

Medicare Claims Processing Manual

Chapter 36 – Competitive Bidding

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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: Medicare Administrative Contractors (MACs), 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 Web site, 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 Web site 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., Web site posting). A listing of the items per CBA for round 1 of the DMEPOS Competitive Bidding Program is available at the CBIC Web site, <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. Web site 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 Web site. 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 - Home Health Agencies (Rev. 1532, Issued: 06-11-08, Effective: 07-01-08, Implementation: 07-07-08)

Home health agencies must submit a bid and be awarded a contract for the DMEPOS Competitive Bidding Program in order to furnish competitively bid items directly to Medicare beneficiaries who maintain a permanent residence in a CBA. If a home health agency is not awarded a contract to furnish competitively bid items, then they must use a contract supplier for these items.

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.

20.5.4 - Items Furnished on a Mail Order Basis (Rev. 1532, Issued: 06-11-08, Effective: 07-01-08, Implementation: 07-07-08)

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.

20.5.4.1 - Mail-Order Suppliers for Diabetic Supplies (Rev. 1532, Issued: 06-11-08, Effective: 07-01-08, Implementation: 07-07-08)

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., wheelchairs 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. 1532, Issued: 06-11-08, Effective: 07-01-08, Implementation: 07-07-08)**

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:

NOTE: This notification should only be sent to beneficiaries who the supplier is currently serving and who maintain a permanent residence in a CBA. The list of ZIP Codes for each CBA, the list of the HCPCS for competitively bid items, and the single payment amounts for these items are located in public use files on the CBIC Web site at:
<http://www.dmecompetitivebid.com/palmetto/cbic.nsf/DocsCat/Home>.

- It should state that the supplier is offering to continue to furnish rental DME, oxygen and oxygen equipment and/or related accessories and supplies 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 Web site at www.dmecompetitivebid.com.

20.6.1.1.4 - Notification to Beneficiaries for Suppliers that Choose Not to Become Grandfathered Suppliers

(Rev. 1532, Issued: 06-11-08, Effective: 07-01-08, Implementation: 07-07-08)

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:

NOTE: This notification should only be sent to beneficiaries who the supplier is currently serving and who maintain a permanent residence in a CBA. The list of ZIP Codes for each CBA, the list of the HCPCS for competitively bid items, and the single payment amounts for these items are located in public use files on the CBIC Web site at:

<http://www.dmecompetitivebid.com/palmetto/cbic.nsf/DocsCat/Home>.

- 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 after 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 Web site 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. 1532, Issued: 06-11-08, Effective: 07-01-08, Implementation: 07-07-08)

Contract suppliers are not required to furnish a specific brand name item or mode of delivery to a beneficiary unless prescribed by a physician or treating practitioner 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 competitively bid item or mode of delivery for an item if he or she determines that the particular brand or mode of delivery is necessary to 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.

This documentation should include the following:

- The product's brand name or mode of delivery;
- The features that this product or mode of delivery has versus other brand name products or modes of delivery; and
- An explanation of how these features are 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 Web site 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.	<u>60 calendar days before</u> 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 <u>final draft</u> of a novation agreement as described in 414.422(d)(2)(iii).	<u>At least 30 calendar days before</u> 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 <u>30 calendar days prior</u> to the anticipated effective date of the CHOW.

Entity	Requirement	Number of Days to Meet Requirement
Successor Entity Only	The successor entity that is acquiring the assets of the existing contract supplier must submit to CMS, <u>a signed novation agreement</u> acceptable to CMS, stating that it will assume all obligations under the contract.	<u>At least 30 calendar days before</u> the anticipated effective date of the change of ownership.
New Entity Only	The new entity must submit to CMS an <u>executed novation</u> agreement acceptable to CMS.	<u>Within 30 calendar days after</u> 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. 1532, Issued: 06-11-08, Effective: 07-01-08, Implementation: 07-07-08)

The single payment amount for each competitively bid 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 Web site at <http://www.dmecompetitivebid.com>. See section 100.5 of chapter 23 of the Claims Processing Manual for instructions regarding adjustments to the single payment amounts as a result of changes in the HCPCS.

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.

40.3.2.1 – Payment for Capped Rental Items (Rev. 3593, Issued: 08-17-16, Effective: 10-01-16, Implementation: 10-03-16)

For rented, grandfathered equipment in the capped rental payment class (e.g., CPAP device or manual wheelchair), after the rental payment cap for the grandfathered equipment and after the rental payment cap on the accessory (when applicable, e.g., elevating leg rests) is reached, the beneficiary must obtain covered accessories and supplies (e.g., CPAP masks) only from a contract supplier. The supplier of the grandfathered equipment is no longer permitted to furnish the covered accessories and supplies once the rental payment cap on the grandfathered equipment is reached, with the exception of completing the rental period for accessories whose first month rental began during the rental period for the grandfathered equipment (e.g., the addition of elevating leg rests during the third rental month for a grandfathered manual wheelchair).

40.3.2.2 – Payment for Inexpensive or Routinely Purchased Items (Rev. 3593, Issued: 08-17-16, Effective: 10-01-16, Implementation: 10-03-16)

For rented, grandfathered equipment in the inexpensive or routinely purchased payment class, after the total payments for the rented, grandfathered equipment (e.g., folding walker) reach the purchase fee schedule amount for the grandfathered equipment and after the rental payment cap on the accessory (when applicable), the beneficiary must obtain covered accessories (e.g., seat attachment) and supplies only from a contract supplier. The supplier of the grandfathered equipment is no longer permitted to furnish the covered accessories and supplies once the capped rental payment cap on the equipment is reached, with the exception of completing the rental period for accessories whose first month rental began during the rental period for the grandfathered equipment.

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.

40.4 - Payment for Rental of Inexpensive or Routinely Purchased DME (Rev. 1532, Issued: 06-11-08, Effective: 07-01-08, Implementation: 07-07-08)

The monthly rental payment amounts for inexpensive or routinely purchased DME (identified using HCPCS modifier RR) are equal to 10 percent of the single payment amount established for purchase of the item.

