each network to bid independently defeats the entire purpose of networking. They disagreed with the primary legal entity being responsible for billing Medicare and receiving the payments. They believed that each supplier should be responsible for its own finances.

Response: We appreciate the support for our proposal that each network must form a legal entity. Each member of the network must meet all the applicable eligibility, financial, and accreditation requirements in order to be awarded a contract and this information must be included with the network bid. The legal entity that submit a bid on behalf of the network must provide all the information required for each member of the network. We agree that a primary supplier should not be responsible for submitting claims to Medicare and receiving payment on behalf of all network member suppliers and are deleting that requirement. We will now require each network member to submit its own Medicare claims and receive payment for those claims.

Comment: A few commenters believed that networks that submit bids to furnish more than one product category could create access problems for beneficiaries because not all the network members will furnish all the product categories. They recommended that CMS add requirements to ensure that network bids are scrutinized to ensure that each network has appropriate mechanisms to service the entire CBA.

Response: All the members of a network must be able to jointly service an entire CBA. While networks can choose the product categories for which they will submit a bid, once a contract is awarded to a network, each member of the network must furnish all of the items within the product categories for which the network is awarded a contract. Also, we will consider each product category separately and ensure there is sufficient supplier capacity within a CBA to meet beneficiary demand for items within all product categories.

Comment: A few commenters requested that CMS disclose the methodology that will be used to calculate the market share and monitor changes over the course of the contract. A few commenters questioned why a limit of 20 percent of the market share was assigned to the network, leaving 80 percent of the Medicare market for a large company. They suggested allowing network members to obtain market share not to exceed 35 percent, as specified in the Department of Justice monopoly guidelines.

Response: We believe that by setting the maximum size of a network's shares at 20 percent of the marketplace at the time of bidding, we will be able to ensure that there will continue to be competition in the area because if all of the winning suppliers are networks, there would still be at least 5 networks. However, once a supplier/network receives a contract, there is no limit on what percentage of the demand in the CBA that the supplier/network can furnish. After winning suppliers are selected, we will not exclude networks or suppliers from expanding and exceeding the 20 percent capacity. We believe that this will ensure sufficient suppliers, provide beneficiaries with more variety and choice, and will ensure that we select a sufficient number of contract suppliers for each product category in each CBA.

Comment: Some commenters suggested that CMS allow suppliers to join up to two networks, stating that many suppliers currently participate in several networks. They believed that this would ensure that the participating supplier is not disadvantaged by a requirement to commit to a single network bid.

Response: We agree with the commenters. We will allow small suppliers to join more than one network, but a small supplier cannot join more than one network that submits a bid to furnish items in the same product category in the same CBA. We believe that this rule is necessary because, without it, the competitive bidding process would be undermined if small suppliers were allowed to bid against themselves to furnish the same product category in the same CBA. In addition, a small supplier would not be able to submit an individual bid to furnish the same product category in the same CBA for which the network in which it is a member is also submitting a bid. However, a small supplier that wishes to furnish two different product categories in a single CBA would be able to join one network that submits a bid to furnish one of the product categories, and another network that submits a bid to furnish the other product category. Provided the small supplier did not join a network to furnish the same product category in the same CBA, the small supplier would also be able to submit an individual bid to furnish the product category.

Comment: A few commenters asked how networks would obtain a supplier billing number.

Response: The Medicare competitive bidding implementation contractor will assign each network a bidder number that will be used to monitor the network. As stated earlier, each member of the network will be allowed to submit its own claims and receive Medicare payments directly.

Comment: A few commenters requested that CMS clarify whether each supplier that is a member of a network would be required to furnish all of the items for the product category for which the network submits a bid.

Response: Each member of the network would be required to furnish all the items within the product category for which the network submits a bid. This is consistent with our requirement that all contract suppliers must furnish all items in a product category. However, as explained above,

network members would not be required to furnish the items in the product category throughout the entire geographic area of the CBA, provided that the network as a whole can fulfill this requirement.

After consideration of the public comments we received, we are adding a definition of the term ''network'' to § 414.402 that provides that a network is an entity meeting the requirements of § 414.418. We are also finalizing § 414.418 as discussed above and with additional technical changes.

XIII. Education and Outreach for Suppliers and Beneficiaries

In the May 1, 2006 proposed rule (71 FR 25683 through 25684), we proposed to undertake a proactive education campaign to provide suppliers and beneficiaries with information about the Medicare DMEPOS Competitive Bidding Program. In the DMEPOS provisions of the FY 2007 IRF final rule (71 FR 48354), we responded to public comments we received on the May 1, 2006 proposed rule on our education and outreach services proposal and finalized our rule. We refer readers to the FY 2007 IRF final rule for a full discussion of these provisions.

As we indicated in the proposed rule, we have established the following Web site; *https://www.cms.hhs.gov/competitiveacqfordmepos/01_overview.asp* 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. 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. We stated that we 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.

XIV. Monitoring and Complaint Services for the Medicare DMEPOS Competitive Bidding Program

In the May 1, 2006 proposed rule (71 FR 25684), we stated that moving to a competitive bidding environment would not adversely affect CMS' program integrity efforts in reviewing claims and rooting out fraud, waste, or abuse. Claims would still be reviewed for medical necessity, coordination of benefits status, and benefits integrity. Any suspected instances of DMEPOS competitive bidding market manipulation and collusion would be referred to the appropriate Federal agencies that are responsible for addressing these issues.

We also proposed to establish a formal complaint monitoring system to address complaints in each CBA. Beneficiaries, referral agents, providers, and suppliers, including physicians, hospitals, nurses, and HHAs, would be able to report problems or difficulties that they encounter regarding the ordering and furnishing of DMEPOS in a CBA. Some examples of problems that we would consider serious include: contract suppliers refusing to furnish items to beneficiaries in the CBA for which they were awarded a contract; contract suppliers furnishing items that are inferior in quality to those that they bid to furnish; and contract suppliers violating assignment and billing requirements.

In addition, we proposed to monitor Medicare claims data to ensure that competitive bidding does not negatively affect beneficiary access to medically necessary items. Claims data would be monitored to identify trends, spikes, or decreases in utilization and changes in utilization patterns within a product category.

Comment: One commenter strongly supported CMS' efforts to detect any abuse that may occur under competitive bidding and urged CMS to be especially aggressive and timely in its oversight for monitoring equipment safety. The commenter believed that there is a potential for one supplier to harm thousands of beneficiaries and recommended that CMS notify affected beneficiaries if a breach of quality has been identified.

Response: Equipment safety is addressed in the DMEPOS quality standards under the heading ''Product Safety.'' The CMS-approved accreditation organizations will monitor supplier compliance with these requirements as part of the accreditation process. In addition, as we proposed, the CBIC will develop and implement a complaint monitoring system for competitively bid items and services. This system will be outlined in more detail through sub-regulatory guidance and enable beneficiaries, referral agents, providers, and suppliers to report problems or difficulties they experience with respect to the furnishing of items under the competitive bidding programs. Additional details will be posted on our Web site, or made publicly available by other means.

Comment: Two commenters believed that beneficiary avoidance of certain contract suppliers would provide a strong indication that the Medicare DMEPOS Competitive Bidding Program is not meeting physician and beneficiary needs in the area. The commenters stated that this activity should be monitored as a measure of whether contract suppliers are providing beneficiaries with a suitable level of quality and access.

Response: We appreciate this comment and will consider it as we develop our monitoring program. The CBIC will be monitoring items furnished by contract suppliers to ensure they are the same quality as the items for which the contract supplier submitted a bid and was awarded a contract. The RFB will require suppliers to indicate the manufacturer, make and model numbers for each type of item the supplier would furnish if awarded a contract. In addition, we will require under the contracts that each contract supplier submit a quarterly report that indicates the items that were actually furnished to beneficiaries. We also note that we will be conducting a comprehensive education campaign to ensure that suppliers, beneficiaries, providers, and referral agents understand that Medicare will only pay for competitively bid DMEPOS items and services if they are furnished by contract suppliers, unless an exception outlined in this final rule applies. For more information about our plans for education on the Medicare DMEPOS Competitive Bidding Program, we refer readers to the DMEPOS provisions of the FY 2007 IRF final rule (71 FR 48354).

Comment: One commenter encouraged CMS to specify clearly in the final rule or require CBICs to identify the necessary telephone and Internet resources that beneficiaries may use to raise questions and concerns related to the Medicare DMEPOS Competitive Bidding Program. The commenter stated that it is extremely important that beneficiaries have readily available access to information during their transition from their former suppliers to their new contract suppliers. The commenter recommended that CMS establish a survey mechanism so that beneficiaries will be able to rate their satisfaction with contract suppliers they have chosen, as recommended in the September 2004 GAO report entitled ''Past Experience Can Guide Future Competitive Bidding for Medical Equipment and Supplies.'' The commenter also stated the proposed rule

fails to provide a method to obtain feedback from beneficiaries concerning their satisfaction level with contract suppliers and disseminate this valuable information to other beneficiaries. The commenter noted that, without such an evaluation system, CBICs would be ill-equipped to judge and, thus, monitor either the quality of products that contract suppliers are furnishing or the accessibility of needed supplies for beneficiaries.

Response: We are establishing an ombudsman program that will require ombudsmen to identify, investigate, and resolve complaints made by, or on behalf of beneficiaries. The telephone numbers and resources will be published through program instructions or by other means, including postings on our Web site. We agree that beneficiaries must have readily available access to information during their transition from their former suppliers to new contract suppliers. We plan to implement an extensive education campaign for beneficiaries as well as for suppliers and referral agents. Our plans for education are described in more detail in the DMEPOS provisions of the FY 2007 IRF final rule (71 FR 48354). We note that the CBIC would administer beneficiary surveys throughout the program to regularly monitor beneficiary experiences with the program. We also expect to have two ombudsmen assigned to each DME MAC region. The CBIC will be providing oversight of this program. We are in the process of assessing the appropriate vehicles to disseminate the information that we collect through the beneficiary survey.

Comment: One commenter supported CMS's plans to establish a formal complaint monitoring system and believed that the information collected will be particularly helpful as CMS prepares to expand competitive bidding. The commenter recommended that CMS include in its complaint monitoring system a collection of brand-specific information on medical complications related to competitively bid items, especially for blood glucose monitoring products and enteral products (if included in competitive bidding) because of the potential for complications to arise with these items. The commenter also recommended that CMS collect data on contract suppliers that do not furnish particular brands of equipment specified by physicians. The commenter further recommended that CMS release timely reports on the results of its complaint monitoring system to encourage public dialogue and analysis regarding the competitive bidding program, and ensure that adequate data are available to guide development of subsequent phases of the program.

Response: We appreciate the suggestions of the commenters and will consider them as we operationalize the monitoring program. As we stated above, we will direct the CBIC to establish a monitoring program that includes beneficiary satisfaction indicators and supplier performance indicators. All parties affected by competitive bidding (for example, beneficiaries, referral agencies, suppliers, and providers) will be able to report problems or difficulties that they encounter regarding the ordering and furnishing of DMEPOS in CBAs. However, in the event we receive complaints regarding medical complications with products, we will convey that information to the FDA.

Comment: One commenter urged CMS to monitor contract suppliers aggressively to ensure that they are not providing a different item than prescribed by the physician or treating practitioner, pressuring the physician to revise his or her order, or delaying delivery of the item. The commenter stated that such actions could result in delays in patient care and increase the risk that the patient will be injured. Another commenter urged CMS to monitor aggressively the impact of the Medicare DMEPOS Competitive Bidding Program on patient access to care. The commenter stated that this is an entirely new and complex program that will significantly change the market dynamics for furnishing certain DMEPOS to beneficiaries, and CMS must ensure that these market changes do not unintentionally limit the current variety of DMEPOS available, thereby adversely affecting beneficiary access to these important Medicare items.

Response: If the contract supplier provides an item that does not match the written prescription from the physician or treating practitioner, the contract supplier should not bill Medicare, as this is considered a noncovered item. Our complaint and monitoring system will ensure that contract suppliers either furnish the items prescribed by a physician or treating practitioner, or assist the beneficiary in finding another contract supplier to furnish the item under the circumstances. We expect that contract suppliers will advise beneficiaries regarding the expected time frames for delivery of items, as required under the ''Consumer Services'' section of the quality standards, and that beneficiaries will receive competitively bid items in a timely fashion. In addition, we will, as part of our monitoring system, be evaluating beneficiary access to competitively bid items, for example, through beneficiary surveys and quarterly reports that will require contract suppliers to disclose exactly what items they have furnished to beneficiaries.

Comment: One commenter asked CMS to clarify how it will monitor the quality of items based on the bid submissions. Another commenter suggested that CMS monitor complaints to ensure there are no problems with inferior products being furnished to beneficiaries. The commenter stated that if the HCPCS codes were too vague, CMS would have problems with monitoring the quality of items. Another commenter acknowledged that although it agrees that it would be a serious problem if a contract supplier furnished items inferior in quality to those for which it bid but urged CMS to monitor this or address complaints if the HCPCS codes are too vague or include multiple technologies. The commenter suggested that, in order for the monitoring policy to be effective, the HCPCS codes that are associated with competitively bid items must include the necessary level of detail and specificity.

Response: As part of the RFB requirements for submission of bids, we are asking suppliers to list the items they will furnish by manufacturer, make, and model number. Under the contracts, we are requiring contract suppliers to submit a quarterly report in which they are required to indicate the items they have supplied under the Medicare DMEPOS Competitive Bidding Program. We note that the MMA requires the Secretary to submit a report to Congress evaluating this program. This report will be finalized in July 2009 and, based on beneficiary surveys, will include information on access to and quality of items and services, and satisfaction of individuals. As discussed in section IX.A. of this final rule, suppliers will be required to allow beneficiaries to select items from the same range of items furnished to non-Medicare beneficiaries.

Comment: One commenter stated that, while claims monitoring may be effective for some purposes, using it to suggest that a spike in certain items' utilization may be attributable to competitive bidding is narrow-minded. The commenter stated that product utilization may have nothing to do with competitive bidding for various reasons, such as baby boomers entering the Medicare program in disproportionately high numbers, the higher incidence of certain diseases in specific areas of the United States, and the development of new products and technologies that

enable a larger number of patients to remain independent at home.

Response: We continue to believe that it is useful to conduct claims monitoring, and we would expect to monitor claims for each CBA. If we identify a utilization spike in a particular item, we can further investigate the cause of the spike, to identify whether the spike happened because of competitive bidding. Our claims monitoring system will allow us to review claims data for each item within a CBA.

Comment: One commenter stated that in a September 2004 report entitled ''Past Experience Can Guide Future Competitive Bidding for Medical Equipment and Supplies,'' the GAO emphasized the importance of ensuring continued quality, especially given that the implementation of competitive bidding will create an added incentive for suppliers to cut costs. The commenter noted that, in GAO's view, the central focus of these efforts should be ''continued monitoring of beneficiary satisfaction,'' perhaps through a toll-free complaint hotline and through beneficiary surveys. The commenter stated that it would be unrealistic to expect beneficiaries to monitor and provide feedback on the quality of the enteral formula they receive, through a hotline, through surveys, or otherwise. The commenter further noted that, given the importance of assuring continued quality during a transition to a significantly revised pricing system, it would be prudent for CMS initially to focus on those items and supplies for which quality can be readily assessed and assured through monitoring efforts.

Response: As part of the monitoring system, we will collect data to evaluate changes in beneficiary satisfaction, service, quality, access and cost-sharing as a result of the new program. Several questions will be customized to suit the particular product line surveyed. These data will also be used to prepare the congressionally mandated study and report due in July 2009, under section 1847(d) of the Act.

Comment: Two commenters urged CMS to ensure that suppliers are distributed throughout the CBAs to ensure beneficiary access. The commenters stated that patients (especially when injured) or the caretaker should not have to travel long distances to obtain needed DMEPOS, as this could put patients at risk and increase Medicare costs.

Response: We are requiring contract suppliers to service the entire CBA, which means that if a beneficiary cannot travel to his or her chosen contract supplier, the contract supplier will still be required to furnish the item to the beneficiary, whether by delivery or mail. Suppliers must include in their bids the cost of providing the item and any requisite services directly associated with the item, such as delivery, set-up, and retrieval. Therefore, we do not believe it is necessary to create special provisions regarding geographic distribution of contract suppliers.

Comment: One commenter agreed that an effective complaint monitoring system is needed as part of the competitive bidding program. The commenter noted that this should be a simple process that incorporates existing mechanisms that allow Medicare beneficiaries to voice complaints, such as an ombudsman program, and should not attempt either to recreate what exists in another section of the program or overcomplicate the process. The commenter noted that the current supplier standards require that suppliers show the NSC the complaint resolution process through onsite inspection prior to the issuance of a supplier number. The commenter also suggested that patients be directed to call their suppliers first regarding any alleged service issues before calling the ombudsman or other contractor.

In addition, the commenter asked that CMS define ''items of inferior quality.'' The commenter believed that, in determining whether a supplier is experiencing a high level of complaints, CMS must view complaints not in an isolated, numerical manner but expressed as a percentage of the total number of in-home deliveries made to Medicare patients in a given month.

Another commenter stated that the proposed rule provides no specifics about the proposed monitoring system. The commenter asked that the final rule provide more information about this system. The commenter urged CMS to assure that ombudsmen are designated for each CBA because they play an important role in addressing and resolving beneficiary complaints.

Response: We agree that an effective complaint monitoring system is needed as part of the Medicare DMEPOS Competitive Bidding Program. As we currently do, we plan to use competitive bidding ombudsmen who will be geographically distributed in each of the DME MAC regions to assist with monitoring activities. The CBIC is responsible for the monitoring program and will be issuing additional information. We plan to have a complaint process in place so that everyone affected by the Medicare DMEPOS Competitive Bidding Program, including beneficiaries, referral agents, suppliers, and providers, will be able to report problems or difficulties that they encounter regarding the ordering and furnishing of DMEPOS in a CBA. The monitoring system will also include a complaint resolution process, as well as a process by which we can track claims data to ensure that items are being properly furnished under the program. CMS or the CBIC will issue additional details regarding this process through program instruction or by other means, such as the RFB, and post them on our Web site. When we referred in the proposed rule to an item being of ''inferior quality,'' we meant items that beneficiaries or referral agents complained were of inferior quality, which would include any product that the contract supplier furnishes to the beneficiary that does not meet the medical needs of the patient.

After consideration of the public comments received, we are finalizing our proposal to implement a monitoring and complaint system under the Medicare DMEPOS Competitive Bidding Program.

