| CMS Manual System | **Department of Health & Human Services (DHHS)** |
|---|---|
| Pub 100-04 Medicare Claims Processing | **Centers for Medicare & Medicaid Services (CMS)** |
| **Transmittal 1502** | **Date: MAY 9, 2008** |
| | **Change Request 5978** |

**SUBJECT: Phase 1 of Manual Revisions to Reflect Payment Changes for DMEPOS Items as a Result of the DMEPOS Competitive Bidding Program and the Deficit Reduction Act (DRA) of 2005**

**I. SUMMARY OF CHANGES:** This is the first of several installments in adding a new chapter (Chapter 36) to the existing Claims Processing Manual in an effort to manualize policies and instructions for Medicare Contractors on the DMEPOS Competitive Bidding Program.

The subsequent installment of this chapter will include information about upgrades, claims processing, limitation on beneficiary liability, non-discrimination information, additional payment rules, and updates to Ch 20 of the claim processing manual as a result of the DRA.

**New / Revised Material**
**Effective Date: June 9, 2008**
**Implementation Date: June 9, 2008**

*Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.*

**II. CHANGES IN MANUAL INSTRUCTIONS:** (N/A if manual is not updated)
R=REVISED, N=NEW, D=DELETED-*Only One Per Row.*

| R/N/D | Chapter / Section / Subsection / Title |
|---|---|
| N | 36/Table of Contents/Competitive Bidding Program for Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) |
| N | 36/01/Foreword |
| N | 36/10/Background |
| N | 36/10.1/Competitive Bidding Implementation Contractor (CBIC) |
| N | 36/10.2/Definitions |
| N | 36/20/DMEPOS Competitive Bidding Process |
| N | 36/20.1/Items Subject to Competitive Bidding |
| N | 36/20.2/Competitive Bidding Areas (CBAs) |
| N | 36/20.3/No Administrative or Judicial Review |
| N | 36/20.4/Eligibility Requirements to Submit a Bid |
| N | 36/20.5/Becoming a Contract Supplier |

| | |
|---|---|
| N | 36/20.5.1/Small Suppliers and Networks |
| N | 36/20.5.2/Skilled Nursing Facilities (SNFs) and Nursing Facilities (NFs) |
| N | 36/20.5.3/Items Furnished on a Mail Order Basis |
| N | 36/20.5.3.1/Mail Order Suppliers for Diabetic Supplies |
| N | 36/20.6/Noncontract Suppliers |
| N | 36/20.6.1/Special Rules for Certain Rented Durable Medical Equipment (DME), Oxygen and Oxygen Equipment (Grandfathered Suppliers and Items) |
| N | 36/20.6.1.1/Requirements for Grandfathered Suppliers |
| N | 36/20.6.1.1.1/Eligibilty |
| N | 36/20.6.1.1.2/Servicing Current Beneficiaries |
| N | 36/20.6.1.1.3/Notification to Beneficiaries by Suppliers that Choose to Become Grandfathered Suppliers |
| N | 36/20.6.1.1.4/Notification to Beneficiaries by Suppliers that Choose Not to Become Grandfathered Suppliers |
| N | 36/20.6.2/New Period of Continuous Use |
| N | 36/20.6.3/Picking Up Equipment |
| N | 36/20.6.4/Transfer of Title for Oxygen Equipment and Capped Rental DME |
| N | 36/20.6.5/Capped Rental DME Furnished Prior to January 1, 2006 |
| N | 36/20.7/Use of Advanced Beneficiary Notice (ABNs) |
| N | 36/30/Contractor Supplier Responsibilities |
| N | 36/30.1/Compliance with Laws and Regulations |
| N | 36/30.2/Requirement to Maintain Medicare Billing Privileges and Accreditation |
| N | 36/30.3/Servicing the Entire Geographic Area of a CBA |
| N | 36/30.4/Prescription for Particular Brand, Item, or Mode of Delivery |
| N | 36/30.5/No Discrimination Against Beneficiaries |
| N | 36/30.6/Quarterly Reports |
| N | 36/30.7/Reporting Change of Ownership (CHOW) |
| N | 36/30.8/Submission of Claims |
| N | 36/30.9/Breach of Contract |
| N | 36/30.10/Request for Reconsideration |

| | |
|---|---|
| N | 36/40/Payment Rules |
| N | 36/40.1/Single Payment Amount |
| N | 36/40.1.1/Adjustments to the Single Payment Amount to Reflect Changes in Healthcare Common Procedure Coding System (HCPCS) Codes |
| N | 36/40.2/Conditions for Payment |
| N | 36/40.3/Payment for Grandfathered Items Furnished During the Initial Competitive Bidding Contract Period/Program |
| N | 36/40.3.1/Payment Categories |
| N | 36/40.3.1.1/Inexpensive or Routinely Purchased Items |
| N | 36/40.3.1.2/Items Requiring Frequent and Substantial Servicing |
| N | 36/40.3.1.3/Oxygen and Oxygen Equipment |
| N | 36/40.3.1.4/Other DME or Capped Rental Items |
| N | 36/40.3.2/Payment for Grandfathered Items Furnished During Subsequent Competitive Bidding Contract Periods/Programs |
| N | 36/40.3.3/Accessories and Supplies for Grandfathered Items |

**III. FUNDING:**

**SECTION A: For Fiscal Intermediaries and Carriers:**
No additional funding will be provided by CMS; Contractor activities are to be carried out within their operating budgets.

**SECTION B: For Medicare Administrative Contractors (MACs):**
The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

**IV. ATTACHMENTS:**

**Business Requirements**

**Manual Instruction**

**Unless otherwise specified, the effective date is the date of service.*

# Attachment - Business Requirements

| Pub. 100-04 | Transmittal: 1502 | Date: May 9, 2008 | Change Request: 5978 |
|---|---|---|---|

**SUBJECT: Phase 1 of Manual Revisions to Reflect Payment Changes for DMEPOS Items as a Result of the DMEPOS Competitive Bidding Program and the Deficit Reduction Act (DRA) of 2005.**

**Effective Date**: June 9, 2008
**Implementation Date:** June 9, 2008

## I. GENERAL INFORMATION

### A. Background:

This chapter has been developed to provide policies and instructions for the DMEPOS Competitive Bidding Program. This first installment of Chapter 36 is to provide a general overview and instructions for Medicare Contractors and suppliers on this program. Subsequent installments will follow this first installment providing additional sections to the chapter that contain more detailed instructions and guidelines.

### B. Policy:

Currently, Medicare payment for most DMEPOS is based on fee schedules. However, §302(b) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), which amended §1847 of the Social Security Act (Act), mandates a competitive bidding program to replace the current DMEPOS methodology for determining payment rates for certain DMEPOS items subject to competitive bidding under this statute. The statute also mandates that the competitive bidding program be phased in beginning in 2007. The Centers for Medicare & Medicaid Services (CMS) has issued the regulation for the competitive bidding program, which was published on April 10, 2007 (72 Federal Register 17992).

## II. BUSINESS REQUIREMENTS TABLE

*Use"Shall" to denote a mandatory requirement*

| Number | Requirement | Responsibility (place an "X" in each applicable column) | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | Shared-System Maintainers | | | | OTHER |
| | | A/B MAC | DME MAC | FI | CARRIER | RHHI | FISS | MCS | VMS | CWF | |
| 5978.1 | Medicare Contractors shall continue to apply all existing instructions for DMEPOS items as applicable, unless otherwise noted in this chapter. | X | X | X | X | X | | | | | |
| 5978.2 | Medicare Contractors shall apply, if applicable, the rules and requirements pertaining to the DMEPOS competitive bidding program. | X | X | X | X | X | | | | | |
| 5978.3 | Medicare Contractors shall be knowledgeable of the Healthcare Common Procedure Coding System (HCPCS) codes and modifiers that are subject to the DMEPOS competitive bidding program. | X | X | X | X | X | | | | | |
| 5978.4 | Medicare Contractors shall be knowledgeable of the specific competitive bidding areas subject to the DMEPOS competitive bidding program. | X | X | X | X | X | | | | | |
| 5978.5 | Medicare Contractors shall pay for Medicare covered non-competitive bidding items according to the existing payment rules for DMEPOS items. | X | X | X | X | X | | | | | |
| 5978.6 | Medicare Contractors shall be knowledgeable that only a competitive bid contract supplier can furnish a competitively bid item to a | X | X | X | X | X | | | | | |

