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42 CFR Parts 411, 414, and 424

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 411, 414, and 424

[CMS–1270–P]

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: Proposed rule.

SUMMARY: This proposed rule would implement competitive bidding programs for certain 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 (the Act). These programs would change the way that Medicare pays for these items under Part B of the Medicare program by utilizing bids submitted by DMEPOS suppliers to establish applicable payment amounts. We would phase in these programs over several years.

This proposed rule would also detail requirements for CMS approved accreditation organizations that will be applying quality standards for all DMEPOS suppliers, including DMEPOS suppliers that participate in the DMEPOS competitive bidding program. In addition, this rule proposes a new fee schedule for home dialysis supplies and equipment still paid on a reasonable charge basis. This proposed rule would also clarify our policy on the scope of the statutory eyeglass coverage exclusion. We are proposing to specify in regulations that the eyeglass exclusion encompasses all devices that use lenses to aid vision or provide magnification of images for impaired vision. Further, this proposed rule would implement a revised methodology for calculating fee schedule amounts for new DMEPOS items.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on June 30, 2006.

ADDRESSES: In commenting, please refer to file code CMS–1270–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (no duplicates, please):

1. *Electronically.* You may submit electronic comments on specific issues in this regulation to *http://www.cms.hhs.gov/eRulemaking.* (Attachments should be in Microsoft Word, WordPerfect, or Excel; however, we prefer Microsoft Word.)

2. *By regular mail.* You may mail written comments (one original and two copies) to the following address only: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1270–P, P.O. Box 8013, Baltimore, MD 21244–8013.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments (one original and two copies) to the following address only: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1270–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments (one original and two copies) before the close of the comment period to one of the following addresses. If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786–7195 in advance to schedule your arrival with one of our staff members. Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201; or 7500 Security Boulevard, Baltimore, MD 21244–1850.

(Because access to the interior of the HHH Building is not readily available to persons without Federal Government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

Submission of comments on paperwork requirements. You may submit comments on this document's paperwork requirements by mailing your comments to the addresses provided at the end of the ''Collection of Information Requirements'' section in this document.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT:

Lorrie Ballantine, (410) 786–7543—Overall implementation.

Joel Kaiser, (410) 786–4499—Overall implementation.

Michael Keane, (410) 786–4495—Overall implementation.

Walter Rutemueller, (410) 786–5395—Overall implementation.

Linda Smith, (410) 786–5650—Quality Standards and Accreditation.

SUPPLEMENTARY INFORMATION:

Submitting Comments: We welcome comments from the public on all issues set forth in this rule to assist us in fully considering issues and developing policies. You can assist us by referencing the file code CMS–1270–P and the specific ''issue identifier'' that precedes the section on which you choose to comment.

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. CMS posts all electronic comments received before the close of the comment period on its public Web site as soon as possible after they have been received. Hard copy comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1–800–743–3951.

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I. Background

A. Payment Under Reasonable Charges

Payment for most DMEPOS items, including supplies and equipment, furnished under Part B of the Medicare program (Supplementary Medical Insurance) is made through contractors known as Medicare carriers. Before January 1, 1989, payment for most of these services was made on a reasonable charge basis by these carriers. The methodology for determining reasonable charges is set forth in section 1842(b) of the Social Security Act (Act) and 42 CFR part 405, subpart E of the regulations. 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) 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 Under Fee Schedules

Section 4062 of the Omnibus Budget Reconciliation Act of 1987 (Pub. L. 100–203) (OBRA ''87) added section 1834 to the Act and implemented 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 new 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, as well as § 414.200 through § 414.232 (with the exception of § 414.228) of the regulations, 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);
- Customized items (section 1834(a)(4) of the Act and § 414.224);
- Oxygen and oxygen equipment (section 1834(a)(5) of the Act and § 414.226);
- Other items of DME (section 1834(a)(7) of the Act and § 414.229).

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 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 and test strips used with blood glucose monitors). These supplies are paid for using the same methodology that we use to pay for 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 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. 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 1995, or the reasonable charges that would have been used in determining payment for these items in 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 are proposing to revise § 414.1 of our regulations to specify that fee schedules were established for PEN items in accordance with our authority under section 1842(s) of Act.

Section 627 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173) amended section 1833(o)(2) of the Act to require 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 believe that 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 that methodology through regulations at part 414, subpart D, and section 627 of the MMA provides that the same methodology shall apply to therapeutic shoes. Section 627 of the MMA was implemented 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.

C. 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 2 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. 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 DME, orthotics, prosthetics, and supplies 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 of 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. The HCPCS Level II Codes will be used to describe the DME, orthotic, and enteral nutrition items furnished under the competitive bidding programs being proposed in this proposed rule, both for the purpose of requesting bids and for establishing payment amounts.

D. Medicare Competitive Bidding Demonstrations

Section 4319 of the Balanced Budget Act of 1997 (BBA) 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 DME and prosthetics, orthotics, and supplies. 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 a quality product.

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 the San Antonio MSA's Bexar, Comal, and Guadalupe counties 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 offers valuable lessons for understanding the impacts of competitive bidding for Medicare services. These lessons are especially important now because the MMA mandates a larger role for competitive bidding within the Medicare program. Specifically, section 302(b) of the MMA requires the Secretary to establish and implement competitive bidding programs for the furnishing of certain DME and associated supplies, enteral nutrition and associated supplies, and off-the-shelf orthotics. In addition, section 303(d) of the MMA requires 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 mandates competitive bidding demonstration projects for clinical laboratory services and managed care.

E. Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108–173)

Section 302(b)(1) of the MMA amended section 1847 of the Act to require the Secretary to establish and implement programs under which competitive bidding areas are established throughout the United States for contract award purposes for the furnishing of certain competitively priced items for which payment is made under Part B (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. In our view, the Medicare DMEPOS Competitive Bidding Program has five objectives, as follows:

- 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 who conduct business in a manner that is beneficial for the program and for Medicare beneficiaries.

F. Deficit Reduction Act of 2005 (Pub. L. 109–171)

Section 5101(a) of the Deficit Reduction Act of 2005 (DRA) amended section 1834(a)(7)(A) of the Act to change the way Medicare pays for capped rental items. This section revised the period of payment for capped rental from 15 to 13 months. After rental payments are made for a 13 month period of continuous use, title to the capped rental items transfers from the supplier to the beneficiary. Once the title has transferred, amended section 1834(a)(7)(A)(iv) provides that reasonable and necessary maintenance and servicing payments (for parts and labor not covered by the supplier's or 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.

Section 5101(b) of the DRA also amended section 1834(a)(5) of the Act to limit monthly payments for oxygen equipment to a 36 month period of continuous use. Then ownership of the oxygen equipment will be transferred from the supplier to the beneficiary. Medicare will continue making monthly payments for oxygen contents when appropriate for beneficiary owned stationary and portable systems in the amounts recognized under section 1834(a)(9) after title to the equipment transfers to the beneficiary. However, under new section 1834(a)(5)(F)(II)(bb), 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 begins January 1, 2006. In a future rulemaking, we will propose to revise regulations found in part 414, subpart D to incorporate these DRA provisions.

G. Program Advisory and Oversight Committee

Section 1847(c) of the Act requires the Secretary to establish a Program Advisory and Oversight Committee (PAOC) that will provide advice to the Secretary with respect to the following functions, including—

- 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; and
- 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 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 of Health and Human Services 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. The first PAOC meeting was announced in a **Federal Register** notice (CMS–1279–N2, 69 FR 31125) and was held at CMS on October 6, 2004.

We have held two additional PAOC meetings where we, along with our contractor RTI, presented material to both the PAOC and the public relating to the provisions that are outlined in this proposed rule. The topics that we presented include—

- 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 being proposed in this proposed rule;
- Existing non-Medicare competitive bidding programs for DMEPOS items;
- Program design options for the Medicare DMEPOS Competitive Bidding Program being proposed in this proposed rule;
- Criteria for selecting Metropolitan Statistical Areas (MSAs) in which competition under the Medicare DMEPOS Competitive Bidding Program will occur in both 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 items;
- 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 all DMEPOS suppliers.

In addition to the PAOC meetings, we have designed and implemented a CMS Web site (*http://cms.hhs.gov/suppliers/dmepos/compbid/paoc.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 our Web site.

H. Quality Standards for Suppliers of (DMEPOS)

Section 302(a)(1) of the MMA added section 1834(a)(20) to the Act, which requires the Secretary to establish and implement quality standards for suppliers of certain items, including consumer service standards, to be applied by recognized independent accreditation organizations. Suppliers of DMEPOS must comply with the quality standards in order to furnish any item for which payment is made under Part B, and to receive and retain a provider or supplier billing number used to submit claims for reimbursement for any such item for which payment may be made under Medicare. Section 1834(a)(20)(D) of the Act requires us to apply these quality standards to suppliers of the following items for which we deem the standards to be appropriate:

- Covered items, as that term is defined in section 1834(a)(13), for which payment may be made under section 1834(a);
- Prosthetic devices and orthotics and prosthetics described in section 1834(h)(4); and
- Items described in section 1842(s)(2) of the Act, which include medical supplies, home dialysis supplies and equipment, therapeutic shoes, parenteral and enteral nutrients, equipment, and supplies, electromyogram devices, salivation devices, blood products, and transfusion medicine.

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 consulted with the PAOC and determined that it is in the best interest of the industry and beneficiaries to publish the quality standards through program instructions and select the accreditation organizations 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. The standards will be applied prospectively and will be published on our website. All suppliers of DMEPOS and other items to which section 1834(a)(20) of the Act applies will be required to meet the quality standards established under that section. Finally, section 1847(b)(2)(A)(i) of the Act requires an entity (a DMEPOS supplier) to meet the quality standards specified by the Secretary under section 1834(a)(20) of the Act before being awarded a contract under the Medicare DMEPOS Competitive Bidding Program.

Since December 11, 2000, suppliers have been required to meet the Medicare enrollment standards at § 424.57, satisfaction of which is required for these suppliers to participate in the Medicare program and

receive Medicare payments for DMEPOS and other items. Even with the implementation of the enrollment standards at § 424.57, we believe there has not been sufficient oversight of suppliers of DMEPOS and other items related to the quality and provision of their products. The Department of Health and Human Services, Office of Inspector General (OIG), has conducted several investigations of suppliers of DMEPOS and other items to determine the legitimacy of their businesses and has uncovered many examples of fraud and abuse. Examples of the types of fraud and abuse that were discovered include—

- Billing for services not performed;
- Billing for a more expensive service than was rendered;
- Billing separately for several services that should be combined into one billing;
- Billing twice for the same service;
- Billing for more expensive equipment or supplies than were used;
- Offering or receiving kickbacks (that is, offering or accepting something in return for services);
- Offering or accepting a bribe to use a particular service or company;
- Providing unnecessary services; and
- Submitting false cost reports.

The OIG began publicizing fraud alerts as a vehicle to identify fraudulent and abusive practices being committed by DMEPOS suppliers within the health care industry.

To enhance the quality of services provided by suppliers of DMEPOS and further reduce fraudulent practices, we are developing quality standards, as required by section 1834(a)(20) of the Act, to address suppliers' accountability, business integrity, provision of quality products to beneficiaries, and performance management. These standards will measure the effect of suppliers' services on beneficiaries. The supplier quality standards will include product specific requirements that will focus on a consumer-directed model of service delivery for suppliers to improve beneficiary access to information about DMEPOS. We believe these requirements will empower beneficiaries to make better-informed choices regarding equipment selection and the proper and safe use of DMEPOS, which we believe will lead to increased beneficiary satisfaction, safe and appropriate use of purchased equipment, and positive health outcomes. The supplier quality standards will provide more efficient processes and standardized materials for suppliers to increase consistency and continuity for supplier services to beneficiaries, beneficiary education, and responsiveness to beneficiary requests for equipment options. We are using contractor support and input from industry suppliers and national associations to develop the quality standards. Additionally, the contractors will meet with beneficiaries who use the specific products to solicit their input and assurance that their needs are being addressed by the quality standards requirements.

The quality standards will include performance management requirements to ensure the development, implementation, monitoring, and evaluation of policies, procedures, and products so that suppliers can maintain compliance with regulatory requirements and our policy instructions. The quality standards will include language from current CMS standards and industry best practice standards for the following areas: Administration; financial management; human resource management; beneficiary services; performance management; environment and safety; beneficiary rights/ethics; and information management. Additionally, the supplier quality standards will include requirements for monitoring beneficiary satisfaction with products and suppliers' responses to beneficiary complaints. As is authorized under section 1834(a)(20)(E), we will be establishing the supplier quality standards through program instructions and will publish them on our Web site. Additionally, in a future rule, we will propose to address DMEPOS supplier requirements for enrollment and enforcement procedures.

I. Accreditation for Suppliers of DMEPOS and Other Items

Section 1834(a)(20)(B) of the Act requires the Secretary, notwithstanding section 1865(b) of the Act, to designate and approve one or more independent accreditation organizations to apply the quality standards to suppliers of DMEPOS and other items. The Medicare program currently contracts with State Agencies to perform survey and review functions for providers and suppliers to approve their participation in or coverage under the Medicare program. Additionally, section 1865(b) of the Act sets forth the general procedures for CMS to designate national accreditation organizations to deem providers or suppliers to meet Medicare conditions of participation or coverage if they are accredited by a national accreditation organization approved by CMS. Many types of providers and suppliers have a choice between having the State Agency or the CMS approved accreditation organization survey them. If the provider or supplier selects the CMS-approved accreditation organization and is in compliance with the accreditation organization standards, it is generally deemed to meet the Medicare conditions of participation or coverage. CMS is responsible for the oversight and monitoring of the State Agencies and the approved accreditation organizations. The procedures, implemented by the Secretary, for designating private and national accreditation organizations and the Federal review process for accreditation organizations are located at 42 CFR parts 422 (for Medicare Advantage organizations) and 488 (for most providers and suppliers). Although, the statute itself does not require us to issue a rulemaking or provide notice in the **Federal Register** in order to designate and approve DMEPOS accreditation organizations, we believe that the Administrative Procedure Act does require us to give notice and an opportunity for comment before we institute our procedures for designating and supervising these organizations. To accommodate suppliers that wish to participate in the Medicare DMEPOS Competitive Bidding Program, we will phase-in the accreditation process and require accreditation organizations to prioritize their surveys to accredit suppliers in the selected MSAs and competitive bidding areas. We will provide further guidance in a **Federal Register** notice on the grandfathering-in of suppliers that have already been accredited, and the submission procedures for accreditation after this rule is finalized.

J. Low Vision Aid Exclusion

Section 1862(a)(7) of the Act excludes payment where ''expenses are for * * * eyeglasses (other than eyewear described in section 1861(s)(8)) or eye examinations for the purpose of prescribing, fitting, or changing eyeglasses, procedures performed (during the course of any eye examination) to determine the refractive state of the eyes * * *.'' The Medicare regulations at § 411.15(b) exclude from coverage eyeglasses and contact lenses, except for—

- Post-surgical prosthetic lenses customarily used during convalescence for eye surgery in which the lens of the eye was removed (for example, cataract surgery);
- Prosthetic lenses for patients who lack the lens of the eye because of congenital absence or surgical removal; and
- One pair of conventional eyeglasses or conventional contact lenses furnished

after each cataract surgery during which an intraocular lens is inserted.

From as early as 1980, we have clarified that we viewed closed circuit visual aid systems and other low vision devices to be subject to the eyeglass coverage exclusion at section 1862(a)(7) of the Act. We have also concurred with carrier policies that have excluded payment for low vision aids because of the eyeglass exclusion. Moreover, the Medicare Appeals Council has recognized that video magnifiers, or closed circuit televisions (CCTVs), are excluded from coverage by section 1862(a)(7) of the Act. However, we have never issued a regulation or national coverage decision that specifically states that the eyeglass exclusion at section 1862(a)(7) of the Act applies to low vision aids. We are proposing to revise § 411.15(b), with certain specific exceptions, to expressly state that the eyeglass exclusion applies to all devices that use one or more lens for the primary purpose of aiding vision. In proposing this revision, we are mindful that three United States district courts have found that section 1862(a)(7) of the Act does not prohibit payment for video magnifiers. (*Collins* v. *Thompson*, No 2:03-cv-265-FtM–29SPC (M.D. Fla. June 4, 2004); *Davidson* v. *Thompson*, No. Civ. 04–32 LFG (D.N.M. 2004); *Currier* v. *Thompson*, 369 F. Supp. 2d 65 (D. Me. 2005).) The Currier court, however, recognized that the statute was ambiguous. Moreover, the Supreme Court has recently recognized that a prior judicial construction of an ambiguous statute does not categorically control an agency's contrary construction. (*National Cable & Telecommunications Association* v. *Brand X Internet Services*, 125 S. Ct. 2688, 2701 (2005).) In section II.O. of this proposed rule, we explain the reasons for our interpretation of the statute that the eyeglass exclusion does apply to low vision aids.

K. Establishing Fee Schedule Amounts for New DMEPOS Items

Since 1989, CMS and its contractors have used an administrative process known as gap-filling to establish fee schedule amounts for DMEPOS items when fee schedule base data is not available, such as when a new code is added to Level II of the HCPCS to describe a new category of items. For example, section 1834(a)(2)(B) of the Act requires that the fee schedules for inexpensive or routinely purchased DME (for example, canes) be based on average reasonable charges for the item from July 1, 1986 through June 30, 1987. When a new code for an item (for example, a new category of canes) falling under this category is added to the HCPCS, reasonable charge data from 1986/87 is not available and the gap-filling process is used to estimate 1986/87 reasonable charges. Since 1989, fee schedule amounts have been gap-filled using either—

- Fee schedule amounts for comparable items;
- Supplier or retail prices; or
- Wholesale or manufacturer prices plus a reasonable mark-up.

There is currently no methodology set forth in regulations for establishing fee schedule amounts for DMEPOS items in these situations. Therefore, in § 414.210, we are proposing a modified version of our existing gap-filling process to be used in establishing fee schedule amounts for DMEPOS items to which are assigned new HCPCS Level II Codes. This process will be used to set payment amounts for all new DMEPOS items, even if those items fall within a product category that is subject to competitive bidding, until bids for those items are available for establishing payments in accordance with section 1847(b)(5) of the Act.

L. New Fee Schedules for Home Dialysis Supplies and Equipment

Section 1842(s)(1) of the Act gives the Secretary the authority to implement fee schedules to be used for payment under Medicare of specific items (listed in section 1842(s)(2) of the Act) still paid using the reasonable charge payment methodology described in section I.A. of this proposed rule. In § 414.107, we are proposing to use this authority to implement a fee schedule payment methodology for home dialysis supplies and equipment, one of these specified items.

M. Covered Item Updates for Class III DME for CYs 2007 and 2008

Sections 1834(a)(14)(H) and (I) of the Act give the Secretary discretion in determining the appropriate fee schedule update percentages for CYs 2007 and 2008, respectively, for DME which are ''class III medical devices described in section 513(a)(1)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(c)(1)(C)).'' In making these determinations, the Secretary must take into account recommendations contained in a report from the Government Accountability Office (GAO) regarding the appropriate update percentages for these devices. The GAO report is mandated by section 302(c)(1)(B) of the MMA and must be submitted to the Congress and transmitted to the Secretary by no later than March 1, 2006. Class III devices paid in accordance with the DME fee schedule payment methodology include osteogenesis or bone growth stimulators, implantable infusion pumps, external defibrillators, and ultraviolet light therapy systems. We are soliciting comments on how to determine the appropriate fee schedule percentage change for these devices for 2007 and 2008 and will consider these comments in conjunction with the recommendations in the GAO report in determining the appropriate update percentage for these devices for 2007 and 2008.

II. Provisions of the Proposed Regulation

We are proposing to add a new subpart F to part 414 to specify the requirements for the Medicare DMEPOS Competitive Bidding Program. Subpart F would set forth policies and procedures relating to the program in §§ 414.400 through 414.446.