XV. Physician or Treating Practitioner Authorization and Consideration of Clinical Efficiency and Value of Items in Determining Categories for Bids

Section 1847(a)(5)(A) of the Act provides authorization to the Secretary 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. In the May 1, 2006 proposed rule (71 FR 25684), we proposed to implement this statutory provision in proposed § 414.420 (in the proposed rule, the regulatory provision was erroneously cited in the preamble as § 414.440), and to also apply it to certain treating practitioners, including physician assistants, nurse practitioners, and clinical nurse specialists, because these practitioners also order DMEPOS for which Medicare makes payment. Because a HCPCS code may contain many brand products made by a wide range of manufacturers, we expect that suppliers will choose to offer only certain brands of products within a HCPCS code. This is a common practice used by suppliers to reduce the amount of inventory they maintain. However, we proposed that the physician or treating practitioner would be able to 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.

We proposed that when a physician or other treating practitioner requests a particular brand, or mode of delivery of an item, contract suppliers would be required to furnish that particular brand or mode of delivery, assist the beneficiary in finding another contract supplier in the CBA that can provide that brand item or mode of delivery, 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 under Medicare.

For the Medicare DMEPOS Competitive Bidding Program, we did not propose to require a contract supplier to provide every brand of products included in a HCPCS code. However, regardless of what brands the contract supplier furnishes, the single payment amount for the HCPCS code would apply. Nonetheless, we noted that this issue will be studied in more detail by the OIG in 2009. At that time, we will evaluate the need for a specific process for certain brand names or modes of delivery.

In addition, section 1847(b)(7) of the Act 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. Currently, HCPCS codes are developed for items that are similar in function and purpose. For this reason, items within the same code are paid at the same rate. We believe that the HCPCS process has worked well in the past, and we believe that it adequately separates items based on their function.

Comment: One commenter stated that CMS should address the quite-common situations in which a supplier does not carry a particular item, or does not know how it works or how it must be maintained. The commenter noted that mandating a contract supplier to furnish an item it does not routinely supply could raise concerns about patient and employee safety and other liability concerns. The commenter further stated that as long as some contract suppliers in the CBA can supply that particular item, this situation should be acceptable to CMS.

Response: We recognize the commenter's concerns, and we note that we did not propose that a contract supplier would be required, no matter what the circumstance, to furnish a brand name item or specific mode of delivery to a beneficiary. We also recognize that the wording of proposed §§ 414.420(b)(1) and (b)(2) and the preamble to the proposed rule may not have been sufficiently clear regarding whether a contract supplier must furnish an item that it does not routinely carry to a beneficiary. Therefore, we are clarifying, in final §§ 414.420(b)(1) through (b)(3) 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.

Comment: One commenter stated that the proposed rule does not establish an appeal or dispute resolution system for cases when the contract supplier in a CBA fails to provide the specific equipment selected by the physician.

Response: As we state in this final rule in § 414.420(d), a contract supplier would be prohibited from billing Medicare if it furnishes an item different from that specified in the written prescription from the beneficiary's physician or treating practitioner.

Comment: One commenter stated that CMS should exercise its discretion under section 1847(a)(5) of the Act, and not permit such brand-specific prescriptions for items within a CBA. As an alternative, the commenter suggested that CMS consider making a finding that, under such circumstances, the competitive bidding is not likely to result in significant savings and, accordingly, exempt these items from the competitive bidding process under section 1847(a)(5) of the Act. The commenter indicated that there is concern that if CMS implements section 1847(a)(5) of the Act, the demand for brand-specific items, will increase even though the ''brand name'' may have the same clinical benefits of other products.

Several commenters opposed the manner in which CMS interpreted the authority of the treating practitioner to order brand-specific items and equipment. They believed that the proposed rule mandates serious financial consequences for the supplier and creates unnecessary uncertainty in the bids to be submitted. They added that forcing suppliers to carry all possible items and equipment will be burdensome and costly for suppliers. The commenters stated that contract suppliers may be financially responsible to provide items outside their normal product line. However, they added that, if a contract supplier does not carry that product, the contract supplier may refer the beneficiary to another contract supplier. The commenters asked that CMS consider an exception process to compensate contract suppliers for provisions of items that are very expensive compared to other products within the same HCPCS code. They also suggested that CMS define ''what is a reasonable effort to locate an alternative supplier.''

Response: We disagree with the commenters. Section 1847(a)(5) of the Act provides the Secretary with the authority to establish a process for certain items and services under which a physician may prescribe a particular brand or mode of delivery of an item or service to the beneficiary to avoid an adverse medical outcome. We proposed that this process would also apply to certain treating practitioners, including physician assistants, nurse practitioners, and clinical nurse specialists, because these practitioners also order DMEPOS for which Medicare makes payment. We stress that this process can only be used when a physician or treating practitioner determines that there is a need for the use of a particular item or mode of delivery to avoid an adverse medical outcome. Because bids will be submitted for HCPCS codes, which are carefully written to include items that perform the same therapeutic function, we do not believe there will be many instances in which a particular brand or mode of delivery is necessary to avoid an adverse medical outcome. Nevertheless, because it is possible such a prescription may be necessary in a few cases, we believe it is important for patient safety to retain this provision. Therefore, we are clarifying that a physician or treating practitioner must document in the beneficiary's medical

records the medical necessity of a particular brand or mode of delivery of an item or service to avoid an adverse medical outcome, if a particular brand or mode of delivery is prescribed. We note that section 1847(a)(5)(B) of the Act provides that a prescription written for a particular brand of item or mode of delivery will not affect the amount of payment otherwise applicable for the item under the HCPCS code involved, and that we do not currently pay a supplier an additional amount for furnishing a particular brand of item or mode of delivery. We also note that a contract supplier would not be required to furnish every brand of item. It would be able to work with the physician or treating practitioner to find a suitable alternative and, if that effort is unsuccessful, to help the beneficiary find another contract supplier that can furnish the item.

We agree that the use of the term ''reasonable effort'' is nebulous and may be subject to misinterpretation. We are deleting the term ''reasonable effort''. Because of the importance for beneficiaries to receive medically appropriate items, we are now requiring that a supplier follow the process set out in final § 414.420(b)(1) though (b)(3).

Comment: Several commenters argued that physician choice for determining appropriate wound care products is of paramount importance. They were concerned that physician choice and access to certain wound care products could be restricted as a result of competitive bidding, specifically Negative Pressure Wound Therapy (NPWT), code E2402. In recent months, new products have been added to code E2402 despite the fact that these new products are clinically different from the original NPWT product. The commenters stated that because of the newer items, it is conceivable that wound healing would be compromised.

Response: A physician or treating practitioner may prescribe a particular brand or mode of delivery to avoid an adverse medical outcome for the beneficiary. We note that HCPCS codes are carefully defined to ensure that only items that have the same therapeutic function fall within particular codes. Therefore, we believe it is unlikely that there would be many instances in which a particular brand within a HCPCS code would be necessary to avoid an adverse medical outcome.

Comment: Several commenters requested that CMS add language to the rule acknowledging that physical therapists and occupational therapists play a key role in specifying the need for a particular brand.

Response: Although we recognize that physical therapists and occupational therapists may furnish certain DMEPOS as part of their professional practice, current Medicare rules only allow physicians, nurse practitioners, clinical nurse specialists, and physician assistants to prescribe DMEPOS items.

Comment: Several commenters asserted that it is not fair that contract suppliers be required to furnish any item within a HCPCS code if their bid was accepted based on an item that they carry in their stock. The commenters stated that if no additional payments would be made for more specific expensive products that are ordered by physicians or treating practitioners, this may result in significant financial losses for the contract supplier if the contract supplier is required to furnish the particular brand or mode of delivery at the single payment amount. Several commenters supported the physician/treating practitioner authorization proposal because it provides a safety net for the beneficiary. Another commenter argued that when a physician or treating practitioner specifies a product for his or her patient, the physician or treating practitioner should have continuous access to the latest innovative technologies.

Response: As stated earlier in this section, we believe that it will rarely be necessary for a physician or treating practitioner to prescribe a particular brand or mode of delivery to avoid an adverse medical outcome. Furthermore, in this final rule, we are specifically providing the contract supplier with a specific process to follow when a physician or treating practitioner requests a specific brand item or mode of delivery to avoid an adverse medical outcome. Under this process, the supplier is required to furnish the item or mode of delivery as prescribed, and if it cannot furnish the item or mode of delivery as prescribed consult with the physician or treating practitioner to find a suitable alternative and have the physician or treating practitioner revise his or her order, and if the physician or treating practitioner does not revise the order, assist the beneficiary in finding another contract supplier. We do not believe these requirements will place an undue financial burden on a contract supplier because there are provisions in this process that give the contract supplier the opportunity to substitute the item or arrange to have another contract supplier furnish the item. We agree that physicians and treating practitioners should have continuous access to the latest innovative technologies and be able to order them for their patients.

Comment: Several commenters stated that the physician/treating practitioner authorization proposal does not provide sufficient details. They pointed out that the term ''adverse medical outcome'' has not been defined. The commenters urged CMS to develop a streamlined and quick process to facilitate the role of a physician or treating practitioner as a key decision maker for each patient. Several commenters argued that it is crucial for the Medicare DMEPOS Competitive Bidding Program to allow health care providers to prescribe specific items with special features when medically necessary. They stated that the proposed rule does not adequately ensure that beneficiaries with diabetes will have access to the products for which their health professionals find are most appropriate and medically necessary for their individualized needs. The commenters remained concerned that contract suppliers will limit products to a narrow range that do not account for a wide spectrum of diabetes-related medical needs, and they will not receive additional payment for providing such items.

The commenters recommended that CMS modify the rule to allow for an adequate variety of diabetes supplies to suit a range of individualized needs of beneficiaries with diabetes. They stated that CMS must create a less burdensome process to ensure that these supplies are rapidly available upon documentation of medical need. The commenters added that it is possible that adjusting the payment rate for these special items upward will encourage contract suppliers to provide them in all cases.

Response: We believe that it is appropriate for physicians and treating practitioners to have the discretion to determine when it is medically necessary to prescribe a particular brand or mode of delivery of an item to avoid an adverse medical outcome. We consider the adverse medical outcome determination to be part of the more general medical necessity requirement that must be met in order for Medicare to pay for an item under section 1862(a)(1)(A) of the Act. As with all medical necessity determinations, there must be documentation in the beneficiary's medical record to support the need for the particular brand or mode of delivery. Therefore, the physician or treating practitioner must note in the beneficiary's medical record the reason why the specific brand or mode of delivery is necessary to avoid an adverse medical outcome so that contract suppliers can make a reasonable effort to furnish the item, then consult with the physician or

treating practitioner to find a suitable alternative, and then make a reasonable effort to assist the beneficiary in locating a contract supplier that can furnish the item. We believe that these requirements, along with other requirements that we have previously discussed in this final rule, will ensure that beneficiaries have access to the most appropriate items for their medical condition under the Medicare DMEPOS Competitive Bidding Program.

Comment: One commenter objected to the statement in the proposed rule that suppliers should not discriminate against beneficiaries in a CBA and that contract suppliers must furnish the same items to beneficiaries that they do to other individuals. The commenter argued that this appears to conflict with the requirement that a supplier must provide product-specific items, if ordered by the physician or treating practitioner.

Response: The nondiscrimination provision in this final rule (§ 414.422(c)) specifies that discrimination against beneficiaries is prohibited under the Medicare DMEPOS Competitive Bidding Program. All Medicare beneficiaries to whom a contract supplier furnishes competitively bid items must have the same choice of items that the contract supplier provides to other customers. We proposed to implement this provision to protect beneficiaries from receiving sub-standard or inferior items in terms of quality. However, we do not believe that this provision conflicts with the physician/treating practitioner authorization rules being implemented in this final rule. Under these rules, a physician or treating practitioner can prescribe a brand name item or mode of delivery to avoid an adverse medical outcome for the beneficiary, and the contract supplier must follow the process outlined in § 414.420(b) upon receiving the prescription. Nothing in these rules would prevent a contract supplier that furnishes a particular brand or mode of delivery from making that brand or mode of delivery available to other beneficiaries or customers.

Comment: One commenter noted that the rule requires a contract supplier get a revised written prescription if the physician treating practitioner allows for a modification of a brand-specific product. The commenter stated that verbal orders are acceptable in most States, and this imposes a significant administrative burden on contract suppliers and physicians/treating practitioners.

Response: The requirement of a written order is consistent with current Medicare rules. The item provided must match the written order in order for the contract supplier to bill Medicare.

After consideration of the public comments we received, we are revising and finalizing proposed § 414.420 as discussed above.

XVI. Other Public Comments Received on the May 1, 2006 Proposed Rule

Comment: Several commenters suggested issuing an interim final rule, with a full 60-day notice and comment period to allow for a more detailed proposal for public comment. In addition, several commenters suggested publishing initial responses to the public comments as a new proposed rule. The commenters believed that this suggestion is consistent with section 1871(a)(4) of the Act that states that a final rule will be treated as a proposed rule if it includes provisions that are not logical outgrowths of a previously published notice of proposed rulemaking. The commenters indicated that another proposed regulation would allow the public to consider and comment on CMS' responses to issues on which CMS requested comment in the May 1, 2006 proposed rule. Other commenters requested that the comment period on the proposed rule be extended until at least 90 days following the publication of the final DMEPOS quality standards.

Several commenters were concerned about Administrative Procedure Act compliance, which states that administrative rulemaking must be sufficiently descriptive of subjects and issues involved so that interested parties may offer informed criticism and comments. The commenters also gave other cites: Agency notices must describe the range of alternatives being considered with reasonable specificity; otherwise, interested parties will not know what to comment on, and notice will not lead to better-informed agency decision making. Finally, the commenters noted that an agency commits a serious procedural error when it fails to reveal portions of technical basis for a proposed rule in time to allow for meaningful commentary.

Response: The proposed rule presented for public comment our proposed rules that will govern the Medicare DMEPOS Competitive Bidding Program. This final rule does not include any provisions that are not logical outgrowths of our proposals in the May 1, 2006 proposed rule. In addition, we believe that our proposed rules were sufficiently detailed to enable the public to provide meaningful comments on them. Indeed, we received over 2,000 comments on the proposed rule, and we have both considered and responded to those comments in this final rule. Therefore, we believe that issuance of an interim final rule is not necessary. We also note that this rule does not finalize the DMEPOS quality standards and that section 1834(a)(20)(E) of the Act explicitly permits us to establish the DMEPOS quality standards by program instruction or otherwise. The quality standards were published on August 15, 2006, and are available on the following Web site: *http://www.cms.hhs.gov/CompetitiveAcqforDMEPOS/04_New_Quality_Standards.asp.* We note that the draft quality standards were published on September 26, 2005, which was more than 7 months prior to the publication of the proposed rule. We also note that the quality standards apply to all suppliers, not just suppliers that wish to participate in the Medicare DMEPOS Competitive Bidding Program, and that we provided a 60-day period for the public to comment on them.

Comment: Several commenters suggested that CMS schedule a meeting of the PAOC (1) After we publish an interim final rule; (2) when we publish the MSAs and the DMEPOS items subject to competitive bidding; and (3) when the final regulation is issued. The commenters noted that scheduling a PAOC meeting following publication of an interim final rule would allow CMS to obtain industry input before publishing a final rule and initiating program implementation. Further, several commenters suggested that CMS include the PAOC in the review of the public comments received during the comment period on the proposed rule and in the development of the final rule. They stated that excluding the important counsel and advice of the PAOC in a critical process would not be consistent with the purpose for which the PAOC was established.

Response: The PAOC meets periodically to review policy considerations and to provide advice on the development and implementation of the Medicare DMEPOS Competitive Bidding Program. Since its establishment, the PAOC has met on five occasions and will continue to be available to provide us with advice until the end of 2009. Section 302 of the MMA gives CMS discretion on when to schedule PAOC meetings. We also discussed with the PAOC the full range of competitive bidding issues, and we continued to consider its advice and counsel as we reviewed the comments and developed this final rule.

Comment: Several commenters noted that the Web site address for the PAOC

that was in the proposed rule was incorrect.

Response: We recognize the importance of having a Web site available to distribute information in a timely manner and regret the error. Our PAOC Meeting Information Web site can be found at the following link: *http://www.cms.hhs.gov/CompetitiveAcqforDMEPOS/PAOCMI/list.asp.* Included on the Web site are materials relating to each PAOC meeting such as agendas, meeting summaries, and presentations.

Comment: One commenter suggested that the PAOC be subject to the Federal Advisory Committee Act (FACA), which requires public access to meetings and proceedings. The commenter believed that the PAOC has great power within the DMEPOS industry and that other affected members of the industry have not had an opportunity to review or respond to PAOC assertions or recommendations.

Response: Section 1847(c)(4) of the Act provides that the provisions of the FACA do not apply to the PAOC. However, the PAOC meetings have been open to the public, and we have published summaries of the meetings on our PAOC Web site *http://www.cms.hhs.gov/CompetitiveAcqforDMEPOS/PAOCMI/list.asp.* Information about the Medicare DMEPOS Competitive Bidding Program has also been made available through other methods, such as electronic supplier listserv messages and open door forums. CMS offers an electronic mailing list service for those interested in receiving news from CMS. From the following link, individuals can subscribe to the ''Homehealth_Hospice DMEODF–L'' listserv to receive notices of upcoming open door forums: *http://www.cms.hhs.gov/apps/mailinglists/.*

Comment: Numerous commenters requested that CMS publish an updated implementation timeline with expected completion dates. The commenters expect that the publication of such a timeline will highlight the significant problems that lie ahead based on an overly aggressive implementation plan. The commenters suggested that the timeline should identify and provide expected completion dates for items such as the publication of the quality standards, approval of the accrediting organizations, and issuance of final regulations. The commenters further suggested that CMS push back the implementation date of October 1, 2007, to a more reasonable timeframe. The commenters believed that a delay in implementation will allow adequate time for small suppliers to create networks and to prepare their organizations for accreditation.

Response: Section 1847(a)(1)(B)(i)(I) of the Act requires that the Medicare DMEPOS Competitive Bidding Program be phased in such that competition under the programs occurs in 10 of the largest MSAs in CY 2007. We are committed to meeting this statutory mandate. We are mindful of the many key tasks that must be completed to ensure the success of this program and are moving forward to complete these tasks expeditiously. We note that the final DMEPOS quality standards were issued on August 15, 2006, and that applications for participation in the DMEPOS accreditation program were solicited from independent accrediting organizations in a **Federal Register** notice published on August 16, 2006 (71 FR 47230). Therefore, we do not believe it is necessary to publish a specific timetable of expected completion dates for other activities. However, we will provide the public with sufficient notice as we proceed with implementation activities.