| Number | Requirement | Responsibility (place an "X" in each applicable column) | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | A/B MAC | DME MAC | FI | CARRIER | RHHI | Shared-System Maintainers | | | | OTHER |
| | | | | | | | FISS | MCS | VMS | CWF | |
| | Medicare beneficiary within a competitive bidding area, unless one of the exceptions noted in requirements 5978.6.2 through 5978.6.4 applies. | | | | | | | | | | |
| 5978.6.1 | Medicare Contractors shall be knowledgeable that contract suppliers are required to furnish items under its supplier competitive bid contract to any beneficiary who maintains a permanent residence in or visits a CBA. | X | X | X | X | X | | | | | |
| 5978.6.2 | Medicare Contractors shall apply the exception that a grandfathered supplier is a supplier not awarded a contract, but that chooses to continue to furnish a grandfathered item to a Medicare beneficiary maintaining a permanent residence within a competitive bidding area. | X | X | X | X | X | | | | | |
| 5978.6.3 | Medicare Contractors shall apply the exception that a physician, or treating practitioner, who has a valid NSC number to serve as a DMEPOS supplier may furnish a walker in a competitive bidding area without the need to bid and be awarded a contract in the competitive bidding program, if the walker is furnished as part of a professional service. | X | X | X | X | X | | | | | |
| 5978.6.4 | Medicare Contractors shall apply the exception that a non-contract supplier may receive a Medicare secondary payment for a competitive bid item furnished to a beneficiary residing in a competitive bidding area, if the beneficiary is required to use that supplier under his/her primary insurance policy. | X | X | X | X | X | | | | | |
| 5978.7 | Medicare Contractors that process competitive bidding claims for beneficiaries in a skilled nursing facility (SNF) or a nursing facility (NF) located in a competitive bidding area shall reimburse only contract suppliers for those items, which may include a SNF or NF that is awarded a contract. | X | X | X | X | X | | | | | |
| 5978.7.1 | A SNF or NF may become a contract supplier or a specialty contract supplier that furnishes competitively bid items to only its own residents. | X | X | X | X | X | | | | | |
| 5978.8 | Medicare Contractors shall implement the policy that a noncontract supplier obtains an advance beneficiary notice (ABN) from a beneficiary in order to hold the beneficiary liable for competitive bid items furnished by a noncontract supplier. Current ABN rules still apply in CBAs. | X | X | X | X | X | | | | | |
| 5978.9 | Medicare Contractors shall pay the single payment amount for competitive bidding items. This payment amount applies regardless of where the beneficiary obtains the item. | | X | | | | | | | | |
| 5978.10 | Medicare Contractors shall manually update their systems with the competitive bid contract supplier single payment amounts, zip and HCPCS codes when instructed through quarterly competitive bid change requests. | | X | | | | | | | | |
| 5978.11 | Medicare Contractors shall make payment for competitive bidding items on an assignment-related basis equal to 80% of the applicable single payment amount less any unmet deductible for the CBA in which the beneficiary maintains a permanent residence. | | X | | | | | | | | |
| 5978.12 | Medicare Contractors shall educate suppliers about the methods for obtaining more information on the competitive bidding program. | X | X | X | X | X | | | | | |
| 5978.13 | Medicare contractors shall be knowledgeable and educate suppliers about the notification requirements, including notification to the beneficiary regarding a noncontract supplier's decision whether to be a grandfathered supplier and the beneficiary's election to use or not use a | X | X | X | X | X | | | | | |

| Number | Requirement | Responsibility (place an "X" in each applicable column) | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | A/B MAC | DME MAC | FI | CARRIER | RHHI | Shared-System Maintainers | | | | OTHER |
| | | | | | | | FISS | MCS | VMS | CWF | |
| | grandfathered supplier. | | | | | | | | | | |
| 5978.14 | Medicare contractors shall be knowledgeable and educate contract and noncontract suppliers that whenever a noncontract supplier chooses not to become a grandfathered supplier the contract and noncontract suppliers must work together to make arrangements suitable to the beneficiary for pick up and delivery of medically necessary rented items. | X | X | X | X | X | | | | | |
| 5978.15 | Medicare Contractors shall pay the single payment amount to a grandfathered supplier throughout the remainder of the rental period unless the exception in 5978.14 applies. | | X | | | | | | | | |
| 5978.16 | Medicare Contractors shall pay the Medicare fee schedule to a grandfathered supplier throughout the remainder of the rental period for any capped rental or inexpensive routinely purchased items that are competitively bid for the first time in a CBA. | | X | | | | | | | | |
| 5978.17 | Medicare Contractors shall implement the policy that a noncontract supplier that elects to not become a grandfathered supplier must submit a claim for the last monthly rental period that prior to the start of the competitive bidding program. | | X | | | | | | | | |

## III. PROVIDER EDUCATION TABLE

| Number | Requirement | Responsibility (place an "X" in each applicable column) | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | A/B MAC | DME MAC | FI | CARRIER | RHHI | Shared-System Maintainers | | | | OTHER |
| | | | | | | | FISS | MCS | VMS | CWF | |
| 5978.18 | A provider education article related to this instruction will be available at http://www.cms.hhs.gov/MLNMattersArticles/ shortly after the CR is released. You will receive notification of the article release via the established "MLN Matters" listserv.<br>Medicare Contractors shall post this article, or a direct link to this article, on their Web site and include information about it in a listserv message within one week of the availability of the provider education article. In addition, the provider education article shall be included in your next regularly scheduled bulletin. Medicare Contractors are free to supplement MLN Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly. | X | X | X | X | X | | | | | |

## IV. SUPPORTING INFORMATION

**Section A: For any recommendations and supporting information associated with listed requirements, use the box below:**
*Use "Should" to denote a recommendation.*

| X-Ref Requirement Number | Recommendations or other supporting information: |
|---|---|
| | |

**Section B: For all other recommendations and supporting information, use this space:**

## V. CONTACTS

**Pre-Implementation Contact(s):** Sabrina Teferi at Sabrina.Teferi@cms.hhs.gov or (410) 786-6884.

**Post-Implementation Contact(s):** Sabrina Teferi at Sabrina.Teferi@cms.hhs.gov or (410) 786-6884.

## VI. FUNDING

**Section A: For *Fiscal Intermediaries (FIs) and Carriers*:**

No additional funding will be provided by CMS; contractor activities are to be carried out within their operating budgets.

**Section B: *For Medicare Administrative Medicare Contractors (MAC)*:**

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

# *Medicare Claims Processing Manual*

## *Chapter 36 - Competitive Bidding Program for Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)*

*Table of Contents*

***(Rev. 1502, 05-09-08)***

***01 – Foreword***
***(Rev. 1502; Issued: 05-09-08; Effective/Implementation Date: 06-09-08)***

*42 CFR 411.15 and 414*

*This chapter provides guidance on the Medicare DMEPOS Competitive Bidding Program and general instructions on billing and claims processing for DMEPOS items subject to this program. General instructions on billing and claims processing for DMEPOS items, except as noted in this chapter, are in Chapter 20 of this manual. The payment rules for DMEPOS items specified in Chapter 20 of this manual generally apply to DMEPOS competitively bid items and services unless otherwise noted in this chapter. Coverage requirements in the Medicare Benefit Policy Manual and National Coverage Determinations manual will continue to apply to the Medicare DMEPOS Competitive Bidding Program unless noted otherwise in this chapter.*

*The instructions in this chapter are applicable to items and services subject to the Medicare DMEPOS Competitive Bidding Program unless otherwise noted. They pertain to Medicare contractors, including, but not limited to: Fiscal Intermediaries (FIs) and Carriers; the Medicare Administrative Contractors (MACs); Durable Medical Equipment Medicare Administrative Contractors (DME MACs); Regional Home Health Intermediaries (RHHIs); Program Safeguard Contractors (PSCs) and the DMEPOS Competitive Bidding Implementation Contractor (CBIC). These instructions are also applicable to DMEPOS suppliers.*

***10 – Background***
***(Rev. 1502; Issued: 05-09-08; Effective/Implementation Date: 06-09-08)***

*Section 1834 of the Social Security Act (the Act), as added by section 4062 of the Omnibus Budget Reconciliation Act of 1987 (OBRA '87), Public Law 100–203, provides for implementation of a fee schedule methodology for most durable medical equipment (DME), prosthetic devices, and orthotic devices furnished after January 1, 1989. The Medicare DMEPOS Competitive Bidding Program is required by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (the MMA) (Pub. L. 108-173), which amended section 1847 of the Act. Section 1847 of the Act, as amended, requires that competitive bidding programs be established and implemented in areas throughout the United States. In general, the statute requires that the Secretary implement a competitive bidding program that replaces the current DMEPOS fee schedule methodology for determining payment rates for certain DMEPOS items in competitive bidding areas. This fee schedule methodology will continue to be used for payment of Medicare covered DMEPOS non-competitively bid items or services.*