40.5 - Payment for Oxygen and Oxygen Equipment (Rev. 1532, Issued: 06-11-08, Effective: 07-01-08, Implementation: 07-07-08)

The monthly payment amounts for oxygen and oxygen equipment are equal to the single payment amounts established for the following classes of items:

- Stationary oxygen equipment (including stationary oxygen concentrators) and oxygen contents (stationary and portable)
- Portable equipment only (gaseous or liquid tanks)
- Oxygen generating portable equipment (OGPE) only (used in lieu of traditional portable oxygen equipment/tanks)
- Stationary oxygen contents (for beneficiary-owned stationary liquid or gaseous equipment)
- Portable oxygen contents (for beneficiary-owned portable liquid or gaseous equipment)

In cases where a supplier is furnishing both stationary oxygen contents and portable oxygen contents, the supplier is paid both the single payment amount for stationary oxygen contents and the single payment amount for portable oxygen contents.

The payment amounts for purchase of supplies and accessories used with beneficiary-owned oxygen equipment are equal to the single payment amounts established for the supply or accessory.

40.5.1 - Change in Suppliers for Oxygen and Oxygen Equipment (Rev. 3953, Issued: 01-19-18, Effective: 07-01-18, Implementation: 07-02-18)

The following rules apply when the beneficiary switches from one supplier of oxygen and oxygen equipment to another supplier after the beginning of each round of competitive bidding:

Noncontract supplier to contract supplier

In general, monthly payment amounts may not exceed a period of continuous use of longer than 36 months. However, if the beneficiary switches from a noncontract supplier to a contract supplier before the end of the 36-month period, at least 10 monthly payment amounts would be made to a contract supplier that begins furnishing oxygen and oxygen equipment in these situations provided that medical necessity for oxygen continues.

For example, if a contract supplier begins furnishing oxygen equipment to a beneficiary in months 2 through 26, payment would be made for the remaining number of months in the 36-month period, because the number of payments to the contract supplier would be at least 10 payments. To provide a more specific example, a contract supplier that begins furnishing oxygen equipment beginning with the 20th month of continuous use would receive 17 payments (17 for the remaining number of months in the 36-month period). However, if a contract supplier begins furnishing oxygen equipment to a beneficiary in month 27 or later, no more than 10 monthly payments would be made assuming the oxygen equipment remains medically necessary.

Contract supplier to another contract supplier

This rule does not apply when a beneficiary switches from a contract supplier to another contract supplier to receive his/her oxygen and oxygen equipment. In this scenario, the new contract supplier is paid based on the single payment amount for the remaining number of months in the 36-month period assuming the oxygen equipment remains medically necessary.

Grandfathered item where there was a noncontract to contract supplier switch in a prior round

This rule does not apply to grandfathered items in subsequent competitive bidding rounds when there was a previous noncontract to contract supplier switch in the prior round and the same supplier has elected to continue furnishing the oxygen equipment. In this case, the grandfathered supplier would be eligible to continue billing for the remaining number payments left in the oxygen rental period at the start of the competitive bidding round. The maximum number of monthly rental payments may not exceed 45 rental payments.

40.6 - Payment for Capped Rental DME Items

(Rev. 1532, Issued: 06-11-08, Effective: 07-01-08, Implementation: 07-07-08)

The monthly rental payment amounts for capped rental DME (identified using HCPCS modifier RR) are equal to 10 percent of the single payment amount established for purchase of the item for each of the first 3 months and 7.5 percent of the single payment amount established for purchase of the item for months 4 through 13.

40.6.1 - Change in Suppliers for Capped Rental DME Items

(Rev. 1532, Issued: 06-11-08, Effective: 07-01-08, Implementation: 07-07-08)

The following rules apply when the beneficiary switches from one supplier of capped rental DME to another supplier after the beginning of each round of competitive bidding:

Noncontract supplier to contract supplier

In general, rental payments may not exceed a period of continuous use of longer than 13 months. However, if the beneficiary switches from a noncontract supplier to a contract supplier before the end of the 13-month rental period, a new 13-month period begins and payment is made on the basis of the single payment amounts described in section 40.6. The contract supplier that the beneficiary switches to is responsible for furnishing the item until medical necessity ends, or the 13-month period of continuous use ends, whichever is earlier. On the first day following the end of the new 13-month rental period, the contract supplier is required to transfer title of the capped rental item to the beneficiary. Once the beneficiary switches from a noncontract supplier to a contract supplier, they may not switch back to a noncontract supplier if he/she continues to maintain a permanent residence in a CBA. If, however, the beneficiary relocates out of the CBA to a non-CBA, then he/she may switch to a noncontract supplier and a new 13-month rental period does not begin. See section 40.3 for instructions for payment of grandfathered items.

Contract supplier to another contract supplier

If the beneficiary switches from a contract supplier to a contract supplier before the end of the 13-month rental period, a new 13-month period does not begin. This provision applies in situations where the beneficiary changes suppliers within a CBA and in situations where the beneficiary relocates and switches from a contract supplier in one CBA to contract supplier in another CBA. The contract supplier that the beneficiary switches to is responsible for furnishing the item until medical necessity ends, or the 13-month period of continuous use ends, whichever is earlier. On the first day following the end of the 13-month rental period of continuous use, the contract supplier is required to transfer title of the capped rental item to the beneficiary.

40.7 - Payment for Purchased Equipment

(Rev. 1532, Issued: 06-11-08, Effective: 07-01-08, Implementation: 07-07-08)

The payment amount for the purchase of new equipment (identified using HCPCS modifier NU), including inexpensive or routinely purchased DME, power wheelchairs, and enteral nutrition equipment, is equal to 100 percent of the single payment amounts established for these items. This payment amount for the purchase of used equipment (identified using HCPCS modifier UE), including inexpensive or routinely purchased DME, power wheelchairs, and enteral nutrition equipment, is equal to 75 percent of the single payment amounts established for new purchase equipment items.

40.8 - Payment for Repair and Replacement of Beneficiary-Owned Equipment

(Rev. 3593, Issued: 08-17-16, Effective: 10-01-16, Implementation: 10-03-16)

Beneficiaries who maintain a permanent residence in a CBA may go to any Medicare-enrolled supplier (contract or noncontract supplier) for the maintenance or repair of beneficiary-owned equipment, including parts that need to be replaced in order to make the equipment serviceable. 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 replacement parts that are part

of the competitive bidding program for the area in which the beneficiary resides is based on the single payment amount for that replacement part in the CBA in which the beneficiary lives. Payment is not made for parts and labor covered under a manufacturer's or supplier's warranty.