Comment: One commenter suggested that CMS allow all beneficiaries to opt out of the Medicare DMEPOS Competitive Bidding Program, select the supplier of their choice, and receive DMEPOS items for which payment is made based on the current fee schedule amounts.

Response: Under section 1847(a) of the Act, we are required to establish and implement competitive bidding programs throughout the United States for the furnishing of certain items for which payment is made under Part B of the Medicare program. To the extent that we implement a competitive bidding program in a particular CBA, we do not believe that we have authority to allow any beneficiary who need items in that CBA to ''opt out'' of receiving those items from contract suppliers and receive Medicare payment. We also note that section 1847(a)(6) of the Act provides that, for each CBA in which a competitive bidding program is implemented, the payment basis established under the competitive bidding program shall be substituted for the payment basis that would otherwise apply (which, in most cases, would be based on a fee schedule). In accordance with section 1847(b)(5)(A) of the Act, we are required to establish a new payment amount for each item in each CBA. This new payment amount is what we would pay to contract suppliers. Under the Medicare DMEPOS Competitive Bidding Program, beneficiaries will be able to select among the winning suppliers. However, we believe that permitting beneficiaries to opt out of the program would create an exception that would significantly undermine the goal of the program to achieve savings.

Comment: One commenter stated that one aspect of the DMEPOS competitive bidding demonstration projects that was never studied was Medicare patient rehospitalization and/or emergency room visit rates. The commenter stated that this is a key outcome measure that CMS should have evaluated to determine if savings created through Medicare Part B were actually resulting in expenditures under Medicare Part A. The commenter believed that it is possible that a price-oriented DMEPOS model might actually lead to higher levels of institutional care. The commenter indicated that it would be prudent for CMS to study this aspect in the CY 2007 round of bidding.

Response: We do not agree that competitive bidding savings will result in higher expenditures under Medicare Part A. Under the Medicare DMEPOS Competitive Bidding Program, beneficiaries will receive items from contract suppliers that have satisfied our quality, accreditation, financial, and eligibility standards. In addition, contract suppliers will be required to furnish to beneficiaries in a CBA the same level of services and quality items that they furnish to other customers. Through our physician and treating practitioner authorization rules, beneficiaries who maintain a permanent residence in a CBA will continue to receive items that meet their medical needs. Because we are enacting safeguards to ensure the quality of items that are furnished under the competitive bidding programs by contract suppliers, as well as rules that we expect will ensure that beneficiaries have access to new technology, we do not believe that expenditures under Medicare Part A will rise or that it is necessary to undertake a study. Moreover, we will monitor the entire program to make sure that complaints are addressed and resolved. We also believe that it would be difficult to develop a study evaluating increases in Medicare Part A costs as a result of adverse competitive bidding outcomes because there are too many intervening variables, such as physician and treating practitioner quality, that affect final patient outcome.

XVII. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA), we are required to provide 30-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for

review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the PRA requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

In response to the May 1, 2006 proposed rule (71 FR 25654), we received several public comments that were submitted on the proposed rule that more appropriately pertain to provisions on the PRA process. We note that specific information requested from suppliers as part of the bid submission and many of the terms and conditions that will be included in the contracts under the Medicare DMEPOS Competitive Bidding Program are discussed in detail in sections VI.G., VII.C., and IX.A. of this final rule. In these sections, we summarize the public comments we received on these specific information requirements and respond to those comments. Other comments and responses on the general paperwork burden that we outlined in the proposed rule follow:

Comment: Two commenters submitted general comments on the specific paperwork burden outlined in the proposed rule. The commenters believed that, due to the lack of specificity in the proposed rule, it is impossible for commenters, or CMS, to estimate accurately the amount of incremental time that will be required of suppliers to complete the bid process to participate in the program. The commenters indicated that only two demonstration projects were performed, and they did not include many of the requirements that we have proposed. The commenters also indicated that, overall, competitive bidding is an administratively burdensome program for suppliers, Medicare, and its contractors, and represents an incremental administrative process that is layered on top of an already complex Medicare Part B system. The commenters urged CMS to adopt existing accreditation standards, existing patient satisfaction tools, existing patient complaints and resolution processes, and existing financial reports, rather than attempt to ''reinvent the wheel,'' in order to reduce both the paperwork and administrative burden. The commenters believed that competitive bidding will increase costs for both suppliers and CMS in the form of increased staff and reporting procedures.

Two commenters stated that they assumed CMS arrived at its estimate of 70 hours per bid for each supplier to furnish information by using the median of the hours that suppliers estimated were required during the two less complicated demonstration projects, and that this estimate was per location. The commenters pointed out that it is unclear as to whether this 70-hour estimate includes time spent attending bidders conferences and preparing internal analyses or whether it is simply an estimate of the amount of time needed to complete the application bidding process. The commenters indicated that if they considered in the estimate the time that executive and mid-level management spent reviewing, analyzing, and responding to the proposed rule, plus an estimated 70 hours per their 25 branches for the application process and the first round of competitive bidding for CY 2007, the companies would invest 1,750 hours in preparing competitive bids.

In regard to the total number of hours that suppliers would invest in regard to the CY 2007 programs, one commenter pointed out that CMS' own estimate is that 1,158,150 hours would be needed by the industry (16,545 bids). The commenters pointed out that if a conservative $35 per hour average salary rate is used, this amounts to an incremental $41 million attributable to the first 10 CBAs alone. The commenter added that, in CY 2008, this escalates dramatically to an incremental 5,100,550 hours needed to prepare 72,865 bids, which in turn computes to $178.5 million in supplier labor, and that these costs have to be accounted for in the bid that suppliers submit to CMS. Two commenters stated that the proposed bid process and certain other provisions of the proposed rule are too paper-intensive and gave recommendations for ways in which CMS could save a significant amount of paperwork for itself and suppliers: (1) Automating the supplier bid process and accreditation organization application process by making it Web-based and allowing an attachment feature; (2) allowing the bid review team to start reviewing those bids that meet the quality and financial standards first before proceeding to review the bid prices; (3) allowing any multi-site supplier that is owned by the same corporate parent or tied to the same tax number to provide certain standard information only one time; (4) adopting a standardized Medicare patient satisfaction questionnaire for DMEPOS; (5) keeping the beneficiary and supplier education simple and low cost; (6) eliminating the brand-specific requirement and associated paperwork; (7) rather than requiring a separate bid for every competitively bid product category in a given MSA, consolidating the application form itself into a check-box format; and (8) rather than creating an all-new government infrastructure that essentially duplicates what exists in the private sector, subcontracting with several large managed care organizations to administer the program for Medicare beneficiaries nationwide.

Response: We need detailed information on suppliers with whom we may enter into a contract. This information will be used to evaluate the suppliers. This is important because both Medicare and the beneficiaries will be dependent on the contract suppliers. We need to evaluate capacity issues in order to ensure that suppliers' capacity meets beneficiary demand; we need to evaluate financial stability in order to ensure that contract suppliers are solvent and will be in business during the contract period; and we need to obtain identification information in order to ensure management is dependable and that the bidding supplier is not excluded from participating as a Medicare supplier.

Our estimate of the time burden required for filling out the forms is based on reports from suppliers that participated in the DMEPOS competitive bidding demonstrations, which implemented competitive bidding in two MSAs. The demonstrations included RFB forms similar to those that will be included in this program and both small and large suppliers filled out the forms. Estimates of the required time ranged from 40 to 100 hours, and we used the midpoint for our estimates. The estimates include internal decision-making processes but do not include the time spent attending bidders' conferences. Based on our consideration of the public comments received, we have eliminated the requirement to submit reviewed and/or audited financials, as well as information regarding investigations. We believe this will lessen the burden on suppliers.

Section 414.412 Submission of Bids Under a Competitive Bidding Program

Section 414.412 outlines the requirements associated with submitting bids under the competitive bidding process. Specifically, § 414.412(a) states that unless an exception applies, suppliers must submit a bid and be

awarded a contract under a competitive bidding program in order to receive payment from Medicare for furnishing the items.

The burden associated with this requirement is the time and effort associated with drafting, completing, and submitting a bid. We estimate that, on average, it will take a supplier 68 hours to complete and submit a bid. We believe that we will receive 15,973 bids for a total annual burden of 1,086,164 hours.

In addition, as part of the Medicare DMEPOS Competitive Bidding Program, beneficiaries will be surveyed to gather information pertaining to their experiences with suppliers. We estimate that the burden associated with completing the survey is 15 minutes per beneficiary. We estimate that the total annual burden associated with this information collection requirement is 2,000 hours.

Section 414.414 Conditions for Awarding Contracts

Section 414.414 contains the rules pertaining to the evaluation and selection of suppliers for contract award purposes under the Medicare DMEPOS Competitive Bidding Program. Specifically, § 414.414(b)(1) states that each supplier must meet the enrollment standards specified in § 424.57. The burden associated with this requirement is subject to the PRA. This requirement is currently approved under OMB control number 0938–0717, with an expiration date of November 30, 2007.

Section 414.420 Physician or Treating Practitioner Authorization and Consideration of Clinical Efficiency and Value of Items

Section 414.420(a) states that a physician or treating practitioner may prescribe, in writing, a particular brand of an item for which payment is made under competitive bidding or a particular mode of delivery for an item, if he or she determines that the particular brand or mode of delivery would avoid an adverse medical outcome for the beneficiary and documents this determination in the beneficiary's medical record. The burden associated with this requirement is the time and effort associated with evaluating the beneficiary and, if necessary, determining the best brand item or mode of delivery to avoid an adverse medical outcome. In addition, there is burden associated with the time and effort involved in writing the prescription for the brand item or the mode of delivery and documenting the medical record. The burden associated with this requirement is not subject to the PRA as stated under 5 CFR 1320.3(b)(2) and (h)(5).

Section 414.422 Terms of Contracts

Section 414.422(d) requires contract suppliers to notify CMS if they are considering or negotiating a change of ownership. The notification must be made 60 days prior to the anticipated effective date of the change. In addition, a supplier must submit a novation agreement to CMS 30 days before the anticipated change of ownership takes effect, stating that it will assume responsibility for meeting all of the terms and conditions of the competitive bidding contract. The new supplier must submit the same documentation required of the original contract supplier unless it has already submitted such documentation during the bidding process and that documentation is still current.

The burden associated with this requirement is the time and effort associated with drafting and submitting the required notification to CMS. While this burden is subject to the PRA, we currently have no way to quantify the number of potential respondents. We will continue to monitor the program requirement and seek OMB approval should the number of respondents surpass the threshold of 10 individuals or entities as specified in 5 CFR 1320.3(c)(4).

TABLE 10.—ESTIMATED ANNUAL REPORTING AND RECORDKEEPING BURDEN

Requirement	OMB control No.	Respondents	Responses	Burden per response (in hours)	Total annual burden (in hours)
§ 414.412(a)	0938—New	15,973	15,973	68	1,086,164
	0938—New	8000	8000	.25	2,000
	0938—New	15,973	15,973	.166667	2662
§ 414.414(b)(1)	0938—0717	35,000	35,000	8	280,000
Total					1,370,826

As required by section 3504(h) of the PRA, we have submitted this final rule to OMB for its review and approval of the information collection requirements.

If you comment on these information collection requirements, please mail copies directly to the following:

Centers for Medicare & Medicaid Services, Office of Strategic Operations and Regulatory Affairs, Regulations Development and Issuance Group, Attn.: William N. Parham, III, CMS–1270–F, Room C5–14–03, 7500 Security Boulevard, Baltimore, MD 21244–1850; and

Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Attn.: Carolyn Lovett, CMS Desk Officer, CMS–1270–F, E-mail: *carolyn_lovett@omb.eop.gov*, Fax: (202) 395–6974.

XVIII. Regulatory Impact Analysis

A. Overall Impact

We have examined the impacts of this final rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), and Executive Order 13132.

1. Executive Order 12866

Executive Order 12866 (as amended by Executive Order 13258, which merely reassigns responsibility of duties) directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (that is, a final rule that would have an annual effect on the economy of $100 million or more in any 1 year, or would

adversely affect in a material way the economy, a sector or the economy, productivity, competition, jobs, the environment, public health or safety, or communities). We have determined that this final rule is an economically significant major rule and thus have prepared a regulatory impact analysis.

2. Regulatory Flexibility Act (RFA)

The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of section 604 of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Approximately 85 percent of DMEPOS suppliers are considered small businesses according to the Small Business Administration's size standards, with total revenues of $6.5 million or less in any 1 year. Individuals and States are not included in the definition of a small entity. We expect that this final rule will have a significant impact on a substantial number of small suppliers. The RFA requires that we analyze regulatory options for small businesses and other entities. The analysis must include a justification concerning the reason action is being taken, the kinds and numbers of small entities the rule affects, and an explanation of any meaningful options that achieve the objectives with less significant adverse economic impact on the small entities. We have provided this analysis in section XVIII.B. of the preamble to this final rule.

3. Small Rural Hospitals

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of an MSA and has fewer than 100 beds. We have determined that this rule will not have a significant effect on small rural hospitals. Rural health care facilities should not be significantly impacted as the program is expected to operate primarily within relatively large MSAs.

4. Unfunded Mandates

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. That threshold level is currently approximately $120 million. We do not expect this final rule will result in direct costs that exceed $120 million per year on State, local, or tribal governments in the aggregate or the private sector, and thus the UMRA would not apply.

5. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. We have determined that this final rule will not have substantial direct effects on the rights, roles, and responsibilities of States.

B. Regulatory Flexibility Analysis

1. Summary

The May 1, 2006 proposed rule did not include a separate initial Regulatory Flexibility Analysis. However, information concerning small suppliers was included throughout the proposed rule preamble and regulatory impact analysis. This document consolidates and summarizes components of the regulation concerning small businesses into a single RFA. Its contents are included in more detail in various parts of the regulatory impact analysis and the regulation preamble.

2. The Need for and Objectives of the Final Rule

Payment for DMEPOS is currently based generally on fee schedule amounts. Section 302(b)(1) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173), requires the Secretary of Health and Human Services to replace the current fee schedule methodology for certain items with a competitive acquisition contracting program that will result in an improved Medicare methodology for setting payment amounts for certain durable medical equipment and supplies, enteral nutrition equipment, nutrients and supplies, and off-the-shelf orthotics. This new bidding process will result in CMS awarding contracts with to winning suppliers. Contracts will stipulate the terms, conditions, and payment rates for items and services for under the program. Generally, only suppliers that submit winning bids and are awarded contracts will be permitted to furnish items under the program and reimbursement for those items from Medicare.

In developing bidding and contract award procedures, section 1847(b)(6)(D) of the Act requires us to take appropriate steps to ensure that small suppliers of items and services have an opportunity to be considered for participation in the Medicare DMEPOS Competitive Bidding Program. Section 1847(b)(2)(A)(ii) of the Act also states that the needs of small providers must be taken into account when evaluating whether an entity meets applicable financial standards.

Set out below is a summary of the significant issues raised by the public comments in response to the initial regulatory flexibility analysis, a summary of the assessment of the agency of such issues, and a statement of any changes made in the proposed rule as a result of such comments.

3. Comments Regarding Small Suppliers

The May 1, 2006 proposed rule did not include a separate initial regulatory flexibility analysis, but all information required for an RFA was contained elsewhere in the regulatory impact analysis or the regulation preamble. Below we list major comments on aspects of the proposed rule which directly concern small suppliers that are included in the final rule.

a. Comments on Small Supplier Focus Groups

Several commenters requested that CMS share the findings from the 9 small supplier focus group meetings that were conducted during April and May 2005. Representatives of DMEPOS suppliers that had less than $3 million in gross revenue and employed up to 10 FTE employees met with CMS' contractor staff and were invited to share thoughts and opinions on the potential impact of quality standards, accreditation, competitive bidding, and financial standards requirements on their businesses. We presented an overview and results of the focus groups related to quality standards and accreditation to the PAOC on September 26, 2005 (access at *http://www.cms.hhs.gov/CompetitiveAcqforDMEPOS/PAOCMI/list.asp#TopOfPage*).

The results of the focus groups related to competitive bidding and financial standards were presented to the PAOC on May 23, 2006. Several focus group participants remarked that the competitive bidding process would force many small suppliers out of business. The participants suggested alternatives to competitive bidding, including: (1) CMS should determine product prices and allow all willing suppliers to provide products at the set price; and (2) CMS should reserve a percentage of winning bids for small suppliers. Many participants believed

that lower payment rates for suppliers would inevitably lead to lower quality goods and services. Participants were particularly emphatic in their belief that CMS continues to neglect the valuable service component that small suppliers provide to their customers. They believed that it is their commitment to service that sets them apart from the national companies. A number of participants were concerned about the possibility of requiring small winning supplier to furnish items in the entire MSA, given the fact that some MSAs cross State boundaries. There was also a consensus among these small suppliers that the impact of competitive bidding would differ by product line. They believed that items involving high-end technology equipment, respiratory equipment, and customized products are more service intensive than other products, such as standard wheelchairs, that involve fewer repairs, set-up time, and patient education.

Finally, many participants in the focus groups believed that tax returns, quarterly standard financial statements, and Dun & Bradstreet were helpful sources of information about a business's credit history and cash flow. The participants noted that suppliers that grossed over $3 million in revenue used audited financial statements, whereas suppliers that grossed less than $3 million in revenue used cash basis accounting principles. A summary of the PAOC discussion related to the focus group results can be accessed at: *http://www.cms.hhs.gov/CompetitiveAcqforDMEPOS/downloads/PAOC_summary.pdf.*

We have used the comments from the focus groups as well as public comment process in developing our final policies for the Medicare DMEPOS Competitive Bidding Program.

b. Comments on the Definition of Small Suppliers

Some comments concerned the definition of small suppliers. Some commented on practitioner and providers, reporting that there are currently 40,000 practitioners and providers enrolled as suppliers, including approximately 1,078 physical therapists. The commenters stated that health care practitioners who provide DMEPOS as an integral part of their professional services specialize in providing items for specific conditions. They added that these suppliers offer considerable expertise in evaluating both the patient and the item in order to provide the patient with the best possible outcome.

Many commenters disagreed with using the definition of the SBA (less than $6 million in annual receipts) because the CY 2003 Medicare data showed that at least 90 percent of suppliers had less than $1 million in allowed charges. They recommended defining a small supplier as a supplier that generates less than $3 million in annual receipts. The commenters believed that a lack of small supplier participation would negatively impact patient care. They added that small businesses would have to endure large expenses in order to participate in the Medicare DMEPOS Competitive Bidding Program. Most suggested that we define a small supplier as a supplier having fewer than 10 FTE employees. They also believe that small suppliers serve rural and underserved urban communities where larger suppliers may not operate.

