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MLN Matters Number: MM5978 **Revised**

Related Change Request (CR) #: 5978

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Related CR Transmittal #: R1502CP

Implementation Date: June 9, 2008

Note: This article is impacted by the Medicare Improvements for Patients and Providers Act of 2008, which was enacted on July 15, 2008. That legislation delays the implementation of the DMEPOS competitive bidding program until 2009 and makes other changes to the program. This article will be further revised and/or replaced as more details of the modified program are available.

Phase 1 of Manual Revisions to Reflect Payment Changes for Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Items as a Result of the DMEPOS Competitive Bidding Program and the Deficit Reduction Act of 2005

This phase includes important information about the processes that suppliers should follow when making their grandfathering decisions prior to July 1, 2008

Provider Types Affected

Medicare DMEPOS suppliers that bill Durable Medical Equipment Medicare Administrative Contractors (DME MACs) as well as providers that bill Medicare Carriers, Fiscal Intermediaries (FIs), Regional Home Health Intermediaries (RHHIs), or Part A/B Medicare Administrative Contractors (A/B MACs) that refer or order DMEPOS for Medicare beneficiaries

What You Need to Know

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CR 5978, from which this article is developed, adds Chapter 36 (Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program) to the *Medicare Claims Processing Manual*.

This chapter manualizes policies and instructions for Medicare Contractors on the DMEPOS Competitive Bidding Program. This first installment provides a general overview and guidance for Medicare Contractors and suppliers on this program.

Subsequent installments will provide additional instructions and guidelines.

This article complements MLN Matters SE0805, SE0806, and SE0807, which already cover many of the sections of Chapter 36 being added to the Medicare Claims Processing Manual.

Background

Medicare payment for most DMEPOS is currently based on fee schedules. However, Section 1847 of the Social Security Act (the Act), as amended by Section 302(b) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) mandates a competitive bidding program to replace the current DMEPOS methodology for determining payment rates for certain DMEPOS items that are subject to competitive bidding under this statute.

The Centers for Medicare & Medicaid Services (CMS) issued the regulation for the Medicare DMEPOS Competitive Bidding Program (published on April 10, 2007 (72 Federal Register 68 (10 April 2007) pp. 17991-18090)). This regulation is available at <http://www.cms.hhs.gov/DMEPOSCompetitiveBid> on the CMS website.

CMS encourages readers of this article to also review MLN Matters article MM6119, which describes additional sections of Chapter 36 of the Medicare Claims Processing Manual. (The article is available at <http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM6119.pdf> on the CMS website.) The new sections added via CR6119 all apply to the competitive bidding program. The topics added include the following:

- Payment for rental of inexpensive or routinely purchased DME;
- Payment for oxygen and oxygen equipment and changing suppliers for oxygen and oxygen equipment;
- Payment for capped rental DME items and changing suppliers for capped rental DME items;
- Payment for purchased equipment and for repair and replacement of beneficiary-owned equipment;
- Payment for enteral nutrition equipment and maintenance and servicing of that equipment;

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- Traveling beneficiaries and transfer of title of oxygen equipment or capped rental items for traveling beneficiaries;
- Advance Beneficiary Notice (ABN) information pertaining to upgrades under the competitive bidding program; and
- Billing procedures related to downcoding under the competitive bidding program.

Key Information in CR5978

Contract Supplier Requirements

Chapter 36 documents contract supplier requirements. For example:

- A contract supplier is required to furnish items under its contract to any Medicare beneficiaries who maintain a permanent residence in or visit the competitive bidding area (CBA).
- Competitively bid items must be provided by a contract supplier unless an exception applies.
- Contract suppliers will be paid for DMEPOS competitively bid items based on bids submitted by qualified DMEPOS suppliers. 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.
- To be considered for participation as a contract supplier in the Medicare DMEPOS Competitive Bidding Program, suppliers must submit a bid for each product category in each CBA that they want to furnish to Medicare beneficiaries. DMEPOS suppliers must submit a bid amount for every item within a product category.

Contract supplier requirements and responsibilities are specified in Chapter 36 and include topics such as: who is eligible to submit bids; small supplier contract suppliers and networks; prescriptions for particular brand, item or mode of delivery; reports; change of ownership; billing privileges, and accreditation. This article will provide detail on some of these provisions, but impacted providers and suppliers should review the official manual revisions contained in CR5978, as well as in the recently released CR6119.

Noncontract Suppliers That Elect To Become “Grandfathered” Suppliers: Notice to Beneficiaries

A **“Grandfathered” supplier** means a noncontract supplier that chooses to continue to furnish grandfathered items to a beneficiary in a CBA to whom the supplier had furnished the items prior to implementation of the competitive bidding program.

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A noncontract supplier that elects to become a grandfathered supplier is responsible for **notifying all its Medicare customers** residing in CBAs to whom it supplies items identified in Section 20.6.1 of the new manual Chapter 36. This chapter is available at

<http://www.cms.hhs.gov/Transmittals/downloads/R1502CP.pdf> on the CMS website.

NOTE: As discussed in the expanded Section 20.6.1 attached to CR6119, 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 website at

<http://www.dmecompetitivebid.com/palmetto/cbic.nsf/DocsCat/Home> on the Internet or at <http://www.cms.hhs.gov/DMEPOSCompetitiveBid/> on the CMS website.

The beneficiary notification should include the following:

- 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 from the grandfathered supplier or to elect to begin receiving the item 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 the written 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 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.