Beneficiaries must obtain replacements of beneficiary-owned competitively bid items that are part of the competitive bidding program for the areas in which the beneficiary resides from a contract supplier unless the item is a replacement part or accessory that is replaced as part of the service of repairing beneficiary-owned base equipment (e.g., wheelchair, walker, hospital bed, continuous positive pressure airway device, oxygen concentrator, etc.). All base equipment that is replaced in its entirety because of a change in the beneficiary's medical condition or because the base equipment the beneficiary was using was either lost, stolen, irreparably damaged, or used beyond the equipment's reasonable useful lifetime (see section 110.2.C of chapter 15 of the Benefit Policy Manual) must be obtained from a contract supplier in order to receive Medicare payment. The contract supplier is not required to replace an entire competitively bid item with the same make and model as the previous item unless a physician or treating practitioner prescribes that make and model. (See section 30.4 of this chapter.)

If beneficiary-owned oxygen equipment or capped rental DME that is a competitively bid item for the CBA in which the beneficiary maintains a permanent residence has to be replaced prior to end of its reasonable useful lifetime, then the replacement item must be furnished by the supplier (contract or noncontract supplier) that transferred ownership of the item to the beneficiary.

Payment for replacement of items that are part of the competitive bidding program for the area in which the beneficiary resides is based on the single payment amount for that item.

For additional information regarding payment of a part of a DMEPOS Item, please see Pub.100-04 chapter 20, section 50.5.

40.9 - Payment for Rental Enteral Nutrition Equipment (Rev. 1532, Issued: 06-11-08, Effective: 07-01-08, Implementation: 07-07-08)

The monthly rental payment amounts for enteral nutrition equipment (identified using HCPCS modifier RR) are equal to 10 percent of the single payment amount established for purchase of the item for each of the first 3 months and 7.5 percent of the single payment amount established for purchase of the item for months 4 through 15.

40.9.1 - Maintenance and Servicing of Enteral Nutrition Equipment (Rev. 1532, Issued: 06-11-08, Effective: 07-01-08, Implementation: 07-07-08)

The contract supplier that furnishes the equipment to the beneficiary in the 15th month of the rental period must continue to furnish, maintain, and service the equipment after the 15 month rental period is completed until a determination is made by the beneficiary's physician or treating practitioner that the equipment is no longer medically necessary. The payment for maintenance and servicing enteral nutrition equipment is 5 percent of the single payment amount established for purchase of the item.

40.10 - Traveling Beneficiaries

(Rev. 1532, Issued: 06-11-08, Effective: 07-01-08, Implementation: 07-07-08)

Beneficiaries may travel, for example, to visit family members or reside in a State with warmer climates during winter months. As a result, beneficiaries will need to consider the following three factors when traveling: (1) where to go to obtain a DMEPOS item; (2) identify whether the item is a competitively bid item or not; and (3) determine the Medicare payment amount for that item. Depending on where the beneficiary travels (whether to a CBA or a non-CBA), the beneficiary may need to obtain DMEPOS from a contract supplier in order for Medicare to cover the item. For example, a beneficiary who travels to a non-CBA may obtain DMEPOS, if medically necessary, from any Medicare-enrolled supplier. On the other hand, a beneficiary who travels to a CBA should obtain competitively bid items in that CBA from a contract supplier in that CBA in order for Medicare to cover the item. The chart below shows whether a beneficiary should go to a contract supplier or any Medicare-enrolled supplier when the beneficiary travels.

Beneficiary Permanently Resides	Travels to	Type of Supplier
a CBA	a CBA	The beneficiary should obtain competitively bid items in that CBA from a contract supplier located in that CBA if the beneficiary wants Medicare to cover the item.
	a non-CBA	Medicare will cover DMEPOS, if medically necessary, from any Medicare-enrolled DMEPOS supplier.
Non-CBA	a CBA	The beneficiary should obtain the competitively bid item from a contract supplier in the CBA if the beneficiary wants Medicare to cover the item.
	Non-CBA	Medicare-enrolled DMEPOS supplier

Suppliers that furnish DMEPOS items to Medicare beneficiaries who maintain a permanent residence in a CBA and who travel to a non-CBA need to be aware of the public use files on the CBIC Web site at: <http://www.dmecompetitivebid.com/palmetto/cbic.nsf/DocsCat/Home>. The public use files contain the ZIP Codes for the CBAs, the HCPCS for competitively bid items, and the single payment amounts for these items. Suppliers will be able to use these files to identify if the beneficiary traveling to the area maintains a permanent residence in a CBA, determine whether the beneficiary is obtaining a competitively bid item, and determine the single payment amount for those items.

The Medicare payment amount is always based on the location in which the beneficiary maintains a permanent residence. For example:

- a. If a beneficiary maintains a permanent residence in a CBA and travels outside of the CBA, payment for a competitively bid item for the CBA in which the beneficiary maintains a permanent residence is the single payment amount for that item in the beneficiary's CBA.

- b. When a beneficiary maintains a permanent residence in an area that is not in a CBA and travels to CBA or non-CBA, the supplier that furnishes the item will be paid the fee schedule amount for the area where the beneficiary maintains a permanent residence.

40.10.1 - Traveling Beneficiaries and Transfer of Title of Oxygen Equipment or Capped Rental Items (Rev. 1532, Issued: 06-11-08, Effective: 07-01-08, Implementation: 07-07-08)

If a beneficiary has two residences in different areas and uses a local supplier in each area or if a beneficiary changes suppliers during or after the rental period, this does not result in a new rental episode. The supplier that provides the item in the 36th month of a rental episode for oxygen equipment or the 13th month of a rental episode for capped rental DME is responsible for transferring title to the equipment to the beneficiary. This applies to “snow bird” or extended travel patients and coordinated services for patients who travel after they have purchased the item.

40.11 - Billing Procedures Related to Advance Beneficiary Notice (ABN) Upgrades under the Competitive Bidding Program (Rev. 1532, Issued: 06-11-08, Effective: 07-01-08, Implementation: 07-07-08)

In general, an item included in a competitive bidding program must be furnished by a contract supplier for Medicare to make payment. This requirement applies to situations where the item is furnished directly or indirectly as an upgrade. An upgrade is an item with features that go beyond what is medically necessary. An upgrade may include an excess component. An excess component may be an item feature or service, which is in addition to, or is more extensive than, the item that is reasonable and necessary under Medicare coverage requirements. An item is indirectly furnished if Medicare makes payment for it because it is medically necessary and is furnished as part of an upgraded item.