A. Purpose and Definitions (Proposed § 414.400 and § 414.402)

[If you choose to comment on issues in this section, please include the caption ''Use of terms'' at the beginning of your comments.]

We propose in § 414.400 to state that the purpose of proposed new 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 are proposing to define certain frequently occurring terms that will be used in competitive bidding. Specifically, we are proposing 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 proposed rule.

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 proposed rule.

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.

(1) An inexpensive or routinely purchased item described in § 414.220;

(2) An item requiring frequent and substantial servicing as described in § 414.222;

(3) Oxygen and oxygen equipment described in § 414.226; and

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

Grandfathered supplier 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:

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

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

(c) Oxygen and oxygen equipment, as specified in § 414.226(b); and

(d) 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 the 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 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 items 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.

B. Implementation Contractor (Proposed § 414.406)

[If you choose to comment on issues in this section, please include the caption ''Implementation Contractor'' at the beginning of your comments.]

Section 1847(b)(9) of the Act provides that the Secretary may contract with appropriate entities to implement the Medicare DMEPOS Competitive Bidding Program. Therefore, in proposed § 414.406(a), we would designate one or more competitive bidding implementation contractors (CBICs) for the purpose of implementing the Medicare 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. The Secretary is exercising this authority to waive all requirements of the FAR, other than provisions dealing with confidentiality, because of the need for expeditious implementation of a program of this significance and magnitude. However, this does not preclude us from voluntarily using or adapting certain provisions of the FAR for purposes of the competitive bidding contracts.

We envision that the Medicare DMEPOS Competitive Bidding Program will 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. We considered the organizational structure and requirements necessary to conduct these functions, and have chosen to exercise our contracting authority under section 1847(b)(9) of the Act and contract with one or more CBICs to assist us with many of these functions.

We considered several options in designing the most appropriate framework for implementing the Medicare DMEPOS Competitive Bidding Program. Since the implementation of competitive bidding involves many functions that are time limited and require specialized skills, for example, setting up bidding areas, reviewing bids, and setting single payment amounts, we believe that it would be prudent to initially implement most aspects of the Medicare Competitive Bidding Program through one or more CBICs. Processing of Medicare claims for most DMEPOS is currently done by four DME regional carriers (DMERCs). These DMERCs would continue to process claims for DMEPOS items subject to competitive bidding and would continue to perform other existing DMERC functions. We have evaluated the anticipated feasibility and cost of using one or more implementation contractor(s) to assist us with implementing the Medicare DMEPOS Competitive Bidding Program, concentrating on the potential for capturing economies of scale and scope, program consistency, existing resources and infrastructure, and the viability of implementation under the timeframe mandated by section 1847(a)(1)(B) of the Act.

We would contract with one or more CBICs to conduct some program functions at a national level and interact with the DMERC contractors. Specifically, we envision that the CBIC(s) would conduct certain functions related to competitive bidding, such as preparing the request for bids (RFB), performing bid evaluations, selecting qualified suppliers, and setting single payment amounts for all competitive bidding areas. Additionally, the CBIC(s) would be charged with educating the DMERCs on the bidding process and procedures. The CBIC(s) would also assist CMS and the DMERCs in monitoring program effectiveness, access, and quality. The DMERCs would continue to provide outreach and education to beneficiaries and suppliers in their regions, process claims, apply the single payment amounts set by the CBIC(s) for each competitive bidding area, and continue to be responsible for complaints related to claims processing. We would continue to be responsible for overall

oversight and decision making, as well as policy related outreach and education to the CBIC(s), DMERCs, suppliers, and beneficiaries.

In our view, this approach would achieve economies of scale since the responsibility for producing program materials and evaluating bids would rest with the CBIC(s). As a result, we believe that this approach would both lower costs and ensure regional consistency in that the responsibility would not be divided between various entities.

We considered two other alternatives for implementation of the Medicare DMEPOS Competitive Bidding Program. The first was to have each DMERC conduct competitive bidding in its respective area and be responsible for all activities related to competitive bidding. The second alternative was to have the CMS Consortium Contractor Management Officer (CCMO)/ Regional Offices (RO) and the DMERCs implement the program. However, we believe that by using one or more specialized CBICs, we can successfully implement and effectively manage this program.

C. Payment Basis (Proposed § 414.408)

[If you choose to comment on issues in this section, please include the caption ''Payment Basis'' at the beginning of your comments.]

1. Payment Basis (§ 414.408(a))

Section 1847(b)(5) of the Act mandates that a single payment amount be established for each item in each competitive bidding area 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 Off-The-Shelf (OTS) orthotics, or section 1842(s) of the Act for enteral nutrition, as appropriate.

We are proposing in § 414.408 that payment to the contract supplier would be based on the single payment amount for the item in the competitive bidding area where the beneficiary maintains a permanent residence. If an item that is included in a competitive bidding program is furnished to a beneficiary who does not maintain a permanent residence in a competitive bidding area, the payment basis for the item would be 80 percent of the lesser of the actual charge for the item, or the applicable fee schedule amount for the item. We are also proposing 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.

2. General Payment Rules (Proposed § 414.408 (c–j))

Section 1834(a) of the Act and § 414.200 through § 414.232 (with the exception of § 414.228) set forth the Medicare Part B payment methodology we 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 area wide 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 the payment of purchased and rented enteral nutrients, equipment, and supplies (see § 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 use to pay for orthotics and prosthetics.

Other than the rules governing calculation of the single payment amount and other proposed modifications to existing policies that are addressed in this regulation, we propose 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, at this time we are proposing only to change the payment basis for these items.

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

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, items requiring frequent and substantial servicing, and capped rental items. Section 1834(a)(5) of the Act mandates that payment be made for oxygen and oxygen equipment 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. We are proposing the grandfathering process described below for rented DME and oxygen and oxygen equipment when these items are included under a competitive bidding program. This process would apply only to suppliers that began furnishing the items described above to beneficiaries who maintain a permanent residence in an area prior to the implementation of a competitive bidding program in that area that includes the same items.

In the case of the specific items identified in this section, we are proposing in § 414.408 to give beneficiaries the choice of deciding whether they would like to continue renting the item from the grandfathered supplier or a contract supplier, unless the grandfathered supplier is not willing to continue furnishing the item under the terms we have specified below. If the grandfathered supplier is not willing to continue furnishing the item under these terms, then 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 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 who agree to be grandfathered suppliers for a specific item must agree to be a grandfathered supplier for all beneficiaries who request to continue to use their service for that item.

b. Payment Amounts to Grandfathered Suppliers (§ 414.408(k))

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

For items requiring frequent and substantial servicing, as well as oxygen and oxygen equipment, we are proposing that a grandfathered supplier may continue furnishing these items to beneficiaries in accordance with

existing rental agreements or supply arrangements. However, we are also proposing that the grandfathered supplier be paid the single payment amounts determined for those items under the competitive bidding program since beneficiaries rent these items for extended time periods as long as the items remain medically necessary. We believe that this payment proposal is consistent with section 1847(a)(4), 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. Since the rental payments 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 not reasonable to continue paying the fee schedule amounts for these items and that payment at the competitively determined rates will comport with an overarching goal of competitive bidding to achieve savings for the Medicare program.

Unlike items requiring frequent and substantial servicing, the duration of the rental payments for capped rental items and inexpensive or routinely purchased items are 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. For items that are furnished on a rental basis under § 414.220 or § 414.229, we are proposing in § 414.408 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 competitive bidding area 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.

(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 rental 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 are proposing to apply section 1847(a)(4) not only in an area 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. We believe this proposal is consistent with section 1847(a)(4), which we interpret as applying to each competitive bidding ''program'' that we implement in an area, since each program will be unique in terms of bidders, contract suppliers, items included in the program, and prices. Our proposed policy would allow beneficiaries 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 are proposing 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) 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.

c. Payment for Accessories for Items Subject to Grandfathering

We propose 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, 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 DME competitive bidding demonstrations in that we paid grandfathered suppliers the competitively bid amount for certain items and the fee schedule amounts for other items. We specifically solicit comments on our grandfathering proposals.

4. Payment Adjustment to Account for Inflation (proposed § 414.408(b))

The fee schedule payment amounts for DMEPOS items are updated by annual update factors described in 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 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 three years. We propose applying an annual inflation update to the single payment amounts established for a competitive bidding program. Specifically, beginning with the second year of a contract entered into under a competitive bidding program, we would update the single payment amounts by the percentage increase in the CPI–U for the 12-month period ending with June of the preceding calendar year. Using the CPI–U index is consistent with Medicare using this index to update the

DME fee schedule. This will obviate the need for the supplier to consider inflation in the cost of business when submitting its bids for furnishing competitively bid items under a multi-year contract.

5. Authority To Adjust Payments in Other Areas (§ 414.408(e))

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 DMEPOS 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. We are proposing to use this authority but have not yet developed a detailed methodology for doing so. Therefore, we specifically invite comments and recommendations on this issue. We believe that our methodology will be informed by our experience and information gained from the competitive bidding programs in 2007 and 2009. When submitting recommendations on a methodology for using this authority, commenters should 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 competitive bidding area(s).

We will fully consider all comments and recommendations we receive on this subject.

6. Requirement To Obtain Competitively Bid Items From a Contract Supplier (§ 414.408(f))

Beneficiaries often travel to visit family members or to reside in a State with a warmer climate during the winter months. So that these beneficiaries do not have to return home to obtain needed DMPEOS items, in § 414.408(f)(2)(ii), we are proposing that beneficiaries on travel status be allowed to obtain items that they would ordinarily be required to obtain from a contract supplier for their competitive bidding area from a supplier that has not been awarded a contract to furnish items for that area. If the area that the beneficiary is visiting is also a competitive bidding area and the item is subject to the competitive bidding program in that area, he or she 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 competitive bidding area, or if the area is a competitive bidding area but the item needed by the beneficiary is not included in the competitive bidding program for that area, he or she 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 paid based on the single payment amount for the item in the competitive bidding area where the beneficiary maintains a permanent residence. We propose 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 competitive bidding area, the proposed travel status exemption would not apply. We plan to closely monitor the programs 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 are also proposing 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 DMERC 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 competitive bidding area 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 competitive bidding area, 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 are proposing that Medicare beneficiaries who maintain their permanent residence in a competitive bidding area 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 II.C.3. above.
- A beneficiary who is outside of the competitive bidding area where he or she maintains a permanent residence may obtain an item from a contract supplier, if he or she is in another competitive bidding area 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 competitive bidding area that does not include the item in its program or is in an area that is not a competitive bidding area.

Unless one of the exceptions discussed above applies, Medicare would not pay for the item.

7. Limitation on Beneficiary Liability for Items Furnished by Noncontract Suppliers (§ 414.408(f))

We are proposing that if a noncontract supplier located in a competitive bidding area furnishes an item included in the competitive bidding program for that area to a beneficiary who maintains a permanent residence in that area, the beneficiary would have no financial liability to the noncontract supplier unless the grandfathering exception discussed in section II.C.3. of this preamble applies. This rule would not apply if the noncontract supplier furnished items that are not included in the competitive bidding program for the area. We are proposing to specially designate the supplier numbers of all noncontract suppliers so that we will be able to easily identify whether a noncontract supplier has furnished a competitively bid item to a beneficiary who maintains a permanent residence in a CBA.

D. Competitive Bidding Areas

[If you choose to comment on issues in this section, please include the caption ''Competitive Bidding Areas'' at the beginning of your comments.]

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

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. Our proposed methodologies for selecting the MSAs for 2007 and 2009 are described in section II.D.1. of this preamble. Once the MSAs are selected for 2007 and 2009, we would define the competitive bidding areas for 2007 and 2009. The process we propose to use in establishing competitive bidding areas in future years is provided in section II.D.2. of this preamble.

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

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 would adopt a definition of the term ''metropolitan statistical area'' consistent with that issued by the Office of Management and Budget (OMB) and applicable for the years 2007 and 2009. 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 2000 (65 FR 82228–82238). Under these standards, an MSA is defined as a core based statistical area (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. The 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. The U.S. Census Bureau, however, 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 are proposing to use this data to identify the largest MSAs.

In this section, we propose formula driven methodology for selecting the MSAs for competitive bidding in 2007 and 2009. After we select the MSAs, we would define the competitive bidding areas. For the purpose of this section, DMEPOS allowed charges are the Medicare fee-for-service (FFS) allowed charge data for DMEPOS items that we have authority to include in a competitive bidding program. This data does not include Medicare expenditures for DMEPOS items under the Medicare Advantage Program.

a. MSAs for 2007

We propose to use a multiple step process in selecting the MSAs for 2007. First, we propose to identify the 50 largest MSAs in terms of total population in 2005 using population estimates published by the U.S. Census Bureau in its table of large MSAs from the Statistical Abstract of the United States. Second, the 25 MSAs out of the 50 MSAs identified in step one would be eliminated from consideration based on our determination that they have the lowest totals of DMEPOS allowed charges for items furnished in calendar year (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. For illustration purposes only, based on DMEPOS allowed charge data for items furnished in CY 2003 and Census Bureau population estimates as of July 1, 2003, the 25 MSAs that would be left for consideration after step two is completed are shown in Table 1. However, we would propose to select the actual MSAs for 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 would propose using population data for 2005 and DMEPOS allowed charge data for 2004 since this data will be the most recently available data at the time that the MSAs are selected for 2007 implementation.

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

MSA	Allowed charges
New York-Northern New Jersey-Long Island, NY-NJ-PA (New York)	$312,124,291
Los Angeles-Long Beach-Santa Ana, CA (Los Angeles)	253,382,483
Miami-Fort Lauderdale-Miami Beach, FL (Miami)	221,660,443
Chicago-Naperville-Joliet, IL-IN-WI (Chicago)	173,922,952
Houston-Baytown-Sugar Land, TX (Houston)	149,060,607
Dallas-Fort Worth-Arlington, TX (Dallas)	139,910,862
Detroit-Warren-Livonia, MI (Detroit)	121,444,298
San Juan, PR	108,478,208
Philadelphia-Camden-Wilmington, PA-NJ-DE-MD (Philadelphia)	97,487,063
Atlanta-Sandy Springs-Marietta, GA (Atlanta)	75,860,276
Tampa-St. Petersburg-Clearwater, FL (Tampa)	71,309,635
Boston-Cambridge-Quincy, MA-NH (Boston)	62,467,094
Washington-Arlington-Alexandria, DC-VA-MD-WV (DC)	61,416,109

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

MSA	Allowed charges
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

Third, we propose 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 would propose to use total DMEPOS allowed charges for items that we have authority to include in a competitive bidding in each MSA as the tiebreaker since this would be an indicator of where more program funds would be spent on DMEPOS items subject to competitive bidding. Table 2 illustrates how the 25 MSAs from Table 1 above would be scored based on data for CY 2003. The MSA rankings for charges per beneficiary and suppliers per beneficiary are listed in parentheses. We propose that the final scoring be based on utilization data for CY 2004 and population data for CY 2005.

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

For purposes of phasing-in the programs, we would propose to exclude from consideration for competitive bidding until 2009 the three largest MSAs in terms of population, as well as any MSA that is geographically located in an area served by two DMERCs. The three largest MSAs based on total population (based on 2003 data) are New York, Los Angeles, and Chicago. We believe that these MSAs should not be phased in until 2009 because of the

logistics associated with the start-up of this new and complex program. As of 2000, these three MSAs all had total populations 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 on to the three largest MSAs. After we have gained experience operating competitive bidding programs in CBAs that encompass smaller MSAs in 2007 and 2008, we would propose to implement programs that include New York, Los Angeles and Chicago in 2009.

However, we are 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), which states that competition under the programs shall occur in 80 of the largest MSAs in 2009 but does not require the competition to occur in the entire MSA. In addition, section 1847 does not prohibit us from implementing a competitive bidding program in an area that is larger than a MSA. We welcome comments on these alternatives.

We are proposing not to include competitive bidding areas that cross DMERC regions because this could complicate implementation by having two DMERCs processing claims from one competitive bidding area.

The next step we propose would entail ensuring that there is at least one competitive bidding area in each DMERC region by first selecting the highest scoring MSA in each DMERC region (other than New York, Los Angeles, Chicago, or MSAs that cross DMERC boundaries). This would ensure that each DMERC gains some experience with competitive bidding prior to 2009, when competitive bidding would be implemented in CBAs that include eighty MSAs. We would also propose to select no more than two MSAs per State among the initial competitive bidding areas selected for 2007 in order to learn how competitive bidding works in more states and regions of the country. In summary, we are proposing to select the ten MSAs in which competition under the programs would occur in 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 3 largest MSAs in terms of population (New York, Los Angeles, Chicago) and any MSA that crosses DMERC boundaries.
- Select the lowest scoring MSA from each DMERC region.
- Select the next 6 lowest scoring MSAs regardless of DMERC region, but not more than 2 MSAs from 1 State.
- Break ties in scores using DMEPOS allowed charges, selecting MSAs with higher total DMEPOS allowed charges.

There are a number of alternative methods for selecting the MSAs for 2007 that we considered. The MSAs could have been 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; 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 this alternative, 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 is 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 webpage. Another advantage of this option is 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 for competitive bidding 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 may 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, do not propose using general population as the sole variable in selecting the MSAs for 2007.

An advantage of selecting MSAs based on the Medicare FFS population is 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 do not propose using FFS population as the sole variable in selecting the MSAs for 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 that are most likely to be directly affected by competitive bidding because they already have a need for these items. A disadvantage of this option 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 to a Medicare Advantage plan. For these reasons, we do not propose using number of beneficiaries receiving DMEPOS items as the sole variable in selecting the MSAs for 2007.

Selecting the MSAs using the steps we propose utilizes a variety of variables that we believe will 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, 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 would 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 request for bids 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.

We welcome comments about the selection method for the original ten MSAs in 2007. We welcome recommendations of other options and criteria for consideration. After further consideration of comments, 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.

b. MSAs for 2009

In selecting the 70 additional MSAs in which competition will occur in 2009, we propose using generally the same criteria used to select the MSAs for 2007. Since the number of MSAs in which competition must occur in 2009 is much higher than the number for 2007, 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 propose using the same criteria to score the MSAs as we would use in selecting the MSAs for 2007, but use data from CY 2006.

One option we are considering and on which we are requesting 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 2007.

In selecting the MSAs for 2009, we do not propose excluding the 3 largest MSAs in terms of population size or MSAs that cross DMERC boundaries from the 80 largest MSAs to be included in the CBAs. In addition, we do not propose limiting the number of MSAs that can be selected from any one state.

2. Establishing Competitive Bidding Areas (§ 414.410)

Section 1847(a)(1) of the Act requires that we phase in competitive bidding programs and establish competitive bidding areas throughout the United States over several years beginning in 2007. Section 1847(a)(3) 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.'' Our proposed methodology for establishing competitive bidding areas under the Medicare DMEPOS Competitive Bidding Program is presented below.

a. Authority To Exempt Rural Areas and Areas With Low Population Density Within Urban Areas (§ 414.410(c))

Section 1847(a)(3) of the Act allows us to exempt from the Medicare DMEPOS Competitive Bidding Program 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. We propose to use this authority to exempt areas from competitive bidding if data for the areas indicate that they are not competitive based on a combination of the following indicators:

- Low utilization of items in terms of number of items and/or allowed charges for DMEPOS in the area relative to other similar geographic areas.
- Low number of suppliers of DMEPOS items subject to competitive bidding serving the area relative to other similar geographic areas; and/or
- Low number of Medicare FFS beneficiaries in the area relative to other similar geographic areas.

We would propose to make decisions regarding what constitutes low (non-competitive) 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 FFS beneficiaries and DMEPOS suppliers in specific geographic areas. In defining urban and rural areas, we propose to use the definitions currently in § 412.64(b)(1)(ii) of the regulations.