We agree with the commenters and recognize the importance of small supplier participation and understand that there are upfront costs associated with submitting a bid under the program. In the final rule, we revised our policies to ensure that small suppliers have an opportunity to be considered for participation in the Medicare DMEPOS Competitive Bidding Program. To assure multiple suppliers, storefront locations, beneficiary access, and increased participation by small suppliers, we have in cooperation with the SBA, revised the final rule such that the definition of a ''small supplier'' is a small supplier that generates gross revenue of $3.5 million or less in annual receipts, including Medicare and non-Medicare revenue (§ 414.402).

c. Comments on the Protections for Small Suppliers

Several commenters noted that section 1847(b)(6)(D) of the Act is entitled ''protection'' of small suppliers and not the mere identification of small suppliers. The commenters proposed the following policies: (1) At least 50 percent of suppliers that receive a contract should be small suppliers (based on $3 million or less in revenue or less than 10 FTE employees); (2) CMS should allow suppliers with less than 10 FTE employees to furnish items to less than the entire CBA; (3) CMS should award contracts to small suppliers with the lowest bids that exceed the pivotal bid; (4) CMS should allow truly small suppliers to promise to accept the single payment amount; and (5) CMS should establish a certain volume of items in each geographic area that will be ''set-aside'' for small suppliers.

The statute at section 1847(b)(6)(D) of the Act requires that the Secretary shall take appropriate steps to ensure that small supplies of items and services have an opportunity to be considered for participation in the program under this section. We recognize the concerns raised by the commenters and have considered the suggested alternatives provided during the small supplier focus groups and through the public comment process. We also recognize the importance of maintaining storefront capabilities to meet the needs of beneficiaries. To help small suppliers have an opportunity to participate in the Medicare DMEPOS Competitive Bidding Program and to support our Departmental goals for contracting with small suppliers, we have established a target for small suppliers' participation in the final rule. Our target for small supplier's participation in each product category will be determined by multiplying 30 percent times the number of suppliers that meet our bidding requirements and whose composite bids are at or lower than the pivotal bid. The number resulting from this multiplication represents our goal for small supplier participation for the product category (§ 414.414(g)(1)(i)). If this 30-percent target is not achieved as a result of this process, we will offer contracts to small suppliers with submitted bids that are above, but closest to, the pivotal bid until we reach the target number or there are no additional small supplier bidders (§ 414.414(g)(1)(iii)). In addition, we are requiring that all contract suppliers must service the entire CBA, and we have clarified that this can be done where appropriate either through home delivery, mail order, or storefront. However, small suppliers that cannot service the entire area independently can join together and bid as a network (§ 414.418). The network, rather than each individual supplier, would be required to service the entire CBA.

d. Comments on Bidding Requirements for Physicians and Other Providers

Several commenters suggested that CMS not require physicians, including podiatric physicians, to participate in the competitive acquisition program for certain DMEPOS. The commenters noted that under the physician self-referral (''Stark'') provisions under section 1877 of the Act, a physician in a group practice may not refer Medicare beneficiaries to the group practice, and the group practice may not bill for any DME except crutches, canes, walkers, folding manual wheelchairs, and blood glucose monitors. The commenters also requested that CMS not require physician assistants, physical therapists, and occupational therapists to participate in the Medicare DMEPOS Competitive Bidding Program because those health care professionals are

licensed by State boards. According to the commenters, if a physician or non-physician practitioner does not participate in the competitive bidding program, he or she should be reimbursed at the competitive bid rate for any DME items that are furnished to his or her own patients. In addition, the commenters requested that CMS clarify how the requirement for physicians to submit bids and provide all items within a product category does not violate the physician self-referral law. Other commenters stated that there is no reason to treat occupational therapists and physical therapists differently from physicians.

Based on these comments, we modified the proposed rule by expanding the definition of the term ''physicians'' and by exempting physicians and other treating practitioners from bidding requirements to provide limited DMEPOS to their own patients (§ 414.402 and § 414.404(b)(1)). We are also modifying the regulation to give physical therapists in private practice and occupational therapists in private practice the option to furnish certain types of competitively bid items without participating in the competitive bidding program (§ 414.404(b)(2)).

e. Comments on Bidding by Product Category

We received numerous comments concerning the definition and use of product categories. We believe that conducting separate bidding processes for individual product categories will encourage the participation of small suppliers that specialize in one or a few product categories. It is our goal to allow Medicare beneficiaries the opportunity to receive all related equipment from the same supplier, thereby minimizing disruption to the beneficiary. Suppliers currently specialize in particular products, and we do not see this process being interrupted by competitive bidding. The use of product categories is intended as a compromise that will maximize beneficiary convenience while still permitting suppliers, particularly small suppliers, to specialize in a certain product category.

A few commenters indicated that conducting separate bidding processes for individual product categories is administratively burdensome. They stated that CMS' assumption that large suppliers could expand their products by offering supplies and equipment easier or more quickly than small suppliers is an erroneous view of a company's ability to expand. They also reported that large organizations must seek approval from their boards or other stakeholders before they can undertake certain business expansion activities.

We received comments arguing that product categories should be defined narrowly or broadly. Others stated that the product categories should not differ from the SADMERC policy groups, believing that combining medical policies may affect beneficiary access or quality of services. Suppliers also noted that suppliers are already familiar with the policy groups as that is how the CMS Web site is organized and this is accessed by suppliers frequently for information. Some commenters suggested that product categories should be uniform and as stable as possible because keeping track of differently defined categories would be very difficult. Some commenters also called for subcategories within product groups.

Based on public comments, we have revised the proposed definition of the term ''product category'' in § 414.402 to mean, ''a grouping of related items that are used to treat a similar medical condition''. The list of product categories and the items included in each product category that is included in each competitive bidding program will be identified in the request for bids document for that competitive bidding program or by other means. The policy groups will serve as the starting point for establishing product categories. Product categories may generally be consistent with the policy groups that are established by the SADMERC, unless CMS determines that a policy group should be redefined for the purposes of competitive bidding. The SADMERC established policy groups for the purposes of developing Medical review policies and for data analysis. However, the product categories for which we would request bids could be a subset of items from a SADMERC policy group or a combination of items from different policy groups. There may be items in a policy group that are not subject to competitive bidding or that we would want to exempt from competitive bidding using our authority to exempt items. In response to the suggestion that we include subcategories within a product category, we do not believe this approach would be consistent with the purpose and definition of product categories because a product category is a group of related items used to treat a medical condition and it would be designed to be appropriate for Medicare competitive bidding purposes. In addition, we do not believe that there is a need for subcategories because we would create a new product category instead of a subcategory.

f. Comments on Financial Standards

Several comments argued that the financial standards were too strict for certain suppliers and should be flexible enough to regulate mail order companies, small local suppliers, SNFs, outpatient departments of hospitals, retail pharmacies, and publicly-traded and privately-held family firms. Other commenters argued that the reporting requirements of the proposed financial standards are too burdensome and discourage small suppliers from participating. They recommended that CMS define different standards for small suppliers and pharmacies. The commenters stated that if financial standards are too restrictive, qualified suppliers may be eliminated from the Medicare Part B program. They added that, conversely, if financial standards are too lax, suppliers may be financially unable to meet the challenges of a competitive market.

We agree with the commenters that it is important to have financial standards that ensure suppliers are able to meet the challenges of competitive bidding and can fulfill their contract obligations. After further consideration and in response to comments, we believe that the financial documentation discussed in the proposed rule is too burdensome, particularly for small suppliers. We have determined that we could obtain the necessary information through collection of a limited number of financial documents and believe that the submission of this information will be less burdensome for all suppliers, including small suppliers. We are clarifying in the final rule that the RFB will specify what financial documents will be required (§ 414.414(d)) so that we can obtain a sufficient amount of information about each supplier while minimizing the burden on both bidding suppliers and the bid evaluation process. This financial information will provide enough information to allow us to determine financial ratios, such as a supplier's debt-to-equity ratio, and credit worthiness, which will allow us to assess a supplier's financial viability. We believe we have balanced the needs of small suppliers and the needs of the beneficiaries in requesting documentation that will provide us with sufficient information to determine the financial soundness of a supplier.

g. Comments on Supplier Networks

The May 1, 2006 proposed rule included a proposal to permit small suppliers to form a legally binding network with other small suppliers for the purpose of submitting a bid. Many commenters believed that the option to

form a network is not a realistic solution for ensuring that small suppliers participate in the competitive bidding program. They expressed concern that forming a network could violate the Federal antitrust laws because those laws do not permit suppliers to reach a mutual consensus on pricing. They also stated that the proposed rule would require suppliers to agree on proposed prices for all items within a competitive bidding product category. They further believed the proposed rule is complex, and that suppliers would not have sufficient time to form a network and comply with all the requirements to meet the competitive bidding implementation timelines.

We agree that forming a network may pose a challenge for some suppliers. However, forming a network is a business decision and we continue to believe that networks should be an option for small suppliers to promote competition and efficiencies that could improve services to beneficiaries. The proposed rule was published May 1, 2006. We believe sufficient notice has been given for suppliers to consider network options and plan accordingly. We believe that our network policy is constructed in a way that maximizes participation of suppliers.

Suppliers that pursue the network option must comply with all applicable Federal antitrust laws. We have taken steps to ensure that each network is not in violation of Federal antitrust laws or exhibits otherwise anticompetitive behavior by including the following requirements:

Network participation will be limited to small suppliers that cannot compete in competitive bidding because they cannot independently service the entire CBA. A written certification will be required from each network supplier that it is unable to compete (that is, cannot service the entire CBA on its own) without joining a network (§ 414.418(b)(6)). We believe this provision will help ensure that a small supplier has a legitimate need to participate in a network. This will minimize the potential for anticompetitive behavior and will assist small suppliers by expanding their opportunity to participate. Network members' Medicare market share at the time of bidding when added together cannot exceed 20 percent of the Medicare market (§ 414.418(b)(7)). This would guard against excessive network market share. Network membership in any one network will be limited to 20 small suppliers to help promote competition among suppliers. Our rationale for limiting the number of small suppliers to no more than 20 is the following:

- This would help avoid collusion which could lead to less competition and higher bids.
- It would ease administrative burden and reduce the overall cost of evaluating each network.
- A 20-supplier network would be able to serve an entire CBA even if each of its members is small. Networks are required to form a legal entity that functions as the bidder. We do not believe that a network should include more members than is necessary to service an entire CBA because other suppliers who are not in networks have to service an entire CBA.

The network provisions do not establish a safe harbor or a safety-zone or in any way protect anticompetitive behavior. All of the Federal laws and regulations that govern anticompetitive behavior, including the Federal antitrust laws, will fully apply.

A few commenters agreed with our proposal to require that suppliers participating in a network form a discrete legal entity and stated that this would prevent the commingling of Medicare funds, as well as violations of the Federal anti-kickback statute, self-referral rules and regulations, and allegations of unfair business practices among the participating network suppliers. Other commenters believed that requiring each network to independently bid defeats the entire purpose of networking. They disagreed with the primary legal entity being responsible for billing Medicare and receiving the payments. They believed that each supplier should be responsible for its own finances.

We appreciate the support for our proposal that each network must form a legal entity. We agree that the primary legal entity should not be responsible for billing Medicare and receiving the payments and have revised § 414.418(b)(4) to reflect this rule. We are requiring each member of the network to submit its own Medicare claims and are specifying that each member will be paid directly for Medicare products and services furnished as part of its individual business. This is consistent with our current Medicare policies for each supplier to submit claims to receive Medicare payments.

A few commenters believed that networks that provide multiple product categories pose a risk because not all the network members will furnish all the product categories; therefore, beneficiaries may not have access to services. They recommended that CMS add requirements to ensure that networks bids are scrutinized to ensure that each network has appropriate mechanisms to service the entire CBA. The commenters recommended that each beneficiary have a single point of contact for the network to ensure satisfactory resolution of performance problems or other issues across the CBA. They also asked if subcontractors needed to meet the same requirements as a contract supplier. Based on these concerns we are requiring that networks form a legal entity, such as a joint venture or limited partnership. Each network member will also be required to satisfy all applicable bidding requirements. Each network member is equally responsible for the quality of care, service, and items that it delivers to Medicare beneficiaries. If any member of the network falls out of compliance with this requirement, we have the option of terminating the network contract.

A few commenters questioned why a limit of 20 percent of the market share was assigned to the network, leaving 80 percent of the Medicare market for a large company. They suggested allowing network members to obtain market share not to exceed 35 percent, as specified in the Department of Justice monopoly guidelines. A few commenters requested that CMS disclose the methodology that will be used to calculate the market share and monitor changes over the course of the contract.

In this final rule, we have decided to finalize the proposed 20-percent market share limitation on the capacity of networks. However, once a network receives a contract, there is no limit on what percentage of the demand in the CBA that the network can furnish. We believe that this will ensure a sufficient number of contract suppliers and provide beneficiaries with more variety and choice.

Some commenters suggested that CMS allow suppliers to join up to two networks, recognizing that many suppliers currently participate in several networks. They believed that this would ensure that the participating supplier is not disadvantaged by a requirement to commit to a single network bid. We agree with the commenters. We will allow suppliers to join more than one network, but a supplier cannot join more than one network for purposes of furnishing items in the same product category in the same CBA. We believe that this policy is necessary because, without it, the competitive bidding process would be undermined by allowing suppliers to bid against themselves for the same product category. In other words, if a

supplier wants to independently furnish items for a product category, it would not be able to join another network that furnishes the same product category in the same CBA. However, a supplier that wishes to furnish products that are in two different product categories would be able to join a different network for each product category or submit a bid as an individual supplier for one product category while joining a network for the other product category.

A few commenters asked how networks would obtain a supplier billing number. The Medicare competitive bidding implementation contractor will assign each network a bidder number that will be used to monitor the network. As stated earlier, each member of the network will be allowed to submit its own claims and receive Medicare payments directly.

A few commenters requested that CMS clarify whether each supplier that is a member of a network would be required to provide all of the items for the product category for which the network submits a bid. The member of the networks would be required to provide all the items within the product category for which the network submits a bid. This is consistent with our requirement that all winning suppliers must furnish all items in a product category. Therefore, each member of the network must be able to provide all items within the product categories for which the network has submitted bids. Although the network must provide items to any beneficiary throughout a CBA, each member of the network is not responsible for providing an item throughout the entire CBA.

4. Description and Estimate of the Number of Small Entities

As of January 2006, the SBA defines a small business as generating less than $6.5 million in annual receipts. We worked with the SBA to define small supplier for the Medicare DMEPOS Competitive Bidding Program. In this final rule, we are defining a small supplier as a supplier that generates gross revenue of $3.5 million or less in annual receipts. Before we receive supplier bids, we do not have information on each supplier's total revenue. We only have information on suppliers' Medicare revenues. As a result, we had to make an assumption about what percent of a supplier's revenues come from Medicare. We looked at filings by public DMEPOS companies and, based on that information, we assume one-half of the average supplier's revenues come from Medicare DMEPOS.

Suppliers that furnish products in a CBA in at least one product category selected for competitive bidding will be affected by this program. A supplier that does not furnish competitively bid items and services to beneficiaries in a CBA will not be affected. Based on analysis of CY 2005 Medicare DMEPOS claims, we estimate the number of suppliers affected in the Regulatory Impact Analysis as described below. This analysis preceded finalization of the product categories and selection of bidding areas and is thus based on a number of assumptions, as detailed in the Regulatory Impact Analysis. Based on CY 2005 claims data, the average MSA in the top 25 MSAs, excluding New York, Los Angeles, and Chicago, has 2,896 DMEPOS suppliers that furnish any DMEPOS product and 1,972 suppliers that furnish products subject to competitive bidding and could potentially be affected by competitive bidding. 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 [1]

[$3.5 million or less in Medicare allowed charges]

Bidding year	Number of affected small suppliers	Total number of affected suppliers	Percent
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

[1] Some suppliers furnish products in more than one selected MSA. Consequently, some suppliers may be counted more than once.

5. Projected Reporting, Recordkeeping, and Other Compliance Requirements

The primary compliance cost of the proposed rule will be the cost of bid submission. As part of a separate rule, all DMEPOS suppliers will be required to gain and maintain accreditation which may lead to significant compliance costs. However these costs are not considered under the competitive acquisition program, and thus we concentrate on the costs of bidding which includes time devoted to supplier education efforts, completing forms, and providing documentation.

Bidders must decide whether to bid, request or download an RFB, attend a bidders conference (optional) and read outreach materials, decide how much to bid for each item, and prepare and submit a bid. In the demonstration, bidders in Polk County, Florida reported spending a total of 40 to 100 hours submitting bids. In the proposed rule we assumed that suppliers would use the midpoint number of hours, 70 hours. We have reduced our estimate of the required hours to 68, due to changes we made to condense the bidding forms requirements, based on comments we received on the proposed rule. According to 2005 Bureau of Labor Statistics (BLS) data, the average hourly wage for an accountant and auditor was $25.54 (National Compensation Survey: Occupational Wages in the United States, June 2005, U.S. Department of Labor, Bureau of Labor Statistics, Bulletin 2568, August 2006. *http://www.bls.gov/ncs/ocs/sp/ncbl0832.pdf*).

Accounting for inflation and overhead, we assume suppliers will incur $33.87 per hour in wage and overhead costs. Based on this information, we assume that a supplier that bids will spend $2,303.16 ($33.87 * 68) to prepare its bid, taking into consideration that the number of product categories included in a bid, on average, will vary by supplier. We calculate the total cost for all supplier bids, including those of both future winning and future losing suppliers. Therefore, we expect that CY 2007 total supplier bidding costs for 15,973 bids will be $36,788,375 ($2,303.16 * 15,973). This estimate is clearly dependent on our assumption that 81 percent of eligible suppliers will bid. Our estimates incorporate the fact that a single organization may submit bids in more than one CBA in each round. For example, a supplier that has 15 offices in the country and currently serves all 10 of the CBAs to be included in the initial round of bidding is counted 10 times in our estimates. Our estimate of the time required for bidding assumes that suppliers in the competitive bidding program will bid on about the same number of individual product categories as suppliers bid on during the demonstration project. We expect that supplier bidding costs will rise with the number of product categories bid upon; however, because there are fixed costs associated with deciding whether to participate in the competitive bidding program and some of the bidding forms are only filled out once, the increase in costs associated with each additional product category may be relatively small. Therefore, our estimate of the time required per bid should be reasonably accurate unless suppliers bid on significantly more or fewer product categories than they bid on during the demonstration.