The billing instructions for upgraded equipment found in section 120 of chapter 20 of the Medicare Claims Processing Manual (Pub. 100-04) continue to apply under the DMEPOS Competitive Bidding Program.

The following scenarios and chart describe situations where a beneficiary, residing in a competitive bidding area, elects to upgrade to an item with features or upgrades that are not medically necessary.

- **Upgrades from a bid item to a non-bid item**
In this situation, Medicare payment will only be made to a contract supplier on an assignment-related basis. Medicare payment will be equal to 80 percent of the single payment amount for the medically necessary bid item.
- **Upgrades from a non-bid item to a bid item**
When upgrading from a non-bid to a bid item, Medicare payment is made to a contract supplier on either an assigned or unassigned basis. Medicare payment will be equal to 80

percent of the lower of the actual charge or the fee schedule amount for the medically necessary non-bid item.

- **Upgrades from a bid item in one product category (category “S”) to a bid item in another product category (category “U”)**

In this case, Medicare payment is only made to a contract supplier for the product category “U” on an assignment-related basis. Medicare payment would be equal to 80 percent of the single payment amount for the medically necessary bid item in product category “S”.

Upgrade Scenarios for Beneficiaries Residing in a Competitive Bidding Area (CBA)

From the Medically Necessary Item	To the Upgraded Item	Must be Furnished by	Assignment Mandatory (Y/N)	Medicare Payment Based Upon
Bid Item	Non-Bid Item	Contract Supplier	Y	Single Payment Amount for the Medically Necessary Item
Non-Bid Item	Bid Item	Contract Supplier	N	Lower of the Actual Charge or Fee Schedule Amount for the Medically Necessary Item
Bid Item in Product Category “S”	Bid Item in Product Category “U”	Contract Supplier for Category “U”	Y	Single Payment Amount for Category “S” for the Medically Necessary Item

The following scenarios and chart describe situations where a beneficiary, who does not reside in a competitive bidding area, but travels to a competitive bidding area, elects to upgrade to an item with features that are not medically necessary.

- **Upgrades from a bid item to a non-bid item**

In this situation, Medicare payment is only made to a contract supplier on an assignment-related basis. Medicare payment will be equal to 80 percent of the lower of the actual charge or the fee schedule amount for the medically necessary bid item.

- **Upgrades from a non-bid item to a bid item**

When upgrading from a non-bid to a bid item, Medicare payment is made to a contract supplier on either an assigned or unassigned basis. Medicare payment will be equal to 80 percent of the lower of the actual charge or the fee schedule amount for the medically necessary non-bid item.

- **Upgrades from a bid item in one product category (category “S”) to a bid item in another product category (category “U”)**

In this case, Medicare payment is only made to a contract supplier for the product category “U” on an assignment-related basis. Medicare payment would be equal to 80

percent of lower of the actual charge or the fee schedule amount for the medically necessary bid item in product category “S”.

Upgrade Scenarios for Beneficiaries Who Do Not Reside In a CBA, But Travel to a CBA

From the Medically Necessary Item	To the Upgraded Item	Must be Furnished by	Assignment Mandatory (Y/N)	Medicare Payment Based Upon
Bid Item	Non-Bid Item	Contract Supplier	Y	Lower of the Actual Charge or Fee Schedule Amount for the Medically Necessary Item
Non-Bid Item	Bid Item	Contract Supplier	N	Lower of the Actual Charge or Fee Schedule Amount for the Medically Necessary Item
Bid Item in Product Category “S”	Bid Item in Product Category “U”	Contract Supplier for Category “U”	Y	Lower of the Actual Charge or Fee Schedule Amount for the Medically Necessary Item

Beneficiary Liability under the Competitive Bidding Program

Under the competitive bidding program, a beneficiary has no financial liability to a non contract supplier that furnishes an item included in the competitive bidding program for a competitive bidding area, unless, prior to receiving the item, the beneficiary selects Option 1 on the ABN and signs the notice. Similarly, beneficiaries who receive an upgraded item from a non-contract supplier in a competitive bidding area are not financially liable for the item unless, prior to giving the beneficiary the upgraded item, the supplier obtains a valid ABN on which the enrollee has selected Option 1 and signed the notice.

In the case of upgrades, for a beneficiary to be liable for the extra cost of an item that exceeds their medical needs, the beneficiary must, select Option 1 and sign a valid ABN prior to receiving the item. See Chapter 20, section 120 of the Medicare Claims Processing Manual for additional information on ABN upgrades.

40.12 - Billing Procedures Related to Downcoding under the Competitive Bidding Program

(Rev. 1532, Issued: 06-11-08, Effective: 07-01-08, Implementation: 07-07-08)

The following downcoding guidelines describe situations where Medicare reduces the level of payment for the prescribed item based on a medical necessity partial denial of coverage for the additional, not medically necessary, expenses associated with the prescribed item. For beneficiaries who reside in a CBA and for whom Medicare determines that the prescribed item should be downcoded to an item that is reasonable and necessary under Medicare’s coverage requirements, the subsequent scenarios and chart detail the type of supplier that can furnish the item and the payment for the item.

- Downcodes from a non-bid item to a bid item
In this situation, Medicare payment will be made to any Medicare enrolled supplier on an assigned or unassigned basis. Medicare payment will be equal to 80 percent of the single payment amount for the medically necessary bid item.
- Downcodes from a bid item to a non-bid item
Medicare payment in this downcoding scenario will be made to a contract supplier on an assignment-related basis. Medicare payment will be equal to 80 percent of the lower of the actual charge or the fee schedule amount for the medically necessary non-bid item.
- Downcodes from a bid item in one product category (category “U”) to a bid item in another product category (category “S”)
In this case, Medicare payment will be made to a contract supplier for the product category “U” on an assignment-related basis. Medicare payment would be equal to 80 percent of the single payment amount for the medically necessary bid item in product category “S”.