*The payment rates for DMEPOS competitively bid items are determined by using bids submitted by DMEPOS suppliers. The intent is to improve the methodology for setting DMEPOS payment amounts. These payments will reduce beneficiary out-of-pocket expenses and save the Medicare program money while ensuring beneficiary access to quality DMEPOS items and services from qualified suppliers.*

*The Medicare DMEPOS Competitive Bidding Program is being phased in, beginning in 2007 with 10 metropolitan statistical areas (MSAs) for certain DMEPOS items. The program will be*

*expanded into 70 additional MSAs in 2009, and then into additional areas (MSAs or other defined areas) after calendar year 2009.*

***10.1– Competitive Bidding Implementation Contractor (CBIC)***

***(Rev. 1502; Issued: 05-09-08; Effective/Implementation Date: 06-09-08)***

*Section 1847 of the Act authorizes CMS to contract with a Competitive Bidding Implementation Contractor (CBIC), to conduct certain functions relating to the administration of the Medicare DMEPOS Competitive Bidding Program. These functions include: preparing the request for bids (RFB); performing preliminary bid evaluations; and ensuring that suppliers meet all applicable financial and quality standards. In addition, the CBIC supports CMS's efforts to conduct an educational program for beneficiaries, suppliers and referral agents. The CBIC also assists CMS and its contractors in monitoring the program's effectiveness, access and quality. The CBIC's website, at http://www.dmecompetitivebid.com, contains important and up-to-date information on the Medicare DMEPOS Competitive Bidding Program.*

***10.2 – Definitions***
***(Rev. 1502; Issued: 05-09-08; Effective/Implementation Date: 06-09-08)***

***Advance Beneficiary Notice (ABN)*** *is a written form provided by the supplier and signed by the Medicare beneficiary in which the beneficiary agrees to pay out of pocket for charges not paid for by Medicare.*

***Bid*** *means an offer to furnish an item in a competitive bidding area (CBA) 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)*** *is the area determined by CMS, wherein suppliers are awarded contracts to furnish certain DMEPOS items to Medicare beneficiaries who obtain competitive bid items in the CBA.*

***Competitive bidding program*** *means a program under the Medicare DMEPOS Competitive Bidding Program established within a designated CBA for a specified product category and contract period.*

***Composite bid*** *means the sum of a supplier's weighted bids for all items within a product category within a CBA for purposes of allowing a comparison across bidding suppliers.*

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

***Grandfathered item*** *means any one of the following categories of items for which payment is made on a rental basis prior to the implementation of a competitive bidding program and for which payment is made after implementation of a competitive bidding program to a*

*grandfathered supplier that continues to furnish the items in accordance with 42 CFR § 414.408(j):*

*(1) Inexpensive or routinely purchased items furnished on a rental basis;*

*(2) Items requiring frequent and substantial servicing;*

*(3) Oxygen and oxygen equipment (not including oxygen contents, supplies or accessories furnished for use in conjunction with beneficiary-owned equipment);*

*(4) Capped rental items furnished on a rental basis.*

***Grandfathered supplier** means a noncontract supplier that elects to continue to furnish grandfathered items to beneficiaries in a CBA to whom the supplier had furnished the items prior to implementation of the competitive bidding program. The beneficiary must elect to continue to receive the item from the grandfathered supplier.*

***Item** means a product included in a competitive bidding program that is identified by a HCPCS code, which may be specified for competitive bidding (for example, a product when it is furnished through mail order), or a combination of codes and/or modifiers. An item also includes the services directly related to the furnishing of that product to the beneficiary, including caregiver training and follow-up, supplier's shipping charges, maintaining rented equipment in proper order, education, delivery, set-up and retrieval as appropriate.*

***Item weight** is a number assigned to an item based on national allowed services for that item when compared to other items in the same product category.*

***Mail order** refers to items ordered remotely (i.e., by phone, email, internet, or mail) and delivered to the beneficiary's residence by common carriers (e.g., U.S. Postal Service, Federal Express, United Parcel Service) and does not include items obtained by beneficiaries from local supplier storefronts.*

***Mail order contract supplier** is a contract supplier from which items are ordered remotely and that furnishes items through common carrier (e.g., U.S. Postal Service, Federal Express, and United Parcel Service) to beneficiaries who maintain a permanent residence in a CBA.*

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

***Minimal self-adjustment** means an adjustment that the beneficiary, caretaker for the beneficiary, or supplier of the device can perform and does not require the services of a certified orthotist (that is, an individual certified by either the American Board for Certification in Orthotics and Prosthetics, Inc., or the Board for Orthotist/Prosthetist Certification) or an individual who has specialized training.*

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

***Nationwide competitive bidding area** means a CBA that includes the United States, its Territories, and the District of Columbia.*

***Nationwide mail order contract supplier*** *means a mail order contract supplier that furnishes items in a nationwide competitive bidding area.*

***Network*** *means a group of small suppliers that form a legal entity to provide competitively bid items throughout the entire geographic area of a CBA.*

***Noncontract supplier*** *means a supplier that is not awarded a contract by CMS to furnish items included in a competitive bidding program.*

***Off-The-Shelf (OTS) orthotics*** *are orthotics that require minimal self-adjustment for appropriate use and do not require expertise in trimming, bending, molding, assembling, or customizing to fit the individual.*

***Pivotal bid*** *means the lowest composite bid based on bids submitted by suppliers for a product category that includes a sufficient number of suppliers to meet beneficiary demand for the items in that product category.*

***Product category*** *means a grouping of related items that are used to treat a similar medical condition.*

***Regional competitive bidding area*** *means a CBA that consists of a region of the United States, its Territories, and the District of Columbia.*

***Regional mail order contract supplier*** *means a mail order contract supplier that furnishes items in a regional competitive bidding area.*

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

***Small supplier*** *means a supplier that generates gross revenue of $3.5 million or less in annual receipts, including Medicare and non-Medicare revenue.*

***Specialty supplier*** *means a skilled nursing facility (SNF) or nursing facility (NF) that, at the time of bidding, elects to furnish certain competitive bidding items only to its residents and that is awarded a contract.*

***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.*

## *20 – DMEPOS Competitive Bidding Process*
***(Rev. 1502; Issued: 05-09-08; Effective/Implementation Date: 06-09-08)***

*To be considered for participation in the Medicare DMEPOS Competitive Bidding Program, suppliers must submit a bid in each CBA for each product category that they want to furnish to Medicare beneficiaries. DMEPOS suppliers must submit a bid amount for every item within a product category. All DMEPOS suppliers that submit a bid must meet the eligibility requirements in 42 CFR 411.414(b)-(d) and the bidding requirements established in the RFB. The RFB may be found on the CBIC website at http://www.dmecompetitivebid.com.*

*Bids are evaluated to determine whether the supplier will be able to participate in the program for the duration of the contract period. A composite bid (a supplier's weighted bids for all items within a product category within a CBA) is calculated for each supplier by product category and by CBA. These composite bids are then ranked in order from the highest to the lowest. The lowest ranked composite bid that includes a sufficient number of qualified suppliers to meet beneficiary demand for the items in a product category will become the pivotal bid.*

*Qualified suppliers that meet all of our requirements and whose composite bids are less than or equal to the pivotal bid will be offered a contract to participate in the Medicare DMEPOS Competitive Bidding Program. Also, additional small suppliers may be added to meet our small supplier target (see section 20.5.1). During the contracting process, additional suppliers may be awarded a contract to meet beneficiary demand.*

### *20.1 – Items Subject to Competitive Bidding*
***(Rev. 1502; Issued: 05-09-08; Effective/Implementation Date: 06-09-08)***

*The general categories of items that are subject to competitive bidding include:*

- *DME and medical supplies, including supplies necessary for the use of DME and items used in infusion and drugs (other than inhalation drugs), but excluding class III devices under the Federal Food, Drug, and Cosmetic Act.*
- *Enteral nutrients, equipment, and supplies.*
- *OTS orthotics*

*DMEPOS items subject to competitive bidding are phased in under the programs, beginning with the highest cost and highest volume items and services or those items and services that the Secretary determines have the largest savings potential. Specific items are designated for inclusion in competitive bidding programs through program instructions or other means (e.g. website posting). A listing of the items per CBA for round 1 of the DMEPOS Competitive Bidding Program is available at the CBIC website, http://www.dmecompetitivebid.com.*