6. Agency Efforts to Minimize the Significant Economic Impact on Small Entities

Small suppliers constitute the large majority of DMEPOS firms, and we anticipate they will form the majority of contract suppliers. Therefore, consideration of small suppliers influenced virtually all aspects of the final rule. We detailed the aspects of the final rule that, in particular, are intended to minimize the impact on small entities. These aspects and the respective section of the preamble of this final rule are as follows:

- Grandfathering of suppliers (see section VI.D.3.a of this final rule).
- Requirement for physicians and certain nonphysician practitioners to submit bids (see section VI.G.3 of this final rule).
- Product categories for bidding purposes (see section VI.G.4 of this final rule).
- Financial standards (see section VII.C, of this final rule)
- Selection of small suppliers (see section XI. of this final rule).
- Opportunity for networks (see section XII. of this final rule)

C. Anticipated Effects

We can anticipate the probable effects of this final rule, but the actual effects will vary depending on which CBAs and product categories are ultimately selected for competitive bidding under the Medicare DMEPOS Competitive Bidding Program. The analysis that follows, taken together with the rest of this preamble, constitutes the final regulatory impact analysis.

As a result, for the purpose of this impact analysis, it is necessary to make several assumptions. These assumptions are due to the uncertainty concerning the actual number of suppliers that will participate, the associated bid amounts, and the specific items and areas for which competitive bidding will be conducted.

First, we assume that 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. We also assume rebidding will only occur every 3 years.

Second, we assume that competitive bidding will occur in 10 of the largest MSAs in CY 2007, excluding New York, Chicago, and Los Angeles. We exclude the three largest MSAs in CY 2007 because we are not including them in the initial phase of implementation. We are excluding the three largest MSAs because we would like to gain more experience in smaller markets before we enter into the largest markets. For the initial competition, we assume that bidding will take place in CY 2007, bids will be evaluated in CY 2007, and prices will go into effect on April 1, 2008. The second round of bidding will take place in 70 of the largest MSAs in CY 2008, and the prices will go into effect on April 1, 2009. The next round of bidding will take place in 10 additional MSAs and will occur in CY 2009, with bid prices going into effect on January 1, 2010. An additional round of bidding will include 10 MSAs and will occur in CY 2010, with bid prices going into effect on January 1, 2011.

Third, we made some assumptions about which product categories would be selected for competitive bidding. We recognize that potential savings, implementation costs, the number of affected suppliers, and supplier bid costs all depend on which product groups are ultimately selected. The product categories have yet to be decided. We expect that approximately 10 product categories will be selected for competitive bidding for CY 2007 and as many as 7 or 8 of the selected product categories will be among the 10 largest in terms of allowed charges. The remaining 2 or 3 product categories will come from the top 20 policy groups ranked by allowed charges. Table 11 shows the top 20 eligible DMEPOS policy groups and their CY 2005 allowed charges.

TABLE 11.—CY 2005 ALLOWED CHARGES: TOP 20 ELIGIBLE DME POLICY GROUPS

Rank	Policy group	Allowed charges 2005*	Percent of eligible DMEPOS charges
1	Oxygen Supplies/Equipment	$2,669,015,203	34
2	Wheelchairs/POVs	1,512,581,843	19
3	Diabetic Supplies & Equipment	1,176,121,037	15
4	Enteral Nutrition	582,085,753	7.5
5	CPAP	378,084,371	4.9
6	Hospital Beds/Accessories	320,372,566	4.1
7	Support Surfaces	184,266,860	2.4
8	Negative Pressure Wound Therapy	169,012,105	2.2
9	Infusion Pumps & Related Drugs**	157,396,292	2.0
10	Respiratory Assist Device	135,023,095	1.7

TABLE 11.—CY 2005 ALLOWED CHARGES: TOP 20 ELIGIBLE DME POLICY GROUPS—Continued

Rank	Policy group	Allowed charges 2005*	Percent of eligible DMEPOS charges
11	Walkers	106,661,034	1.4
12	Nebulizers	97,574,696	1.3
13	Ventilators	70,625,578	0.9
14	Commodes/Bed Pans/Urinals	47,861,299	0.6
15	Patient Lift	27,768,236	0.4
16	TENS	23,536,834	0.3
17	Seat Lift Mechanism	17,159,455	0.2
18	CPM Device	17,023,378	0.2
19	Suction Pump	14,096,633	0.2
20	Off-the-shelf Orthotics	13,807,205	0.2
Total for 20 Groups		7,719,487,197	99

*2005 allowed charges projected based on 98 percent claims processed through March 2006.
**Includes $50 million in allowed charges for drugs.

However, we reiterate that the discussion in this impact analysis should in no way be interpreted as signifying which product categories will be selected for the actual competitive bidding program. Our product category selection for this impact analysis is only to assist us in estimating the potential savings, costs of implementation, and supplier and beneficiary impacts.

Fourth, we assume that the Medicare DMEPOS fee schedule will increase at the rate of inflation for those years in which a statutory freeze has not been put in place by the Act. We base our estimates on the expected growth in Medicare Part B expenditures from the Trustees Reports. (Tables IV.F.2 and IV.F.3 of the 2004 Medicare Trustees Report.).

This final rule is expected to affect the Medicare program and its beneficiaries, certain CMS contractors, and DMEPOS suppliers. Although the workload of referral agents, including hospital discharge planners and some health care practitioners, appeared to increase during implementation of the demonstration, we do not anticipate that competitive bidding will result in a large, ongoing burden on referral agents. For many DMEPOS product categories, referral agents play an important role in helping beneficiaries select DMEPOS suppliers that can meet the beneficiaries' needs. During the demonstration, those referral agents who previously referred beneficiaries to non-demonstration suppliers had to change their referral patterns. It is difficult to quantify this burden because we have no data on the number of referral agents who will be affected, nor do we have information on the effort associated with identifying a new supplier. We note that we plan to take steps to mitigate any burden that might arise for referral agents. For example, we are planning an extensive educational campaign for suppliers, referral agents, and beneficiaries. Educational materials, including an on-line supplier directory, will expedite the process for identifying and locating contract suppliers and therefore minimizing any burden. In addition, we will post on the internet the list of brands that each contract supplier furnishes. This brand information should be extremely useful for referral agents and may even reduce burden under the program.

The DMEPOS supplier industry is expected to be significantly impacted by this final rule. However, not all suppliers will be affected directly by the competitive bidding program. Suppliers that furnish products in a CBA in at least one product category selected for competitive bidding will be affected. A supplier that does not furnish competitively bid items and services to beneficiaries in a CBA will not be affected. Based on analysis of CY 2005 Medicare DMEPOS claims, we estimate that approximately 30,000 suppliers offer at least one product eligible for competitive bidding and are located in one of the largest 100 MSAs and, therefore, could be impacted by the program. Some of these suppliers will be affected in multiple CBAs if they offer products in more than one CBA.

Based on our analysis of CY 2005 claims data, we also estimate that approximately 85 percent of registered DMEPOS suppliers are considered small according to the SBA definition. According to the SBA, ''A small business is a concern that is organized for profit, with a place of business in the United States, and which operates primarily within the United States or makes a significant contribution to the U.S. economy through payment of taxes or use of American products, materials or labor. Further, the concern cannot be dominant in its field, on a national basis. Finally, the concern must meet the numerical small business size standard for its industry. SBA has established a size standard for most industries in the U.S. economy.'' The size standard for NAICS code 532291, Home Health Equipment Rental, is $6.5 million. (See the Web site: *http://www.sba.gov/size/sizetable2002.html*, read November 30, 2006.)

Many of these suppliers provide minimal amounts of DMEPOS, and thus the remaining larger suppliers control significant market share. We anticipate that the fixed costs required to undergo the bidding process may be a larger deterrent to small businesses than larger firms. Because suppliers can choose whether to submit a bid for the Medicare DMEPOS Competitive Bidding Program, this final rule imposes no direct costs and, therefore, does not reach the $120 million direct cost threshold under the UMRA. While not included in this final rule, we expect that the separate MMA requirement for accreditation of suppliers will result in added supplier costs beyond those included in this final rule.

Comment: One commenter stated that the RFA analysis of the impact of the proposed regulation was incomplete and inadequate because it did not consider the impact of the proposed regulation on long-term care hospitals and Medicare beneficiaries who reside in these facilities. Other commenters suggested that long-term care facilities would incur increased costs and the quality of treatment received by their patients would be diminished if they are included in the Medicare DMEPOS Competitive Bidding Program and offered alternatives to competitive

bidding that they believed would achieve cost savings.

Response: We considered the impact of the Medicare DMEPOS Competitive Bidding Program on all suppliers. We believe our estimates reflect the costs on average that will be incurred by the suppliers that participate in the program. If a long-term care hospital decides to submit a bid to furnish items and services under the program, its bid should reflect its costs to furnish those items and services. In addition, the quality standards for DMEPOS suppliers require that suppliers furnish quality items and services.

Comment: One commenter disagreed with CMS' assumption that the DMEPOS fee schedule will increase at the rate of inflation for those years in which a statutory freeze is not in effect and that total charges will increase at the same rate as Medicare Part A and Medicare Part B expenditures (71 FR 25691). The commenter suggested that non-DME, non-home health care costs are the driving forces causing increases in these programs. Other commenters suggested that home care expenditures are not increasing and that rising hospital, nursing home, physician, and medication costs were the causes of rising overall Medicare expenditures.

Response: Based on the public comments we received, we have clarified in this final revised impact analysis that our estimates on expected growth will be based on Medicare Part B expenditures. DMEPOS expenditures have been growing at varying rates in recent years (expenditures for 26 product categories rose 5 percent between 2004 and 2005 and 21 percent between 2002 and 2005), and the rate of growth has varied widely between product categories, making precise estimates of growth for DMEPOS difficult. We believe that the overall growth rate for Medicare Part Be expenditures provides a reasonable estimate of the growth rate for DMEPOS because both growth rates are driven by changes in Part B enrollment and overall growth in medical care use. To address inflation, we will be asking the suppliers to submit bids that include all costs associated with furnishing each item for all 3 years of the contract.

Comment: A number of commenters objected to the data in Table 11 of the proposed rule (71 FR 25691) indicating that 2003 allowed charges for infusion pumps and related devices were approximately $149 million. These commenters believed that the correct amount was approximately $87 million. The commenters believed that the $149 million amount inappropriately includes charges for insulin and insulin pumps which are not provided by infusion pharmacies.

Response: The data in the proposed analysis include allowed charges for insulin and infusion pumps. Although these items may not be furnished by infusion pharmacies, they are included because they are subject to competitive bidding under the Act.

Comment: Several commenters disagreed with the statement in the preamble of the proposed rule (71 FR 25692) that the UMRA does not apply to this rule. One commenter suggested that virtually all affected suppliers would submit bids (and thus would incur costs) and even using CMS estimates (that the commenter believed to be too low), the costs for the CY 2008 round of bidding would be $178 million, an amount that the commenter believed exceeded the UMRA's threshold of $120 million.

Response: We have updated our estimates in this final rule using CY 2005 data. Based upon the estimated number of suppliers that will submit bids, the costs of submitting bids, and the fact that the average number of suppliers per CBA will decrease in future rounds of competitive bidding, we do not expect that costs will exceed the UMRA's $120 million threshold.

D. Implementation Costs

CMS will incur administrative costs in connection with the implementation and operation of the Medicare DMEPOS Competitive Bidding Program, which can affect the net savings that can be expected under this final rule. However, 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.

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. In addition to the initial startup costs, we will also incur maintenance costs and bid solicitation and evaluation costs. We will need to pay maintenance costs every year for the running of the program. However, we will only need to pay bid costs in the years in which competitive bidding is conducted. Yearly maintenance costs will depend on the number of CBAs in which the program has been implemented, while bid solicitation and evaluation costs will depend on the number of sites that have bidding that year.

Our maintenance costs will include a small staff to oversee the program, office costs for the staff, as well as staff travel costs, and overhead. In addition, the CBIC(s) will be responsible for most of the program maintenance. The maintenance costs could also include the costs for an ombudsman(s) to assist suppliers, beneficiaries, and referral agents with the competitive bidding process and questions. We also expect to incur costs for education and outreach expenses such as staff resources and material costs for producing education materials and supplier directories.

We will incur bid costs in the years in which we conduct competitive bidding and when we evaluate bids. These costs will be a direct result of the bid solicitation and evaluation process. Bid solicitation costs include costs associated with mailing necessary information to suppliers, printing, duplicating, and the cost of administering an electronic bidding program. The actual costs will vary by CBA and will depend on the number of potential suppliers. We will incur bid evaluation costs whenever bidding occurs in a CBA. 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. However, because the Medicare DMEPOS Competitive Bidding Program uses quality standards and accreditation as a separate process, we expect that the time required to evaluate bids will be less than in the demonstration. The total bid evaluation costs will ultimately depend on the number of suppliers that choose to submit bids.

Comment: Several commenters believed that the regulatory analysis in the proposed rule significantly underestimated the administrative costs associated with implementing the competitive bidding program, further reducing any net savings. One commenter referred to a study that estimated that CMS would need 1,600 new staff to implement the proposed regulation.

Response: As explained in the proposed rule, we are making the best estimates based on the experience in the demonstrations. Even though these estimates will be affected by the number of suppliers and items for which we do competitive bidding, nevertheless they represent our best estimates. After careful review of the study referenced by the commenter, we disagree with the estimate of the number of extra staff

needed to implement the proposed regulation. We believe our original estimates better reflect the resource needs for the competitive bidding program.

E. Program Savings

We estimate significant savings from the Medicare DMEPOS Competitive Bidding Program. Our estimates of gross savings utilize as a starting point the results in the demonstration. Excluding surgical dressings, which are not eligible for competitive bidding, the average product group savings rate in the demonstration ranged from 9 to 30 percent per round, with most product groups having about a 20-percent savings. Table 12 shows the savings rate for selected product groups and CBAs by round during the DMEPOS demonstration.

TABLE 12.—DMEPOS COMPETITIVE BIDDING DEMONSTRATION SAVINGS RATES

Product group	Polk County Round 1	Polk County Round 2	San Antonio
Oxygen Equipment and Supplies	$2,364,811 (17%)	$1,525,490 (20%)	$2,096,707 (19%)
Hospital Beds and Accessories	$290,715 (23%)	$195,140 (31%)	$644,514 (19%)
Urological Supplies	$36,169 (18%)	$12,585 (9%)	Not included
Surgical Dressings	−$30,321 (−12%)	−$637 (−1%)	Not included
Enteral Nutrition	$342,251 (17%)	Not Included	Not included
Wheelchairs and Accessories	Not included	Not included	$796,617 (19%)
General Orthotics	Not included	Not included	$89,462 (23%)
Nebulizer Drugs	Not included	Not included	$1,020,072 (26%)

Source: Evaluation of Medicare's Competitive Bidding Demonstration for DMEPOS, Final Evaluation Report (November 2003), pages 90 and 92.

Under this final rule, we will set prices for individual items equal to the median winning bid for that item. In contrast, the demonstration used a more complicated pricing rule that adjusted fees for each item to ensure that each suppliers overall payment was equal to the pivotal bid. 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.

Table 13 shows the impact on the FFS program for the 10 policy groups. In the table, savings are reported as negative values. The savings are attributable to the lower payment amounts anticipated from competitive bidding. The table shows the reduction in Medicare allowed charges, without any impact on the Medicare Advantage program, associated with the program for the calendar year. The impact includes reductions in Medicare payments (80 percent) and reductions in beneficiary coinsurance (20 percent).

TABLE 13.—PROGRAM IMPACT FOR 10 POLICY GROUPS

[in millions] *

	Calendar Year					
	2007	2008	2009	2010	2011	2012
Allowed Charges	$0	−$108	−$766	−$1126	−$1224	−$1301
Medicare Share of Allowed Charges (80 percent of allowed charges)	0	−86	−613	−901	−979	−1041
Beneficiary Costs (20 percent of allowed charges)	0	−22	−153	−225	−245	−260

* Numbers may not add up due to rounding.

Table 14 presents the impact differently than Table 13. In contrast to Table 13, which is on a Medicare allowed charge-incurred basis and does not consider the Medicare Advantage program impact, Table 14 considers fiscal year cash impact on the entire Medicare program, including Medicare Advantage for the fiscal year rather than calendar year. The fiscal year–calendar year distinction is an important one when comparing savings. For example, the prices for the Medicare DMEPOS Competitive Bidding Program will be in effect for 6 months of fiscal year 2008, but for 9 months of calendar year 2008.[1] Table 14 considers the impact on program expenditures, and does not include beneficiary coinsurance.

Finally, the estimates in Table 14 incorporate spillover effects from the competitive acquisition program onto the Medicare Advantage program. The expectation is that lower prices for DME products in FFS will lead to lower prices in the Medicare Advantage market.[2]

[1] Fiscal year 2008 will begin October 1, 2007, and the Medicare DMEPOS Competitive Bidding Program payments become effective on April 1, 2008.

[2] In addition, most managed care plan rates are linked to FFS expenditures. Therefore, a decrease in FFS expenditures should translate into a

TABLE 14.—FISCAL YEAR COST ON THE MEDICARE PROGRAM

[in millions]

Fiscal year	Program impact	Beneficiary costs
2007	$0	$0
2008	−70	−20
2009	−530	−130
2010	−1,000	−250
2011	−1,240	−310
2012	−1,370	−340

Comment: Several commenters believed that the regulatory analysis overstated the potential savings of the proposed rule because many of the savings in the earlier demonstrations can no longer be achieved in other areas of the country due to changes in payment policies for major categories of DMEPOS such as oxygen, subsequent CPI freezes, and increases in supplier costs in areas such as fuel and labor. Another commenter suggested that potential savings would be reduced if suppliers submit higher bids in order to account for costs related to quality standards and accreditation costs. One commenter recommended that CMS recalculate these estimates. Another commenter stated that some of these factors also resulted in understating the adverse impact of the proposed regulations on suppliers.

Response: We have updated the tables in the impact analysis of this final rule to reflect all of the recent changes in policy related to items subject to competitive bidding, including any payment reductions. 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.

decrease in Medicare Advantage plan payment rates. The rate calculations for the Medicare Advantage program reflect all the FFS adjustments, including the Medicare DMEPOS Competitive Bidding Program savings. The Managed Care add-on increases the FFS savings by 24.9 percent in CY 2008. This is a dynamic number that increases over time.