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

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

Section 1847(a)(1)(B) of the Act requires that the competition ''occurs in'' 10 of the largest MSAs in 2007, and in 80 of the largest MSAs in 2009, but does not require us to define the competition boundaries concurrently with the MSA boundaries, as long as 10 MSAs are involved in 2007 and 80 MSAs are involved in 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 2007 or 2009. We propose that an area (for example, a county, parish, zip code, etc.) outside the boundaries of an MSA be considered for inclusion in a competitive bidding area for 2007 and/or 2009 if all of the following apply:

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

As explained in section D.1. above, we are defining 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, the 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 believe that it would be practical and beneficial to include this area in the competitive bidding area. The savings to the program associated with adding the area to the competitive bidding area would likely offset any incremental administrative costs incurred by the implementation contractor associated with including the area in the competitive bidding program for the MSA. Finally, we are not proposing to consider counties that do not adjoin an MSA for inclusion in a competitive bidding area for 2007 or 2009 because we believe that these outlying counties are too far removed from the areas that OMB has determined to be economically integrated. We are proposing 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 will detail in the request for bids the exact boundaries of each CBA. We invite comments on the criteria to be used in considering whether to include counties outside MSAs in a competitive bidding area in 2007 or 2009.

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

Our data shows that a significant percentage of certain items such as diabetic testing supplies (blood glucose test strips and lancets) are furnished to beneficiaries by national mail order suppliers. Therefore, we propose 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 order outlet. The national or regional competitive bidding areas under this program would be phased in after 2009, and payment would be based on the bids submitted and accepted for the furnishing of items through mail order throughout the nation or region. Suppliers that furnish these items through mail order on either a national or regional basis would be required to submit bids to participate in any competitive bidding program implemented for the furnishing of mail order items.

We propose that prior to the establishment of a nationwide or regional competitive bidding program in 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 2007 and 2009 implementation phases. In addition, beginning with programs implemented in 2010, 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. National 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. They would, however, 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 propose that suppliers who furnish these same items in the local market and do not furnish them via mail order would not be required to participate in the national or regional mail order competitive bidding program. However, we would only allow these suppliers to continue furnishing the items in areas if they were selected as a contract supplier.

We propose to allow these non-mail 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 that do not maintain a permanent residence in a competitive bidding area, non-mail order suppliers would be paid based on the payment amount applicable to the area where the beneficiary maintains his or her permanent residence.

In its September 2004 report (GAO–04–765), the 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. We are asking for comments on our proposal to implement this recommendation, as well as for comments on the types of items that would be suitable for a mail order competitive bidding program. In addition, we are requesting public comment on an alternative that would require replacement of all supplies such as test strips and lancets for Medicare beneficiaries to be furnished by mail order suppliers under a nationwide or regional mail order program. For example, there are services paid under the physician fee schedule 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 patient, the services associated with furnishing the supplies must be provided on a timely basis and the patient must receive the brand of test strips needed for his or her monitor. We invite public comment on whether the service of furnishing replacement test strips, lancets or other supplies can easily, effectively, and conveniently be performed by national mail order suppliers.

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

Section 1847(a)(1)(B)(III) of the Act requires that competition under the Medicare DMEPOS Competitive Bidding Program occur in additional areas after 2009. Beginning in 2010, we would designate through program instructions additional competitive bidding areas 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.

E. Criteria for Item Selection

If you choose to comment on issues in this section, please include the caption ''Criteria for Item Selection'' at the beginning of your comments.≤

Section 1847(a)(2) of the Act describes the items subject to competitive bidding as follows:

- 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.
- Off-The-Shelf (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.

We are proposing that minimal self-adjustment would mean adjustments that the beneficiary, caretaker for the beneficiary, or supplier of the device can perform without the assistance of a

certified orthotist (that is, an individual certified by either the American Board for Certification in Orthotics and Prosthetics, Inc. or the Board for Orthotist/Prosthetist Certification). By contrast, we would consider any adjustments that can only be made by a certified orthotist to be adjustments that require an expertise in trimming, bending, molding, assembling, or customizing to fit the individual. We are proposing 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 welcome 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 propose 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 program 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 are proposing 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 Program. In section II.F. of this preamble, we propose to conduct competitive bidding for product categories that would be described in each RFB. Suppliers will submit a separate bid for each item under a defined product category, unless specifically excluded in the RFB. We propose to include a ''core'' set of product categories in each competitive bidding area. We may elect to phase in some individual product categories in a limited number of competitive bidding areas in order to test and learn about their suitability for competitive bidding.

Because we have not yet identified the product categories for competitive bidding, we are using 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 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 DMERC medical review policy. For example, the policy group, oxygen and supplies, consists of approximately 20 HCPCS codes. Although the product categories subject to competitive bidding will not necessarily correspond to these policy groups, we present 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 propose 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.—2003 HIGH VOLUME ITEMS

[HCPCS Codes]

HCPCS	Allowed charges	Product description	Product 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 several codes above have been modified. We expect that power wheelchairs (K0011) will be billed under several new HCPCS codes in the near future.

Because we propose that we will conduct competitive bidding for items grouped into product categories, we will 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 a competitive bidding program. Data from the SADMERC for claims received in 2003 is used for all policy groups except those for nebulizers and OTS orthotics. For the nebulizer and OTS orthotics groups, data is included from the CMS BESS (Part B Extract and Summary System) database for items furnished in 2003. The percentage of total allowed Medicare charges for DMEPOS that each policy group makes up is included in Table 4.

TABLE 4.—2003 DMEPOS ALLOWED CHARGES BY POLICY GROUP

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

* Data is from BESS (Date of Service). Data for orthoses policy groups excludes 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. We are proposing to use a combination of the following variables when making determinations about an item's potential savings as a result of the application of competitive bidding.

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

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

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 competitive bidding area 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 demonstration 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 Program were included in at least one round of the DMEPOS demonstration: Oxygen equipment and supplies; hospital beds and accessories; enteral nutrition; wheelchairs and accessories; and general orthotics.

The demonstration results 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 demonstration occurred more than three years ago and the fee schedule has changed as a result of certain provisions in the MMA, such as, section 302(c)(2) (codified at 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 employee health plan (FEHP).

The Office of Inspector General (OIG) and the 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(s) if it were included in competitive bidding. Examples of relevant studies from the OIG 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 DMERCs 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. 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 do 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 the results of these studies.

F. Submission of Bids Under the Competitive Bidding Program (Proposed § 414.412)

[If you choose to comment on issues in this section, please include the caption ''Submission of Bids Under the Competitive Bidding Program'' at the beginning of your comments.]

Sections 1847(b)(6)(A)(i) and (ii) of the Act state that payment will not be made 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 competitive bidding area to receive payment for those items, the supplier must have submitted a bid to furnish those particular items and must have been awarded a contract to do so by CMS. There are limited exceptions to this requirement for beneficiaries who reside in a competitive bidding area but are out of the area and need items. There is also an exception for suppliers that are grandfathered to continue to provide and service certain items, as discussed in section II.C.3. of this preamble.

1. Providers (Proposed § 414.404, § 414.422)

We are proposing that providers that furnish Part B items and are located in a competitively bidding area and are also DMEPOS suppliers, must submit bids in order to furnish competitively bid items to Medicare beneficiaries. Providers that are not awarded contracts must use a contract supplier to furnish these items to the Medicare beneficiaries to whom they provide services. However, a skilled nursing facility (SNF) 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. This is consistent with the current practice of some SNFs to furnish Part B services only to their own residents.

2. Physicians (Proposed § 414.404, § 414.422)

We are proposing that physicians that are also DMEPOS suppliers must 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. Physicians that do not become contract suppliers must use a contract supplier to furnish competitively bid items to their Medicare patients. However, they will not be required to furnish these items to beneficiaries who are not their patients if they choose not to function as commercial suppliers. In proposing this policy for physicians who are also DMEPOS suppliers, we recognize that the physician self-referral law (section 1877 of the Act) generally prohibits physicians from furnishing to their office patients a variety of common DMEPOS items. 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.

We have established a Web site where requests for bids (RFBs) and other pertinent program information will be posted, and we plan to alert the supplier community by e-mail of all postings on this 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 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 the supplier is included as part of the bid evaluation process.

We considered requiring all suppliers to be physically located within a competitive bidding area in order to submit a bid to furnish items in that area. However, we feel that this requirement would be too proscriptive. We believe that suppliers that are located outside of a competitive bidding area, but do business in the competitive bidding area and are able to service beneficiaries residing within the CBA should be permitted to submit bids and participate in the competitive bidding program for that area.

3. Product Categories for Bidding Purposes (Proposed § 414.412)

We propose to conduct bidding for items that are grouped into product categories. Suppliers would be required 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, suppliers would only be required to 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 RFB. We propose to define the term ''product category'' as a group of similar items used in the treatment of a related medical condition (for example, hospital beds and accessories). We believe that 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.

There were 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 DMERCs. However, these policy groups were not established for the purpose of competitive bidding. We are proposing to specifically develop product categories for the purpose of competitive bidding. We anticipate that the product categories will range from Breast Prosthesis, Dialysis Equipment and Supplies, to Oxygen and Power Wheelchairs. 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 would propose not to include items in a product category if they are rarely used or billed to the program. In addition, we would not include items within a product category if we believed that these were items for which we might not realize a savings. Therefore, under this approach, we propose to establish product categories to identify those items included in competitive bidding and may establish different product categories from one CBA to another, as well as in different rounds of competitive bidding in the same CBA.

We chose 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 who want to specialize in one or a few product categories. For example, if a supplier wants to specialize in the treatment of respiratory conditions, the supplier can 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. This approach is also more favorable to small suppliers because they can choose to specialize in only one product category. It would be more difficult for a small supplier rather than a large supplier to furnish all product categories. This approach is also more convenient for Medicare beneficiaries, as they can 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 their condition. We recognize 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 will facilitate the transition for those beneficiaries who have to change suppliers. It is also our goal to establish a productive relationship between the supplier and the beneficiary, and we believe we can accomplish this goal by designing the competitive bidding program so the beneficiary has the option of selecting one supplier that would be responsible for the delivery of all medically necessary items that fall within a product category.

4. Bidding Requirements (§ 414.408)

In preparing a bid in response to the request for bids, we would propose that suppliers look to our existing regulations at part 414, subparts C and 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

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

b. DME Items Requiring Frequent and Substantial Servicing

We propose that bids be submitted for the monthly rental of items in this payment category with the exception of continuous passive motion exercise devices. We propose 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, this is consistent with § 414.222(b) our 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

If included under a competitive bidding program, we would propose that the single payment amounts for oxygen and oxygen equipment be calculated based on separate bids submitted and accepted for furnishing on a monthly basis of each of the oxygen and oxygen equipment categories of services described in § 414.226(b)(1)(i) through (b)(1)(iv).

d. Capped Rental Items

With the exception of power wheelchairs, payment for items that fall into this payment category is currently made on a rental basis only. The rental fee schedule payments for months 1 through 3 are based on 10 percent of the purchase price for the item as determined under § 414.229(c). 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). Since the DRA change does not apply to beneficiaries using a capped rental item prior to January 1, 2006, these beneficiaries may still elect either to take ownership of the item after 13 months of continuous use or to continue renting the item beyond 13 months of continuous use. In addition, the DRA leaves in tact 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 suppliers to transfer title to the item to the beneficiary after 13 months of continuous use. Under the Medicare DMEPOS Competitive Bidding Program, we propose that separate payment for reasonable and necessary maintenance and servicing only be made for beneficiary-owned DME. Payment for maintenance and servicing of rented equipment would be included in the single payment amount for rental of the item. We propose that the lump sum purchase option in § 414.229(d) for power wheelchairs be retained under the Medicare DMEPOS Competitive Bidding Program.

Under the Medicare DMEPOS Competitive Bidding Program, we propose that ''purchase'' bids be submitted for the furnishing of new items in this category. Based on these bids, a single payment amount for purchase of a new item will be calculated for each item in this category for the purpose of determining both the single payment amount for the lump sum purchase of a new power wheelchair, and for calculating the single payment amounts for the rental of all items in this category. 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 believe 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.

e. Enteral Nutrition Equipment and Supplies

Enteral nutrition equipment is currently paid on a purchase or rental basis. Section 6112(b)(2)(A) of the Omnibus Budget Reconciliation Act of 1989 (Pub. L. 101–239) (OBRA 89) limits the rental payments to 15 months. To be consistent with the bidding requirements proposed above for capped rental DME, we propose 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 nutrition equipment, the single payment amount for new enteral nutrition equipment would be based on the bids submitted and accepted for new enteral nutrition equipment, and the single payment amount for used enteral nutrition equipment would be based on 75 percent of the single payment amount for the purchase of new enteral nutrition equipment.

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

f. Maintenance and Servicing of Enteral Nutrition Equipment

Section 6112(b)(2)(B) of OBRA 89 requires payment 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 require 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 propose 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 propose 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. In addition, we propose to establish the maintenance and service payments for enteral nutrition equipment so that they are equal to 5 percent of the single payment amounts for the purchase of new enteral nutrition equipment. 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. We are proposing 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. This proposed policy is similar to current Medicare payment rules in Chapter 20 of the claims processing manual, section 40.3.

g. Supplies Used in Conjunction With DME

We propose 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. OTS Orthotics

We propose 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.

G. Conditions for Awarding Contracts (Proposed § 414.414)

[If you choose to comment on issues in this section, please include the caption ''Conditions for Awarding Contracts'' at the beginning of your comments.]

1. Quality Standards and Accreditation (Proposed § 414.414(c))

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) instructs the Secretary to establish and implement quality standards for all DMEPOS suppliers in the Medicare program, not just for suppliers in the competitive bidding areas. All suppliers will have to meet these quality standards to be eligible to submit claims to the Medicare program, irrespective of the competitive bidding program. The quality standards are to be applied by recognized independent accreditation organizations designated by the Secretary under section 1834(a)(20)(B) of the Act. 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. We solicit public comments on the length of time for the grace period.

Suppliers that received a valid accreditation before CMS-approved accreditation organizations are designated will be considered to be grandfathered if the accreditation was granted by an organization that we designate through the process described in proposed § 424.58. These suppliers will not need to be re-accredited until their next regularly scheduled accreditation.

2. Eligibility (Proposed § 414.414(b))

We propose that all bidders must meet eligibility rules to be considered for selection under the Medicare DMEPOS Competitive Bidding Program. The eligibility rules are included in the supplier standards regulation at § 424.57. Also, each bidder must be enrolled with Medicare and be a current supplier, in good standing with the Medicare program, and not under any current Medicare sanctions. Each bidding supplier must certify in its bid that it, 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.

Sanctions would include, but are not limited to, debarment from any Federal program, sanctions issued by the Office of Inspector General, or sanctions issued at the State or local level. In addition, the bidder must have all State and local licenses required to furnish the items that are being bid. Finally, the supplier must agree to all of the terms in the contract outlined in the RFBs. We would suspend or terminate a contract if a supplier loses its good standing with us or any other government agency.

3. Financial Standards (Proposed § 414.414(d))

Section 1847(b)(2)(A)(ii) specifies that we may not award a contract to an entity unless the entity meets applicable financial standards specified by the Secretary. Evaluation of financial standards for 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, the RFBs will identify the specific information we will require to evaluate suppliers, which may include: a supplier's bank reference that reports general financial condition, credit history, insurance documentation, business capacity and line of credit to successfully fulfill the contract, net worth, and solvency. We welcome comments on the financial standards, in particular the most appropriate documents that will 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.

As we develop our methodology for financial standards, we will further consider which individual measures should be required so that we can obtain as much information as possible while minimizing the burden on bidding suppliers and the bid evaluation process.

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

We are proposing to select the product categories that include individual items for which we will require competitive bidding. Individual products will be identified by the Healthcare Common Procedure Coding System (HCPCS Codes) and will be further described in the RFB. Suppliers will be required to submit bids for each individual item within each product category they are seeking to furnish under the program, but will not be required to bid for every product category.

a. Market Demand and Supplier Capacity (Proposed § 414.414(e))

Section 1847(b)(4)(A) of the Act requires that in awarding competitive bidding contracts, the Secretary must select the number of contract suppliers necessary to furnish items to meet the projected demand in the geographic area. Therefore, the first step is for us to determine the expected demand for an item in a competitive bidding area. We propose to calculate expected demand in each competitive bidding area in a relatively straightforward way using existing Medicare claims. We will examine claims data to determine the number of units of each item supplied to Medicare beneficiaries during the past 2 years, and then determine the number of new beneficiaries that have entered the market during the last 2 years. We feel that 2 years worth of data is sufficient to allow us to identify trend analyses and utilization measurements. We will also gather data on the number of new fee-for-service Medicare enrollees coming into a competitive bidding area and use this number to project the number of new enrollees.

We propose to calculate two years worth of claims on a monthly basis to determine beneficiary demand. We will 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 propose to use 2 years of data to identify any time trends. If there are no seasonal effects or time trends, we propose to use the average monthly total and new patient figures as the market demand measures. If there are seasonal effects or changes identified only during certain months, the maximum monthly total and new patient figures would be used as the market demand measures. If trends show that there is noticeable growth or reduction in beneficiary demand for products in an area, we would take these factors into consideration when developing estimates of beneficiary demand for competitively bid items.

We propose to adopt the following approach to estimate supplier capacity

to meet the projected demand in a CBA. First, we propose to analyze Medicare claims to determine how many items a supplier is currently providing in the competitive bidding area, as well as in total. Second, as part of the bid, we would ask suppliers to say how many units they are 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 would 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 would 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 this data to make estimates about capacity because suppliers may have more capacity potential than they are currently exhibiting. During the DMEPOS demonstration, demonstration suppliers were able to expand their output to meet market demand and replace market share previously provided by non-demonstration 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 welcome comments on our proposed approach for calculating market demand and estimating supplier capacity. We are 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.

b. Composite Bids (Proposed § 414.414(e))

When suppliers are 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 supplier should be selected since different suppliers may submit the lowest bids for different items. Therefore, we propose to use a composite bid to compare all of the suppliers' bids submitted for an entire product category in a CBA. Using a composite bid is a way to aggregate a supplier's bids for individual items within a product category into a single bid for the whole product category. This will 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 seek comment on the best method of weighting individual items within a product category to determine the composite bid. One approach we are considering is 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 are considering is 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. This approach may better reflect the relative value of each item because it is based on how much we actually pay for an item. This is the approach that we used in the round 1 bidding in Polk County under the competitive bidding demonstration program. However, we 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 who offered lower bids having a higher composite bid than a supplier who offered a higher bid for individual items.

We use volume of items or units as the basis of the following examples but we are requesting comments on which weighting method should be used in calculating the composite. We also request 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 a 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 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. The table 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 this 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), 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 bid selection we would first ensure that suppliers meet quality and financial standards prior to arraying the bids and selecting suppliers.

c. Determine the Pivotal Bid (Proposed § 414.414(e))

We propose that the pivotal bid would be the point where expected combined capacity of the bidders is sufficient to meet expected demands of beneficiaries for items in a product category. In the example below, the projected demand would be for 1000 units, therefore supplier 10's composite bid would represent the pivotal bid, since the cumulative capacity of 1100 would exceed the projected demand of 1000. The statute requires multiple winners, so in all cases where we award bids, we would need to accept at least two winning bidders. All bidders who are eligible for selection and whose composite bid for the product category is less than or equal to the pivotal bid would be selected as winning bidders. In the table 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 realize that this approach may leave out other suppliers with very close, but slightly higher bids.

TABLE 7.—DETERMINE THE PIVOTAL BID

[Point where beneficiary demand is met by supplier capacity—for this example, beneficiary expected demand is 1000 units—supplier 10's bid is the pivotal bid]

Supplier number	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 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.