### *20.2 – Competitive Bidding Areas (CBAs)*
***(Rev. 1502; Issued: 05-09-08; Effective/Implementation Date: 06-09-08)***

*A CBA is designated by specific zip codes. A CBA that is identified with a specific MSA may be concurrent with, larger than or smaller than the related MSA depending on a variety of considerations. Areas that may be exempt from the Medicare DMEPOS Competitive Bidding Program include rural areas and areas with low population density within urban areas (i.e, MSAs) that are not competitive, unless there is a significant national market through mail order for a particular item or service. The CBA will be the area within which certain DMEPOS items must be furnished by contract suppliers unless an exception applies.*

*CBAs are designated through program instructions or other means (e.g. website posting). A listing of the zip codes per CBA for round 1 of the DMEPOS Competitive Bidding Program is available at CBIC web site, http://www.dmecompetitivebid.com. Zip codes for future rounds will also be listed on this website. The DME MACs will be notified of any changes to zip codes as often as weekly via systematic updates to VMS.*

***20.3 – No Administrative or Judicial Review***
***(Rev. 1502; Issued: 05-09-08; Effective/Implementation Date: 06-09-08)***

*There is no administrative or judicial review for:*

- *The awarding of contracts;*
- *The establishment of payment amounts;*
- *Designation of CBAs;*
- *The phase-in of competitive bidding programs;*
- *The selection of items for competitive bidding programs; or*
- *The bidding structure and number of contract suppliers selected.*

*A denied claim is not appealable if the denial is based on a determination by CMS that a competitively bid item was furnished in a CBA in a manner not authorized by 42 CFR 414 Subpart F.*

***20.4 – Eligibility Requirements to Submit a Bid***
***(Rev. 1502; Issued: 05-09-08; Effective/Implementation Date: 06-09-08)***

*To be eligible to bid, all suppliers must meet the requirements in 42 CFR 414.414. For example, the suppliers must be in good standing and have an active National Supplier Clearinghouse number (NSC#), meet quality standards and be accredited by a CMS approved accreditation organization (unless CMS specifies that a pending accreditation application is acceptable) for the item being bid. Suppliers must be accredited by the deadline specified by CMS in order to be offered a contract.*

***20.5 – Becoming a Contract Supplier***
***(Rev. 1502; Issued: 05-09-08; Effective/Implementation Date: 06-09-08)***

*Qualified suppliers that meet all competitive bidding requirements including, but not limited to, eligibility, financial and accreditation requirements and whose composite bids are less than or equal to the pivotal bid, will be offered a contract to become a contract supplier. Contract*

*suppliers will be held to all of the terms of their contracts for the duration of the contract period. See section 30 of this chapter for more information about contract supplier responsibilities. For the first round of competitive bidding, the contract period is July 1, 2008 through June 30, 2011, with the exception of mail order diabetic supplies, whose contract period is July 1, 2008 through March 31, 2010. The length of a contract period may not exceed 3 years.*

***20.5.1 – Small Suppliers and Networks***
***(Rev. 1502; Issued: 05-09-08; Effective/Implementation Date: 06-09-08)***

*The Act mandates that appropriate steps be taken to ensure that small suppliers have an opportunity to be considered for participation in the Medicare DMEPOS Competitive Bidding Program. For competitive bidding purposes, the definition of a small supplier is a supplier that generates $3.5 million or less in annual receipts, including Medicare and non-Medicare revenue.*

*Small suppliers have the option to form networks for bidding purposes. A network is a group of small suppliers that form a legal entity to provide competitively bid items throughout the entire geographical area of a CBA. The requirements for networks are as follows:*

- *A single legal entity must be formed for the purpose of submitting a bid as a network.*
- *One supplier must be designated as the primary supplier.*
- *The network must identify itself as a network and identify all members of the network in the bid application. Each member of the network must be independently eligible to bid. Each member of the network must satisfy all required eligibility, financial and accreditation requirements, and is responsible for the quality of the products, care and services provided to Medicare beneficiaries. If any member of the network is not compliant with these requirements, the network contract may be terminated.*
- *All contracts or other legal documents necessary to create the network entity must be in place and signed before the network entity may submit a bid.*
- *The network must include at least two but not more than 20 members. Each member of a network must furnish all the items in the product category for which the network is awarded a contract.*
- *Network members can only join one network per product category per CBA.*
- *Only small suppliers that are unable independently to serve the entire geographic area of a CBA may join the network.*
- *Each member of the network must sign a certification statement that must be included as part of the network's bid application. The certification statement must*

*specify that the supplier joined the network because it is unable independently to furnish all of the items in the product category for which the network is submitting a bid to beneficiaries throughout the entire geographic area of the CBA.*

- *The network cannot be anticompetitive. Any suspected cases of Federal antitrust violations are referred to the Department of Justice for review.*

- *For bid evaluation purposes, a network's combined total market share for each product category cannot exceed 20 percent of the Medicare demand for that product category in the CBA at the time of bidding. However, once a network receives a contract, the network may expand and exceed the 20 percent limit on market share.*

- *Network members may not bid independently or as a member of another network for the same product category for which the network submits a bid in the same CBA. A supplier can join different networks for different product categories or in different CBAs.*

- *If a network is awarded a contract, each member of the contracted network will submit its own Medicare claims and will be paid directly by Medicare for products and services it furnishes under the Medicare DMEPOS Competitive Bidding Program.*

***20.5.2 – Skilled Nursing Facilities (SNFs) and Nursing Facilities (NFs)***
***(Rev. 1502; Issued: 05-09-08; Effective/Implementation Date: 06-09-08)***

*The Medicare DMEPOS Competitive Bidding Program applies to SNFs and NFs located in a CBA to the extent their residents receive competitively bid items under Medicare Part B. Unlike most suppliers, SNFs and NFs have the option to bid for, and be awarded, contracts to be "specialty suppliers" that only furnish competitively bid items to their own residents. SNFs and NFs may elect to submit a bid as a specialty supplier by indicating on the RFB that they will only furnish competitive bid items to their own residents. Any SNF or NF awarded a contract would be paid the single payment amount for those items. SNFs and NFs that elect to be specialty suppliers may not furnish competitively bid items and services to Medicare beneficiaries outside their facilities for purposes of Medicare payment. If a SNF or NF is not awarded a contract, it must use a contract supplier for the CBA to furnish competitively bid items to its residents. SNFs and NFs can also become regular contract suppliers that furnish competitively bid items to beneficiaries throughout a CBA.*

*If a SNF or NF is not a contract supplier (either a specialty contract supplier or a regular contract supplier), it must use a contract supplier for its CBA to furnish competitively bid items to its residents.*

***20.5.3 – Items Furnished on a Mail Order Basis***
***(Rev. 1502; Issued: 05-09-08; Effective/Implementation Date: 06-09-08)***

*A Medicare beneficiary who maintains a permanent residence in a CBA for which we have done competitive bidding for mail order items may purchase their mail order items from: (1) a mail order contract supplier for that CBA; or (2) a noncontract supplier, if the item is purchased at a storefront. In situations where the beneficiary elects to obtain the item from a local storefront or from a local supplier via a mode of delivery other than mail order and the item is not subject to a competitive bidding program established for non-mail order items, the beneficiary may obtain the item from any Medicare enrolled supplier.*

***20.5.3.1 – Mail-Order Suppliers for Diabetic Supplies***
***(Rev. 1502; Issued: 05-09-08; Effective/Implementation Date: 06-09-08)***

*Medicare beneficiaries who maintain a permanent residence in a CBA in which CMS has implemented a competitive bidding program for mail order diabetic supplies may purchase their diabetic testing supplies from:*

- *A mail order contract supplier for the CBA in which the beneficiary resides; or*
- *Any enrolled Medicare supplier if the diabetic testing supplies are furnished at a storefront and are not subject to a competitive bidding program established for non-mail order diabetic supplies.*

*Mail order contract suppliers will be reimbursed at the single payment amount for mail order diabetic supplies for the CBA in which the beneficiary maintains a permanent residence. In situations where a competitive bidding program has not been established for non-mail order diabetic supplies, noncontract suppliers that do not furnish items through mail order will be reimbursed at the fee schedule amount for the state in which the beneficiary maintains a permanent residence. Medicare payment will not be made to noncontract suppliers that furnish mail order diabetic testing supplies to Medicare beneficiaries residing in a CBA.*