Downcoding Scenarios for Beneficiaries Residing in a CBA

From a Higher Level of Service Item	To a Medically Necessary Item	Must be Furnished by	Assignment Mandatory (Y/N)	Medicare Payment Based Upon
Non-Bid Item	Bid Item	Any Medicare Enrolled Supplier	N	Single Payment Amount for the Medically Necessary Item
Bid Item	Non-Bid Item	Contract Supplier	Y	Lower of the Actual Charge or Fee Schedule Amount for the Medically Necessary Item
Bid Item in Product Category “U”	Bid Item in Product Category “S”	Contract Supplier for Category “U”	Y	Single Payment Amount for Category “S” for the Medically Necessary Item

The following scenarios and chart describe situations where the prescribed item for a beneficiary that does not reside in a CBA, but travels to a CBA is downcoded to an item that is reasonable and necessary under Medicare’s coverage requirements.

- **Downcodes from a non-bid item to a bid item**
In this situation, Medicare payment will be made to any Medicare enrolled supplier on an assigned or unassigned basis. Medicare payment will be equal to 80 percent of the lower of the actual charge or the fee schedule amount for the medically necessary bid item.
- **Downcodes from a bid item to a non-bid item**

Medicare payment in this downcoding scenario will only be made to a contract supplier on an assignment-related basis. Medicare payment will be equal to 80 percent of the lower of the actual charge or the fee schedule amount for the medically necessary non-bid item.

- **Downcodes from a bid item in one product category (category “U”) to a bid item in another product category (category “S”)**

In this case, Medicare payment will only be made to a contract supplier for the product category “U” on an assignment-related basis. Medicare payment will be equal to 80 percent of the lower of the actual charge or the fee schedule amount for the medically necessary bid item in product category “S”.

Downcoding Scenarios for Beneficiaries Who Do Not Reside In a CBA, But Travel to a CBA

From a Higher Level of Service Item	To a Medically Necessary Item	Must be Furnished by	Assignment Mandatory (Y/N)	Medicare Payment Based Upon
Non-Bid Item	Bid Item	Any Medicare Enrolled Supplier	N	Lower of the Actual Charge or Fee Schedule Amount for the Medically Necessary Item
Bid Item	Non-Bid Item	Contract Supplier	Y	Lower of the Actual Charge or Fee Schedule Amount for the Medically Necessary Item
Bid Item in Product Category “U”	Bid Item in Product Category “S”	Contract Supplier for Category “U”	Y	Lower of the Actual Charge or Fee Schedule Amount for the Medically Necessary Item

50 - Special Billing Instructions for the DMEPOS Competitive Bidding Program

(Rev. 11427; Issued: 05-20-22; Effective: 01-01-23; Implementation: 01-03-23)

NOTE: CMS seeks to reduce burden and modernize processes to ensure a reduction in improper payments and an increase in customer satisfaction. The Certificate of Medical Necessity (CMN) form and DME Information Form (DIF) were originally required to help document the medical necessity and other coverage criteria for selected Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) items. In the past, a supplier received a signed CMN from the treating physician or created and signed a DIF to submit with the claim. Due to improvements in claims processing and medical records management, the information found on CMNs or DIFs is available either on the claim or in the medical record and is redundant. Therefore, to reduce burden and increase customer satisfaction, providers and suppliers no longer need to submit these forms for services rendered after January 1, 2023.

- ***For claims with dates of service on or after January 1, 2023*** – providers and suppliers no longer need to submit CMNs or DIFs with claims. Due to electronic filing requirements, claims received with these forms attached will be rejected and returned to the provider or supplier.
- ***For claims with dates of service prior to January 1, 2023*** – processes will not change and if the CMN or DIF is required, it will still need to be submitted with the claim, or be on file with a previous claim.

This statement applies throughout the Program Integrity Manual wherever CMNs and DIFs are mentioned.

Claims for competitively bid items shall be submitted under the general DMEPOS claims billing guidelines specified in Chapter 20, §110 of the Medicare Claims Processing Manual, with the following exceptions described in this section.

50.1 - Electronic Submission of Claims and Mandatory Assignment (Rev. 2979, Issued: 06-27-14, Effective: 01-01-12, Implementation: 07-28-14)

Under the DMEPOS Competitive Bidding Program, all claims shall be submitted electronically using the ASC X12 837 professional claim format except for MSP claims. (**NOTE:** Claims with multiple MSP situations may be submitted on a paper claim.) Exceptions to the mandatory electronic billing requirement granted under the Administrative Simplification Compliance Act (ASCA) do not apply to DMEPOS Competitive Bidding claims.

All DMEPOS Competitive Bidding Program claims are subject to mandatory assignment. Mandatory assignment denotes that a supplier shall accept the Medicare payment as payment in full for their services. The beneficiary’s liability is limited to any applicable deductible plus the 20 percent coinsurance. For additional information concerning mandatory assignment of claims, see Chapter 1, §30.3.1 of the Medicare Claims Processing Manual.

50.2 - New Modifiers for DMEPOS Competitive Bidding Billing (Rev. 1544, Issued: 06-26-08, Effective: 07-01-08, Implementation: 07-07-08)

Table 1 below describes the modifiers implemented for the DMEPOS Competitive Bidding Program. Specific instructions for the use of each modifier for billing are included in subsequent subsections.

Table 1: Modifiers Implemented for DMEPOS Competitive Bidding Billing

Modifier	Effective Date	Definition
KG	7/1/07	DMEPOS Item Subject to DMEPOS Competitive Bidding Program Number 1
KK	7/1/07	DMEPOS Item Subject to DMEPOS Competitive Bidding Program Number 2

Modifier	Effective Date	Definition
KU	7/1/07	DMEPOS Item Subject to DMEPOS Competitive Bidding Program Number 3
KL	7/1/07	DMEPOS Item Delivered Via Mail
KT	7/1/07	Beneficiary Resides in a Competitive Bidding Area and Travels Outside that Competitive Bidding Area and Receives a Competitive Bid Item
KV	1/1/08	DMEPOS Item Subject to DMEPOS Competitive Bidding Program that is Furnished as Part of a Professional Service
KW	1/1/08	DMEPOS Item Subject to DMEPOS Competitive Bidding Program Number 4
KY	1/1/08	DMEPOS Item Subject to DMEPOS Competitive Bidding Program Number 5

50.3 - Billing for Items in Multiple Product Categories
(Rev. 2231, Issued: 05-27-11, Effective: 08-28-11, Implementation: 08-28-11)

New HCPCS modifiers were developed to facilitate implementation of various policies that apply to certain competitive bidding items. The KG, KK, KU, KW, and KY modifiers are pricing modifiers that suppliers must use to identify when the same supply or accessory HCPCS code is furnished in multiple competitive bidding product categories. For example, HCPCS code E0981 (Wheelchair Accessory, Seat Upholstery, Replacement Only, Each) is found in both the standard and complex rehabilitative power wheelchair competitive bidding product categories. Contract suppliers for the standard power wheelchair product category shall submit E0981 claims using the KG modifier, whereas contract suppliers for the complex rehabilitative power wheelchair product category shall use the KK modifier. All suppliers, including grandfathered suppliers, shall submit claims for competitive bid items using the aforementioned competitive bidding modifiers. The KG and KK modifiers are used in Round I of the competitive bidding program and the KU and KW modifiers are reserved for future program use.