There are other options that we have considered to determine the pivotal bid. One of these options would be 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 be set equal to the median bid from eligible suppliers. This option has the advantage that the pivotal bid could be set near the central distribution of bids. We considered including additional suppliers who are close to the central distribution as being eligible to become a contract supplier. Both options would likely affect the number of contract suppliers. Finally, the exact summary statistic or percentile can be increased or decreased to reflect our trade-off between the number of winners and program costs. One negative aspect of this approach would be that winners may have insufficient capacity. In addition, with a given percentile cutoff, the pivotal bid might include an excessive number of winning bidders. As the number of eligible bidders increases, so does the number of winners. If additional bidders have higher costs, and their bids fall into the upper half of the distribution, the pivotal bid will increase, resulting in greater payments by the Medicare program and a loss of savings.

Another option would be to base the pivotal bid on a target number of winners. For example, we may decide to select 5 winners in each product category. Suppliers may respond to this approach by bidding aggressively, knowing that only a fixed number of winners are guaranteed to be selected. A negative aspect of this approach is that there is no assurance that a predetermined target number of winners would have sufficient capacity to meet projected market demand. In addition, the target number of winners must somehow be selected and this could result in selecting an arbitrary number. If too high, suppliers may have little incentive to bid aggressively.

We also considered an option to base the pivotal bid on a target composite bid, for example, we would choose a target that was 20 percent below the DMEPOS fee schedule amount for that product category. A possible advantage of this approach is that the target composite bid can 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.

We are proposing that the pivotal bid be at the point where we have a sufficient number of suppliers to ensure we have enough capacity to meet projected demand and that beneficiaries have adequate access to quality items.

d. Assurance of Savings (Proposed § 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 competitive bidding area are expected to be less than the total amounts that would otherwise be paid. We are proposing 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 competitive bidding area are expected to be less for a competitively bid item than would have otherwise been paid. Therefore, we would not accept any bid for an item that is higher than the current fee schedule amount for that item. This approach would require that single payment amounts for each item in a product category be equal to or less than our current fee schedule amount for that item.

An alternative interpretation of ''less than the total amounts that would otherwise be paid'' could mean contracts will 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 that would have otherwise been paid. During the demonstration, several product categories received overall savings, whereas payment amounts increased for a few individual items within those product categories. This approach may not result in adequate savings, and we believe a reasonable interpretation of the Act would be one in which ''the total amounts'' mean payment at the item level. One concern with this approach is that there may be a greater potential for shifting of utilizations from one item to another higher priced item.

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

e. Assurance of Multiple Contractors (Proposed § 414.414(g))

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 will have multiple contract suppliers in each competitive bidding area for each product category if at least two suppliers meet all requirements for participation, and the single payment amounts to be paid to those suppliers do not exceed the fee schedule amounts for the items that were bid. We know 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 quality of items. We have to weigh that advantage against the disincentive for a supplier to submit its best bid if we select too many suppliers to service a competitive bidding area. Therefore, we believe that having multiple suppliers servicing one product category in a competitive bidding area will allow us to accomplish these goals.

f. Selection of New Suppliers After Bidding (Proposed § 414.414(h))

We are proposing to select only as many suppliers as necessary to ensure we have enough capacity to meet projected demand. However, we may 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 could 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 would propose 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 would propose to then refer to the list of suppliers that submitted bids for that product category in that round of competitive bidding in that competitive bidding area, use the list of composite bids that 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 would 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 competitive bidding area. 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, CMS was told 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 are not proposing, 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.

H. Determining Single Payment Amounts for Individual Items (Proposed § 414.416)

[If you choose to comment on issues in this section, please include the caption ''Determining Single Payment Amounts for Individual Items'' at the beginning of your comments.]

1. Setting Single Payment Amounts for Individual Items (Proposed § 414.416(b))

Section 1847(b)(5)(A) of the Act requires that the Secretary determine a single payment amount for each item in each competitive bidding area based on the bids submitted and accepted for that item. 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 are considering several different methodologies for determining the single payment amounts. Each of the options under consideration are discussed in detail in this section. After careful consideration of these options, we are proposing 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 have 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.

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 the winning bids for that item. This methodology also has the advantage of being easily understood by suppliers and implemented by our contractors. It also results in what we consider to be a reasonable payment amount based on prices available in the marketplace. As illustrated in Table 8, this methodology would reduce the effect of excessively high or excessively low bids and would also help to ensure savings for the Medicare program. We believe it is also consistent with the intent of competitive bidding.

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 is our proposed approach, we are soliciting 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 require the following steps. The first step of this methodology would be to calculate the average of the winning bids per individual item. The second step would be 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 be 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 take the average of the winning bids per item and multiply 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 become the single payment amount for the individual item. This is the price that all contract suppliers within a competitive bidding area would be 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 ensure that the overall payment amounts that contract suppliers received was 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 do not favor this alternative because, in general, most payment amounts would be higher than the actual bids as a result of the adjustment factor being greater than zero. This is 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. While this approach is still under consideration, we are considering whether this approach is reflective of the actual winning bids accepted. Also, we are concerned that this methodology may 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 do not favor this alternative because we also do 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 since 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.

We are still in the process of determining the appropriate approach for setting payment amounts, as well as the alternatives considered and outlined above and invite comments on our proposed methodology. We will consider all comments in the final regulation.

2. Rebate Program (Proposed § 414.416(c))

We are proposing to allow contract suppliers that submitted bids for an individual item below the single payment amount to provide the beneficiary with a rebate. 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:

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 co-insurance 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 co-insurance, the contract supplier would be responsible for providing the beneficiary with a $10 rebate. We are soliciting comments on how to handle those cases in which the rebates would exceed the co-payment amount.

Before deciding to propose this methodology, we considered whether to make the rebates mandatory or optional. We are proposing that the rebates be voluntary but that contract suppliers cannot implement them on a case by case basis. If a contract supplier submits 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 may be voluntary, once a contract supplier decides to provide rebates, the rebates become a binding contractual condition for payment during the term of the contract with CMS. Moreover, the contract supplier may 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.

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 reasons for allowing these contract suppliers to offer rebates is to allow beneficiaries the ability to realize additional savings and the full benefits of the Medicare DMEPOS Competitive Bidding Program.

We are asking for comments concerning the rebate process outlined in this proposed rule. CMS will continue to evaluate the fraud and abuse risks of the proposed rebate program, and we are specifically soliciting comments on such risks.

I. Terms of Contracts (Proposed § 414.422)

[If you choose to comment on issues in this section, please include the caption ''Terms of Contract'' at the beginning of your comments.]

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. Section 1847(b)(3)(B) requires the Secretary to recompete contracts under the Medicare DMEPOS Competitive Bidding Program at least every 3 years. The length of the contracts may be different for different product categories, and we propose to specify the length of each contract in the Request for Bids.

1. Terms and Conditions of Contracts

We propose 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.
- Non-discrimination against beneficiaries in a competitive bidding area (so that all beneficiaries inside and outside of a competitive bidding area receive the same products that the contract supplier would provide to other customers).
- Supplier enrollment and quality standards.
- The single payment amounts for covered items.
- Other terms as we may specify.

2. Furnishing of Items (Proposed § 414.422(c))

A contract supplier must agree to furnish the items included in its contract to all beneficiaries who maintain a permanent residence or who visit the competitive bidding area and request those items from the contract supplier. However, as explained in sections II.F.1 and II.F.2 above, a skilled nursing facility defined in section 1819(a) of the Act that is also a contract supplier must only agree to furnish the items included in its contract to patients to whom it would otherwise furnish Part B services. In addition, a physician that is also a contract supplier must only agree to furnish the items included in its contract to his or her patients.

3. Repairs and Replacements of Patient Owned Items Subject to Competitive Bidding. (Proposed § 414.422(c))

Repair or replacement of patient-owned DME, enteral nutrition equipment or off-the-shelf orthotics, that are subject to the competitive bidding program, must be furnished by a contract supplier because only winning suppliers can provide these items in a competitive bidding area. The contract supplier cannot refuse to repair or replace patient-owned items subject to competitive bidding. This proposed policy will help ensure that the beneficiaries will get the items from qualified suppliers, and it is consistent with the competitive bidding program in that it directs business to contract suppliers.

Therefore, we propose that repair or replacement of patient-owned items subject to a competitive bidding program must be furnished by a contract supplier. This requirement does not apply to beneficiaries who are outside of a competitive bidding area.

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

We propose 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. This policy will prohibit contract suppliers 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 are proposing 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 II.C.3. above. Suppliers must factor the cost of furnishing items in these situations into their bid submissions. Also, 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, the contract supplier must agree to give the beneficiary or his or her caregiver the choice of either renting or purchasing the item and must furnish the item on a rental or purchase basis as directed by the beneficiary or the beneficiary's caregiver. Suppliers must factor the cost of furnishing these items on both a rental and purchase basis into their bid submissions.

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

In order to obtain medically necessary DMEPOS or other equipment, a beneficiary whose permanent residence is located outside of a CBA must use a contract supplier to obtain all items subject to competitive bidding in the competitive bidding area that he or she visits. We considered allowing beneficiaries whose residence is outside of a competitive bidding area to obtain these items from noncontract suppliers when coming into a competitive bidding area. However, consistent with section 1847(b)(6), we are proposing that they 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 competitive bidding area if they qualified for the grandfathering program discussed in section II.C.3 above.

6. Information Collection From the Supplier

The following is a list of some of the terms, conditions and information that we propose a supplier must agree to provide to CMS for purposes of assessment prior to becoming a contract supplier:

- Information on product integrity.
- Information on business integrity.
- Organizational conflicts of interest.
- Name.
- Physical address.
- Billing address.
- Phone number.
- NSC number.
- Names of all owners.
- NSC number of any affiliated company.
- Address and phone number of any affiliated company.
- Employee information.
- Number of employees.
- Training and qualifications.
- Customer service protocol.
- Information on any bankruptcy proceedings involving the bidding company or any affiliated company.

We invite comments on what terms and conditions should be included in a contract for the competitive bidding program. We are interested both in terms and conditions that should be omitted as well as terms and conditions that should be added.

7. Change in Ownership (Proposed § 414.422(d))

We propose to evaluate a company'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 are proposing 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 anti-competition prohibitions. Therefore, contract suppliers must notify CMS in writing 60 days prior to any changes of ownership, mergers or acquisitions being finalized.

We 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.
- 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 non-fulfillment of obligations of the original contract supplier.

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

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

Contract suppliers are held to all the terms of their contracts for the full length of the contract period. Any deviation from contract requirements, including a failure to comply with governmental agency or licensing organization requirements, would constitute a breach of contract. 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 (that may include reprocurement costs), precluding the supplier from participating in the competitive bidding program, or availing ourselves of other remedies permitted by law. We would also have the right to terminate the contract for convenience.

J. Administrative or Judicial Review (§ 414.424)

[If you choose to comment on issues in this section, please include the caption ''Administrative or Judicial Review'' at the beginning of your comments.]

Section 1847(b)(10) of the Act provides that there will be no administrative or judicial review 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 competitive bidding areas for the Medicare DMEPOS Competitive Bidding Program;
- Phased-in implementation of the Medicare DMEPOS Competitive Bidding Program;
- Selection of items for a competitive bidding program.
- Bidding structure and number of contract suppliers selected under a competitive bidding program.

This proposed regulation has 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 competitive bidding area in a manner not authorized by this rule.

K. Opportunity for Participation by Small Suppliers

[If you choose to comment on issues in this section, please include the caption ''Opportunity for Participation by Small Suppliers'' at the beginning of your comments.]

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 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 into either 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 million in annual receipts.

We propose using the SBA small business definition when evaluating whether a DMEPOS supplier is a small supplier. We are relying on the expertise of the SBA to determine what constitutes the appropriate definition of a small supplier. All contract suppliers are expected to service the whole competitive bidding area. However, we considered allowing a small supplier that has fewer than 10 full-time equivalent employees to designate a geographic service area that is smaller than the entire competitive bidding area. However, we are not proposing this approach because we want to ensure that beneficiaries have the choice of going to any contract supplier in their respective CBA. Carve out areas could lead to confusion for the beneficiary faced with multiple competitive bidding sub-areas. 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 seek 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 2003. The figure of $1 million could be an underestimate of total receipts, since 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 demonstration. 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. We propose 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 would have to somehow 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 propose 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 recognize the importance of small suppliers in the DMEPOS industry, and we welcome comments on any the options identified above. We are also interested 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. We will review our efforts to ensure participation by small suppliers in the Medicare DMEPOS Competitive Bidding Program after we review comments to this proposed rule and the results of the focus groups. We will consider the findings of the focus groups along with additional options and comments presented on this proposed rule.

L. Opportunity for Networks (Proposed § 414.418)

[If you choose to comment on issues in this section, please include the caption ''Opportunity for Networks'' at the beginning of your comments.]

We propose allowing suppliers the option to form networks for bidding purposes. Networks are several companies joining together via some type of legal contractual relationship to submit bids for a product category under competitive bidding. This option will 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 demonstration project, but no networks submitted bids. Still, we believe that networking may be a useful option for suppliers in some cases, so we propose to offer it as an option. If suppliers do decide to form networks, we propose 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 are specifically requesting 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 will 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, we would have the option of terminating the network contract.
- The network cannot be anti-competitive. We propose that the network members' market shares for competitive bid item(s) when added together, cannot exceed 20 percent of the Medicare market within a competitive bidding area. 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 are requesting comment 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 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 reimbursements to the other network members.

M. Education and Outreach

[If you choose to comment on issues in this section, please include the caption ''Education and Outreach'' at the beginning of your comments.]

1. Supplier Education

We would also propose to undertake a proactive education campaign to provide all suppliers with information about the Medicare DMEPOS Competitive Bidding Program, bidding timelines, and bidding and program requirements. The goal of this campaign would be to make it as easy as possible for suppliers to submit bids.

To ensure that suppliers have timely access to accurate information on competitive bidding, we are proposing to instruct the CBIC and the DMERCs to provide early education and resources to all suppliers, referral agents, beneficiaries and other providers who service a competitive bidding area. Customer service support, ombudsmen networks, and the claims processing system would all be used to notify and educate all parties regarding competitive bidding. The CBIC(s) would be instructed to utilize data analysis in tailoring outreach to those that will be directly affected by competitive bidding.

After the release of bidding instructions, we would also propose to hold bidders conferences that would provide an open forum for suppliers and allow us to disseminate additional information. More information on the bidders conferences and other competitive bidding activities will be available on our Web site at *http://cms.hhs.gov/suppliers/dmepos/compbid/paoc.asp*.

We are also proposing that each DMERC include discussions and updates on competitive bidding as part of its existing outreach mechanisms. The fundamental goal of our supplier educational outreach is to ensure that those who supply DMEPOS products to Medicare beneficiaries receive information they need in a timely

manner so they have an understanding of the program and our expectations.

2. Beneficiary Education

The competitive bidding program will have an impact on the beneficiaries who receive DMEPOS items in a competitive bidding area. Competitive bidding represents a new way for Medicare beneficiaries to receive their DMEPOS products, so we believe that education is important to the success of the program.

We propose to educate beneficiaries utilizing numerous approaches. For example, our press office may consider creating press releases and fact sheets for each CBA. Notices would provide summaries of competitive bidding, background information, and objectives of the competitive bidding program. Publications may also be available on CMS Web sites, and from local contractors and the DMERCS.

We believe that it is important for beneficiaries to learn about the benefits of the Medicare DMEPOS Competitive Bidding Program, such as lower out-of-pocket expenses and increased quality of products, from suppliers that have completed the detailed selection process that CMS will require under the program. Enforcement of supplier standards and the threat of exclusion from the Medicare program will encourage suppliers to maintain a high level of service. These factors make an extensive outreach approach critical to the program's success.

Although we are not proposing at this time any additional education requirements, we are interested in seeking comments on other mechanisms that might be utilized to inform beneficiaries and suppliers about the competitive bidding program.

N. Monitoring and Complaint Services for the Competitive Bidding Program

[If you choose to comment on issues in this section, please include the caption ''Monitoring and Complaint Services for the Competitive Bidding Program'' at the beginning of your comments.]

Moving to a competitive bidding environment will not adversely affect CMS'' program integrity efforts in reviewing claims and rooting out fraud, waste, or abuse. Claims will still be reviewed for medical necessity, coordination of benefits status, and benefits integrity. Any suspected instances of DMEPOS competitive bidding market manipulation and collusion will be referred to the appropriate federal agencies that are responsible for addressing these issues.

We are proposing to establish a formal complaint monitoring system to address complaints in each competitive bidding area. Beneficiaries, referral agents, providers, and suppliers, including physicians, hospitals, nurses, and home health agencies, will be able to report problems or difficulties that they encounter regarding the ordering and furnishing of DMEPOS in a competitive bidding area. Some examples of problems that we would consider to be serious include: Contract suppliers refusing to furnish items to beneficiaries in the competitive bidding area for which they were awarded a contract; contract suppliers furnishing items of inferior quality than those that they bid to furnish; or contract suppliers violating assignment and billing requirements.

We also propose to monitor Medicare claims data to ensure that competitive bidding does not negatively impact beneficiary access to medically necessary items. Claims data will be monitored to identify trends, spikes or decreases in utilization and changes in utilization patterns within a product category.

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

[If you choose to comment on issues in this section, please include the caption ''Physician Authorization/Treating Practitioner'' at the beginning of your comments.]

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. We are proposing to implement this section in proposed § 414.440, and to also apply it to certain treating practitioners, including physician assistants, nurse practitioners, and clinical nurse specialists, since these practitioners also order DMEPOS for which Medicare makes payment. Since a HCPCS code may contain many brand products made by a wide range of manufacturers, we expect that suppliers will choose to only offer 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 are proposing 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.

When a physician or other treating practitioner requests a specific item, brand, or mode of delivery, contract suppliers would be required to furnish that item or mode of delivery, assist the beneficiary in finding another contract supplier in the CBA that can provide that item, or consult with the physician or treating practitioner to find a suitable alternative product or mode of delivery for the beneficiary. If, after consulting with the contract supplier, the physician or treating practitioner is willing to revise his or her order, that decision must be reflected in a revised written prescription. However, if the contract supplier decides to provide an item that does not match the written prescription from the physician or treating practitioner, the contract supplier should not bill Medicare as this would be considered a non-covered item.

For the Medicare DMEPOS Competitive Bidding Program, we would not 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. This issue will be studied in more detail by the Office of the Inspector General 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. We welcome public comment on this issue.

P. Quality Standards and Accreditation for Suppliers of DMEPOS

[If you choose to comment on issues in this section, please include the caption ''Quality Standards and Accreditation for Supplies of DMEPOS'' at the beginning of your comments.]

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. Any supplier seeking to participate in the Medicare DMEPOS Competitive Bidding Program will need to satisfy the quality standards issued under section 1834(a)(20) of the Act. Additionally, section 1834(a)(20) of the Act gives us the authority to establish through program instructions or otherwise quality standards for all suppliers of DMEPOS and other items, including those who do not participate in competitive bidding, and to designate one or more independent accreditation organizations to implement the quality standards. Therefore, to ensure the integrity of suppliers' businesses, products, we are proposing to revise § 424.57 and add a new § 424.58.

1. Special Payment Rules for Items Furnished by DMEPOS Suppliers and Issuance of DMEPOS Supplier Billing Privileges (§ 424.57)

In accordance with sections 1834(a)(20) and 1834(j)(1)(B)(ii)(IV) of the Act, we propose to amend § 424.57 as discussed in this section of the proposed rule. In paragraph (a), Definitions, we would propose to define the following terms:

- *CMS-approved accreditation organization* is an independent accreditation organization selected by CMS to apply the supplier quality standards established by CMS;
- *Accredited DMEPOS* supplier means a supplier that has been accredited by an independent accreditation organization meeting the requirements of and approved by CMS in accordance with § 424.58; and
- *Independent accreditation organization* means an accreditation organization that accredits a supplier of DMEPOS and other items and services for a specific DMEPOS product category or a full line of DMEPOS product categories.

Proposed new paragraph (c)(22) would specify that all suppliers of DMEPOS and other items be accredited by a CMS approved accreditation organization before receiving a supplier billing number.