*Mail order diabetic suppliers must use the HCPCS modifier KL on each claim to indicate that the item was furnished on a mail order basis. The modifier must be used for both competitive bidding and non-competitive bidding mail order diabetic supplies. Suppliers that furnish mail order diabetic items that fail to use the HCPCS modifier KL on the claim may be subject to penalties under of the False Claims Act.*

***20.6 – Noncontract Suppliers***
***(Rev. 1502; Issued: 05-09-08; Effective/Implementation Date: 06-09-08)***

*Noncontract suppliers that furnish competitively bid items in a CBA are not eligible for Medicare payment for the competitively bid items for that CBA unless one or more of the following exceptions applies:*

- ***Suppliers of Grandfathered DME** – Beneficiaries who are receiving oxygen and oxygen equipment or rented DME at the time the competitive bidding program becomes effective may elect to continue to receive these items from a noncontract*

*supplier if the supplier is willing to continue furnishing these items. See section 20.6.1 of this chapter for more information on grandfathering.*

- ***Repairs/Replacement*** *- Beneficiaries who maintain a permanent residence in a CBA may go to any Medicare-enrolled supplier (contract or noncontract supplier) for repairs or replacement parts for beneficiary owned items. Labor to repair equipment is not subject to competitive bidding and, therefore, will be paid in accordance with Medicare's general payment rules. Payment for parts that are not competitively bid items and that are needed to repair a beneficiary-owned item will also be paid in accordance with these rules. Payment for replacement parts that are part of the competitive bidding program for the areas in which the beneficiary resides would be paid at the single payment amount. Unlike repairs, beneficiaries must obtain replacements of certain base equipment they own (e.g. wheechairs or hospital beds) from a contract supplier, when the base equipment must be replaced in its entirety, rather than replacement parts for the repair of the base equipment. A contract supplier is required to service all rented items included in its contract.*

- ***Physicians and Other Practitioners Who are Enrolled Medicare DMEPOS Suppliers*** *- Physicians and treating practitioners have the option to furnish certain types of competitively bid items in a CBA to their own patients without submitting a bid and being a selected as a contract supplier, provided the following requirements are met:*

    - *The items are limited to crutches, canes, walkers, folding manual wheelchairs, blood glucose monitors, and infusion pumps that are DME.*

    - *The items must be billed using a billing number assigned to the physician, the treating practitioner or a group practice to which the physician or treating practitioner has reassigned the right to receive Medicare payment for competitive bid items.*

  *Physicians and treating practitioners who do not to become contract suppliers may only provide the bid items identified above to their own patients and will not be allowed to act as contract suppliers to provide bid items to beneficiaries for purposes of Medicare payment.*

  *The physician or treating practitioner will be paid the single payment amount when the furnished item is a competitive bid item and the beneficiary maintains a permanent residence in a CBA.*

- ***Physical Therapists and Occupational Therapists in Private Practice Who are Enrolled Medicare DMEPOS Suppliers --*** *Physical therapists and occupational therapists in private practice have the option to furnish certain types of competitively bid items to their own patients without submitting a bid and*

*being a selected as a contract supplier, provided the following requirements are met:*

- *The only competitive bid items they may furnish without becoming a contract supplier are OTS orthotics.*
- *The items must be furnished only to their own patients as part of the physical or occupational therapy service.*

*Physical and occupational therapists in private practice who do not to become contract suppliers may only provide competitive bid OTS orthotics to their own patients and will not be allowed to act as contract suppliers for purposes of Medicare payment.*

*The physical or occupational therapist will be paid at the single payment amount when the furnished item is a competitive bid item and the beneficiary maintains a permanent residence in a CBA.*

- ***Medicare Secondary Payer** - If a Medicare beneficiary is required under his or her primary insurance policy to use a supplier that is a noncontract supplier, Medicare may make a secondary payment to a noncontract Medicare-enrolled supplier for competitive bid items. The supplier must have a valid NSC# and be eligible to receive secondary payments. The amount paid to the supplier will be calculated in accordance with established Medicare secondary payment rules.*

*If none of the exceptions above apply, then the noncontract supplier is responsible for notifying the beneficiary that it is not a contract supplier for the competitive bidding item in the CBA, and the beneficiary must go to a contract supplier for that item in order for Medicare to make payment for the item. CMS has a supplier locator tool in order to assist beneficiaries and suppliers in finding contract suppliers. The supplier locator tool can be found at www.medicare.gov. Beneficiaries may also call 1-800-Medicare to obtain information about contract suppliers.*

***20.6.1 – Special Rules for Certain Rented Durable Medical Equipment (DME), Oxygen and Oxygen Equipment (Grandfathered Suppliers and Items)***
***(Rev. 1502; Issued: 05-09-08; Effective/Implementation Date: 06-09-08)***

*Suppliers that were furnishing certain rented DME, or oxygen and oxygen equipment at the time a competitive bidding program begins in a CBA, may become grandfathered suppliers by continuing to furnish these items to the Medicare beneficiaries who have been receiving these items, even if the suppliers do not become contract suppliers for these items in the CBA. Grandfathered items must be any of the following:*

*(1) Inexpensive or routinely purchased items furnished on a rental basis;*

*(2) Items requiring frequent and substantial servicing;*

*(3) Oxygen and oxygen equipment (not including oxygen contents, supplies or accessories furnished for use in conjunction with beneficiary-owned equipment);*

*(4) Capped rental items furnished on a rental basis.*

***20.6.1.1 – Requirements for Grandfathered Suppliers***
***(Rev. 1502; Issued: 05-09-08; Effective/Implementation Date: 06-09-08)***

***20.6.1.1.1 – Eligibility***
***(Rev. 1502; Issued: 05-09-08; Effective/Implementation Date: 06-09-08)***

*All suppliers must be in good standing and have an active NSC number which requires that the supplier meet any local and State licensure requirements, if any, for provision of the grandfathered item.*

***20.6.1.1.2 – Servicing Current Beneficiaries***
***(Rev. 1502; Issued: 05-09-08; Effective/Implementation Date: 06-09-08)***

*A supplier that chooses to continue to furnish a grandfathered item(s) to any beneficiary in a CBA must continue to furnish that grandfathered item(s) to all beneficiaries who elect to continue receiving that item(s) from that supplier for the remainder of the payment period for the item(s), unless the item is no longer medically necessary. In order to participate as a grandfathered supplier, the supplier must update its billing systems to incorporate any new billing codes, modifiers or other billing instructions for grandfathered suppliers in the Medicare DMEPOS Competitive Bidding Program.*

***20.6.1.1.3 – Notification to Beneficiaries by Suppliers that Choose to Become Grandfathered Suppliers***
***(Rev. 1502; Issued: 05-09-08; Effective/Implementation Date: 06-09-08)***

*A noncontract supplier that elects to become a grandfathered supplier is responsible for providing notification to its Medicare customers residing in CBAs who are furnished items identified in section 20.6.1. This notification should meet the following guidelines:*

- *It should state that the supplier is offering to continue to furnish rental DME and/or oxygen and oxygen equipment that it is currently furnishing to the beneficiary (i.e., before the start of the competitive bidding program) and to provide these items to the beneficiary for the remainder of the rental period.*
- *It should state that the beneficiary has the choice to continue to receive a grandfathered item(s) from the grandfathered supplier or to elect to begin receiving the item(s) from a contract supplier after the competitive bidding program begins.*
- *It should provide the supplier's telephone number so the beneficiary or caregiver may call and notify the supplier of his/her election.*
- *The supplier should provide notification to the beneficiary at least 30 days before the start date of the implementation of the Medicare DMEPOS Competitive Bidding Program.*

- *The supplier should receive an election from a beneficiary and maintain a record as to whether the beneficiary chose to continue to receive the item from a grandfathered supplier, chose to go to a contract supplier to receive the item or did not respond. The record should indicate, at a minimum, the date that the beneficiary is notified that the supplier elected to become a grandfathered supplier for the item(s), the date the beneficiary made an election (if applicable), and the methods of communication used in the case of each election activity (e.g. letter to the beneficiary).*
- *The supplier should inform the beneficiary of the end date of service and that arrangements will be made to pick-up the item within 10 days of picking up the item.*
- *The supplier should remind the beneficiary of the date and time the equipment will be picked up within 2 business days of picking up the equipment.*