50.4 - Claims Jurisdiction and Billing Procedures for Traveling Beneficiaries
(Rev. 1544, Issued: 06-26-08, Effective: 07-01-08, Implementation: 07-07-08)

Claims for non-mail order competitively bid items furnished to beneficiaries who maintain a permanent residence in a CBA, but who are traveling outside of their CB when they obtain the item, must be submitted with a “KT” modifier to indicate a traveling beneficiary. Claims for competitively bid items furnished to beneficiaries who obtain the item outside of their CBA that do not have a “KT” modifier shall be denied. Jurisdiction for these claims remains with DME MAC with jurisdiction for the beneficiary based on the beneficiary’s permanent residence. Claims for mail order competitively bid items that have a “KT” modifier shall be denied.

50.5 - Claims for DMEPOS Items Furnished to a Beneficiary by a Skilled Nursing Facility (SNF) or Nursing Facility (NF)
(Rev. 1544, Issued: 06-26-08, Effective: 07-01-08, Implementation: 07-07-08)

For purposes of claims adjudication under DMEPOS Competitive Bidding, beneficiaries who maintain a permanent residence in a CBA and, while a resident of a SNF or NF outside of a CBA, obtain a competitively bid item from that SNF or NF are treated as traveling beneficiaries when their permanent address is within a CBA. As a result, the SNF or NF shall submit a “KT” modifier on any claims for competitively bid items furnished to beneficiaries, under these circumstances.

A claim must include a place of service “31” to indicate that the beneficiary resides in a SNF or “32” to indicate that the beneficiary resides in a NF, as applicable. See §20.5.2 for the policies applicable to SNFs and NFs that furnish competitively bid items under DMEPOS Competitive Bidding Program.

50.6 - Billing for Mail Order Items

(Rev. 1544, Issued: 06-26-08, Effective: 07-01-08, Implementation: 07-07-08)

The “KL” modifier has been established for use in submitting claims for mail order DMEPOS items (e.g., diabetic supplies). Beneficiaries who maintain a permanent residence in CBAs for which there is a competitive bidding program for mail order diabetic supplies may choose to obtain their diabetic supplies through mail order or at a storefront.

A beneficiary who resides in a CBA and chooses to obtain their diabetic supplies through mail order must obtain these supplies from a contract supplier for mail order diabetic supplies for the CBA where they maintain a permanent residence. Claims for mail order diabetic supplies furnished to beneficiaries who maintain a permanent residence in a CBA must be billed with the modifier “KL”. If the beneficiary chooses to obtain their diabetic supplies at a storefront, DMEPOS competitive bidding rules do not apply and these claims will be processed under the normal guidelines for supply claims. See §20.5.3 for additional information on mail-order contract suppliers of diabetic supplies.

50.7 - Claims Submitted for Physicians and Treating Practitioners Who Furnish Competitively Bid Items

(Rev. 1544, Issued: 06-26-08, Effective: 07-01-08, Implementation: 07-07-08)

Under DMEPOS Competitive Bidding, physicians and treating practitioners may furnish certain competitively bid items without submitting a bid and being awarded a contract. This exception requires that the items be furnished by the physician or treating practitioner to his or her own patients as part of his or her professional service.

The professional service must be furnished on the same date as the date that the DME item is initially furnished. In addition, physicians and treating practitioners must submit their office visit claim on the same day that they submit the DME claim to ensure timely and accurate claims processing. Physicians and treating practitioners who provide DME items in their offices shall continue to be paid even though they are not a contract supplier for the items. See §20.6 for additional information.

Physicians and treating practitioners that are located in a CBA must submit the “KV” modifier on claims for competitively bid items and related accessories that are furnished in accordance with this exception to receive payment for these items for the CBA where the beneficiary maintains a permanent residence. Physician and treating practitioner submitted competitive bidding claims that do not have an accompanying office visit will be denied. Physicians and treating practitioners located outside a CBA who furnish DME competitively bid items and/or related accessories as part of a professional service to traveling beneficiaries who maintain a permanent residence in a CBA must also affix the “KV” modifier to claims submitted for these items.

50.8 - Billing for Oxygen and Oxygen Equipment (Rev. 1544, Issued: 06-26-08, Effective: 07-01-08, Implementation: 07-07-08)

Noncontract suppliers of oxygen and oxygen equipment may elect to become “grandfathered suppliers” and continue furnishing these items and services to beneficiaries after the start of the DMEPOS Competitive Bidding Program, if the beneficiary agrees to the arrangement. This grandfathering process only applies to suppliers that began furnishing oxygen and oxygen equipment to beneficiaries in a CBA prior to the implementation of the competitive bidding program for that area and choose to continue to furnish the grandfathered oxygen and oxygen equipment to these same beneficiaries in the CBA after the start of the DMEPOS Competitive Bidding Program. See §20.6 for additional information on payments to noncontract suppliers.

If a noncontract supplier does not want to continue furnishing oxygen and oxygen equipment to its existing customers/beneficiaries, the beneficiaries must use a contract supplier to obtain the oxygen and oxygen equipment. Ordinarily, the title to the oxygen equipment would transfer to the beneficiary after rental payments have been made for 36 months of continuous use. However, Medicare allows for a minimum of 10 months of payments to be made to a contract supplier for oxygen and oxygen equipment furnished to a beneficiary who changes suppliers under the DMEPOS Competitive Bidding Program because the current supplier chose not to become a grandfathered supplier. Therefore, under the DMEPOS Competitive Bidding Program, up to 45 continuous payments could be made for the oxygen and oxygen equipment. The beneficiary is liable for co-payments for all paid oxygen and oxygen equipment claims.