2. Accreditation (§ 424.58)

Under section 1834(a)(20) of the Act, we would add a new section § 424.58 to address the requirements for CMS approved accreditation organizations in the application of the quality standards to suppliers of DMEPOS and other items.

To promote consistency in accrediting providers and suppliers throughout the Medicare program, we would use existing procedures for the application, reapplication, selection, and oversight of accreditation organizations detailed at Part 488 and apply them to organizations accrediting suppliers of DMEPOS and other items. We would make modifications to the existing requirements for accreditation organizations to meet the specialized needs of the DMEPOS industry. These modifications may require an independent accreditation organization applying for approval or re-approval of deeming authority to—

- Identify the product-specific types of DMEPOS suppliers for which the organization is requesting approval or re-approval;
- Provide CMS with a detailed comparison of the organization's accreditation requirements and standards with the applicable Medicare quality standards (for example, a crosswalk);
- Provide a detailed description of the organization's survey processes including procedures for performing unannounced surveys, frequency of the surveys performed, copies of the organization's survey forms, guidelines and instructions to surveyors, quality review processes for deficiencies identified with accreditation requirements;
- Describe the decision-making processes; describe procedures used to notify suppliers of compliance or noncompliance with the accreditation requirements;
- Describe procedures used to monitor the correction of deficiencies found during the survey; and
- Describe procedures for coordinating surveys with another accrediting organization if the organization does not accredit all products the supplier provides.

We also propose to use the application procedure currently specified in § 488.4(c) through (i) as the application process for DMEPOS accreditation organizations.

We may request detailed information about the professional background of the individuals who perform surveys for the accreditation organization including: The size and composition of accreditation survey teams for each type of supplier accredited; the education and experience requirements surveyors must meet; the content and frequency of the continuing education training provided to survey personnel; the evaluation systems used to monitor the performance of individual surveyors and survey teams; and policies and procedures for a surveyor or institutional affiliate of an accrediting organization that participates in a survey or accreditation decision regarding a DMEPOS supplier with which this individual or institution is professionally or financially affiliated.

We may request a description of the organization's data management, analysis, and reporting system for its surveys and accreditation decisions, including the kinds of reports, tables, and other displays generated by that system. We may require a description of the organization's procedures for responding to and investigating complaints against accredited facilities including policies and procedures regarding coordination of these activities with appropriate licensing bodies, ombudsmen programs, National Supplier Clearinghouse, and with CMS; a description of the organization's policies and procedures for notifying CMS of facilities that fail to meet the requirements of the accrediting organization; a description of all types, categories, and duration of accreditation decisions offered by the organization; a list of all currently accredited DMEPOS suppliers; a list of the types and categories of accreditation currently held by each supplier; a list of the expiration date of each supplier's current accreditation; and a list of the next survey cycles for all DMEPOS suppliers accreditation surveys scheduled to be performed by the organization.

We may require the accreditation organization to submit the following supporting documentation:

- A written presentation that would demonstrate the organization's ability to furnish CMS with electronic data in ASCII-comparable code;
- A resource analysis that would demonstrate that the organization's staffing, funding and other resources are sufficient to perform the required surveys and related activities; and
- An acknowledgement that the organization would permit its surveyors to serve as witnesses if CMS took an adverse action against the DMEPOS supplier based on the accreditation organization's findings.

We propose to survey accredited suppliers from time to time to validate the survey process of a DMEPOS accreditation organization (validation survey). These surveys would be conducted on a representative sample basis, or in response to allegations of supplier noncompliance with quality standards. When conducted on a representative sample basis, the survey would be comprehensive and address all Medicare supplier quality standards or would focus on a specific standard. When conducted in response to an allegation, the CMS survey team would survey for any standard that CMS determined was related to the

allegations. If the CMS survey team substantiated a deficiency and determined that the supplier was out of compliance with Medicare supplier quality standards, we would revoke the supplier's billing number and re-evaluate the accreditation organization's approved status. A supplier selected for a validation survey would be required to authorize the validation survey to occur and authorize the CMS survey team to monitor the correction of any deficiencies found through the validation survey. If a supplier selected for a validation survey failed to comply with the requirements at § 424.58, it would no longer meet the Medicare supplier quality standards and its supplier billing number would be revoked.

3. Ongoing Responsibilities of CMS Approved Accreditation Organizations

A DMEPOS independent accreditation organization approved by CMS would be required to undertake the following activities on an ongoing basis:

• Provide to CMS in written form and on a monthly basis all of the following:

++ Copies of all accreditation surveys along with any survey-related information that CMS may require (including corrective action plans and summaries of CMS requirements that were not met).

++ Notice of all accreditation decisions.

++ Notice of all complaints related to suppliers of DMEPOS and other items.

++ Information about any suppliers of DMEPOS and other items for which the accrediting organization has denied the supplier's accreditation status.

++ Notice of any proposed changes in its accreditation standards or requirements or survey process. If the organization implemented the changes before or without CMS approval, CMS could withdraw its approval of the accreditation organization.

• Submit to CMS (within 30 days of a change in CMS requirements):

++ An acknowledgment of CMS's notification of the change;

++ A revised cross-walk reflecting the new requirements; and

++ An explanation of how the accreditation organization would alter its standards to conform to CMS' new requirements, within the time frames specified by CMS in the notification of change it received.

• Permit its surveyors to serve as witnesses if CMS takes an adverse action based on accreditation findings.

• Provide CMS with written notice of any deficiencies and adverse actions implemented by the independent accreditation organization against an accredited DMEPOS supplier within 2 days of identifying such deficiencies, if such deficiencies pose immediate jeopardy to a beneficiary or to the general public.

• Provide written notice of the withdrawal to all accredited suppliers within 10 days of CMS's notice to withdraw approval of the accreditation organization.

• Provide, on an annual basis, summary data specified by CMS that related to the past year's accreditation activities and trends.

4. Continuing Federal Oversight of Approved Accreditation Organizations

This paragraph would establish specific criteria and procedures for continuing oversight and for withdrawing approval of an accreditation organization.

a. Equivalency Review

We would compare the accreditation organization's standards and its application and enforcement of those standards to the comparable CMS requirements and processes when: CMS imposed new requirements or changed its survey process; an accreditation organization proposed to adopt new standards or changes in its survey process; or the term of an accreditation organization's approval expired.

b. Validation Review

A CMS survey team would conduct a survey of an accredited organization, examine the results of the accreditation organization's own survey procedure onsite, or observe the accreditation organization's survey, in order to validate the organization's accreditation process. At the conclusion of the review, we would identify any accreditation programs for which validation survey results indicated:

• A 10 percent rate of disparity between findings by the accreditation organization and findings by CMS on standards that did not constitute immediate jeopardy to patient health and safety if not met;

• Any disparity between findings by the accreditation organization and findings by CMS on standards that constituted immediate jeopardy to patient health and safety if not met; or

• There were widespread or systemic problems in the organization's accreditation process such that the accreditation no longer provided assurance that suppliers met or exceeded the Medicare requirements, irrespective of the rate of disparity.

c. Notice of Intent To Withdraw Approval for Deeming Authority

If an equivalency review, validation review, onsite observation, or our concerns with the ethical conduct of the accreditation organization suggest that the accreditation organization is not meeting the requirements of proposed § 424.58, we would provide the organization written notice of its intent to withdraw approval of the accreditation organization's deeming authority.

d. Withdrawal of Approval for Deeming Authority

We could withdraw approval of an accreditation organization at any time if we determine that: Accreditation by the organization no longer guaranteed that the suppliers of DMEPOS and other items met the supplier quality standards and the failure to meet those requirements could pose an immediate jeopardy to the health or safety of Medicare beneficiaries or constitute a significant hazard to the public health; or the accreditation organization failed to meet its obligations for application and reapplication procedures.

e. Reconsideration

An accreditation organization dissatisfied with a determination that its accreditation requirements did not provide or do not continue to provide reasonable assurance that the entities accredited by the accreditation organization met the applicable supplier quality standards would be entitled to a reconsideration. We would reconsider any determination to deny, remove, or not renew the approval of deeming authority to accreditation organizations if the accreditation organization filed a written request for a reconsideration through its authorized officials or through its legal representative.

The request would have to be filed within 30 days of the receipt of CMS notice of an adverse determination or nonrenewal. The request for reconsideration would be required to specify the findings or issues with which the accreditation organization disagreed and the reasons for the disagreement. A requestor could withdraw its request for reconsideration at any time before the issuance of a reconsideration determination. In response to a request for reconsideration, we would provide the accrediting organization the opportunity for an informal hearing that would be conducted by a hearing officer appointed by the Administrator of CMS and provide the accrediting organization the opportunity to present, in writing

and in person, evidence or documentation to refute the determination to deny approval, or to withdraw or not renew deeming authority.

We would provide written notice of the time and place of the informal hearing at least 10 days before the scheduled date. The informal reconsideration hearing would be open to CMS and the organization requesting the reconsideration, including authorized representatives, technical advisors (individuals with knowledge of the facts of the case or presenting interpretation of the facts), and legal counsel. The hearing would be conducted by the hearing officer who would receive testimony and documents related to the proposed action. Testimony and other evidence could be accepted by the hearing officer. However, it would be inadmissible under the usual rules of court procedures. The hearing officer would not have the authority to compel by subpoena the production of witnesses, papers, or other evidence. Within 45 days of the close of the hearing, the hearing officer would present the findings and recommendations to the accrediting organization that requested the reconsideration. The written report of the hearing officer would include separate numbered findings of fact and the legal conclusions of the hearing officer. The hearing officer's decision would be final.

Q. Low Vision Aid Exclusion (Proposed § 414.15)

[If you choose to comment on issues in this section, please include the caption ''Low vision aid exclusion'' at the beginning of your comments.]

We are proposing to clarify that the scope of the eyeglass coverage exclusion encompasses all devices irrespective of their size, form, or technological features that use one or more lens to aid vision or provide magnification of images for impaired vision. This proposed regulatory provision clarifies that the statute does not support the interpretation that the term eyeglasses only applies to lenses supported by frames that pass around the nose and ears. The underlying technology and the function of eyeglasses are to use lenses to assist persons with impaired vision. *Dorland's Illustrated Medical Dictionary* (28th Ed. 1994) defines ''eyeglass'' simply as a ''lens for aiding sight.'' We interpret the eyeglass exclusion at section 1862(a)(7) of the Act as encompassing all of the various types of devices that use lenses for the correction of vision unless there is a statutory provision that provides for coverage. For example, section 1861(s)(8) of the Act provides for intraocular lenses, conventional eyeglasses and contact lenses after each cataract surgery with insertion of an intraocular lens. We specifically invite public comment on this issue.

We note that if the term ''eyeglasses'' as used at section 1862(a)(7) of the Act only refers to the exclusion of payment for lenses supported by frames that pass around the nose and ears, then the eyeglass exclusion would not apply to contact lenses and there would have been no reason for the Congress to make an exception to section 1862(a)(7) of the Act for contact lenses. However, the Congress did make such an exception to section 1862(a)(7) of the Act for conventional contact lenses after cataract surgery.

A comparison of sections 1862(a) and 1861(s) of the Act indicate that the eyeglass exclusion also applies to contact lenses except for one pair after cataract surgery. By applying the eyeglass exclusion to contact lenses, the statute reinforces the interpretation that the use of lenses to aid impaired vision is the scope of what is excluded by the eyeglass exclusion and not just lenses supported by frames that pass around the nose and ears. Also, when referring to ''conventional eyeglasses,'' section 1861(s)(8) of the Act is affirming that the term ''eyeglasses'' has a wider application than ''conventional eyeglasses'' and the terms ''conventional eyeglasses'' and ''eyeglasses'' are not synonymous in the statute.

This interpretation of the term eyeglasses is consistent with the regulatory language used for the optional benefit in the Medicaid program under § 440.120(d) for eyeglasses, which is ''lenses, including frames, and other aids to vision * * *'' This language gives States that cover eyeglasses the flexibility to adopt a reasonable definition that includes low vision aids that are determined medically necessary. The definition used by the Medicaid program demonstrates that the term eyeglasses can appropriately be defined to include low vision aids. Consistent with this framework, we consider the eyeglass exclusion for the Medicare program to apply to eyepieces, hand-held magnifying glasses, contact lenses and other instruments, such as closed-circuit televisions and video magnifiers that use lenses to aid vision.

Although the technology of using lenses to aid low vision may be improved with new innovations, such as contact lenses, progressive lenses and low vision aids, this does not exempt the new technology from the eyeglass exclusion. The adaptation of the vision aid technology does not change the essential nature of the device: A video magnifier is still a device that utilizes a lens to enhance vision. We believe this interpretation is consistent with the decision in *Warder* v. *Shalala*, 149 F 3d73 (1st Cir. 1998), in which the United States Court of Appeals for the First Circuit held, in part, that the Secretary's classification of a technologically advanced seating system as DME, and not as an orthotic, was supported by the Medicare statute and regulations. In reaching this conclusion, the court stated that the Secretary could conclude that the seating system met the definition of DME, which ''unequivocally includes 'wheelchairs','' since the system served the same (as well as additional) functions as a wheelchair. We believe this case affirms the principle that the Secretary has the discretion to interpret the statute and to assign a product to a particular Medicare category even when this will result in non-coverage determinations by Medicare.

R. Establishing Payment Amounts for New DMEPOS Items (Gap-Filling) (Proposed § 414.210(g))

[If you choose to comment on issues in this section, please include the caption ''Gap-filling'' at the beginning of your comments.]

There is no process set forth in the statute or regulations for calculating fee schedule amounts for new DMEPOS items (that is, new HCPCS codes representing categories of items for which there is no historic Medicare pricing information). Since 1989, CMS and its contractors have used a process referred to as ''gap filling'' to establish fee schedule amounts for items for which fee schedule base data is not available. In the past, the gap-filling process was described in the Medicare Carriers Manual. The process is now contained in the Medicare Claims Processing Manual and provides that fee schedule amounts are to be gap-filled using fee schedule amounts already established for comparable items; properly calculated fee schedule amounts from a neighboring carrier; or supplier price lists with prices in effect during the database year.

If the only available price information is from a period other than the fee schedule base period (for example, 1992 for surgical dressings), a deflation factor is applied to the price in order to approximate the base year price for gap-filling purposes. The deflation factors are based on the percentage change in

the CPI–U from the mid-point of the fee schedule base period (for example, June 1992 for surgical dressings) to the mid-point (that is, June) of the calendar year that the gap-filling source price is in effect. When gap-filling base fees for capped rental items, it is necessary to first gap-fill the purchase fee and then compute the rental fee based on 10 percent of the gap-filled purchase fee. For used equipment, base fees are gap-filled using 75 percent of the gap-filled fee for new equipment.

The process of gap-filling essentially estimates what the average reasonable charges would be for an item if it was paid for under Medicare during the fee schedule base period. The gap-filled base fees are updated by the covered item updates and are subject to regional fees, and ceiling and floor limitations, if applicable. We have consistently used the gap-filling process as the method for replicating historical charge data. However, this method can lead to very high or very low fee schedule amounts without validation that these amounts are realistic and equitable relative to the cost of furnishing the item. Since the gap-filling process began in 1989, most base fees have been gap-filled using either supplier price lists or manufacturers' suggested retail prices. Many manufacturers are aware of the process and realize that if a unique HCPCS code is added for their device, they can establish inflated suggested retail prices that would be used to establish the Medicare fee schedule payment amounts. We also view the continued use of deflation factors to replicate historic prices or charges to be an imperfect method of establishing base fee schedule amounts. Under the Medicare DMEPOS benefits, there is an inherent responsibility to pay enough for beneficial new technologies to ensure beneficiary access to care, while also being a prudent payer. To increase the Medicare program's ability to ensure fair treatment across technologies, we have focused on developing strategies that recognize those technologies that provide a demonstrated clinical benefit and clearly identify the additional benefits over existing technologies. This initiative has been endorsed by the Council on Technology and Innovation (CTI), which was established under section 942 of the MMA to coordinate the activities of coverage, coding, and payment processes affecting new technologies and procedures and to coordinate the exchange of information on new technologies between CMS and other entities that make similar decisions.

We procured two contractors to conduct a pilot study on the benefits, effectiveness, and costs of several products. These projects were very successful in compiling the technical information that is necessary to evaluate technologies for the purpose of making payment and HCPCS coding decisions for new items. The products studied were assessed in terms of three main areas as follows:

- Functional Assessment—This step involved evaluating the device's operations, safety, and user documentation relative to the Medicare population. Interviews were conducted with health care providers to determine how and under what circumstances they would prescribe the product for a Medicare beneficiary.
- Price Comparison Analysis—A comparative cost analysis determined how the cost of this product compared to similar products on the market or alternative treatment modalities.
- Medical Benefit Assessment—This step focused on the effectiveness of the product in doing what it claims to do. Scientific literature reviews and interviews with health care providers were conducted to determine if the product significantly improved clinical outcomes compared to other products and treatment modalities.

Competitive bidding will allow market forces to determine the price Medicare pays for certain DMEPOS items. In order to ensure that only quality products are provided to our beneficiaries, we are proposing to use the three types of assessments described above to assist us in ensuring that the HCPCS codes for DMEPOS items reflect current technology and functional differences in items and that new products are included within the appropriate HCPCS code. The functional technology assessment will allow us to compare older, similar products already on the market and newer more expensive products. The functional assessment and medical benefit assessment of devices will greatly aid our decision-making process regarding the need to create unique HCPCS code categories. The price comparison analysis of devices will help us determine if manufacturers' suggested retail prices are overly inflated, will provide a basis for establishing adequate payment amounts for new items, and will assist in establishing payment amounts for new items that are introduced after a bidding cycle has begun.

Sections 1834(a), (h), (i) and 1833(o) of the Act require the establishment of fee schedule amounts to pay for DME, prosthetic devices, orthotics, prosthetics, surgical dressings, and therapeutic shoes. In addition, payment for PEN is also based on fee schedule amounts authorized by section 1842(s) of the Act. The fee schedule amounts are based on average payments made under the previous reasonable charge payment methodology as mandated by the statute. When a new HCPCS code is created for a category of items, the gap-filling process outlined in this section is used to establish the fee schedule amounts for the new code. We are proposing that this gap-filling process be revised as follows:

- We would continue to make every effort to utilize existing fee schedule amounts or historic Medicare payment amounts, if applicable, in establishing payment amounts for new HCPCS codes. In addition, the method of using payment amounts for comparable items would be retained under the revised process for establishing payment amounts for new HCPCS codes.
- We would discontinue the practice of deflating supplier prices and manufacturers suggested retail prices to the fee schedule base period. When fee schedule amounts are established based on pricing information, prices in effect at the time that the fee schedule amounts are established would be used. For subsequent years, the fee schedule amounts established using supplier or manufacturer pricing information would be updated as required by the statute as it is applicable to each category of items. In the past, when retail pricing information is not available, wholesale prices plus an appropriate mark-up are used to establish the fee schedule amounts.
- We would use the functional technology assessment process, in part or in whole, as another method for establishing payment amounts for new items. Based on the results of the technology assessment, the fee schedule amounts would be established using fee schedule amounts for items determined to be comparable to the new item or an amount determined to be appropriate for the new item based on the cost comparison analysis. We can use the technology assessment process at any time to adjust prices on or after January 1, 2007 that were previously established using the gap-filling methodology if it is determined that those pricing methods resulted in payment amounts that do not reflect the cost of furnishing the item. Fee schedule amounts established using this process would be updated as required by the statute as it is applicable to each category of items.

In those cases where the addition of the HCPCS code for a new item occurs in the middle of a bidding cycle and a Medicare pricing history or profile does not exist for the item or is not applicable

for the new code category, we propose that the revised gap-filling process for establishing fee schedule payment amounts for new DMEPOS items would also be used in establishing payment amounts for new items until they are added to a product category subject to competitive bidding. Any qualified Medicare supplier will be allowed to supply one of these items until the next bidding cycle. The next bidding cycle will set a new single payment amounts for this item.