***Recommended Schedule for Suppliers to Notify Beneficiaries of the Necessity to Decide on Arrangements for Choosing to Use a Grandfathered Supplier or Contract Supplier***

| ***Notification – Supplier*** | ***Number of Days Before the Start Date of the Competitive Bidding Program*** |
|---|---|
| *Initial Notification in writing* | *30 days* |
| *Notification before picking up equipment* | *Within 10 days before picking up the equipment.* |
| *Final Notification before picking up equipment* | *Within 2 business days of picking up the equipment* |

*** A sample notification letter will be posted on the CBIC website at www.dmecompetitivebid.com.*

***20.6.1.1.4 – Notification to Beneficiaries for Suppliers that Choose Not to Become Grandfathered Suppliers***
***(Rev. 1502; Issued: 05-09-08; Effective/Implementation Date: 06-09-08)***

*A noncontract supplier that elects not to become a grandfathered supplier should provide notification to the beneficiary stating the supplier will not continue to furnish, after the start of the Medicare DMEPOS Competitive Bidding Program, the competitively bid item(s) that the beneficiary has been receiving from the supplier. This notification should meet the following guidelines:*

- *It should state that the supplier will not continue to furnish rental DME and/or oxygen and oxygen equipment that it is currently furnishing to the beneficiary before the start of the competitive bidding program and that the beneficiary may need to select a contract supplier to continue to receive these items.*
- *It should inform the beneficiary of the start of the competitive bidding program and the date the supplier plans to pick up the item.*
- *It should inform the beneficiary that he/she may obtain information about the competitive bidding program by calling 1-800-MEDICARE or accessing www.medicare.gov on the Internet. It should also refer him/her to the supplier locator tool on www.medicare.gov.*

- *The supplier should provide this written notification to the beneficiary 30 days before the start date from the implementation of the Medicare DMEPOS Competitive Bidding Program.*
- *The supplier should inform the beneficiary of the end date of service and that arrangements will be made to pick-up the item within 10 days of picking up the item.*
- *The supplier should remind the beneficiary of the date and time the equipment will be picked up within 2 business days of picking up the equipment.*

***Recommended Schedule for Suppliers to Notify Beneficiaries to Locate a Contract Supplier***

| ***Notification – Supplier*** | ***Number of Days Before the Start Date of the Competitive Bidding Program*** |
|---|---|
| *Initial Notification in writing* | *30 days* |
| *Notification before picking up equipment* | *Within 10 days before picking up the equipment.* |
| *Final Notification before picking up equipment* | *Within 2 business days of picking up the equipment* |

*** A sample notification letter will be posted on the CBIC website at www.dmecompetitivebid.com.*

***20.6.2 – New Period of Continuous Use***
***(Rev. 1502; Issued: 05-09-08; Effective/Implementation Date: 06-09-08)***

*In the case of grandfathered items that are oxygen and oxygen equipment or capped rental DME, whenever a new period of continuous use begins following a break in use of greater than 60 days plus the days remaining in the last rental month, after the start of the competitive bidding program, the new or additional equipment covered under the new period of continuous use must be obtained from a competitive bidding contract supplier. See 42 CFR 414.230 for determining a period of continuous use.*

***20.6.3 – Picking Up Equipment***
***(Rev. 1502; Issued: 05-09-08; Effective/Implementation Date: 06-09-08)***

*Under no circumstances may the supplier discontinue services by picking up a medically necessary item(s) prior to the end of a month for which the supplier is eligible to receive a rental payment, even if the last day ends after the start date of the Medicare DMEPOS Competitive Bidding Program. A noncontract supplier may only pick up medically necessary oxygen equipment or capped rental DME prior to the start of the competitive bidding program or prior to the end of the month for which the supplier is eligible to receive payment if the beneficiary relocates his/her permanent residence outside the CBA and outside the normal service area of the supplier. The pick up by the noncontract supplier and the delivery by the contract supplier of the equipment should occur on the same day and month as the item rental anniversary date. The anniversary date is the day of the month on which the item was first delivered to the beneficiary. For capped rental DME or oxygen and oxygen equipment, the noncontract supplier is responsible for submitting a claim for any rental period that begins prior to the start of the competitive bidding program. In all cases, we expect the contract supplier to consult with the*

*noncontract supplier to obtain the anniversary date. The noncontract supplier should work with the contract supplier so that there is no break in service or furnishing of medically necessary items. We expect the contract supplier and the current supplier will work together to make arrangements suitable to the beneficiary's needs.*

***Examples: Using July 1st as the beginning date of the Medicare DMEPOS Competitive Bidding Program***

***A.*** *If a beneficiary's last anniversary date before the beginning of the competitive bidding program is* ***June 29****, the noncontract supplier must submit a claim for the rental month beginning June 29 and ending July 28th.*

*The noncontract supplier must not pick up the equipment prior to July 29th. In this case, the current supplier would pick up its equipment, on July 29th, and the contract supplier would deliver its equipment on July 29th.*

***B.*** *If a beneficiary's anniversary date is* ***July 1st****, the beginning date for the competitive bidding program, the noncontract supplier must not pick up the equipment before July 1st and must not submit a claim for the July rental period. The contract supplier should deliver the equipment to the beneficiary on July 1st and must submit a claim for this month.*

***20.6.4 – Transfer of Title for Oxygen Equipment and Capped Rental DME***
***(Rev. 1502; Issued: 05-09-08; Effective/Implementation Date: 06-09-08)***

*Title to oxygen equipment transfers to the beneficiary on the first day that begins after the 36th continuous month during which Medicare payment is made for rental of the equipment. Title for capped rental equipment transfers to the beneficiary on the first day that begins after the 13th continuous month during which Medicare payment is made for the capped rental DME equipment. These requirements apply to all suppliers without regard to their grandfathered status. Suppliers that do not become contract suppliers or grandfathered suppliers must transfer title for the equipment to the beneficiary in accordance with these requirements even in situations where the 36th continuous month for oxygen equipment or the 13th continuous month for capped rental DME ends after the start date of the competitive bidding program.*

***20.6.5 – Capped Rental DME Furnished Prior to January 1, 2006***
***(Rev. 1502; Issued: 05-09-08; Effective/Implementation Date: 06-09-08)***

*This section addresses situations where the beneficiary did not elect the purchase option described in section 30.5.2 of Chapter 20 for capped rental DME for which the first rental month occurred prior to January 1, 2006. In accordance with section 30.5.4 of Chapter 20, the supplier that provides the item in the 15th month of the rental period is responsible for supplying the equipment and for maintenance and servicing after the 15-month period. This requirement is not eliminated by any requirement under the competitive bidding program and applies to both contract and noncontract suppliers without regard to their grandfathered status. (See section 50.1 of Chapter 20).*

***20.7 – Use of Advanced Beneficiary Notice (ABNs)***
***(Rev. 1502; Issued: 05-09-08; Effective/Implementation Date: 06-09-08)***

*Except where an exception applies, a beneficiary has no financial liability to a noncontract supplier that furnishes an item included in the competitive bidding program for a CBA, unless the beneficiary has signed an Advance Beneficiary Notice (ABN).*

*However, if a noncontract supplier in a CBA obtains a signed ABN indicating that the beneficiary was informed in writing prior to receiving the competitively bid item or service that there would be no payment by Medicare due to the supplier's non-contract status, the noncontract supplier may charge the beneficiary for the item or service. In this circumstance, non-contract suppliers cannot bill Medicare and receive payment for the competitively bid item or service.*

*An ABN is a written form provided by the supplier and signed by the Medicare beneficiary in which the beneficiary agrees to pay out of pocket for charges not paid for by Medicare. See Chapter 30 - Financial Liability Protections of this manual for general instructions relating to ABN requirements. In addition to the other uses of an ABN as defined in Chapter 30, an ABN informs a beneficiary before he or she receives specified items or services from a noncontract supplier that Medicare will probably not pay for the specified items or services for that particular beneficiary on that particular occasion if furnished by a noncontract supplier.*

***30 – Contract Supplier Responsibilities***
***(Rev. 1502; Issued: 05-09-08; Effective/Implementation Date: 06-09-08)***

***30.1 – Compliance with Laws and Regulations***
***(Rev. 1502; Issued: 05-09-08; Effective/Implementation Date: 06-09-08)***

*A contract supplier, and its affiliated companies and subcontractors, must comply with all applicable Federal and State laws and regulations including, without limitation, the final rule on Competitive Acquisition for Certain DMEPOS and Other Issues that appeared in the Federal Register on April 10, 2007 (72 Fed. Reg. 17992) and 42 CFR, Part 414, Subpart F. A contract supplier must also comply with any applicable State licensing requirements pertaining to its functions as a contract supplier.*