50.9 - Billing for Capped Rental DME Items (Rev. 1544, Issued: 06-26-08, Effective: 07-01-08, Implementation: 07-07-08)

Noncontract suppliers of capped rental DME equipment may elect to become “grandfathered suppliers” and continue furnishing equipment to their existing beneficiaries after the start of the DMEPOS Competitive Bidding Program, if the beneficiary agrees to the arrangement. This grandfathering process only applies to suppliers that began furnishing the capped rental DME item to beneficiaries in a CBA prior to the implementation of the competitive bidding program for that area and choose to continue to furnish the grandfathered item to these same beneficiaries in the CBA after the start of the DMEPOS Competitive Bidding Program. See §20.6 for additional information on payments to noncontract suppliers.

If a noncontract supplier does not want to continue furnishing capped rental DME to its existing customers/beneficiaries after the start of the DMEPOS Competitive Bidding Program, the beneficiary must use a contract supplier to obtain the item. Ordinarily, the title to the capped rental DME item would transfer to the beneficiary after rental payments have been made for 13 months of continuous use. However, for beneficiaries that switch from a noncontract supplier to a contract supplier, the 13 month capped rental period starts over again. In this case, Medicare allows for a minimum of 13 months of rental payments to be made to a contract supplier because their current supplier chose not to become a grandfathered supplier. Therefore, under DMEPOS Competitive Bidding Program, when a beneficiary switches from a noncontract supplier to a contract supplier, up to 25 continuous payments could be made for the capped rental DME item. The beneficiary is liable for co-payments for all paid capped rental DME equipment claims.

50.9.1 - Certificates of Medical Necessity (CMN) and Capped Rental Billing (Rev. 1544, Issued: 06-26-08, Effective: 07-01-08, Implementation: 07-07-08)

Suppliers are not required to obtain a new Certificate of Medical Necessity (CMN) for situations in which a beneficiary who was receiving a capped rental item prior to the implementation of DMEPOS Competitive Bidding goes to a new supplier after the implementation of the DMEPOS Competitive Bidding Program (e.g., the previous supplier decides not to become a grandfathered supplier), unless the beneficiary's medical necessity for the item has changed. Notwithstanding this situation, the new supplier shall bill using the appropriate modifiers for their first rental month (KH), the second and third rental months (KI), and all subsequent rental months (KJ).

50.10 - Claims Submitted for Hospitals Who Furnish Competitively Bid Items (Rev. 2231, Issued: 05-27-11, Effective: 08-28-11, Implementation: 08-28-11)

Under DMEPOS Competitive Bidding, hospitals may furnish certain types of competitively bid DME to their patients on the date of discharge without submitting a bid and being awarded a contract. The DME items that a hospital may furnish as part of the exception are limited to: crutches, canes, walkers, folding manual wheelchairs, blood glucose monitors, and infusion pumps. Payment for items furnished under this exception will be made based on the single payment amount for the item for the CBA where the beneficiary resides. Separate payment is not made for walkers and related accessories furnished by a hospital on the date of admission because payment for these items is included in the Part A payment for inpatient facility services. Refer to Pub. 100-04, the Medicare Claims Processing Manual, Chapter 1, 10.1.1.1 for instructions for submitting claims.

50.11 - Claims Submitted for Medicare Beneficiaries Previously Enrolled in a Medicare Advantage Plan (Rev. 2231, Issued: 05-27-11, Effective: 08-28-11, Implementation: 08-28-11)

Under DMEPOS Competitive Bidding, if a beneficiary resides in a CBA and elects to leave their MA plan or loses his/her coverage under this plan, the beneficiary may continue to receive items requiring frequent and substantial servicing, capped rental, oxygen and oxygen equipment, or inexpensive or routinely purchased rented items from the same DME supplier under the MA plan without going to a contract supplier under the Medicare DMEPOS Competitive Bidding

Program. However, the supplier from whom the beneficiary previously received the item under the plan must be a Medicare enrolled supplier; meet the Medicare FFS coverage criteria and documentation requirements; and must elect to become a grandfathered supplier. All competitive bid grandfathering rules apply in these situations.

50.12 - Claims for Repairs and Replacements

(Rev. 2231, Issued: 05-27-11, Effective: 08-28-11, Implementation: 08-28-11)

Under the DMEPOS Competitive Bidding Program, any DMEPOS supplier, provided they have a valid Medicare billing number, can furnish and bill for services (labor and parts) associated with the repair of DME or enteral nutrition equipment owned by beneficiaries who reside in a CBA. In these situations, Medicare payment for labor will be made based on the standard payment rules. Medicare payment for claims for replacement parts associated with repairing competitively bid DME or enteral nutrition equipment, that are submitted with the RB modifier, will be based on the single payment amount for the part if the part and equipment being repaired are included in the same competitive bidding product category in the CBA. Otherwise, Medicare payment for replacement parts associated with repairing equipment owned by the beneficiary will be made based on the standard payment rules.

The replacement of an entire item, as opposed to the replacement of a part for repair purposes, which is subject to the DMEPOS Competitive Bidding Program, must be furnished by a contract supplier. Medicare payment for the replacement item would be based on the single payment amount for the item in the beneficiary's CBA. Refer to Pub. 100-04, the Medicare Claims Processing Manual, Chapter 20, 10.2 for instructions on submitting claims for repairs and replacements.

50.13 - Billing for Oxygen Contents to Suppliers After the 36th Month Rental Cap

(Rev. 2231, Issued: 05-27-11, Effective: 08-28-11, Implementation: 08-28-11)

The Medicare law requires that the supplier that furnishes liquid or gaseous oxygen equipment (stationary or portable) for the 36th continuous month must continue to furnish the oxygen contents necessary for the effective use of the liquid or gaseous equipment during any period after the payment cap and of medical need for the remainder of the reasonable useful lifetime established for the equipment. This requirement continues to apply under the Medicare DMEPOS Competitive Bidding Program, regardless of the role of the supplier (i.e., contract supplier, grandfathered supplier, or non-contract supplier) and the location of the beneficiary (i.e. residing within or outside a CBA).

Should a beneficiary travel or temporarily relocate to a CBA, the oxygen supplier that received the payment for the 36th continuous month must make arrangements for furnishing oxygen contents with a contract supplier in the CBA in the event that the supplier that received the 36th month payment elects to make arrangements for a temporary oxygen contents billing supplier.