We propose that other revisions to HCPCS codes for items under a competitive bidding program that occur in the middle of a bidding cycle will 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 will not be higher than the payment for the original item. Suppliers selected through competitive bidding to provide the item will also provide the components of the item. During the subsequent competitive bidding cycle, suppliers will bid on each new code for the components of the item, and we will 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 will continue to be the same payment amount applied to the single code until the next competitive bidding cycle. During the next cycle, suppliers will 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 will 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 will continue to supply the item using the new code. During the subsequent bidding cycle, suppliers will 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 will be the average (arithmetic mean) weighted by frequency of payments for the formerly separate codes. Suppliers providing the items originally will also provide the item under the new single code. During the subsequent bidding cycle, suppliers will bid on the new single code and determine a new single payment amounts for this code.

S. Fee Schedules for Home Dialysis Supplies and Equipment (Proposed § 414.107)

[If you choose to comment on issues in this section, please include the caption ''Fee Schedules for Home Dialysis Supplies and Equipment'' at the beginning of your comments.]

Section 1842(s) of the Act provides authority for implementing statewide or other area wide fee schedules to be used for payment of home dialysis supplies and equipment. Section 1842(s)(1) of the Act provides that the fee schedules are to be updated on an annual basis by the percentage increase in the CPI–U (United States city average) for the 12-month period ending with June of the preceding year. Section 4315(d) of the BBA requires that the fee schedules that are established using this authority are set initially so that total payments under the fee schedules are approximately equal to the estimated total payments that would be made under the reasonable charge payment methodology.

On July 27, 1999, we published a proposed rule, Replacement of Reasonable Charge Methodology by Fee Schedules (64 FR 40534), to establish fee schedules for these items. Fee schedules were established for PEN items and services in 2002 following the publication of the final rule, Replacement of Reasonable Charge Methodology by Fee Schedules for Parenteral and Enteral Nutrients, Equipment, and Supplies, on August 28, 2001 (66 FR 45173). However, fee schedule amounts were not established for home dialysis supplies and equipment because the data needed to establish budget neutral fee schedule amounts was not available at the time that final rule was published. We are now proposing to establish fee schedule amounts for home dialysis supplies and equipment because the data needed to establish budget neutral fee schedule amounts are now available.

Sections 1832(a)(1) and 1861(s)(2)(F) of the Act establish that home dialysis supplies and equipment are a covered benefit under Part B of the Medicare program. Home dialysis supplies and equipment are defined under section 1881(b)(8) of the Act as ''medically necessary supplies and equipment (including supportive equipment) required by an individual suffering from end stage renal disease in connection with renal dialysis carried out in his home (as defined in regulations), including obtaining, installing, and maintaining such equipment.'' We implemented these provisions in title 42, part 414 subpart E of the regulations.

Total monthly payments to a supplier for home dialysis supplies and equipment may not exceed the limit for equipment and supplies established in § 414.330(c)(2). We have determined that total monthly payments for these items per supplier were equal to the monthly limit 79 percent of the time for items furnished from January 1, 2004 through November 30, 2004. This means that suppliers billed up to or in excess of the monthly payment limit in 79 percent of the claims submitted during this 11-month period. We are proposing that nationwide fee schedule amounts be implemented for these items effective January 1, 2007. These amounts would be based on the average allowed charges calculated using data for allowed services furnished from January 1, 2005 through December 31, 2005, increased by the percentage change in the CPI–U for the 24-month period ending June of 2006. We expect that the total payments made under the fee schedule will be approximately equal to the total payments that would be made under the reasonable charge payment methodology because the overall payment limit for equipment and supplies established in § 414.330(c)(2) is not affected by implementation of the fee schedules for these items. By using the average, we do not anticipate a significant impact on utilization of home dialysis, supplies and equipment.

Beginning with 2008, the fee schedule amounts for home dialysis supplies and equipment will be updated on an annual basis by the percentage increase in the CPI–U for the 12-month period ending with June of the preceding year under section 1842(s)(1) of the Act.

T. Fee Schedules for Therapeutic Shoes (Proposed § 414.228(c))

[If you choose to comment on issues in this section, please include the caption ''Fee Schedules for Therapeutic Shoes'' at the beginning of your comments.]

We are proposing to add § 414.228(c) to part 414, subpart D of the regulations to specify 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. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 60-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 Paperwork Reduction Act of 1995 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.

We are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements.

Section 414.412 Submission of Bids Under the Competitive Bidding Program

Section 414.412 establishes the requirements for the submission of bids under the competitive bidding process. The burden associated with these requirements is the time and effort necessary to prepare and submit a bid. The burden is estimated to be 70 hours per bid. In the competitive bidding demonstration, suppliers estimated that they spent between 40 and 100 hours to complete the bids. We therefore use the median of 70 hours per bid. In connection with the competitive bidding programs that we are proposing to begin implementing in 2006, we assume that 90 percent of suppliers of potentially eligible products in the designated competitive bidding areas will submit bids resulting in 16,545 bids. Therefore, we estimate it would take 1,158,150 total annual hours to complete the bids in 2006. In later years, as additional CBAs are added, the number of bids will increase as will the estimated total annual number of hours to complete the bids. By 2008, if 90 percent of suppliers of eligible products in the bidding CBAs submit bids there will be 72,865 bids. We estimate that the annual hours to complete the bids will rise to 5,100,550 total annual hours in connection with the competitive bidding round that we expect to occur in 2008, which will involve 70 of the largest MSAs. However, the number of hours necessary to complete the bids may fall over time as suppliers become more familiar with the forms and the competitive bidding process. The number of hours may also be lower if additional suppliers do not submit bids. As a result, it is possible that the above figures overestimate the number of hours required to fill out the bidding forms.

The cost associated with the requirements pertaining to the accreditation program are not included as part of the cost or burden for the competitive bidding program.

If you comment on these information collection and recordkeeping requirements, please mail copies directly to the following:

Centers for Medicare & Medicaid Services, Office of Strategic Operations and Regulatory Affairs, Regulations Development and Issuances Group, Attn: William Parham, Room C4–26–05, 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, *carolyn_lovett@omb.eop.gov.* Fax (202) 395–6974.

IV. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

V. Regulatory Impact Analysis

[If you choose to comment on issues in this section, please include the caption ''Regulatory Impact Analysis'' at the beginning of your comments.]

A. Overall Impact

We have examined the impacts of this 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.

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).

Since this rule is considered to be a major rule because it is economically significant, we have prepared a regulatory impact analysis. We expect that this 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.

B. Anticipated Affects

We can anticipate the probable effects of the regulation, but the actual effects will vary depending on which competitive bidding areas and product categories are ultimately selected for competitive bidding. The analysis which follows, taken together with the rest of this preamble, constitutes both a regulatory impact analysis (RIA) and an initial regulation flexibility analysis (IRFA).

Therefore, for the purpose of this impact analysis, because of the uncertainty concerning the actual number of suppliers who will participate, the bid amounts and the specific items and areas for which competitive bidding will be conducted, it is necessary to make several assumptions.

First, we assume that the first round of bidding will occur in 2006 with prices taking effect in October, 2007, and the second round of bidding will occur in 2008 with prices taking effect in January, 2009. We also assume rebidding will only occur every three years.

Second, we assume that competitive bidding will occur in 10 of the largest MSAs in 2006, excluding New York, Chicago, and Los Angeles. We exclude the three largest MSAs in 2006 because we are proposing not to include them in the initial phase implementation. We are excluding the three largest MSAs because they are significantly larger than any of the areas in which we implemented the competitive bidding demonstrations and we would like to gain more experience in smaller markets before we enter into the largest markets.

Competitive bidding will take place in 70 of the largest MSAs in 2008 and an additional 10 competitive bidding areas (CBAs) will be added in both 2009 and 2010 for a total of 100 CBAs. For the initial competition, we assume that bidding will take place in fall 2006, bids will be evaluated in 2007, and prices will go into effect in October 2007. We also assume that the same timeframes will apply when bidding takes place in the initial 10 MSAs in fall 2009. In all other cases, we assume that competitive bidding will take place in the fall and prices will go into effect on January 1 of the following year in the relevant CBAs.

Third, we make 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 estimate that approximately 10 product categories will be selected for competitive bidding for 2006 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 product groups ranked by allowed charges. Table 10 shows the top 20 eligible DMEPOS policy groups and their 2003 allowed charges.

TABLE 10.—2003 ALLOWED CHARGES: TOP 20 ELIGIBLE DME POLICY GROUPS

Rank	Policy group	2003	Percent of eligible DMEPOS charges
1	Oxygen Supplies/Equipment	$2,433,713,269	29
2	Wheelchairs/POVs	1,926,210,675	23
3	Diabetic Supplies & Equipment	1,110,934,736	13
4	Enteral Nutrition	676,122,703	8
5	Hospital Beds/Accessories	373,973,207	4
6	CPAP	204,774,837	2
7	Support Surfaces	193,659,248	2
8	Infusion Pumps & Related Drugs	149,208,088	2
9	Respiratory Assist Device	133,645,918	2
10	Lower Limb Orthoses*	122,813,555	1
11	Nebulizers	98,951,212	1
12	Walkers	96,654,035	1
13	Negative Pressure Wound Therapy	88,530,828	1
14	Commodes/Bed Pans/Urinals	51,372,352	1
15	Ventilators	42,890,761	0
16	Spinal Orthoses*	40,731,646	0
17	Upper Limb Orthoses*	29,069,027	0
18	Patient Lift	26,551,310	0
19	Seat Lift Mechanism	15,318,552	0
20	TENS	15,258,579	0
	Total for 20 Groups	7,830,384,538	92

*Excludes Custom Fabricated Items; but does not exclude all items that might require more than minimal self-adjustment or expertise in trimming, bending, molding, assembling, or customizing to fit the individual.

However, we reiterate that our selection for the 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 impact.

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 MMA, and that total charges will increase at the same rate as Part A and Part B Medicare expenditures. We exclude Part D expenditure growth because this data is not currently available. We base our estimates on the expected growth in Part A and Part B expenditures from the Trustees Reports. (Tables IV.F.2 and IV.F.3 of the 2004 Medicare Trustees Report).

This proposed rule is expected to affect Medicare and its beneficiaries, certain CMS contractors including the four current DMERCs, the SADMERC, the NSC, one or more proposed CBICs, and DMEPOS suppliers. Although the work-load of referral agents, including hospital discharge planners and some healthcare providers, appeared to increase during implementation of the demonstration, we do not anticipate that competitive bidding will result in an appreciable, ongoing burden on referral agents. In addition, rural healthcare facilities should not be significantly impacted as the program is expected to operate primarily within relatively large MSAs.

The DMEPOS supplier industry is expected to be significantly impacted by this rule when finalized. However, not all suppliers will be affected directly by the competitive bidding program. Only suppliers who furnish products in at least one product category eligible for competitive bidding and in areas selected for competitive bidding could potentially be affected. A customized orthotics supplier in Manhattan that does not supply off-the-shelf orthotics will not be affected. 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 could therefore 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 2003 claims data, we also estimate that approximately 90 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 million. (*see http://www.sba.gov/size/sizetable2002.html,* read May 9, 2005.)

Many of these suppliers provide minimal amounts of DMEPOS, and thus the remaining larger suppliers control significant market share. We anticipate that the bidding process will be designed to neither reward nor penalize small suppliers, however the fixed costs required to undergo the bidding process may be a larger deterrent to small businesses than larger firms. We do not expect that the regulation will result in direct costs that exceed $120 million per year, and thus the Unfunded Mandates Reform Act (UMRA) would not apply. Since suppliers can choose whether to submit a bid for the competitive bid program, the regulation imposes no direct costs and therefore does not reach the $120 million direct cost threshold under UMRA. While not included in this regulation, it is expected that the separate MMA requirement for accreditation will result in added supplier costs beyond those included in this regulation.

The proposed rule will also impact CMS and its contractors. There are four DMERCs currently contracted by CMS to process claims for the DMEPOS benefit. The Statistical Analysis DME Regional Carrier, (SADMERC), the existing contractor assigned to perform statistical support and the National Supplier Clearinghouse, (NSC), which maintains a registry of approved suppliers, will need to adapt to the competitive bidding environment. Finally, we will need to devote resources necessary for overseeing program operations.

C. Implementation Costs

We will incur administrative costs in connection with the implementation and operation of competitive bidding, which can affect the net savings that can be expected under the proposed 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 do not estimate bid solicitation and evaluation costs at this time.

We will incur initial start up costs. We estimate the costs to CMS and its contractors will include approximately $1 million in immediate fixed costs for contractor startup and system changes for the initial competitive bidding phase in 2006. In addition to the initial start up 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 where the program has been implemented, while bid solicitation and evaluation costs will depend on the number of sites which 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, we propose that the CBIC(s) will be responsible for much of the program maintenance. The maintenance costs could also include the costs for an Ombudsman(s) per DMERC region 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 beneficiaries, printing, and duplicating. 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. We are proposing that the bid evaluation will be done by the CBIC(s). According to the DMEPOS evaluation report, it took about 9.4 hours to evaluate each bid during the demonstration. However, since the Medicare DMEPOS Competitive Bidding Program entails Quality Standards/Accreditation as a separate process, we expect that the time required to evaluate bids will be lower than in the demonstration. The total bid evaluation costs will ultimately depend on the number of suppliers that choose to submit bids.

D. Program Savings

We estimate large savings from the competitive bidding program. Our estimates of gross savings utilize as a starting point the savings results in the demonstration. Excluding surgical dressings that are not eligible for competitive bidding, the average product group savings rate in the demonstration ranged from 9 to 30 percent in a CBA round with most product groups around a 20 percent savings. Table 11 shows the savings rate for selected product groups and CBAs by round during the DMEPOS demonstration.

TABLE 11.—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%)	(1)
Surgical Dressings	−$30,321 (−12%)	−$637 (−1%)	(1)
Enteral Nutrition	$342,251 (17%)	(1)	(1)
Wheelchairs and Accessories	(1)	(1)	$796,617 (19%)
General Orthotics	(1)	(1)	$89,462 (23%)

TABLE 11.—DMEPOS COMPETITIVE BIDDING DEMONSTRATION SAVINGS RATES—Continued

Product group	Polk County round 1	Polk County round 2	San Antonio
Nebulizer Drugs	(1)	(1)	$1,020,072 (26%)

Source: Evaluation of Medicare's Competitive Bidding Demonstration for DMEPOS, Final Evaluation Report (November 2003), pages 90 and 92.
[1] Not included.

In our estimates, we have taken into account that some DMEPOS prices have been adjusted downward since 2000. We assume that if prices for an individual item have already been reduced by 10 percent after the demonstrations were completed, then prices would most likely fall 10 percent rather than 20 percent. We, therefore, netted out any statutory reductions in prices that had already occurred such as the 2005 reductions in oxygen supplies.

Table 12 shows the fee-for-service program impact for the 10 policy groups. In the table, savings are reported as negative values. The savings are attributable to the lower prices anticipated from competitive bidding. The table shows the reduction in Medicare allowed charges, without any impact on Medicare Advantage, associated with the program for the calendar year. The impact includes reductions in Medicare payments (80 percent) and reductions in beneficiary co-insurance (20 percent).

TABLE 12.—PROGRAM IMPACT FOR 10 POLICY GROUPS IN MILLIONS*

	Year					
	2006	2007	2008	2009	2010	2011
Allowed Charges	−$0	−$38	−$120	−$844	−$1000	−$1,199
Medicare share of allowed charges (80% of allowed charges)	−0	−30	−96	−675	−800	−959
Beneficiary Costs (20% of allowed charges)	0	−8	−24	−169	−200	−240

* Numbers may not add up due to rounding.

Table 13 presents the impact differently than Table 12. In contrast to Table 12, which is on a Medicare-allowed-charge-incurred basis and is without considering the Medicare Advantage impact, Table 13 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 0 months of fiscal year 2007, but for 3 months of calendar year 2007.[1] Table 13 considers the impact on program expenditures, and does not include beneficiary coinsurance. Finally, the estimates in Table 13 incorporate spillover effects from the competitive acquisition program onto the MA program. The expectation is that lower prices for DME products in FFS will lead to lower prices in the MA market.[2]

TABLE 13.—FISCAL YEAR COST ON THE MEDICARE PROGRAM

[In millions]

Year	10 products
2006	$0
2007	0
2008	−110
2009	−620
2010	−990
2011	−1,230

E. Effect on Beneficiaries

Possible impacts on beneficiaries are a primary concern during the design and implementation of the 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 analysis of the impact of the DMEPOS competitive bidding demonstration on patient access to care and quality showed minimal adverse results. Therefore, we assume that there will be no 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 minimal in many product categories because of the existence of grandfather policies for products such as capped rentals.

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 14.—BENEFICIARY CO-INSURANCE SAVINGS ESTIMATES FOR 10 PRODUCTS

[In millions]

Year	10 products
2007	$8
2008	24
2009	169
2010	200
2011	240

F. Effect on Suppliers

We expect DME suppliers to be significantly impacted by the implementation of the proposed rule. We assume that suppliers may be affected in one of 3 ways as follows:

[1] Fiscal year 2007 will end September 30, 2007, and the Medicare DMEPOS Competitive Bidding Program will begin on October 1, 2007.

[2] In addition, most managed care plan rates are linked to FFS expenditures, so a decrease in FFS expenditures should translate into a decrease in Medicare Advantage plan payment rates.

- Suppliers that wish to participate in competitive bidding will have to incur the cost of submitting a bid.
- Noncontract suppliers (including suppliers who 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 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 offset the decrease in revenue per item.

1. Affected Suppliers

Based on 2003 claims data, the average MSA in the top 25 MSAs, excluding New York, Los Angeles, and Chicago, has 2754 DMEPOS suppliers that furnish any DMEPOS product and 1838 suppliers that furnish products subject to competitive bidding and could potentially be affected by competitive bidding.

We estimate that 27,540 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 only 18,383 suppliers will furnish products subject to competitive bidding and will be affected by competitive bidding. This means in 2006, the remaining 9157 suppliers in the 10 selected MSAs will not be affected by competitive bidding because they do not furnish products subject to competitive bidding. However, the actual number 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 covered services will choose to participate in order to maintain and expand their businesses. For the calculations below, we assume that 90 percent of suppliers will submit a bid. We assume the remaining 10 percent of suppliers will not have received the necessary accreditation to submit a bid. Based on this assumption, 16,545 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 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. As a result, we expect that there will be 8272 contract suppliers and 10,111 non contract suppliers in the competitive bidding areas that we initially designate. The 10,111 suppliers that are not awarded a contract, either because they chose not to submit a bid or did not submit a winning bid would represent about 37 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. It is important to note that there will be a revenue shift from the non contract suppliers to the contract suppliers, and that although some suppliers may be worse off, it is because they did not offer competitive prices or quality. We also note that if a supplier submitted a bid in multiple product categories, its probability of winning would increase, so that the total number of wining suppliers would be higher, and the number of non contract suppliers would be lower.

It is difficult to estimate how much revenue a losing supplier will lose because of the DMEPOS competitive acquisition program. The amount will depend on how much revenue the supplier previously received from Medicare and whether the supplier continues to provide services to existing patients under transition 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 patients, then 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 2008, the first full year after the prices take effect, and increase to almost $2 billion in 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 who submit bids will incur a cost of bidding. In the demonstration, bidders in Polk County, Florida reported spending 40 to 100 hours submitting bids. We therefore assume that suppliers will use the midpoint number of hours, 70 hours, to complete their bids. According to 2003 Bureau of Labor Statistics (BLS) data, the average hourly wage for an accountant and auditor was $24.35. Accounting for inflation and overhead, we assume suppliers will incur $31.25 per hour in wage and overhead costs. Based on this information, we assume that a supplier that bids will spend $2,187.50 ($31.25*70) to prepare its bid. We calculate the total cost for all supplier bids, including those of both future winning and future losing suppliers. Therefore, we expect that 2006 total supplier bidding costs for 16,545 bids will be $36,192,187 ($2187.50*16545). This estimate is clearly dependent on our assumption that all eligible suppliers will bid.