***30.2 – Requirement to Maintain Medicare Billing Privileges and Accreditation***
***(Rev. 1502; Issued: 05-09-08; Effective/Implementation Date: 06-09-08)***

*A contract supplier must satisfy the enrollment standards specified in 42 CFR §424.57(c), meet applicable quality standards (both general quality standards and product specific quality standards) developed by CMS in accordance with section 1834(a)(20) of the Act, and be accredited by a CMS-approved accreditation organization for the duration of the contract period. Contract suppliers must maintain appropriate enrollment and accreditation throughout the term of their contracts. The contract supplier must notify the CBIC in writing at the US postal or certified (physical) mailing address identified in the supplier's contract within five (5) business days of any changes to its Medicare billing privileges or accreditation status.*

***30.3 – Servicing the Entire Geographic Area of a CBA***
***(Rev. 1502; Issued: 05-09-08; Effective/Implementation Date: 06-09-08)***

*A contract supplier must agree to furnish all items under its contract to any beneficiary who maintains a permanent residence in or visits a CBA and requests those items from the contract supplier unless an exception applies. There are two exceptions. First, SNFs or NFS that become specialty suppliers only furnish competitive bidding items to their residents. Second, individual network members are not required to provide services through the entire geographic of a CBA. However, the network as a whole must provide services throughout the entire geographic area of a CBA.*

***30.4 – Prescription for Particular Brand, Item, or Mode of Delivery***
***(Rev. 1502; Issued: 05-09-08; Effective/Implementation Date: 06-09-08)***

*Contract suppliers are not required to furnish a specific brand name item or mode of delivery to a beneficiary unless prescribed to avoid an adverse medical outcome. A physician or treating practitioner (that is a physician assistant, clinical nurse specialist, or nurse practitioner) may prescribe, in writing, a particular brand of a bid item or 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. The physician or treating practitioner must document in the beneficiary's medical record the reason why the specific brand or mode of delivery is necessary to avoid an adverse medical outcome.*

*If a physician or treating practitioner prescribes a particular brand or mode of delivery to avoid an adverse medical outcome, the contract supplier must either:*

1. *Furnish the particular brand or mode of delivery as prescribed by the physician or treating practitioner;*
2. *Consult with the physician or treating practitioner to find another appropriate brand of item or mode of delivery for the beneficiary and obtain a revised written prescription from the physician or treating practitioner; or*
3. *Assist the beneficiary in locating a contract supplier that can furnish the particular brand of item or mode of delivery prescribed by the physician or treating practitioner.*

*Any change in the prescription requires a revised written prescription for Medicare payment. A contract supplier is prohibited from submitting a claim to Medicare if it furnishes an item different from that specified in the written prescription received from the beneficiary's physician or treating practitioner.*

***30.5 – No Discrimination Against Beneficiaries***
***(Rev. 1502; Issued: 05-09-08; Effective/Implementation Date: 06-09-08)***

*42 CFR § 414.422(c) specifies that contract suppliers may not discriminate against beneficiaries under the Medicare DMEPOS Competitive Bidding Program. The items furnished by a contract*

*supplier must be the same items that the contract supplier makes available to other customers. All products provided must meet product specifications identified by the HCPCS coding system.*

***30.6 – Quarterly Reports***
***(Rev. 1502; Issued: 05-09-08; Effective/Implementation Date: 06-09-08)***

*The contract supplier must submit quarterly reports to the CBIC using Form CMS-10169C, "The Medicare DMEPOS Competitive Bidding Program Contract Supplier Quarterly Report" (OMB No. 0938-1016), which can be accessed at the CBIC website at: http://www.dmecompetitivebid.com.*

*The contract supplier must submit to the CBIC a quarterly report no later than ten (10) calendar days after each of the following dates: March 31, June 30, September 30, and December 31. If the due date for a particular quarterly report falls on a Saturday, Sunday, or Federal holiday, the report is due on the next business day. As provided in Form CMS-10169C, each quarterly report must disclose the following regarding each item specified by CMS that was furnished under its contract during the calendar quarter immediately preceding the report's due date: the item's HCPCS code; the approximate number of items furnished; the manufacturer of the item; the item's model name; and the item's model number. The contract supplier must submit each quarterly report to the CBIC's regular or certified mailing address identified in its contract.*

*When the contract supplier submits the required quarterly reports, it should also review the Medicare Supplier Directory, found at http://www.medicare.gov (in the section entitled "Find Suppliers of Medical Equipment in Your Area") to determine whether the supplier's information is current, including the lists that indicate which manufacturers' products that the contract supplier makes available to beneficiaries. If the information is not current, the contract supplier should submit current information to the CBIC's regular or certified mailing address identified in its contract within ten (10) business days of the close of each quarter.*

***30.7 – Reporting Change of Ownership (CHOW)***
***(Rev. 1502; Issued: 05-09-08; Effective/Implementation Date: 06-09-08)***

*Pursuant to 42 CFR §414.422(d)(2), CMS may award a contract to an entity that merges with, or acquires, the contract supplier if (1) the successor entity meets all requirements applicable to contract suppliers for the competitive bidding program(s) to which the contract supplier's contract applies; and (2) the successor entity submits to CMS the documentation described in 42 CFR §§414.414(b)-(d) if that documentation has not previously been submitted by the successor entity or the contract supplier that is being acquired, or is no longer current. The documentation required by 42 CFR §§414.414(b)-(d) is necessary to substantiate compliance with basic eligibility requirements, quality standards, accreditation requirements and financial standards. The successor entity that is acquiring the assets of the contract supplier must also submit to CMS, at least 30 calendar days before the anticipated effective date of the change of ownership, an executed novation agreement acceptable to CMS. The novation agreement must state that the successor entity will assume all obligations under the contract.*

*If a new entity will be formed as a result of the merger or acquisition, the existing contract supplier must submit to CMS for review, at least 30 calendar days before the anticipated effective date of the change of ownership, its final draft of a novation agreement stating that the new entity will assume all obligations under the contract. With the final draft novation agreement, the existing contract supplier must submit the documentation described in 42 CFR 414.414(b)-(d) if the information previously submitted by the contract supplier is no longer current. The new entity must also submit to CMS, within 30 calendar days after the effective date of the change of ownership, an executed novation agreement acceptable to CMS stating that it will assume all obligations under the contract. The new entity must meet all requirements applicable to contract suppliers for the applicable competitive bidding program.*

*The following chart illustrates the CHOW requirements needed to remain a contract supplier described above.*

| ***Entity*** | ***Requirement*** | ***Number of Days to Meet Requirement*** |
|---|---|---|
| ***Contract Supplier Only*** | • *The existing contract supplier must notify CMS if it is negotiating a CHOW.* | ***60 calendar days before*** *the anticipated date of the change.* |
| | • *If a new entity will be formed as a result of the merger or acquisition, the existing contract supplier must submit to CMS, its* ***final draft*** *of a novation agreement as described in 414.422(d)(2)(iii) .* | ***At least 30 calendar days before*** *the anticipated date of the CHOW* |
| ***Successor Entity or New Entity*** | *The successor entity or new entity must submit to CMS the documentation in 414.414(b)-(d), if not submitted previously by the successor or the contract supplier or if no longer current. Duplicates of previously submitted information need not be submitted if that information is still current.* | *Within* ***30 calendar days prior*** *to the anticipated effective date of the CHOW* |
| ***Successor Entity Only*** | *The successor entity that is acquiring the assets of the existing contract supplier must submit to CMS,* ***a signed novation agreement*** *acceptable to CMS, stating that it will assume all obligations under the contract* | ***At least 30 calendar days before*** *the anticipated effective date of the change of ownership.* |
| ***New Entity Only*** | *The new entity must submit to CMS an* ***executed novation*** *agreement acceptable to CMS.* | ***Within 30 calendar days after*** *the effective date of the CHOW* |
| ***NOTE: Successor and new entities must meet all requirements applicable to contract suppliers for the applicable competitive bidding program.*** | | |

*Any communication with CMS regarding the change of ownership must be in writing and mailed to the appropriate address designated in the contract.*

***30.8 – Submission of Claims***
***(Rev. 1502; Issued: 05-09-08; Effective/Implementation Date: 06-09-08)***

*A contract supplier must submit Medicare claims for payment in accordance with rules in this chapter.*