The Medicare payment amount is always based on the location in which the beneficiary maintains a permanent residence. If the beneficiary resides in a CBA, payment for the oxygen

contents will be based on the single payment amount for that CBA. If the beneficiary resides outside of a CBA and travels to a CBA, payment for the oxygen contents will be based on the fee-schedule amount for the area where the beneficiary maintains a permanent residence.

50.14 - Purchased Accessories & Supplies for Use With Grandfathered Equipment

(Rev. 2231, Issued: 05-27-11, Effective: 08-28-11, Implementation: 08-28-11)

Non-contract grandfathered suppliers must use the KY modifier on claims for CBA-residing beneficiaries with dates of service on or after January 1, 2011, for purchased, covered accessories or supplies furnished for use with rented grandfathered equipment. The following HCPCS codes are the codes for which use of the KY modifier is authorized:

- Continuous Positive Airway Pressure Devices, Respiratory Assistive Devices, and Related Supplies and Accessories - A4604, A7030, A7031, A7032, A7033, A7034, A7035, A7036, A7037, A7038, A7039, A7044, A7045, A7046, E0561, and E0562
- Hospital Beds and Related Accessories - E0271, E0272, E0280, and E0310
- Walkers and Related Accessories - E0154, E0156, E0157 and E0158

Grandfathered suppliers that submit claims for the payment of the aforementioned purchased accessories and supplies for use with grandfathered equipment should submit the applicable single payment amount for the accessory or supply as their submitted charge on the claim. Non-contract grandfathered suppliers should be aware that purchase claims submitted for these codes without the KY modifier will be denied. In addition, claims submitted with the KY modifier for HCPCS codes other than those listed above will be denied.

After the rental payment cap for the grandfathered equipment is reached, the beneficiary must obtain replacement supplies and accessories from a contract supplier. The supplier of the grandfathered equipment is no longer permitted to furnish the supplies and accessories once the rental payment cap is reached.

50.15 - Hospitals Providing Walkers and Related Accessories to Their Patients on the Date of Discharge

(Rev. 2231, Issued: 05-27-11, Effective: 08-28-11, Implementation: 08-28-11)

Hospitals may furnish walkers and related accessories to their own patients for use in the home during an admission or on the date of discharge and receive payment at the applicable single payment amount, regardless of whether the hospital is a contract supplier or not. Separate payment is not made for walkers furnished by a hospital for use in the hospital, as payment for these items is included in the Part A payment for inpatient hospital services.

To be paid for walkers as a non-contract supplier, the hospital must use the modifier J4 in combination with the following HCPCS codes: A4636; A4637; E0130; E0135; E0140; E0141; E0143; E0144; E0147; E0148; E0149; E0154; E0155; E0156; E0157; E0158; and E0159. Under

this exception, hospitals are advised to submit the claim for the hospital stay before or on the same day that they submit the claim for the walker to ensure timely and accurate claims processing.

Hospitals that are located outside a CBA that furnish walkers and/or related accessories to travelling beneficiaries who live in a CBA must affix the J4 modifier to claims submitted for these items.

The J4 modifier should not be used by contract suppliers.

50.16 - Exception for Wheelchair Accessories Furnished with Non-Competitively Bid Wheelchair Base Equipment
(Rev. 3324, Issued: 08-14-15, Effective: 07-01-13, Implementation: 01-04-16)

Effective for claims with dates of service on or after July 1, 2013, competitively bid wheelchair accessories are paid in accordance with standard Medicare DMEPOS payment rules, not competitive bidding rules, when furnished with non-competitively bid wheelchair base equipment.

Transmittals Issued for this Chapter

Rev #	Issue Date	Subject	Impl Date	CR#
<u>R11427CP</u>	05/20/2022	Claims Processing Manual Update - Pub. 100.04 for Elimination of Certificates of Medical Necessity (CMNs) and Durable Medical Equipment Forms (DIFs)	01/03/2023	12734
<u>R11414CP</u>	05/12/2022	Claims Processing Manual Update - Pub. 100.04 for Elimination of Certificates of Medical Necessity (CMNs) and Durable Medical Equipment Forms (DIFs) - Rescinded and replaced by Transmittal 11427	06/13/2022	12734
<u>R3953CP</u>	01/19/2018	Revisions to the Claims Processing for Grandfathered Oxygen Claims that Span Competitive Bidding Rounds	07/02/2018	10420
<u>R3593CP</u>	08/17/2016	Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Competitive Bidding Program (CBP): Additional Instructions for the Implementation of Round 2 Recompete of the DMEPOS CBP and National Mail Order (NMO) Recompete	10/03/2016	9579
<u>R3565CP</u>	07/20/2016	Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Competitive Bidding Program (CBP): Additional Instructions for the Implementation of Round 2 Recompete of the DMEPOS CBP and National Mail Order (NMO) Recompete - Rescinded and replaced by Transmittal 3593	10/03/2016	9579
<u>R3500CP</u>	04/28/2016	Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Competitive Bidding Program (CBP): Additional Instructions for the Implementation of Round 2 Recompete of the DMEPOS CBP and National Mail Order (NMO) Recompete - Rescinded and replaced by Transmittal 3565	10/03/2016	9579
<u>R3324CP</u>	08/14/2015	Clarification of the Policy for Competitively-Bid Wheelchair Accessories Furnished with Non-Competitively Bid Wheelchair Base Equipment	01/04/2016	9272
<u>R2979CP</u>	06/27/2014	Update to Pub. 100-04, Chapter 36 to Provide Language-Only Changes for Updating ASC X12	07/28/2014	8771
<u>R2231CP</u>	05/27/2011	Phase 3 of Manual Revisions to Reflect Payment Changes for Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS)	08/28/2011	7401

Rev #	Issue Date	Subject	Impl Date	CR#
		Items as a Result of the DMEPOS Competitive Bidding Program and the Deficit Reduction Act of 2005		
<u>R1544CP</u>	06/26/2008	Manual Revisions to Reflect Special Billing Instructions for DMEPOS Items as a Result of the DMEPOS Competitive Bidding Program	07/07/2008	6007
<u>R1532CP</u>	06/11/2008	Phase 2 of Manual Revisions to Reflect Payment Changes for DMEPOS Items as a Result of the DMEPOS Competitive Bidding Program and the Deficit Reduction Act of 2005	07/07/2008	6119
<u>R1502CP</u>	05/09/2008	Initial Release of Chapter-Competitive Bidding	06/09/2008	5978

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