In 2008, we will conduct competitive bidding in 80 MSAs, which may include New York, Los Angeles, and Chicago; and in 2009 and 2010 we will add additional areas. This will increase the number of affected suppliers, contract suppliers, and non contract suppliers. For the purposes of the impact analysis, we assume that there will be at least 10 additional large CBAs added in both 2009 and 2010. We also assume bid cycles will be three years in length. Under our assumptions, we will conduct bidding for programs that involve the initial 10 MSAs in 2006 and 2009, for programs that involve 70 additional MSAs in 2008 and 2011, and for programs that involve additional areas in 2009 and 2010. It is interesting to note that the average number of suppliers per CBA decreases over time. This is because smaller CBAs with fewer beneficiaries and lower allowed charges have fewer suppliers. Table 15 summarizes the effect on suppliers for 2006 through 2011.

TABLE 15.—SUPPLIERS BIDDING YEARS: 2006–2011

[10 product categories]

	Bidding year					
	2006	2007	2008	2009	2010	2011
Average number of suppliers per CBA	2754	2754	1863	1776	1687	1863
Average number of affected suppliers per CBA	1838	1838	1242	1183	1125	1242
Total number of suppliers	27540	27540	149035	159864	168702	149035
Total number of affected suppliers	18383	18383	99344	106439	112471	99344
Number of bidding suppliers	16545	0	72865	22930	5429	72865
Cost of bidding	$36,192,188	$0	$159,392,188	$50,159,375	$11,875,938	$159,392,188
Number of contract suppliers	8272	8272	44705	47898	50612	44705
Number of non contract suppliers	10111	10111	54639	58541	61859	54639
Non contract suppliers as a percent of total suppliers	37%	37%	37%	37%	37%	37%

[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.

2. Small Suppliers

We use the Small Business Administration definition of a small supplier. The SBA defines a small supplier in Home Health Equipment (NAICS Code 532291) as having less than $6 million in revenues. 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 DEMPOS. We therefore classified a small supplier as any supplier with fewer than $3 million in Medicare allowed charges for all DMEPOS products whether or not they are eligible for competitive bidding. For example, an orthotics supplier's allowed charges could include charges for both customized and off-the-shelf orthotics, but customized orthotics are not subject to competitive bidding. By this definition, the majority of DMEPOS suppliers are small. Table 16 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.

TABLE 16.—NUMBER OF SMALL SUPPLIERS [1]

[$3 million or less in Medicare allowed charges]

Bidding year	Number of affected small suppliers	Total number of affected suppliers	Percent
2006	16,741	18,383	91
2007	16,741	18,383	91
2008	88,912	99,344	90
2009	94,969	106,439	89
2010	100,083	112,471	89
2011	100,083	112,471	89

[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 $2187.50. 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, $1,000,000, and $3,000,000 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:

- Networking: As stated in section L of the preamble we discuss our proposal for allowing suppliers the option to form networks for bidding purposes. Networks are several companies 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, and it also poses challenges for bid evaluation and program monitoring.
- Not requiring bids for every product category: As discussed previously in the preamble, we are proposing to 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.
- Another option we considered but did not accept would have allowed small suppliers to be exempted from the requirement that a contract supplier must service an entire CBA. This option

is also discussed in further detail in the preamble.

• We also considered the option to allow a small supplier to not submit a bid and then decide after the bidding whether or not they would accept the new competitive bidding single payment amounts. We are not accepting this option because the statue is clear about the requirement that suppliers must have submitted a bid in order to be a contract supplier. We believe that to allow this option would be an inappropriate interpretation of the statute.

G. 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 proposed 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 proposed rule. All expenditures are classified as transfers to the Federal Government from DMEPOS suppliers.

TABLE 17.—ACCOUNTING STATEMENT—CLASSIFICATION OF ESTIMATED EXPENDITURES, FROM FY 2007 TO FY 2011

Category	Transfers
Annualized Monetized Transfers	$570.3 (in Millions).
From Whom To Whom?	To Federal Government From Medicare DMEPOS Suppliers.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

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.

42 CFR Part 424

Emergency medical services, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 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—

A. Revising paragraph (b).

B. Adding new paragraph (s).

The revision and addition read as follows:

§ 411.15 Particular services excluded from coverage.

* * * * *

(b) *Low vision aid exclusion.* (1) *Scope.* The scope of the eyeglass exclusion encompasses all devices irrespective of their size, form, or technological features that use one or more lens to aid vision or provide magnification of images for impaired vision.

(2) *Exceptions.* (i) Post-surgical prosthetic lenses customarily used during convalescence for eye surgery in which the lens of the eye was removed (for example, cataract surgery).

(ii) Prosthetic intraocular lenses and one pair of conventional eyeglasses or contact lenses furnished subsequent to each cataract surgery with insertion of an intraocular lens.

(iii) Prosthetic lenses used by Medicare beneficiaries who are lacking the natural lens of the eye and who were not furnished with an intraocular lens.

* * * * *

(s) Unless § 414.408(f)(2) of this chapter 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 chapter) is furnished by a supplier other than a contract supplier (as defined in § 414.402).

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 A—General Provisions

4. Section 414.1 is amended by adding in numerical order the statutory sections to read as follows:

§ 414.1 Basis and scope.

* * * * *

1842(s)—Fee schedules for parenteral and enteral nutrition (PEN) nutrients, equipment, and supplies and home dialysis supplies and equipment.

1847(a) and (b)—Competitive bidding for certain durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS).

* * * * *

4a. The heading for subpart C is revised to read as follows:

Subpart C—Fee Schedules for Parenteral and Enteral Nutrition (PEN) Nutrients, Equipment, and Supplies, and Home Dialysis Supplies and Equipment

5. Section 414.100 is revised to read as follows:

§ 414.100 Purpose.

This subpart implements fee schedules for parenteral and enteral nutrition (PEN) items and services and home dialysis supplies and equipment as authorized by section 1842(s) of the Act.

6. Section 414.102 is revised to read as follows:

§ 414.102 General payment rules.

(a) *General rule.* For PEN items and services specified under paragraph (b) of this section and furnished on or after January 1, 2002, and for home dialysis supplies and equipment specified under paragraph (b) of this section and furnished on or after January 1, 2007, Medicare pays for the items and services on the basis of 80 percent of the lesser of—

(1) The actual charge for the item or service; or

(2) The fee schedule amount for the item or service, as determined in accordance with § 414.104 or § 414.107.

(b) *Payment classification.* (1) CMS or the carrier determines fee schedules for PEN nutrients, equipment, and supplies

in accordance with § 414.104, and the fee schedules for home dialysis supplies and equipment in accordance with § 414.107.

(2) CMS designates the specific items and services in each category through program instructions.

(c) *Updating the fee schedule amounts.* (1) For each calendar year subsequent to CY 2002, the fee schedule amounts of the preceding year for PEN items and services are updated by the percentage increase in the CPI–U for the 12-month period ending with June of the preceding calendar year.

(2) For each calendar year subsequent to CY 2007, the fee schedule amounts of the preceding year for home dialysis supplies and equipment are updated by the percentage increase in the CPI–U for the 12-month period ending with June of the preceding calendar year.

(d) *Establishing payment amounts for new items.* (1) The DMERC or local carrier uses the process described in paragraph (d)(3) of this section to establish the fee schedule amounts for the items and services included in a new HCPCS code created for a category of items and services payable under this subpart, but only if reasonable charge data are not available to calculate a fee schedule amount.

(2) The fee schedule amounts are updated in accordance with this subpart.

(3) CMS calculates the Medicare fee schedule amounts for the items and services described in paragraph (d)(1) of this section taking into account one or more of the following:

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

(ii) Fee schedule amounts for comparable items; or

(iii) A functional technology assessment of the items or services classified under the new HCPCS code that takes into account one or more of the following factors:

(A) Functional assessment.

(B) Price comparison analysis.

(C) Medical benefit assessment.

(4) A functional technology assessment described in paragraph (d)(2)(iii) of this section is also used to adjust fee schedule amounts calculated under paragraph (d)(2) of this section if CMS determines that these amounts do no reflect the costs of furnishing the item or service.

7. A new § 414.107 is added to read as follows:

§ 414.107 Home dialysis supplies and equipment.

(a) *Payment rules.* Payment for home dialysis supplies and equipment defined in § 410.52(a)(1) and (a)(2) of this chapter is made in a lump sum for supplies and equipment that are purchased, and on a monthly basis for supplies and equipment that are rented. Total payments per month for supplies and equipment may not exceed the payment limits described in § 414.330(c)(2) of this part.

(b) *Fee schedule amount.* The fee schedule amount for payment of home dialysis supplies and equipment defined in § 410.52(a)(1) and (a)(2) of this chapter and furnished in CY 2007 is the average reasonable charge for the supplies and equipment furnished from January 1, 2005 through December 31, 2005, increased by the percentage change in the CPI–U for the 24-month period ending June 2006.

Subpart D—Payment for Durable Medical Equipment and Prosthetic and Orthotic Devices

8. Section 414.210 is amended by adding a new paragraph (g) to read as follows:

§ 414.210 General payment rules.

* * * * *

(g) *Establishing fee schedule amounts for new items and services.* (1) The DMERC or local carrier uses the process described in paragraph (g)(2) of this section to establish the fee schedule amounts for the items and services included in a new HCPCS code created for a category of items and services payable under this subpart, but only if reasonable charge data are not available to calculate a fee schedule amount.

(i) The fee schedule amounts are updated in accordance with this subpart.

(ii) Items described in § 414.224 are not subject to paragraph (g)(1) of this section.

(2) CMS calculates the Medicare fee schedule amounts for the items and services described in paragraph (g)(1) of this section taking into account one or more of the following:

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

(ii) Existing fee schedule amounts for comparable items; or

(iii) A functional technology assessment of the items or services classified under the new HCPCS code that takes into account one or more of the following factors:

(A) Functional assessment.

(B) Price comparison analysis.

(C) Medical benefit assessment.

(3) A functional technology assessment described in paragraph (g)(2)(iii) of this section is also used to adjust fee schedule amounts calculated under paragraph (g)(2) of this section if CMS determines that these amounts do not reflect the costs of furnishing the item or service.

9. Section 414.228 is amended by adding paragraph (c) to read as follows:

§ 414.228 Prosthetic and orthotic devices.

* * * * *

(c) *Payment for therapeutic shoes.* The payment rules specified in paragraphs (a) and (b) of this section are applicable to custom molded and extra depth shoes, modifications, and inserts (therapeutic shoes) furnished after December 31, 2004.

Subpart E—Determination of Reasonable Charges Under the ESRD Program

10. Section 414.330 is amended by revising paragraph (a)(2) introductory text to read as follows:

§ 414.330 Payment for home dialysis equipment, supplies, and support services.

(a) * * *

(2) *Exception.* If the conditions in paragraphs (a)(2)(i) through (a)(2)(iv) of this section are met, Medicare pays for home dialysis equipment and supplies on a fee schedule basis in accordance with § 414.102, but the amount of payment may not exceed the limit for equipment and supplies described in paragraph (c)(2) of this section.

* * * * *

11. A new subpart F is added to read as follows:

Subpart F—Competitive Bidding for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)

Sec.

414.400 Purpose.
414.402 Definitions.
414.404 Basis, scope, and applicability.
414.406 Implementation of programs.
414.408 Payment rules.
414.410 Phased-in implementation of competitive bidding programs.
414.412 Submission of bids under a competitive bidding program.
414.414 Conditions for awarding contracts.
414.416 Determination of competitive bidding payment amounts.
414.418 Opportunity for networks.
414.420 Physician or treating practitioner authorization and consideration of clinical efficiency and value of items.
414.422 Terms of contracts.

414.424 Administrative or judicial review.
414.426 Adjustments to competitive bidding payment amounts to reflect changes in the HCPCS.

Subpart F—Competitive Bidding for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)

§ 414.400 Purpose.

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.

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.

Competitive bidding program means a program established under this subpart.

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:

(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 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(b).

(iv) Other durable medical equipment (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.

§ 414.404 Basis, scope, and applicability.

This subpart applies to the following entities that furnish the items described in § 414.402 to beneficiaries under a competitive bidding program:

(a) Suppliers.

(b) Providers that furnish items under Medicare Part B as suppliers.

(c) Physicians that furnish items under Medicare Part B as suppliers.

§ 414.406 Implementation of programs.

(a) *Implementation contractor.* CMS designates one or more implementation contractors for the purpose of implementing this subpart.

(b) *Competitive bidding areas.* CMS designates through program instructions each competitive bidding area in which a competitive bidding program may be implemented under this subpart.

(c) *Revisions to competitive bid.* CMS may revise the competitive bidding areas 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.

(e) *Claims processing.* The regional carrier designated under § 421.210 of this chapter to process DMEPOS claims for a particular geographic region also processes claims for items furnished under a competitive bidding program in the same geographic region.

§ 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 competitive bidding area 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 competitive bidding area, 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 subparts C or D of this part.

(b) *Updating the single payment amounts.* Beginning with the second year of a contract entered into under this subpart, the single payment amounts are updated by the percentage increase in the CPI–U for the 12-month period ending with June of the preceding calendar year.

(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) *Adjustment of payment amounts in other areas.* For items furnished to Medicare beneficiaries on or after January 1, 2009 for which payment is made under this subpart, CMS may use the single payment amounts determined under § 414.416 of this subpart to adjust the amounts Medicare pays for the same items in areas that are not designated as competitive bidding areas.

(f) *Requirement to obtain competitively bid items from a contract supplier.* (1) *General rule.* 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 (k) of this section.

(ii) If a beneficiary is outside of the competitive bidding area in which he or she maintains a permanent residence, he or she may obtain an item included in the competitive bidding program for that area from a—

(A) Contract supplier, if the beneficiary is in another competitive bidding area and the item is included in the competitive bidding program for that area; or

(B) Supplier, if the beneficiary is not in another competitive bidding area.

(iii) Unless paragraph (f)(2) of this section applies, a beneficiary who maintains a permanent residence in a competitive bidding area has no financial liability to a supplier that furnishes an item included in the competitive bidding program for that area in violation of paragraph (f)(1) of this section.

(3) CMS separately designates the supplier numbers of all noncontract suppliers to monitor compliance with paragraph (f)(1) of this section.

(g) *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, if included under a competitive bidding program, are calculated based on the bids submitted and accepted for these items. (2) Payment for used purchased durable medical equipment and enteral nutrition equipment, if included under a competitive bidding program, is made in an amount equal to 75 percent of the single payment amounts calculated for new purchased equipment under paragraph (g)(1) of this section.

(h) *Purchased supplies and orthotics.* The single payment amounts for the following purchased items, if included under a competitive bidding program, 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) Orthotics.

(i) *Rented equipment.* (1) Payment for capped rental durable medical equipment, if included under a competitive bidding program, is made in an amount equal to 10 percent of the single payment amounts calculated for new durable medical equipment under paragraph (g)(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) Separate maintenance and servicing payments will not be made for any rented equipment. Payment for maintenance and servicing of rented equipment is included in the single payment amount for rental of the item.

(3) Payment for enteral nutrition equipment, if included under a competitive bidding program, is made in an amount equal to 10 percent of the single payment amounts calculated for new enteral nutrition equipment under paragraph (g)(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 (g)(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.

(4) Payment for the maintenance and servicing of rented enteral nutrition equipment, if included under a competitive bidding program, is made in an amount equal to 5 percent of the single payment amounts calculated for these items under paragraph (g)(1) of this section.

(5) Payment for inexpensive or routinely purchased durable medical equipment furnished on a rental basis, if included under a competitive bidding program, is made in an amount equal to 10 percent of the single payment amount calculated for new purchased equipment.

(6) The single payment amounts for rented durable medical equipment requiring frequent and substantial servicing, if included under a competitive bidding program, are calculated based on the bids submitted and accepted for these items.

(j) *Monthly payment amounts for oxygen and oxygen equipment.* The single payment amounts for oxygen and oxygen equipment, if included under a competitive bidding program, are calculated based on the separate bids submitted and accepted for the furnishing on a monthly basis of each of the four categories of oxygen and oxygen equipment described in § 414.226(b)(1)(i) through (b)(1)(iv).

(k) *Special rules for certain rented durable medical equipment and oxygen and oxygen equipment.* (1) *Supplier election.* (i) A supplier that is furnishing DME on a rental basis or is furnishing oxygen and oxygen equipment on a monthly basis to a beneficiary prior to the implementation of a competitive bidding program in the area 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 a grandfathered item to all beneficiaries who elect to continue receiving the grandfathered item from that supplier.

(2) *Payment for grandfathered items furnished during the first competitive bidding program implemented in an area.* Medicare pays for grandfathered items furnished during the first competitive bidding program implemented in an area as follows:

(i) For items described in § 414.220, payment is made in the amount determined under § 414.220(b).

(ii) For items that meet the definition of a capped rental item in § 414.229, payment is made in the amount determined under § 414.229(b).

(iii) For items described in § 414.222, payment is made in the amount determined under § 414.416.

(iv) For items described in § 414.226, payment is made in the amount determined under § 414.416.

(3) *Payment for grandfathered items furnished during all subsequent competitive bidding programs in an area.* Beginning with the second competitive bidding program implemented in an area, payment is made for grandfathered items in the amounts determined under § 414.416.

(4) *Choice of suppliers.* (i) Beneficiaries described in paragraph (k)(1) of this section may elect to obtain a grandfathered item from a grandfathered supplier.

(ii) A beneficiary who is otherwise entitled to obtain an item from a grandfathered supplier under paragraph

(k) 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 item from a contract supplier, payment is made for the item in the amount determined under § 414.416.

§ 414.410 Phased-in implementation of competitive bidding programs.

(a) *Phase-in of MSA for CY 2007, CY 2009, and subsequent calendar years.* CMS phases in competitive bidding programs so that competition under the programs occurs in—

(1) Ten of the largest MSAs in CY 2007;

(2) Eighty of the largest MSAs in CY 2009;

(3) Additional areas after CY 2009.

(b) *Selection of MSAs for CY 2007 and CY 2009.* CMS selects the MSAs for purposes of designating competitive bidding areas 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 (FFS) beneficiary in an MSA.

(3) The total number of DMEPOS suppliers per FFS beneficiary that received DMEPOS items in an MSA.

(4) An MSA's geographic location.

(c) *Exclusions from a competitive bidding area.* CMS may exclude from a competitive bidding area a rural area (as defined in § 412.64(b)(1)(ii)(C) of this chapter), or an area with low population density based on the following factors—

(1) Low utilization of DMEPOS items by Medicare FFS beneficiaries relative to similar geographic areas;

(2) Low number of DMEPOS suppliers relative to similar geographic areas; or

(3) Low number of Medicare FFS beneficiaries relative to similar geographic areas.

(d) *Selection of additional areas after CY 2009.* (1) Beginning in CY 2010, CMS designates additional competitive bidding areas based on CMS' determination that the implementation of a competitive bidding program in an area is likely to result in significant savings to the Medicare program.

(2) CMS may designate one or more regional or nationwide competitive bidding areas for purposes of implementing competitive bidding programs for items that are furnished through the mail.

§ 414.412 Submission of bids under a competitive bidding program.

(a) 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) Bids are submitted for items grouped into product categories.

(c) 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 that is included in a particular competitive bidding program, are identified in the request for bids for that competitive bidding program.

(d) 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.

(e) A bid must include all costs related to furnishing an item, including all services directly related to the furnishing of the item.

(f) *Mail order suppliers.* (1) Suppliers that furnish items through the mail must submit a bid to furnish these items in any area in which a competitive bidding program is implemented which includes the items.