***30.9 – Breach of Contract***
***(Rev. 1502; Issued: 05-09-08; Effective/Implementation Date: 06-09-08)***

*Pursuant to 42 CFR 414.422(f)(1), any violation of the terms of the contract by the contract supplier, including a failure to comply with licensing and accreditation requirements, constitutes a breach of contract.*

*If a supplier breaches its contract, CMS may take one or more of the following actions:*

- *(i) Require the contract supplier to submit a corrective action plan (CAP);*
- *(ii) Suspend the contract supplier's contract;*
- *(iii) Terminate the contract;*
- *(iv) Preclude the contract supplier from future participation in the competitive bidding program;*
- *(v) Revoke the supplier number of the contract supplier; or*
- *(vi) Avail itself of other remedies allowed by law.*

*CMS will notify the DME MACs in the event that a CMS action results in a termination or suspension of the contract.*

***30.10 – Request for Reconsideration***
***(Rev. 1502; Issued: 05-09-08; Effective/Implementation Date: 06-09-08)***

*CMS will notify the contract supplier before it takes a breach of contract action and will notify the supplier at that time of how it can ask for reconsideration of any breach of contract determination.*

***40 – Payment Rules***
***(Rev. 1502; Issued: 05-09-08; Effective/Implementation Date: 06-09-08)***

*A single payment amount is established for each competitive bid item for each CBA based on the bids submitted and accepted for that item. All payment for competitive bidding items is made on an assignment related basis. The payment basis for an item is 80 percent of the applicable single payment amount for the CBA in which the beneficiary maintains a permanent residence, less any unmet Part B deductible described in §1833(b) of the Act. If an item that is included in a competitive bidding program is furnished to a beneficiary who does not maintain a permanent residence in a CBA, the payment basis for the item is 80 percent of the lesser of the actual charge of the item, or the applicable fee schedule amount for the item. The single payment amount calculated for each item under each competitive bidding program is paid for the duration of the competitive bidding program and will not be adjusted by any update factor.*

*Payment for items or services furnished by a supplier under the Medicare Secondary Payer rules will be calculated in accordance with the established related payment rules.*

***40.1 – Single Payment Amount***
***(Rev. 1502; Issued: 05-09-08; Effective/Implementation Date: 06-09-08)***

*The single payment amount for each competitive bidding item in each CBA is based on the bids submitted and accepted for that item. Only bids from qualified suppliers (those that met all quality and financial standards and eligibility and accreditation requirements) are considered in setting the single payment amount. The single payment amount for an item furnished under the competitive bidding program is equal to the median of the bids submitted for that item by qualified suppliers whose composite bids for the product category are equal to or below the pivotal bid for that product category. The single amount is determined by CMS and remains in effect for the duration of a contract period and is not adjusted for inflation. A listing of the single payment amounts will be posted at the CBIC website at http://www.dmecompetitivebid.com.*

***40.1.1 – Adjustments to the Single Payment Amounts to Reflect Changes in Healthcare Common Procedure Coding System (HCPCS) Codes***
***(Rev. 1502; Issued: 05-09-08; Effective/Implementation Date: 06-09-08)***

*If a HCPCS code for an item is changed for purposes other than to modify the descriptor for clarification purposes, the single payment amount will be adjusted as follows:*

- *If a single HCPCS code for an item ("the item") is divided into two or more HCPCS codes for the components of that item, the sum of single payment amounts for the new HCPCS codes equals the single payment amount for the item. The payment amounts for the HCPCS codes for the components will be established based on the corresponding fee schedule amounts for these codes as established in accordance with claims processing manual, Chapter 23, §60.3. These amounts will then be adjusted by the same percentage to the level where the sum of the payment amounts for the HCPCS codes for the components equals the single payment amount for the item. Contract suppliers must furnish the components of the item and submit claims using the new HCPCS codes. Contract suppliers may only bill for items that are actually furnished.*

- *If a single HCPCS code is divided into two or more separate HCPCS codes,*

*the single payment amount for each of the new separate HCPCS codes is equal to the single payment amount applied to the single HCPCS code. Contract suppliers must furnish the items and submit claims using the new separate HCPCS codes.*

- *If the HCPCS codes for components of an item are merged into a single HCPCS code for the item, the single payment amount for the new HCPCS code is equal to the total of the separate single payment amounts for the components. Contract suppliers must furnish the item and submit claims using the new HCPCS code.*

- *If multiple HCPCS codes for similar items are merged into a single HCPCS code, the items to which the new HCPCS codes apply may be furnished by any supplier that has a valid Medicare billing number.*

*If a HCPCS code is deleted or becomes invalid for Medicare use and none of the scenarios above applies, the code is eliminated from the product category.*

*DME MACs will receive updates to the single payment amounts and HCPCS codes on a quarterly basis.*

***40.2 – Conditions for Payment***
***(Rev. 1502; Issued: 05-09-08; Effective/Implementation Date: 06-09-08)***

*Unless an exception is allowed (see section 20.6), Medicare does not make payment for any DMEPOS items and services subject to competitive bidding unless such items are furnished by a contract supplier for that item.*

***40.3– Payment for Grandfathered Items Furnished During the Initial Competitive Bidding Contract Period/Program***
***(Rev. 1502; Issued: 05-09-08; Effective/Implementation Date: 06-09-08)***

*Payment for a grandfathered item(s) furnished during the initial competitive bidding contract period (i.e, when the item is bid for the first time in a CBA) varies depending on the payment category to which the item(s) belongs (See section 40.3.1 of this chapter). In all cases, assignment of claims is mandatory, and suppliers must accept the Medicare allowed payment amount as payment in full.*

***40.3.1 – Payment Categories***
***(Rev. 1502; Issued: 05-09-08; Effective/Implementation Date: 06-09-08)***

***40.3.1.1 – Inexpensive or Routinely Purchased Items***
***(Rev. 1502; Issued: 05-09-08; Effective/Implementation Date: 06-09-08)***

*The standard provisions for determining the payment amount for inexpensive or routinely purchased items in section 30.1 of chapter 20 of this manual continue to apply when these items are furnished by grandfathered suppliers. Payment for the items is based on the lower of the actual charge or fee schedule amount for each item.*

***40.3.1.2 – Items Requiring Frequent and Substantial Servicing***
***(Rev. 1502; Issued: 05-09-08; Effective/Implementation Date: 06-09-08)***

*When items requiring frequent and substantial servicing are furnished by a grandfathered supplier, payment is based on the single payment amount established in accordance with 42 CFR § 414.408(a)(1) for the CBA in which the beneficiary maintains a permanent residence.*

***40.3.1.3 – Oxygen and Oxygen Equipment***
***(Rev. 1502; Issued: 05-09-08; Effective/Implementation Date: 06-09-08)***

*When oxygen and oxygen equipment are furnished by a grandfathered supplier, payment is based on the single payment amount established in accordance with 42 CFR § 414.408(a)(1) for the CBA in which the beneficiary maintains a permanent residence.*

***40.3.1.4 – Other DME or Capped Rental Items***
***(Rev. 1502; Issued: 05-09-08; Effective/Implementation Date: 06-09-08)***

*The standard payment provisions in section 30.5 of chapter 20 of this manual continue to apply when capped rental DME items are furnished by grandfathered suppliers. Payment for the items is based on the lower of the actual charge or fee schedule amount for each item.*

***40.3.2 – Payment for Grandfathered Items Furnished During Subsequent Competitive Bidding Contract Periods/Programs***
***(Rev. 1502; Issued: 05-09-08; Effective/Implementation Date: 06-09-08)***

*Payment for any grandfathered item furnished during a subsequent competitive bidding contract period (i.e., when an item is re-bid in a CBA and a new single payment amount is established) is based on the single payment amount for the round of competitive bidding during which the item is furnished and for the CBA in which the beneficiary maintains a permanent residence.*

***40.3.3 – Accessories and Supplies for Grandfathered Items***
***(Rev. 1502; Issued: 05-09-08; Effective/Implementation Date: 06-09-08)***

*Accessories and supplies that are used in conjunction with and are necessary for the effective use of a grandfathered item may be furnished by the same grandfathered supplier that furnishes the grandfathered item. Examples of medically necessary accessories and supplies used in conjunction with DMEPOS items include tubes, hoses, and masks with respiratory equipment and administration sets with infusion pumps. Payment for these items to a grandfathered supplier is based on the single payment amount if the item is a competitive bid item for the CBA in which the beneficiary maintains a permanent residence (see §36.40.1 of chapter 20 in this manual). If the item is not a competitive bidding item, payment will be made in accordance with the standard payment rules.*