F. Effect on Beneficiaries

Possible impacts on beneficiaries are a primary concern during the design and implementation of the Medicare DMEPOS Competitive Bidding Program. While there may be some decrease in choice of suppliers, there will be a sufficient number of suppliers to ensure adequate access. We also expect there will be an improvement in quality because we will more closely scrutinize the suppliers before, during, and after implementation of the program. The evaluation of the impact of the DMEPOS competitive bidding demonstration on patient access to care and quality showed minimal adverse results (Final Report to Congress: Evaluation of Medicare's Competitive Bidding Demonstration For Durable Medical Equipment, Prosthetics, Orthotics, and Supplies; *http://www.cms.hhs.gov/DemoProjectsEvalRpts/downloads/CMS_rtc.pdf).* Moreover, because of the quality standards and the provisions in this final rule to ensure access to and the furnishing of quality products, we assume that there will be few negative impacts on beneficiary access, as a sufficient number of quality suppliers will be selected to serve the entire market.

We acknowledge that implementation of competitive bidding may result in some beneficiaries needing to switch from their current supplier if their current supplier is not selected for competitive bidding. However, we anticipate that the necessity of switching suppliers will be minimized because of the existence of grandfathering policies for rental products such as capped rentals. For purchased items that are not grandfathered, some beneficiaries currently using DMEPOS will have to switch from noncontract to contract suppliers. This switch will not be very burdensome, because the beneficiaries will already be making new purchases. We note that, if a beneficiary owns an item subject to competitive bidding, the beneficiary has the choice of having the item serviced by either a noncontract or contract supplier. Beneficiaries who maintain a permanent residence in a CBA who are traveling and need to rent or purchase DMEPOS during their travels will have to make arrangements to receive their equipment either from a contract supplier in their CBA, from a contract supplier in the visited area if that area is in a CBA and the item is included in the competitive bidding for that CBA, or—if the visited area is not in a CBA—from a noncontract supplier who must accept the reimbursement rate from the beneficiaries home CBAs. It is not clear whether this will have a large impact on beneficiaries. There is little evidence on how frequently beneficiaries receiving DMEPOS travel outside their CBA. Under current policy, a traveling beneficiary must already make arrangements for receipt of his or her DMEPOS during travel and payment is already based on the fee schedule for the beneficiary's residence. We do not believe that our policy will have a large impact on beneficiaries because we will ensure that we have a sufficient number of contract suppliers to meet beneficiary demand.

Because beneficiaries face a 20 percent coinsurance rate for DMEPOS, we assume that beneficiary out-of-pocket expenses will decrease by 20 percent of program gross savings for those products for which we do competitive bidding (Table 15).

TABLE 15.—BENEFICIARY COINSURANCE ANNUAL SAVINGS ESTIMATES FOR 10 PRODUCTS

[in millions]

Calendar year	10 products
2007	$0
2008	22
2009	153
2010	225
2011	245
2012	260

Comment: One commenter argued that since the analysis projects that 37 percent of suppliers will not become contract suppliers, the impact on beneficiaries, especially those requiring diabetic supplies and equipment, will be greater than the analysis indicates.

Response: Our methodology will ensure that beneficiaries requiring diabetic supplies and equipment will have access to a sufficient number of suppliers to meet their needs. As explained in various sections of the preamble to this final rule, we will be taking several steps to ensure that there will be a sufficient number of suppliers to meet beneficiary demand. These steps include the following:

- Evaluating the bidding suppliers' capacity to ensure that there is enough supplier capacity to meet the Medicare demand for each product category in each CBA.
- Implementing a small supplier target under which we will attempt to offer a sufficient number of small suppliers the opportunity to participate in the Medicare DMEPOS Competitive Bidding Program.
- Requiring that all commonly owned or controlled suppliers must submit a single bid on behalf of all locations

within the CBA, and additional locations that would furnish items in the CBA.

• Establishing a capacity calculation methodology that caps the estimated capacity of each bidding supplier capacity at 20 percent for purposes of determining the pivotal bid for the product category.

In addition, our estimates indicate that beneficiaries will save money on their diabetic supplies and equipment under the program.

G. Effect on Suppliers

We expect DMEPOS suppliers to be significantly impacted by the implementation of this final rule. We assume that suppliers may be affected in one of three ways as follows:

• Suppliers that wish to participate in competitive bidding will have to incur the cost of submitting a bid.

• Noncontract suppliers that furnished competitively bid items before the Medicare DMEPOS Competitive Bidding Program took effect (including suppliers that do not submit bids) will see a decrease in revenues because they will no longer receive payment from Medicare for competitively bid items.

• Contract suppliers will see a decrease in expected revenue per item as a result of lower allowed charges from lower bid prices. However, because there will be fewer suppliers, a contract supplier's volume could increase. As a result, because we do not know which effect will dominate, the net effect on an individual contract supplier's revenue is uncertain prior to bidding. The increase in the supplier's volume could help offset the decrease in revenue per item.

1. Affected Suppliers

Based on CY 2005 claims data, the average MSA in the top 25 MSAs, excluding New York, Los Angeles, and Chicago, has 2,896 DMEPOS suppliers that furnish any DMEPOS product and 1,972 suppliers that furnish products subject to competitive bidding and could potentially be affected by competitive bidding.

We estimate that 28,960 suppliers will provide DMEPOS 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; 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.

Deciding whether or not to submit a bid is a business decision that will be made by each DMEPOS supplier. We expect that most suppliers providing competitively bid items will choose to participate in order to maintain and expand their businesses. For the calculations in the proposed rule, 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. Based on comments we received on the May 1, 2006 proposed rule, we will permit physicians and certain nonphysician practitioners to furnish certain limited items as part of their professional practice without submitting a bid and being awarded a contract, provided certain conditions are met. These physicians and non-physician practitioners would be required to submit bids and be awarded contracts if they wish to furnish other types of competitively bid items. These physicians and non-physician practitioners account for about 10 percent of all DMEPOS suppliers, according to the NSC. Therefore, we now assume that 81 percent (= 0.9 *0.9) of affected suppliers will submit bids. Based on this assumption, 15,973 suppliers 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.

It is difficult to estimate the impact the Medicare DMEPOS Competitive Bidding Program will have on noncontract suppliers. The effect will depend on how much revenue the supplier previously received from Medicare and whether the supplier continues to provide services to existing beneficiaries under the grandfathering policies. Estimates can be made by making assumptions about these factors. For example, if bidding occurred in 10 product categories, losing suppliers previously provided 50 percent of allowed charges in these product categories, and losing suppliers did not continue to serve any existing beneficiaries, the average lost Medicare allowed charges per losing supplier per CBA would be between $35,000 and $40,000. Under these assumptions, the total allowed charges lost by losing suppliers would be $275 million in CY 2008, the first full year after the prices take effect, and increase to almost $2 billion in CY 2011. These estimates reflect our best assumptions. As noted, because of the nature of competitive bidding, winning bidders will absorb much of the allowed charges lost by losing suppliers.

Suppliers that submit bids will incur a cost of bidding. Bidders must decide whether to bid, request or download an RFB, read the RFB, attend a bidders conference (optional) and read outreach materials, decide how much to bid for each item, and prepare and submit a bid. In the demonstration, bidders in Polk County, Florida reported spending a total of 40 to 100 hours submitting bids. In the proposed rule we assumed

that suppliers would use the midpoint number of hours, 70 hours. We have reduced our estimate of the required hours to 68, due to changes we made to condense the bidding forms requirements, based on comments we received on the proposed rule. According to 2005 Bureau of Labor Statistics (BLS) data, the average hourly wage for an accountant and auditor was $25.54 (National Compensation Survey: Occupational Wages in the United States, June 2005, U.S. Department of Labor, Bureau of Labor Statistics, Bulletin 2568, August 2006. *http://www.bls.gov/ncs/ocs/sp/ncbl0832.pdf*). Accounting for inflation and overhead, we assume suppliers will incur $33.87 per hour in wage and overhead costs. Based on this information, we assume that a supplier that bids will spend $2,303.16 ($33.87*68) to prepare its bid, taking into consideration that the number of product categories included in a bid, on average, will vary by supplier. We calculate the total cost for all supplier bids, including those of both future winning and future losing suppliers. Therefore, we expect that CY 2007 total supplier bidding costs for 15,973 bids will be $36,788,375 ($2,303.16*15,973). This estimate is clearly dependent on our assumption that 81 percent of eligible suppliers will bid. Our estimates incorporate the fact that a single organization may submit bids in more than one CBA in each round. For example, a supplier that has 15 offices in the country and currently serves all 10 of the CBAs to be included in the initial round of bidding is counted 10 times in our estimates. Our estimate of the time required for bidding assumes that suppliers in the competitive bidding program will bid on about the same number of individual product categories as suppliers bid on during the demonstration project. We expect that supplier bidding costs will rise with the number of product categories bid upon; however, because there are fixed costs associated with deciding whether to participate in the competitive bidding program and some of the bidding forms are only filled out once, the increase in costs associated with each additional product category may be relatively small. Therefore, our estimate of the time required per bid should be reasonably accurate unless contract bidders bid on significantly more or fewer product categories than they bid on during the demonstration.

Comment: One commenter believed that the statement in the impact section of the proposed rule that not all suppliers will be affected directly by the competitive bidding process (71 FR 25691) is not accurate because the commenter believed that costs for mandatory accreditation alone will force small suppliers out of business. The commenter asked questions relating to the basis for determining that an accountant would prepare the bid and that the cost per hour of $31.25 is appropriate. The commenter believed that it would cost small suppliers more to prepare and submit bids because large suppliers have more experience with managed care contracts and may be bidding in multiple MSAs.

Response: The accreditation program is mandatory and affects all DMEPOS suppliers; therefore, it is not a cost attributable to the Medicare DMEPOS Competitive Bidding Program. As we explained in the proposed rule (71 FR 25694), we used 2003 BLS data, adjusted for inflation and overhead, to arrive at our estimate of $31.25 per hour in wage and overhead costs for an accountant and auditor to prepare a supplier's bid. In our current estimates, we have used 2005 BLS data on wages, and adjusted this number to account for inflation through 2007. We took the midpoint of the reported number of hours to prepare bids for the demonstration projects to develop our estimate of the number of hours needed to prepare a bid. We believe that these average estimated costs would be the same for large or small suppliers. We are not requiring that suppliers use accountants or auditors to prepare the bid submission form. However, to calculate cost estimates for completing the form, we used the wages for accountants or auditors as a benchmark to determine the estimated costs to the supplier.

In CY 2008, we will conduct competitive bidding in 70 MSAs, which may include New York, Los Angeles, and Chicago; and in CYs 2009 and 2010, we will add additional areas. This will increase the number of affected suppliers, contract suppliers, and noncontract suppliers. For the purposes of the impact analysis, we assume that there will be at least 10 additional large CBAs added in both CYs 2009 and 2010. We also assume bid cycles will be 3 years in length. Under our assumptions, we will conduct bidding for the initial 10 CBAs in CY 2007, for 70 additional CBAs in CY 2008, and for additional areas in CYs 2009 and 2010. We note that the estimated average number of suppliers per CBA decreases over time. This is because smaller CBAs with fewer beneficiaries and/or lower allowed charges have fewer suppliers. Table 16 summarizes the effect on suppliers for CYs 2007 through 2012. The table includes the costs of rebidding for the first 10 CBAs in 2010, for 70 CBAs in 2011, and for 10 CBAs in 2012. We assume that rebidding will require the same resources as the initial bids. However, it is possible that suppliers will need less time for bidding after gaining experience during their initial round of bidding. Table 16 differs from the corresponding table in the proposed rule because—(1) The number of suppliers is now based on 2005 claims data; (2) the cost per hour to prepare a bid has been increased from $31.25 to $33.87 to reflect wage increases through 2007; (3) the number of hours required to submit bids has been reduced from 70 to 68; and (4) we now estimate that 81 percent (rather than 90 percent) of suppliers will submit bids.

TABLE 16.—SUPPLIERS BIDDING YEARS: CYS 2007–2012

[10 product categories]

	Bidding year					
	CY 2007	CY 2008	CY 2009	CY 2010	CY 2011	CY 2012
Average number of suppliers per CBA	2,896	1,960	1,866	1,791	1,791	1,791
Average number of affected suppliers per CBA	1,972	1,331	1,268	1,218	1,218	1,218
Total number of suppliers	28,960	156,767	167,921	179,075	179,075	179,075
Total number of affected suppliers	19,720	106,470	114,154	121,838	121,838	121,838
Number of bidding suppliers	15,973	70,268	6,224	22,197	70,268	6,224
Cost of bidding	$36,788,375	*$161,838,447	$14,334,868	$51,123,243	$161,838,447	$14,334,868
Number of contract suppliers	9,584	51,744	55,479	59,213	59,213	59,213
Number of noncontract suppliers	10,136	54,726	58,675	62,625	62,625	62,625

TABLE 16.—SUPPLIERS BIDDING YEARS: CYS 2007–2012—Continued

[10 product categories]

	Bidding year					
	CY 2007	CY 2008	CY 2009	CY 2010	CY 2011	CY 2012
Noncontract suppliers as a percent of total suppliers	35%	35%	35%	35%	35%	35%

[1] Actual numbers will depend on CBAs selected, product groups selected, number of suppliers that choose to submit a bid, the prices bid, and the number of contract suppliers selected.
[2] Some suppliers furnish products in more than one selected CBA. Consequently, some suppliers may be counted more than once.
[3] Numbers in the table are rounded.
* The spike in the private sector costs in CY 2008 is due to the addition of 70 additional CBAs that will be included in competitive bidding, which would include the costs to suppliers submitting bids.

As noted in the start of this section, affected suppliers will be impacted by any reduction in Medicare allowed charges that results from the competitive bidding program. The estimated overall reduction in allowed charges is shown in the first row of Table 13.

As previously noted, noncontract suppliers that furnished competitively bid items before the program took effect (including suppliers that do not submit bids) will see a decrease in revenues because they will no longer receive payment from Medicare for competitively bid items. Contract suppliers will see a decrease in expected revenue per item as a result of lower allowed charges from lower bid prices, but this decrease may be offset by an increase in volume. As a result, because we do not know which effect will dominate, the net effect on an individual contract supplier's revenue is uncertain prior to bidding.

2. Small Suppliers

As of January 2006, the SBA defines a small business as generating less than $6.5 million in annual receipts. The SBA definition refers to small businesses rather than ''small suppliers.'' We worked with the SBA to define small supplier for the Medicare DMEPOS Competitive Bidding Program. In cooperation with the SBA, we are defining a small supplier as a small business that generates gross revenue of $3.5 million or less in annual receipts in accordance with 13 CFR 121.104. We are using this new small supplier definition to focus on the smallest of the DMEPOS suppliers in each CBA. Before we receive supplier bids, we do not have information on each supplier's total revenue. We only have information on suppliers' Medicare revenues. As a result, we had to make an assumption about what percent of a supplier's revenues come from Medicare. We looked at filings by public DMEPOS companies and, based on that information, we assume one-half of the average supplier's revenues come from Medicare DMEPOS. Table 17 shows our estimate of the number of affected small suppliers and total affected suppliers. Some suppliers are counted more than once if they are affected in more than one CBA. These estimates are based on 10-digit National Supplier Clearinghouse (NSC) identification numbers. Some organizations have multiple NSC codes representing multiple locations; however, these organizations tend to be larger suppliers. For the purpose of designating small suppliers for program purposes on the basis of revenue, revenue will be calculated based on an organization's tax identification number.

TABLE 17.—NUMBER OF SMALL SUPPLIERS [1]

[$3.5 million or less in Medicare allowed charges]

Bidding year	Number of affected small suppliers	Total number of affected suppliers	Percent
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

[1] Some suppliers furnish products in more than one selected CBA. Consequently, some suppliers may be counted more than once.

Small suppliers are likely to have similar costs for submitting bids as large suppliers. As discussed in the previous section, the average cost of submitting a bid in one CBA is $2,125. The cost of bidding as a share of Medicare revenue will depend on the size of the small supplier's Medicare revenue. The share for a supplier with $50,000 in Medicare revenue would be 4.4 percent; the totals for suppliers with $100,000, $1 million, and $3 million would be 2.2 percent, 0.2 percent, and less than 0.01 percent, respectively.

We considered the following options for minimizing the burden of competitive bidding on small businesses. The first two options were included in the demonstration project. Some of the new options may increase Medicare potential savings, while others may lower or have no effect on potential savings.

• Networks: As stated in section XII. of this final rule, we discuss the option for suppliers to form networks for bidding purposes. Networks are several small suppliers joining together to submit bids for a product category under competitive bidding. This option will allow small suppliers to band together to lower bidding costs, expand service options, or attain more favorable purchasing terms. We recognize that forming a network may be challenging

for suppliers but believe it is still a viable and worthwhile option. Networking was allowed in the demonstration project, but no networks submitted bids. If suppliers can form networks efficiently, they may be able to submit lower bids than the individual suppliers could submit, possibly increasing Medicare savings.

• Not requiring bids for every product category: As discussed in section VII. of this final rule, we will conduct separate bidding for items grouped together in product categories rather than conduct a single bidding program for all items. Therefore, small suppliers will have the option of deciding how many product categories for which they want to submit bids. We believe this will help minimize the burden on small suppliers. This option was available during the demonstration projects, and most suppliers did not bid in every product category. We believe these provisions will allow suppliers to bid on the product category that they can most efficiently supply, and therefore contributes to Medicare savings.

• Small supplier target: Our goal for small supplier participation in each product category will be determined by multiplying 30 percent times the number of suppliers whose composite bids are at or lower than the pivotal bid for the product category. This target was not included in the demonstration project. However, small suppliers were selected in most product categories. We expect that this provision will not affect potential Medicare savings because (1) The target may be met through the normal selection process; and (2) if the target is not met, the additional small suppliers that are selected will have to agree to accept the single payment amount.

• Capacity limit: The capacity limit was not included in the demonstration project. It is possible that the limit will increase the pivotal bid because it may take more suppliers to reach the estimated need for capacity. The higher pivotal bid will reduce potential Medicare savings. We have established a capacity limit for purposes of calculating the pivotal bid such that no supplier's or network's estimated capacity can be considered to meet more than 20 percent of the total need for capacity. Once winning suppliers are selected, we will not exclude networks or suppliers from expanding and exceeding the 20-percent capacity. This will increase the opportunity for small suppliers to be considered and participate in the program. It will also help ensure that we meet the requirement at section 1847(b)(4) of the Act that the Secretary shall award contracts to multiple entities and ensure that we have sufficient contract suppliers to meet the anticipated needs of beneficiaries for competitive bid items on a timely basis.

• Streamlined financial standards: We have streamlined the financial standards to require submission of certain tax information and other basic financial information such as a compiled balance sheet. This provision, which was not included in the demonstration, should make it easier for small suppliers to bid. This has the potential to increase Medicare savings, but it is not clear by how much.