(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 program.* Suppliers that do not furnish items through the mail are not required to participate in a national or regional mail order competitive bidding program that includes the same items. Suppliers may continue to furnish these items in—

(1) A competitive bidding area, if the supplier is awarded a contract under this subpart; or

(2) An area not designated as a competitive bidding area.

§ 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 bidding supplier must meet the enrollment standards specified in § 424.57 of this chapter.

(2) Each bidding supplier must—

(i) Certify in its bid that it, its high level employees, chief corporate officers, members of its board of directors, its affiliated companies, and its subcontractors are not now and was not sanctioned by any governmental agency or accreditation or licensing organization, or

(ii) 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.

(3) Each bidding supplier must submit with its bid evidence of all State and local licenses required to perform the services identified in its response to the request for bids.

(4) Each bidding supplier must agree to all the terms contained in the request for bids and the supplier contract.

(c) *Quality standards and accreditation.* (1) *Quality standards.* All bidding suppliers must meet applicable quality standards developed by CMS in accordance with section 1834(a)(20) of the Act.

(2) *Accreditation.* (i) All bidding suppliers must be accredited by a CMS approved accreditation organization, as defined under § 424.57(a) of this chapter.

(ii) A supplier satisfies paragraph (c)(2)(i) of this section if it was accredited by an organization that CMS designates as a CMS-approved accreditation organization under § 424.58 of this chapter.

(d) *Financial standards.* All suppliers must meet the applicable financial standards specified in the request for bids.

(e) *Evaluation of bids.* CMS evaluates bids submitted for a product category by—

(1) Calculating the expected beneficiary demand in a competitive bidding area for items in a product category;

(2) Establishing a composite bid for each supplier that submitted a bid for the product category;

(3) Arraying the composite bids from the lowest to the highest;

(4) Calculating the pivotal bid for the product category; and

(5) Selecting all bidding suppliers 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.* CMS does not award a contract under this subpart unless CMS determines that the amounts to be paid to a contract supplier 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 subparts C or D of this part.

(g) *Sufficient number of suppliers.* If the requirements in paragraphs (e)(5) and (f) of this section are satisfied by two or more suppliers for a product category under a competitive bidding

program, then CMS awards at least two contracts for the furnishing of that product category under a competitive bidding program.

(h) *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 competitive bidding area.

(2) Before CMS awards additional contracts under paragraph (h)(1) of this section, a supplier must submit updated eligibility information, and CMS must determine that the supplier continues to meet 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 accepted bids for that item that are at or below the pivotal bid for the product category that includes the item.

(2) The single payment amount for an item must be less than the amount that would otherwise be paid for the same item under subparts C or D of this part.

(c) *Rebate.* (1) A contract supplier that submitted a bid for an item in an amount that is below the single payment amount calculated by CMS for that item may elect to issue a rebate.

(2) A contract supplier that elects to offer a rebate under paragraph (c)(1) of this section must agree to issue the same rebate to all beneficiaries to whom it furnishes an item to which a rebate applies.

(3) A contract supplier's election to offer a rebate will be included as an express term in the contract supplier's contract to furnish items under this subpart.

(4) The rebate election cannot be amended or otherwise modified during the term of the contract.

(5) A contract supplier may not advertise that it issues a rebate for any item furnished under this subpart.

§ 414.418 Opportunity for networks.

(a) For purposes of this section, a network is comprised of at least two suppliers that collectively submit a single bid to furnish the items included in a product category under a competitive bidding program.

(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.

(2) Each member of the network must be independently eligible to bid. If CMS determines that a member of the network is ineligible to bid, CMS notifies the network, and the network has 10 business days to resubmit its bid.

(3) Each network member must meet all accreditation and quality standards that are required. Each member is responsible for the quality of care, service, and items that it furnishes to Medicare beneficiaries. If any network member does not comply with this requirement, CMS may terminate its contract with the network.

(4) The network cannot be anticompetitive. The network members' market shares for a product category, when added together, cannot exceed 20 percent of the Medicare market within a competitive bidding area.

(5) A supplier may only join one network and cannot submit individual bids if part of a network. The network must identify itself as a network and identify all of its members.

(6) The network must designate a primary contract supplier among its members. The primary contract supplier bills and receives payment on behalf of the network members. The primary contract supplier is responsible for appropriately distributing reimbursement to other network members.

§ 414.420 Physician or treating practitioner authorization and consideration of clinical efficiency and value of items.

(a) 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.

(b)(1) The contract supplier must make a reasonable effort to furnish the particular brand or mode of delivery of an item as prescribed by the physician or treating practitioner.

(2) A contract supplier that, despite making a reasonable effort under paragraph (b)(1) of this section, cannot furnish an item as prescribed under paragraph (a) of this section, must consult with the physician or treating practitioner to find an appropriate item, or mode of delivery, for the beneficiary.

(3) Any change to a prescription made in accordance with paragraph (b)(2) of this section must be memorialized in a revised written prescription.

(c) Medicare does not make an additional payment to a contract supplier that furnishes a particular item or provides a particular mode of delivery for an item, as directed by a prescription written by the beneficiary's physician or treating practitioner.

(d) A contract supplier is prohibited from billing Medicare if it furnishes an item different from that specified in the written prescription received from the beneficiary's physician or treating practitioner.

§ 414.422 Terms of contracts.

(a) 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) *Repair and replacement of patient owned equipment.* (1) Beneficiary owned items furnished under a competitive bidding program must be serviced by a contract supplier for that competitive bidding program, and a contract supplier must agree to service all items included in its contract and furnished to any beneficiary who maintains a permanent residence in that contract supplier's competitive bidding area.

(2) Paragraph (c)(1) of this section does not apply if the beneficiary is outside the competitive bidding area.

(d) *Change of ownership.* (1) A contract supplier must notify CMS in writing 60 days prior to any change of ownership, mergers or acquisitions.

(2) CMS may award a contract to an entity that merges with, or acquires, a contract supplier if—

(i) CMS determines that awarding a contract to the successor entity is necessary to ensure that beneficiary

demand for the items furnished by the contract supplier continues to be met;

(ii) The successor entity meets all requirements applicable to contract suppliers for the applicable competitive bidding program;

(iii) The successor entity agrees to assume all obligations and liabilities borne by the prior contract supplier under the contract;

(iv) The successor entity executes a novation agreement.

(e) *Furnishing of items.* (1) A contract supplier must agree to furnish items under a competitive bidding program to any beneficiary who maintains a permanent residence in, or who visits, the competitive bidding area and who requests those items from that contract supplier.

(2) *Exceptions.* (i) A skilled nursing facility defined under section 1819(a) of the Act that is also a contract supplier must agree to furnish items under a competitive bidding program to patients to whom it would otherwise furnish Part B services.

(ii) A physician that is also a contract supplier must agree to furnish items under the competitive bidding program to his or her patients.

(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 the contract, CMS may take one or more of the following actions:

(i) Require the contract supplier to correct the breach condition;

(ii) Suspend performance under the contract;

(iii) Terminate the contract for default (which may include requiring the contract supplier to reimburse CMS' reprocurement costs);

(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.

(g) CMS has the right to terminate performance under the contract in whole or in part when termination would be in CMS' interest.

§ 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 competitive bidding areas.

(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 CMS determines that a competitively bid item was furnished in a competitive bidding area 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 during a competitive bidding program, CMS adjusts the single payment amount for that item as follows:

(a) If a single HCPCS code for an item is divided into multiple codes for the components of that item, the sum of single payment amounts for the new codes equals the single payment amount for the original item, and contract suppliers must furnish the components of the item in accordance with the new codes.

(b) If a single HCPCS code for two or more similar items is divided into two or more separate codes, the single payment amount applied to these codes is the same single payment amount applied to the single code, and contract suppliers must furnish the items in accordance with the new codes.

(c) If the HCPCS codes for components of an item are merged into a single code for the item, the single payment amount for the new code is equal to the total of the separate single payment amounts for the components, and contract suppliers must furnish the item in accordance with the new code.

(d) If multiple codes for similar items are merged into a single code, the single payment amount for the new single code is the average (arithmetic mean) weighted by the frequency of payments for the formerly separate codes, and contract suppliers must furnish the item under the new single code.

PART 424—CONDITIONS FOR MEDICARE PAYMENT

12. The authority citation for part 424 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 Provisions

13. Section 424.1 is amended by adding in numerical order the statutory sections to read as follows:

§ 424.1 Basis and scope.

* * * * *

1834(a)—Payment for durable medical equipment.

1834(j)—Requirements for suppliers of medical equipment and supplies.

* * * * *

Subpart D—To Whom Payment is Ordinarily Made

14. Section 424.57 is amended by—

A. Adding the definitions ''Accredited DMEPOS supplier,'' ''CMS approved accreditation organization'' and ''Independent accreditation organization'' in alphabetical order in paragraph (a).

B. Adding a new paragraph (c)(22).

The additions read as follows:

§ 424.57 Special payment rules for items furnished by DMEPOS suppliers and issuance of DMEPOS supplier billing privileges.

(a) Definitions. * * *

* * * * *

Accredited DMEPOS supplier means a supplier that has been accredited by a recognized independent accreditation organization meeting the requirements of and approved by CMS in accordance with § 424.58.

CMS approved accreditation organization means a recognized independent accreditation organization approved by CMS under § 424.58.

* * * * *

Independent accreditation organization means an accreditation organization that accredits a supplier of DMEPOS and other items and services for a specific DMEPOS product category or a full line of DMEPOS product categories.

* * * * *

(c) *Application certification standards.* * * *

(22) All suppliers of DMEPOS and other items and services must be accredited by a CMS approved accreditation organization before receiving a supplier billing number.

* * * * *

15. A new § 424.58 is added to read as follows:

§ 424.58 Accreditation.

(a) *Scope and purpose.* This part implements section 1834(a)(20)(B) of the Act, which requires the Secretary to designate and approve one or more independent accreditation organizations for purposes of enforcing the quality standards for suppliers of DMEPOS and other items of service. Section 1847(b)(2)(A)(i) of the Act requires a DMEPOS supplier to meet the quality standards under section 1834(a)(20) of

the Act before being awarded a contract under part 414, subpart F of this chapter.

(b) *Application and reapplication procedures for accreditation organizations.* (1) An independent accreditation organization applying for approval or reapproval of authority to survey suppliers for compliance with Medicare DMEPOS supplier quality standards is required to furnish the following to CMS:

(i) A list of the product-specific types of DMEPOS suppliers for which the organization is requesting approval.

(ii) A detailed comparison of the organization's accreditation requirements and standards with the applicable Medicare quality standards, such as a crosswalk.

(iii) A detailed description of the organization's survey process, including procedures for performing unannounced surveys, frequency of the surveys performed, copies of the organization's survey forms, guidelines and instructions to surveyors, accreditation survey review process and the accreditation status decision-making process.

(iv) Procedures used to notify suppliers of compliance or noncompliance with the accreditation requirements.

(v) Procedures used to monitor the correction of deficiencies found during an accreditation survey.

(vi) Procedures for coordinating surveys with another accrediting organization if the organization does not accredit all products the supplier provides.

(vii) Detailed professional information about the individuals who perform surveys for the accreditation organization, including the size and composition of accreditation survey teams for each type of supplier accredited, and the education and experience requirements surveyors must meet. The information must include the following:

(A) The content and frequency of the continuing education training provided to survey personnel.

(B) The evaluation systems used to monitor the performance of individual surveyors and survey teams.

(C) Policies and procedures for a surveyor or institutional affiliate of the independent accrediting organization that participates in a survey or accreditation decision regarding a DMEPOS supplier with which that individual or institution is professionally or financially affiliated.

(viii) A description of the organization's data management, analysis and reporting system for its surveys and accreditation decisions, including the kinds of reports, tables, and other displays generated by that system.

(ix) Procedures for responding to, and investigating complaints against, accredited facilities, including policies and procedures regarding coordination of these activities with appropriate licensing bodies, ombudsmen programs, the National Supplier Clearinghouse, and CMS.

(x) The organization's policies and procedures for notifying CMS of facilities that fail to meet the accreditation organization's requirements.

(xi) A description of all types, categories, and durations of accreditations offered by the organization.

(xii) A list of the following:

(A) All currently accredited DMEPOS suppliers.

(B) The types and categories of accreditation currently held by each supplier.

(C) The expiration date of each supplier's current accreditation.

(D) The upcoming survey cycles for all DMEPOS suppliers' accreditation surveys scheduled to be performed by the organization. (xiii) A written presentation that demonstrates the organization's ability to furnish CMS with electronic data in ASCII comparable code.

(xiv) A resource analysis that demonstrates that the organization's staffing, funding and other resources are adequate to perform fully the required surveys and related activities.

(xv) An agreement that makes surveyors available as witnesses if CMS takes an adverse action based on accreditation findings.

(2) *Validation survey.* CMS surveys suppliers of DMEPOS and other items and services accredited under this section on a representative sample basis, or in response to substantial allegations of noncompliance, in order to validate the accreditation organization's survey process. When conducted—

(i) On a representative sample basis, the CMS survey may be comprehensive or focus on a specific standard;

(ii) In response to a substantial allegation, CMS surveys for any standard that CMS determines is related to the allegations.

(3) *Discovery of a deficiency.* If CMS discovers a deficiency and determines that the DMEPOS supplier is out of compliance with Medicare supplier quality standards, CMS may revoke the suppliers' billing number or require the accreditation organization to perform a subsequent full accreditation survey at the accreditation organization's expense.

(4) *A supplier selected for a validation survey.* A supplier selected for a validation survey must authorize the—

(i) Validation survey to take place; and

(ii) CMS survey team to monitor the correction of any deficiencies found through the validation survey.

(5) *Refusal to cooperate with survey.* If a supplier selected for a validation survey fails to comply with the requirements specified at paragraph (b)(4) of this section, it is deemed to no longer meet the Medicare supplier quality standards and may have its supplier billing number revoked.

(6) *Validation survey findings.* If a validation survey results in a finding that the supplier is out of compliance with one or more Medicare supplier quality standards, the supplier no longer meets the Medicare standards and may have its supplier billing number revoked.

(c) *Ongoing responsibilities of a CMS approved accreditation organization.* An accreditation organization approved by CMS must undertake the following activities on an ongoing basis:

(1) Provide to CMS all of the following in written format and on a monthly basis all of the following:

(i) Copies of all accreditation surveys, together with any survey-related information that CMS may require (including corrective action plans and summaries of unmet CMS requirements).

(ii) Notice of all accreditation decisions.

(iii) Notice of all complaints related to suppliers of DMEPOS and other items and services.

(iv) Information about any suppliers of DMEPOS and other items and services against which the CMS approved accreditation organization has taken remedial or adverse action, including revocation, withdrawal, or revision of the supplier's accreditation.

(v) Notice of any proposed changes in its accreditation standards or requirements or survey process. If the organization implements the changes before or without CMS' approval, CMS may withdraw its approval of the accreditation organization.

(2) Within 30 days of a change in CMS requirements, submit to CMS:

(i) An acknowledgment of CMS' notification of the change.

(ii) A revised cross-walk reflecting the new requirements.

(iii) An explanation of how the accreditation organization plans to alter its standards to conform to CMS's new requirements, within the timeframes

specified in the notification of change it receives from CMS.

(3) Permit its surveyors to serve as witnesses if CMS takes an adverse action based on accreditation findings.

(4) Within 2 calendar days of identifying a deficiency of an accredited DMEPOS supplier that poses immediate jeopardy to a beneficiary or to the general public, provide CMS with written notice of the deficiency and any adverse action implemented by the accreditation organization.

(5) Within 10 days after CMS's notice to a CMS approved accreditation organization that CMS intends to withdraw approval of the accreditation organization, provide written notice of the withdrawal to all the CMS approved accreditation organization's accredited suppliers.

(6) Provide, on an annual basis, summary data specified by CMS that relate to the past year's accreditation activities and trends.

(d) *Continuing Federal oversight of approved accreditation organizations.* This paragraph establishes specific criteria and procedures for continuing oversight and for withdrawing approval of a CMS approved accreditation organization.

(1) *Equivalency review.* CMS compares the accreditation organization's standards and its application and enforcement of those standards to the comparable CMS requirements and processes when—

(i) CMS imposes new requirements or changes its survey process;

(ii) An accreditation organization proposes to adopt new standards or changes in its survey process; or

(iii) The term of an accreditation organization's approval expires.

(2) *Validation survey.* CMS or its designated survey team may conduct a survey of an accredited DMEPOS supplier, examine the results of a CMS approved accreditation organization's survey of a supplier, or observe a CMS approved accreditation organization's onsite survey of a DMEPOS supplier, in order to validate the CMS approved accreditation organization's accreditation process. At the conclusion of the review, CMS identifies any accreditation programs for which validation survey results indicate—

(i) A 10 percent rate of disparity between findings by the accreditation organization and findings by CMS or its designated survey team on standards that do not constitute immediate jeopardy to patient health and safety if unmet;

(ii) Any disparity between findings by the accreditation organization and findings by CMS on standards that constitute immediate jeopardy to patient health and safety if unmet; or

(iii) That, irrespective of the rate of disparity, there are widespread or systemic problems in an organization's accreditation process such that accreditation by that accreditation organization no longer provides CMS with adequate assurance that suppliers meet or exceed the Medicare requirements.

(3) *Notice of intent to withdraw approval.* CMS provides the organization written notice of its intent to withdraw approval if an equivalency review, validation review, onsite observation, or CMS's daily experience with the accreditation organization suggests that the accreditation organization is not meeting the requirements of this section.

(4) *Withdrawal of approval.* CMS may withdraw its approval of an accreditation organization at any time if CMS determines that—

(i) Accreditation by the organization no longer guarantees that the suppliers of DMEPOS and other items and services are meeting the supplier quality standards, and that failure to meet those requirements could jeopardize the health or safety of Medicare beneficiaries and could constitute a significant hazard to the public health; or

(ii) The accreditation organization has failed to meet its obligations with respect to application or reapplication procedures.

(e) *Reconsideration.* (1) An accreditation organization dissatisfied with a determination that its accreditation requirements do not provide or do not continue to provide reasonable assurance that the entities accredited by the accreditation organization meet the applicable supplier quality standards is entitled to a reconsideration. CMS reconsiders any determination to deny, remove, or not renew the approval of deeming authority to accreditation organizations if the accreditation organization files a written request for reconsideration by its authorized officials or through its legal representative.

(2) The request must be filed within 30 days of the receipt of CMS notice of an adverse determination or non renewal.

(3) The request for reconsideration must specify the findings or issues with which the accreditation organization disagrees and the reasons for the disagreement.

(4) A requestor may withdraw its request for reconsideration at any time before the issuance of a reconsideration determination.

(5) In response to a request for reconsideration, CMS provides the accreditation organization the opportunity for an informal hearing to be conducted by a hearing officer appointed by the Administrator of CMS and provide the accreditation organization the opportunity to present, in writing and in person, evidence or documentation to refute the determination to deny approval, or to withdraw or not renew deeming authority.

(6) CMS provides written notice of the time and place of the informal hearing at least 10 days before the scheduled date.

(7) The informal reconsideration hearing is open to CMS and the organization requesting the reconsideration, including authorized representatives; technical advisors (individuals with knowledge of the facts of the case or presenting interpretation of the facts); and legal counsel.

(i) The hearing is conducted by the hearing officer who receives testimony and documents related to the proposed action.

(ii) Testimony and other evidence may be accepted by the hearing officer even though it is inadmissible under the rules of court procedures.

(iii) The hearing officer does not have the authority to compel by subpoena the production of witnesses, papers, or other evidence.

(8) Within 45 days of the close of the hearing, the hearing officer presents the findings and recommendations to the accreditation organization that requested the reconsideration.

(9) The written report of the hearing officer includes separate numbered findings of fact and the legal conclusions of the hearing officer. The hearing officer's decision is final.

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program; Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: August 15, 2005.

Mark B. McClellan,

Administrator, Centers for Medicare & Medicaid Services.

Approved: April 3, 2006.

Michael O. Leavitt,

Secretary.

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