• Permitting physicians and certain non-physician practitioners to furnish certain limited items. We will permit physicians and certain practitioners to furnish certain limited items that are provided to beneficiaries as part of their professional practice without submitting a bid and being awarded a contract, provided that certain conditions are met. These physicians and non-physician practitioners would be required to submit bids if they wished to furnish any other competitively bid items. This provision was not included in the demonstration projects. We do not believe it will have a significant effect on Medicare savings, because relatively few items will be covered.

• Another option we considered but did not adopt would have allowed small suppliers to be exempted from the requirement that a contract supplier must service an entire CBA. However, we note that if a small supplier joined a network, an exception to this rule would apply. This option is also discussed in further detail in section XI. of the preamble of this final rule.

Comment: Several commenters believed that the analysis in the proposed rule suggests potential capacity issues for successful bidders. These commenters argued that if 37 percent of existing suppliers will become noncontract suppliers as a result of not bidding or not submitting successful bids as projected in Table 15 of the proposed rule (71 FR 25695), and the current ratio of beneficiaries to suppliers is roughly the same for contract and noncontract suppliers, each contract supplier will experience, on average, a 59 percent increase in the number of beneficiaries that it must serve. The commenters stated that CMS indicated in the preamble to the proposed rule that the PAOC, during its February 28, 2006 meeting, suggested ''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'' (71 FR 25676). The commenters argued that the proposal creates the possibility that contract suppliers may, therefore, need to expand capacity beyond the 20-percent PAOC estimate. Two commenters noted that such expansions could raise accreditation and licensure issues.

Response: Our methodology will ensure that we select a sufficient number of suppliers to meet the needs of Medicare beneficiaries for competitively bid items. We also note that, as we stated in the preamble to the proposed rule (71 FR 25676), the PAOC indicated that suppliers of products such as diabetes supplies that require relatively little labor may be able to expand capacity even more. We will be selecting multiple contract suppliers, and we will be asking suppliers that plan to increase their capacity to submit plans on how they will achieve this increased capacity. However, no contract supplier will be required to increase its capacity. In addition, as a general rule, for a selection tool, we would not assign more than 20 percent of the total Medicare demand for a product category to any one supplier in estimating how many suppliers we need in a given CBA. Based on these factors, we do not believe that contract suppliers will experience capacity problems.

Comment: A number of commenters believed that the regulatory analysis in the proposed rule minimized the impact of the proposed rule on small businesses because CMS estimates that half of the bidding suppliers will not be selected as contract suppliers. The commenters believed that this group would be disproportionately comprised of small businesses that are now providing DMEPOS and that many, faced with the loss of Medicare business for competitively bid items, would go out of business.

Response: Our current estimates indicate that, of all the DMEPOS suppliers in a CBA, only 22 percent would be noncontract suppliers because they submitted a losing bid. Many DMEPOS items are not subject to competitive bidding. Therefore, many small suppliers such as suppliers of specialty items, for example, are not likely to be affected by competitive bidding. For those suppliers that currently furnish competitively bid items, we are taking specific steps to ensure that they have the opportunity to participate in the competitive bidding program. These steps include offering suppliers the opportunity to form networks, small supplier targets, and

not requiring suppliers to submit bids for all product categories.

H. Accounting Statement

As required by OMB Circular A–4 (available at *http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf*), in the following table below, we have prepared an accounting statement showing the classification of the expenditures associated with the provisions of this final rule. This table provides our best estimate of the decreased expenditures in Medicare payments under the Medicare DMEPOS Competitive Bidding Program as a result of the changes presented in this final rule. All expenditures are classified as transfers to the Federal Government from DMEPOS suppliers.

TABLE 18.—ACCOUNTING STATEMENT—CLASSIFICATION OF ESTIMATED EXPENDITURES, FROM FY 2007 TO FY 2012

Category	Transfers
Annualized Monetized Transfers	547.9 (in Millions).
From Whom To Whom?	To Federal Government from Medicare DMEPOS Suppliers.
Annualized Monetized Transfers	137.0.
From Whom To Whom?	To Beneficiaries from Medicare DMEPOS Suppliers.

I. Executive Order 12866

In accordance with the provisions of Executive Order 12866, this final rule was reviewed by the OMB.

List of Subjects

42 CFR Part 411

Kidney diseases, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 414

Administrative practice and procedure, Health facilities, Health professions, Kidney diseases, Medicare, Reporting and recordkeeping requirements.

■ For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services is amending 42 CFR Chapter IV as set forth below:

PART 411—EXCLUSIONS FOR MEDICARE AND LIMITATIONS ON MEDICARE PAYMENT

■ 1. The authority for part 411 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

Subpart A—General Exclusions and Exclusions of Particular Services

■ 2. Section 411.15 is amended by adding a new paragraph (s) to read as follows.

§ 411.15 Particular services excluded from coverage.

* * * * *

(s) Unless § 414.404(d) or § 414.408(e)(2) of this subchapter applies, Medicare does not make payment if an item or service that is included in a competitive bidding program (as described in Part 414, Subpart F of this subchapter) is furnished by a supplier other than a contract supplier (as defined in § 414.402 of this subchapter).

PART 414—PAYMENT FOR PART B MEDICAL AND OTHER HEALTH SERVICES

■ 3. The authority citation for part 414 continues to read as follows:

Authority: Secs. 1102, 1871, and 1881(b)(1) of the Social Security Act (42 U.S.C. 1302, 1395hh, and 1395rr(b)(1)).

Subpart F—Competitive Bidding for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)

■ 4. New §§ 414.400, 414.402, and 414.404 are added to Subpart F to read as follows:

§ 414.400 Purpose and basis.

This subpart implements competitive bidding programs for certain DMEPOS items as required by sections 1847(a) and (b) of the Act.

§ 414.402 Definitions.

For purposes of this subpart, the following definitions apply:

Bid means an offer to furnish an item for a particular price and time period that includes, where appropriate, any services that are directly related to the furnishing of the item.

Competitive bidding area (CBA) means an area established by the Secretary under this subpart.

Competitive bidding program means a program established under this subpart within a designated CBA.

Composite bid means the sum of a 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.

DMEPOS stands for durable medical equipment, prosthetics, orthotics, and supplies.

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 and for which payment is made after implementation of a competitive bidding program to a grandfathered supplier that continues to furnish the items in accordance with § 414.408(j):

(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.

(4) Other DME described in § 414.229.

Grandfathered supplier means a noncontract supplier that chooses to continue to furnish grandfathered items to a beneficiary in a CBA.

Item means a product included in a competitive bidding program that is identified by a HCPCS code, which may be specified for competitive bidding (for example, a product when it is furnished through mail order), or a combination of codes and/or modifiers, and includes the services directly related to the furnishing of that product to the beneficiary. Items that may be included in a competitive bidding program are:

(1) Durable medical equipment (DME) other than class III devices under the Federal Food, Drug, and Cosmetic Act, as defined in § 414.202 of this part and further classified into the following categories:

(i) Inexpensive or routinely purchased items, as specified in § 414.220(a).

(ii) Items requiring frequent and substantial servicing, as specified in § 414.222(a).

(iii) Oxygen and oxygen equipment, as specified in § 414.226(c)(1).

(iv) Other DME (capped rental items), as specified in § 414.229.

(2) Supplies necessary for the effective use of DME other than inhalation drugs.

(3) Enteral nutrients, equipment, and supplies.

(4) Off-the-shelf orthotics, which are orthotics described in section 1861(s)(9) of the Act that require minimal self-adjustment for appropriate use and do not require expertise in trimming, bending, molding, assembling or customizing to fit a beneficiary.

Item weight is a number assigned to an item based on its beneficiary utilization rate using national data when compared to other items in the same product category.

Mail order contract supplier is a contract supplier that furnishes items through the mail to beneficiaries who maintain a permanent residence in a competitive bidding area.

Metropolitan Statistical Area (MSA) has the same meaning as that given by the Office of Management and Budget.

Minimal self-adjustment means an adjustment that the beneficiary, caretaker for the beneficiary, or supplier of the device can perform and does not require the services of a certified orthotist (that is, an individual certified by either the American Board for Certification in Orthotics and Prosthetics, Inc., or the Board for Orthotist/Prosthetist Certification) or an individual who has specialized training.

Nationwide competitive bidding area means a CBA that includes the United States, its Territories, and the District of Columbia.

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 to provide competitively bid items throughout the entire CBA.

Noncontract supplier means a supplier that is not awarded a contract by CMS to furnish items included in a competitive bidding program.

Physician has the same meaning as in section 1861(r) of the Act.

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.

Regional competitive bidding area means a CBA that consists of a region of the United States, its Territories, and the District of Columbia.

Regional mail order contract supplier means a mail order contract supplier that furnishes items in a regional competitive bidding area.

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.

Supplier means an entity with a valid Medicare supplier number, including an entity that furnishes an item through the mail.

Treating practitioner means a physician assistant, nurse practitioner, or clinical nurse specialist, as those terms are defined in section 1861(aa)(5) of the Act.

Weighted bid means the item weight multiplied by the bid price submitted for that item.

§ 414.404 Scope and applicability.

(a) *Applicability.* Except as specified in paragraph (b) of this section, this subpart applies to all suppliers that furnish the items defined in § 414.402 to beneficiaries, including providers, physicians, treating practitioners, physical therapists, and occupational therapists that furnish such items under Medicare Part B.

(b) *Exceptions.* (1) 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.

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

(3) Payment for items furnished in accordance with paragraphs (b)(1) and (b)(2) of this section will be paid in accordance with § 414.408(a).

■ 5. Section 414.406 is amended by adding paragraphs (b), (c), and (d) to read as follows:

§ 414.406 Implementation of programs.

* * * * *

(b) *Competitive bidding areas.* CMS designates through program instructions or by other means, such as the request for bids, each CBA in which a competitive bidding program may be implemented under this subpart.

(c) *Revisions to competitive bidding areas.* CMS may revise the CBAs designated under paragraph (b) of this section.

(d) *Competitively bid items.* CMS designates the items that are included in a competitive bidding program through program instructions or by other means

* * * * *

■ 6. New §§ 414.408, 414.410, 414.412, 414.414, 414.416, 414.418, 414.420, 414.422, 414.424, and 414.426 are added to Subpart F to read as follows:

§ 414.408 Payment rules.

(a) *Payment basis.* (1) The payment basis for an item furnished under a competitive bidding program is 80 percent of the single payment amount calculated for the item under § 414.416 for the CBA in which the beneficiary maintains a permanent residence.

(2) If an item that is included in a competitive bidding program is furnished to a beneficiary who does not maintain a permanent residence in a CBA, the payment basis for the item is 80 percent of the lesser of the actual charge for the item, or the applicable fee schedule amount for the item, as determined under Subpart C or Subpart D.

(b) *No changes to the single payment amount.* The single payment amount calculated for each item under each competitive bidding program is paid for the duration of the competitive bidding program and will not be adjusted by any update factor.

(c) *Payment on an assignment-related basis.* Payment for an item furnished under this subpart is made on an assignment-related basis.

(d) *Applicability of advanced beneficiary notice.* Implementation of a program in accordance with this subpart does not preclude the use of an advanced beneficiary notice.

(e) *Requirement to obtain competitively bid items from a contract supplier.* (1) *General rule.* Except as provided in paragraph (e)(2) of this section, all items that are included in a competitive bidding program must be furnished by a contract supplier for that program.

(2) *Exceptions.* (i) A grandfathered supplier may furnish a grandfathered item to a beneficiary in accordance with paragraph (j) of this section.

(ii) Medicare may make a secondary payment for an item furnished by a noncontract supplier that the beneficiary is required to use under his or her primary insurance policy. The provisions of this paragraph do not supersede Medicare secondary payer statutory and regulatory provisions, including the Medicare secondary payment rules located in §§ 411.32 and 411.33 of this subchapter, and payment will be calculated in accordance with those rules.

(iii) If a beneficiary is outside of the CBA in which he or she maintains a permanent residence, he or she may obtain an item from a—

(A) Contract supplier, if the beneficiary obtains the item in another CBA and the item is included in the competitive bidding program for that CBA; or

(B) Supplier with a valid Medicare billing number, if the beneficiary obtains the item in an area that is not a CBA, or if the beneficiary obtains the item in another CBA but the item is not included in the competitive bidding program for that CBA.

(iv) A physician, treating practitioner, physical therapist in private practice, or occupational therapist in private practice may furnish an item in accordance with § 414.404(b) of this subpart.

(3) Unless paragraph (e)(2) of this section applies:

(i) Medicare will not make payment for an item furnished in violation of paragraph (e)(1) of this section, and

(ii) A beneficiary has no financial liability to a noncontract supplier that furnishes an item included in the competitive bidding program for a CBA in violation of paragraph (e)(1) of this section, unless the beneficiary has signed an advanced beneficiary notice.

(4) CMS separately designates the Medicare billing number of all noncontract suppliers to monitor compliance with paragraphs (e)(1) and (e)(2) of this section.

(f) *Purchased equipment.* (1) The single payment amounts for new purchased durable medical equipment, including power wheelchairs that are purchased when the equipment is initially furnished, and enteral nutrition equipment are calculated based on the bids submitted and accepted for these items.

(2) Payment for used purchased durable medical equipment and enteral nutrition equipment is made in an amount equal to 75 percent of the single payment amounts calculated for new purchased equipment under paragraph (f)(1) of this section.

(g) *Purchased supplies and orthotics.* The single payment amounts for the following purchased items are calculated based on the bids submitted and accepted for the following items:

(1) Supplies used in conjunction with durable medical equipment.

(2) Enteral nutrients.

(3) Enteral nutrition supplies.

(4) OTS orthotics.

(h) *Rented equipment.* (1) *Capped rental DME.* Subject to the provisions of paragraph (h)(2) of this section, payment for capped rental durable medical equipment is made in an amount equal to 10 percent of the single payment amounts calculated for new durable medical equipment under paragraph (f)(1) of this section for each of the first 3 months, and 7.5 percent of the single payment amounts calculated for these items for each of the remaining months 4 through 13.

(2) *Additional payment to certain contract suppliers for capped rental DME.* (i) Except as specified in paragraph (h)(2)(ii) of this section, Medicare makes 13 monthly payments to a contract supplier that furnishes capped rental durable medical equipment to a beneficiary who would otherwise be entitled to obtain the item from a grandfathered supplier under paragraph (j) of this section. Payment is made using the methodology described in paragraph (h)(1) of this section. 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 in accordance with this paragraph.

(ii) Medicare does not make payment to a contract supplier under paragraph (h)(2)(i) of this section if the contract supplier furnishes capped rental durable medical equipment to a beneficiary who previously rented the equipment from another contract supplier.

(3) *Maintenance and servicing of rented DME.* Separate maintenance and servicing payments are not made for any rented durable medical equipment.

(4) *Payment for rented enteral nutrition equipment.* Payment for rented enteral nutrition equipment is made in an amount equal to 10 percent of the single payment amounts calculated for new enteral nutrition equipment under paragraph (f)(1) of this section for each of the first 3 months, and 7.5 percent of the single payment amount calculated for these items under paragraph (f)(1) of this section for each of the remaining months 4 through 15. 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 equipment until a determination is made by the beneficiary's physician or treating practitioner that the equipment is no longer medically necessary.

(5) *Maintenance and servicing of rented enteral nutrition equipment.* Payment for the maintenance and servicing of rented enteral nutrition equipment beginning 6 months after 15 months of rental payments is made in an amount equal to 5 percent of the single payment amounts calculated for these items under paragraph (f)(1) of this section.

(6) *Payment for inexpensive or routinely purchased durable medical equipment.* Payment for inexpensive or routinely purchased durable medical equipment furnished on a rental basis is made in an amount equal to 10 percent of the single payment amount calculated for new purchased equipment.

(7) *Payment amounts for rented DME requiring frequent and substantial servicing.* (i) *General rule.* Except as provided in paragraph (h)(7)(ii) of this section, the single payment amounts for rented durable medical equipment requiring frequent and substantial servicing are calculated based on the rental bids submitted and accepted for the furnishing of these items on a monthly basis.

(ii) *Exception.* The single payment amounts for continuous passive motion exercise devices are calculated based on the bids submitted and accepted for the furnishing of these items on a daily basis.

(i) *Monthly payment amounts for oxygen and oxygen equipment.* (1) *Basic payment amount.* Subject to the provisions of paragraph (i)(2) of this section, the single payment amounts for oxygen and oxygen equipment are calculated based on the bids submitted and accepted for the furnishing on a monthly basis of each of the five classes of oxygen and oxygen equipment described in § 414.226(c)(1).

(2) *Additional payment to certain contract suppliers.* (i) Except as specified in paragraph (i)(2)(iii) of this section, Medicare makes monthly payments to a contract supplier that furnishes oxygen equipment to a beneficiary who would otherwise be entitled to obtain the item from a grandfathered supplier under paragraph (j) of this section as follows:

(A) If Medicare made 26 or less monthly payments to the former supplier, Medicare makes a monthly payment to the contract supplier for up

to the number of months equal to the difference between 36 and the number of months for which payment was made to the former supplier.

(B) If Medicare made 27 or more monthly payments to the former supplier, Medicare makes 10 monthly payments to the contract supplier.

(ii) Payment is made using the methodology described in paragraph (i)(1) of this section. On the first day after the month in which the final rental payment is made under paragraph (i)(2)(i) of this section, the contract supplier must transfer title of the oxygen equipment to the beneficiary.

(iii) Medicare does not make payment to a contract supplier under paragraph (i)(2) of this section if the contract supplier furnishes oxygen equipment to a beneficiary who previously rented the equipment from another contract supplier.

(j) *Special rules for certain rented durable medical equipment and oxygen and oxygen equipment.* (1) *Supplier election.* (i) A supplier that is furnishing durable medical equipment or is furnishing oxygen or oxygen equipment on a rental basis to a beneficiary prior to the implementation of a competitive bidding program in the CBA where the beneficiary maintains a permanent residence may elect to continue furnishing the item as a grandfathered supplier.

(ii) A supplier that elects to be a grandfathered supplier must continue to furnish the grandfathered items to all beneficiaries who elect to continue receiving the grandfathered items from that supplier for the remainder of the rental period for that item.

(2) *Payment for grandfathered items furnished during the first competitive bidding program implemented in a CBA.* Payment for grandfathered items furnished during the first competitive bidding program implemented in a CBA is made as follows:

(i) For inexpensive and routinely purchased items described in § 414.220(a), payment is made in the amount determined under § 414.220(b).

(ii) For other durable medical equipment or capped rental items described in § 414.229, payment is made in the amount determined under § 414.229(b).

(iii) For items requiring frequent and substantial servicing described in § 414.222, payment is made in accordance with paragraph (a)(1) of this section.

(iv) For oxygen and oxygen equipment described in § 414.226(c)(1), payment is made in accordance with paragraph (a)(1) of this section.

(3) *Payment for grandfathered items furnished during all subsequent competitive bidding programs in a CBA.* Beginning with the second competitive bidding program implemented in a CBA, payment is made for grandfathered items in accordance with paragraph (a)(1) of this section.

(4) *Choice of suppliers.* (i) Beneficiaries who are renting an item that meets the definition of a grandfathered item in § 414.402 of this subpart may elect to obtain the item from a grandfathered supplier.

(ii) A beneficiary who is otherwise entitled to obtain a grandfathered item from a grandfathered supplier under paragraph (j) of this section may elect to obtain the same item from a contract supplier at any time after a competitive bidding program is implemented.

(iii) If a beneficiary elects to obtain the same item from a contract supplier, payment is made for the item accordance with paragraph (a)(1) of this section.

(5) *Payment for accessories and supplies for grandfathered items.* Accessories and supplies that are used in conjunction with and are necessary for the effective use of a grandfathered item may be furnished by the same grandfathered supplier that furnishes the grandfathered item. Payment is made in accordance with paragraph (a)(1) of this section.

(k) *Payment for maintenance, servicing and replacement of beneficiary-owned items.*

(1) Payment is made for the maintenance and servicing of beneficiary-owned items, provided the maintenance and servicing is performed by a contract supplier or a noncontract supplier having a valid Medicare billing number, as follows:

(i) Payment for labor is made in accordance with § 414.210(e)(1) of Subpart D.

(ii) Payment for parts that are not items (as defined in § 414.402) is made in accordance with § 414.210(e)(1) of Subpart D.

(iii) Payment for parts that are items (as defined in § 414.402) is made in accordance with paragraph (a)(1) of this section.

(2) Additional payments are made in accordance with §§ 414.210(e)(2) and (e)(3) of subpart D for the maintenance and servicing of oxygen equipment if performed by a contract supplier or a noncontract supplier having a valid Medicare billing number.

(3) Beneficiaries must obtain a replacement of a beneficiary-owned item, other than parts needed for the repair of beneficiary-owned equipment from a contract supplier. Payment is made for the replacement item in accordance with paragraph (a)(1) of this section.

§ 414.410 Phased-in implementation of competitive bidding programs.

(a) *Phase-in of competitive bidding programs.* CMS phases in competitive bidding programs so that competition under the programs occurs in—

(1) 10 of the largest MSAs in CY 2007;

(2) 80 of the largest MSAs in CY 2009;

(3) Additional CBAs after CY 2009.

(b) *Selection of MSAs for CY 2007 and CY 2009.* CMS selects the MSAs for purposes of designating CBAs in CY 2007 and CY 2009 by considering the following variables:

(1) The total population of an MSA.

(2) The Medicare allowed charges for DMEPOS items per fee-for-service beneficiary in an MSA.

(3) The total number of DMEPOS suppliers per fee-for-service beneficiary who received DMEPOS items in an MSA.

(4) An MSA's geographic location.

(c) *Exclusions from a CBA.* CMS may exclude from a CBA a rural area (as defined in § 412.64(b)(1)(ii)(C) of this subchapter), or an area with low population density based on one or more of the following factors—

(1) Low utilization of DMEPOS items by Medicare beneficiaries receiving fee-for-service benefits relative to similar geographic areas;

(2) Low number of DMEPOS suppliers relative to similar geographic areas; or

(3) Low number of Medicare fee-for-service beneficiaries relative to similar geographic areas.

(d) *Selection of additional CBAs after CY 2009.* (1) Beginning after CY 2009, CMS designates through program instructions or by other means additional CBAs based on CMS' 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.

(2) Beginning after CY 2009, CMS may designate through program instructions or by other means a nationwide CBA or one or more regional CBAs for purposes of implementing competitive bidding programs for items that are furnished through the mail by nationwide or regional mail order contract suppliers.

§ 414.412 Submission of bids under a competitive bidding program.

(a) *Requirement to submit a bid.* Except as provided under § 414.404(b), in order for a supplier to receive payment for items furnished to beneficiaries under a competitive bidding program, the supplier must

submit a bid to furnish those items and be awarded a contract under this subpart.

(b) *Grouping of items into product categories.* (1) Bids are submitted for items grouped into product categories.

(2) The bids submitted for each item in a product category cannot exceed the payment amount that would otherwise apply to the item under Subpart C or Subpart D of this part.

(c) *Furnishing of items.* A bid must include all costs related to furnishing an item, including all services directly related to the furnishing of the item.

(d) *Separate bids.* For each product category that a supplier is seeking to furnish under a competitive bidding program, the supplier must submit a separate bid for each item in that product category.

(e) Commonly-owned or controlled suppliers. (1) For purposes of this paragraph—

(i) An ownership interest is the possession of equity in the capital, stock or profits of another supplier;

(ii) A controlling interest exists if one or more of owners of a supplier is an officer, director or partner in another supplier; and

(iii) Two or more suppliers are commonly-owned if one or more of them has an ownership interest totaling at least 5 percent in the other(s).

(2) A supplier must disclose in its bid each supplier in which it has an ownership or controlling interest and each supplier which has an ownership or controlling interest in it.

(3) Commonly-owned or controlled suppliers must submit a single bid to furnish a product category in a CBA. Each commonly-owned or controlled supplier that is located in the CBA for which the bid is being submitted must be included in the bid. The bid must also include any commonly-owned or controlled supplier that is located outside of the CBA but would furnish the product category to the beneficiaries who maintain a permanent residence in the CBA.

(f) *Mail order suppliers.* (1) Suppliers that furnish items through the mail must submit a bid to furnish these items in a CBA in which a mail order competitive bidding program that includes the items is implemented.

(2) Suppliers that submit one or more bids under paragraph (f)(1) of this section may submit the same bid amount for each item under each competitive bidding program for which it submits a bid.

(g) *Applicability of the mail order competitive bidding program.* Suppliers that do not furnish items through the mail are not required to participate in a nationwide or regional mail order competitive bidding program that includes the same items. Suppliers may continue to furnish these items in—

(1) A CBA, if the supplier is awarded a contract under this subpart; or

(2) An area not designated as a CBA.

§ 414.414 Conditions for awarding contracts.

(a) *General rule.* The rules set forth in this section govern the evaluation and selection of suppliers for contract award purposes under a competitive bidding program.

(b) *Basic supplier eligibility.* (1) Each supplier must meet the enrollment standards specified in § 424.57(c) of this chapter.

(2) Each supplier must disclose information about any prior or current legal actions, sanctions, revocations from the Medicare program, program-related convictions as defined in section 1128(a)(1) through (a)(4) of the Act, exclusions or debarments imposed against it, or against any members of the board of directors, chief corporate officers, high-level employees, affiliated companies, or subcontractors, by any Federal, State, or local agency. The supplier must certify in its bid that this information is completed and accurate.

(3) Each supplier must have all State and local licenses required to perform the services identified in the request for bids.

(4) Each supplier must submit a bona fide bid that complies with all the terms and conditions contained in the request for bids.

(5) Each network must meet the requirements specified in § 414.418.

(c) *Quality standards and accreditation.* Each supplier must meet applicable quality standards developed by CMS in accordance with section 1834(a)(20) of the Act and be accredited by a CMS-approved accreditation organization that meets the requirements of § 424.58 of this subchapter, unless a grace period is specified by CMS.

(d) *Financial standards.* Each supplier must submit along with its bid the applicable financial documentation specified in the request for bids.

(e) *Evaluation of bids.* CMS evaluates bids submitted for items within a product category by—

(1) Calculating the expected beneficiary demand in the CBA for the items in the product category;

(2) Calculating the total supplier capacity that would be sufficient to meet the expected beneficiary demand in the CBA for the items in the product category;

(3) Establishing a composite bid for each supplier and network that submitted a bid for the product category.

(4) Arraying the composite bids from the lowest composite bid price to the highest composite bid price;

(5) Calculating the pivotal bid for the product category;

(6) Selecting all suppliers and networks whose composite bids are less than or equal to the pivotal bid for that product category, and that meet the requirements in paragraphs (b) through (d) of this section.

(f) *Expected savings.* A contract is not awarded under this subpart unless CMS determines that the amounts to be paid to contract suppliers for an item under a competitive bidding program are expected to be less than the amounts that would otherwise be paid for the same item under Subpart C or Subpart D.

(g) *Special rules for small suppliers.* (1) *Target for small supplier participation.* CMS ensures that small suppliers have the opportunity to participate in a competitive bidding program by taking the following steps:

(i) Setting a target number for small supplier participation by multiplying 30 percent by the number of suppliers that meet the requirements in paragraphs (b) through (d) of this section and whose composite bids are equal to or lower than the pivotal bid calculated for the product category;

(ii) Identifying the number of qualified small suppliers whose composite bids are at or below the pivotal bid for the product category;

(iii) Selecting additional small suppliers whose composite bids are above the pivotal bid for the product category in ascending order based on the proximity of each small supplier's composite bid to the pivotal bid, until the number calculated in paragraph (g)(1)(i) of this section is reached or there are no more composite bids submitted by small suppliers for the product category.

(2) The bids by small suppliers that are selected under paragraph (g)(1)(iii) of this section are not used to calculate the single payment amounts for any items under § 414.416 of this subpart.

(h) *Sufficient number of suppliers.*

(1) Except as provided in paragraph (h)(3) of this section. CMS will award at least five contracts, if there are five suppliers satisfying the requirements in paragraphs (b) through (f) of this section; or

(2) CMS will award at least two contracts, if there are less than five suppliers meeting these requirements and the suppliers satisfying these requirements have sufficient capacity to satisfy beneficiary demand for the

product category calculated under paragraph (e)(1) of this section.

(3) The provisions of paragraph (h)(1) of this section do not apply to regional or nationwide mail order CBAs under § 414.410(d)(2) of this subpart.

(i) *Selection of new suppliers after bidding.* (1) Subsequent to the awarding of contracts under this subpart, CMS may award additional contracts if it determines that additional contract suppliers are needed to meet beneficiary demand for items under a competitive bidding program. CMS selects additional contract suppliers by—

(i) Referring to the arrayed list of suppliers that submitted bids for the product category included in the competitive bidding program for which beneficiary demand is not being met; and

(ii) Beginning with the supplier whose composite bid is the first composite bid above the pivotal bid for that product category, determining if that supplier is willing to become a contract supplier under the same terms and conditions that apply to other contract suppliers in the CBA.

(2) Before CMS awards additional contracts under paragraph (i)(1) of this section, a supplier must submit updated information demonstrating that the supplier meets the requirements under paragraphs (b) through (d) of this section.

§ 414.416 Determination of competitive bidding payment amounts.

(a) *General rule.* CMS establishes a single payment amount for each item furnished under a competitive bidding program.

(b) *Methodology for setting payment amount.* (1) The single payment amount for an item furnished under a competitive bidding program is equal to the median of the bids submitted for that item by suppliers whose composite bids for the product category that includes the item are equal to or below the pivotal bid for that product category. If there is an even number of bids, the single payment amount for the item is equal to the average of the two middle bids.

(2) The single payment amount for an item must be less than or equal to the amount that would otherwise be paid for the same item under Subpart C or Subpart D.

§ 414.418 Opportunity for networks.

(a) A network may be comprised of at least 2 but not more than 20 small suppliers.

(b) The following rules apply to networks that seek contracts under this subpart:

(1) Each network must form a single legal entity that acts as the bidder and submits the bid. Any agreement entered into for purposes of forming a network must be submitted to CMS. The network must identify itself as a network and identify all of its members.

(2) Each member of the network must satisfy the requirements in § 414.414(b) through (d).

(3) A small supplier may join one or more networks 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 to furnish the same product category in the same CBA.

(4) The network cannot be anticompetitive, and this section does not supersede any Federal law or regulation that regulates anticompetitive behavior.

(5) A bid submitted by a network must include a statement from each network member certifying that the network member joined the network because it is unable independently 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.

(6) At the time that a network submits a bid, the network's total market share for each product category that is the subject of the network's bid cannot exceed 20 percent of the Medicare demand for that product category in the CBA.

(c) If the network is awarded a contract, each supplier must submit its own claims and will receive payment directly from Medicare for the items that it furnishes under the competitive bidding program.

§ 414.420 Physician or treating practitioner authorization and consideration of clinical efficiency and value of items.

(a) *Prescription for a particular brand item or mode of delivery.* (1) A physician or treating practitioner may prescribe, in writing, a particular brand of an item for which payment is made under a competitive bidding program, or a particular mode of delivery for an item, if he or she determines that the particular brand or mode of delivery would avoid an adverse medical outcome for the beneficiary.

(2) When a physician or treating practitioner prescribes a particular brand or mode of delivery of an item under paragraph (a)(1) of this section, the physician or treating practitioner must document the reason in the beneficiary's medical record why the particular brand or mode of delivery is medically necessary to avoid an adverse medical outcome.

(b) *Furnishing of a prescribed particular brand item or mode of delivery.* If a physician or treating practitioner prescribes a particular brand of an item or mode of delivery, the contract supplier must—

(1) Furnish the particular brand or mode of delivery as prescribed by the physician or treating practitioner;

(2) Consult with the physician or treating practitioner to find an appropriate alternative brand of item or mode of delivery for the beneficiary and obtain a revised written prescription from the physician or treating practitioner; or

(3) Assist the beneficiary in locating a contract supplier that can furnish the particular brand of item or mode of delivery prescribed by the physician or treating practitioner.

(c) *Payment for a particular brand of item or mode of delivery.* Medicare does not make an additional payment to a contract supplier that furnishes a particular brand or mode of delivery for an item, as directed by a prescription written by the beneficiary's physician or treating practitioner.

(d) *Prohibition on billing for an item different from the particular brand of item or mode of delivery prescribed.* A contract supplier is prohibited from submitting a claim to Medicare if it furnishes an item different from that specified in the written prescription received from the beneficiary's physician or treating practitioner. Payment will not be made to a contract supplier that submits a claim prohibited by this paragraph.

§ 414.422 Terms of contracts.

(a) *Basic rule.* CMS specifies the terms and conditions of the contracts entered into with contract suppliers under this subpart. A contract supplier must comply with all terms of its contract, including any option exercised by CMS, for the full duration of the contract period.

(b) *Recompeting competitive bidding contracts.* CMS recompetes competitive bidding contracts at least once every 3 years.

(c) *Nondiscrimination.* The items furnished by a contract supplier under this subpart must be the same items that the contract supplier makes available to other customers.

(d) *Change of ownership.* (1) A contract supplier must notify CMS if it is negotiating a change in ownership 60 days before the anticipated date of the change.

(2) CMS may award a contract to an entity that merges with, or acquires, a contract supplier if—

(i) The successor entity meets all requirements applicable to contract suppliers for the applicable competitive bidding program;

(ii) The successor entity submits to CMS the documentation described under § 414.414(b) through (d) if that documentation has not previously been submitted by the successor entity or the contract supplier that is being acquired, or is no longer current. This documentation must be submitted within 30 days prior to the anticipated effective date of the change of ownership. A successor entity is not required to duplicate previously submitted information if the previously submitted information is still current;

(iii) The successor entity is acquiring the assets of the existing contract supplier, it submits to CMS, at least 30 days before the anticipated effective date of the change of ownership, a signed novation agreement acceptable to CMS stating that it will assume all obligations under the contract; or

(iv) A new entity will be formed as a result of the merger or acquisition, the existing contract supplier submits to CMS, at least 30 days before the anticipated effective date of the change of ownership, its final draft of a novation agreement as described in paragraph (d)(2)(iii) of this section for CMS review. The successor entity must submit to CMS, within 30 days after the effective date of the change of ownernship and executed novation agreement acceptable to CMS.

(e) *Furnishing of items.* Except as otherwise prohibited under section 1877 of the Act, or any other applicable law or regulation:

(1) A contract supplier must agree to furnish items under its contract to any beneficiary who maintains a permanent residence in, or who visits, the CBA and who requests those items from that contract supplier.

(2) A skilled nursing facility defined under section 1819(a) of the Act or a nursing facility defined under section 1919(a) of the Act that has elected to furnish items only to its own residents and that is also a contract supplier may furnish items under a competitive bidding program to its own patients to whom it would otherwise furnish Part B services.

(f) *Breach of contract.* (1) Any deviation from contract requirements, including a failure to comply with governmental agency or licensing organization requirements, constitutes a breach of contract.

(2) In the event a contract supplier breaches its contract, CMS may take one or more of the following actions:

(i) Require the contract supplier to submit a corrective action plan;

(ii) Suspend the contract supplier's contract;

(iii) Terminate the contract;

(iv) Preclude the contract supplier from participating in the competitive bidding program;

(v) Revoke the supplier number of the contract supplier; or

(vi) Avail itself of other remedies allowed by law.

§ 414.424 Administrative or judicial review.

(a) There is no administrative or judicial review under this subpart of the following:

(1) Establishment of payment amounts.

(2) Awarding of contracts.

(3) Designation of CBAs.

(4) Phase-in of the competitive bidding programs.

(5) Selection of items for competitive bidding.

(6) Bidding structure and number of contract suppliers selected for a competitive bidding program.

(b) A denied claim is not appealable if the denial is based on a determination by CMS that a competitively bid item was furnished in a CBA in a manner not authorized by this subpart.

§ 414.426 Adjustments to competitively bid payment amounts to reflect changes in the HCPCS.

If a HCPCS code for a competitively bid item is revised after the contract period for a competitive bidding program begins, CMS adjusts the single payment amount for that item as follows:

(a) If a single HCPCS code for an item is divided into two or more HCPCS codes for the components of that item, the sum of single payment amounts for the new HCPCS codes equals the single payment amount for the original item. Contract suppliers must furnish the components of the item and submit claims using the new HCPCS codes.

(b) If a single HCPCS code is divided into two or more separate HCPCS codes, the single payment amount for each of the new separate HCPCS codes is equal to the single payment amount applied to the single HCPCS code. Contract suppliers must furnish the items and submit claims using the new separate HCPCS codes.

(c) If the HCPCS codes for components of an item are merged into a single HCPCS code for the item, the single payment amount for the new HCPCS code is equal to the total of the separate single payment amounts for the components. Contract suppliers must furnish the item and submit claims using the new HCPCS code.

(d) If multiple HCPCS codes for similar items are merged into a single HCPCS code, the items to which the new HCPCS codes apply may be furnished by any supplier that has a valid Medicare billing number. Payment for these items will be made in accordance with Subpart C or Subpart D.

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Leslie Norwalk,

Acting Administrator, Centers for Medicare & Medicaid Services.

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Michael O. Leavitt,

Secretary.

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