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Sample election/notification letters are available at <http://www.dmecompetitivebid.com> on the Internet.

Noncontract Suppliers That Do Not Elect To Become “Grandfathered” Suppliers: Notice to Beneficiaries

A noncontract supplier that elects not to become a grandfathered supplier as defined above 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.

NOTE: As mentioned in the updated section 20.6.1 attached to CR6119, 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 website at

<http://www.dmecompetitivebid.com/palmetto/cbic.nsf/DocsCat/Home> or at <http://www.cms.hhs.gov/DMEPOSCompetitiveBid/> on the CMS website.

The notification should include the following:

- It should state that the supplier will not continue to furnish rental DME and/or oxygen and oxygen equipment that it had been furnishing to the beneficiary **after** the start of the competitive bidding program and that the beneficiary will 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 further information on the program by calling 1-800-Medicare or accessing <http://www.medicare.gov> on the Internet.
- The supplier should provide this written notification to the beneficiary 30 days before the start date for 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.

Sample election/notification letters are available at <http://www.dmecompetitivebid.com> on the Internet.

Picking Up Equipment

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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.

In all cases, CMS expects 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. CMS expects 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.

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.

Exceptions

Medicare DME MACS will continue to apply all existing instructions for DMEPOS unless otherwise noted in CR 5978. In general, noncontract suppliers will not be paid for furnishing DMEPOS competitively bid items to beneficiaries in a CBA.

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Only a contract supplier is eligible for Medicare payment for competitively bid items furnished to a Medicare beneficiary within a CBA, unless an exception applies. For example:

1. A noncontract supplier that has a valid National Supplier Clearinghouse (NSC) number may receive a Medicare secondary payment for a competitively bid item furnished to a beneficiary residing in a CBA if the beneficiary is required to use that supplier under his/her primary insurance policy.
2. A grandfathered supplier may continue to furnish a grandfathered item to a beneficiary residing in a CBA. Grandfathered items are limited to inexpensive or routinely purchased items furnished on a rental basis; items requiring frequent and substantial servicing; oxygen and oxygen equipment; and capped rental items furnished on a rental basis.
3. A physician, treating practitioner, physical therapist in private practice or occupational therapist in private practice may furnish certain competitively bid items in a CBA if certain requirements are met.

Important Note Regarding Rented Enteral Nutrition Infusion Pumps

The grandfathering option does **NOT** apply to enteral nutrition equipment. In accordance with current instructions in Section 30.7.1 of Chapter 20 of the *Medicare Claims Processing Manual*, payment for rental of enteral infusion pumps is limited to a total of 15 months during a period of medical need. The supplier that collects the last month of rental (i.e., the 15th month) is responsible for ensuring that the beneficiary has a pump for the duration of medical necessity and for maintenance and servicing of the pump during the duration of therapy. Therefore, if a supplier is currently furnishing an enteral nutrition infusion pump to a Medicare beneficiary in a CBA on a rental basis and has not been awarded a contract to furnish enteral nutrients, supplies, and equipment, the supplier must either:

1. Inform the beneficiary if they are in rental months 1 thru 14 that they will need to contact a contract supplier for this product category to arrange for continuation of all of their enteral nutrition services; or
2. Inform the beneficiary if they are beyond rental month 15 that they will continue to furnish and maintain the pump for the duration of medical necessity, but that the beneficiary will need to contact a contract supplier to arrange for continuation of the services of furnishing the enteral nutrients and supplies.

With regard to scenario number 1 above, 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. 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

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which the item was first delivered to the beneficiary. In all cases, CMS expects the contract supplier to consult with the noncontract supplier to obtain the anniversary date.

With regard to both scenarios above, the noncontract supplier should work with the contract supplier so that there is no break in service or furnishing of medically necessary nutrients, supplies, and equipment. CMS expects the contract supplier and the current supplier will work together to make arrangements suitable to the beneficiary's needs.

Payment

- The Medicare payment amount for competitively bid items is based on the CBA in which the beneficiary maintains a permanent residence.
- Medicare will make payment for competitively bid items on an assignment-related basis equal to 80% of the applicable single payment amount.

Prescription for Particular Brand, Item, or Mode of Delivery

As discussed in section 30.4 on the manual section added in CR6119, 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

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- (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.

Other Provisions Already Covered in Special Edition MLN Articles SE0805, SE0806, SE0807, and MM6119

- Medicare will pay mail order contract suppliers the single payment amount for furnishing competitively bid mail order diabetic testing supplies to Medicare beneficiaries residing in the CBAs for which they have contracts. All mail order diabetic supplies suppliers must use the HCPCS modifier KL on each claim to indicate that the competitively bid 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 claims. Suppliers that furnish mail order diabetic supplies that fail to use the HCPCS modifier KL on the claim may be subject to penalties under the False Claims Act.
- Medicare will pay the fee schedule amount for non-mail order diabetic testing supplies to Medicare enrolled suppliers for the State where the beneficiary maintains a permanent residence.
- Medicare allows for the repair and replacement of parts for beneficiary-owned items by any Medicare enrolled supplier. *Note: Labor to repair equipment is not subject to competitive bidding and will be paid according to Medicare's general payment rules.*
- Competitive bidding applies to skilled nursing facilities (SNFs) and nursing facilities (NFs) to the extent that their residents receive competitively bid items under Medicare Part B. 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 or become a regular contract supplier that furnishes 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.
- 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). ABN forms are available at http://www.cms.hhs.gov/BNI/02_ABNGABNL.asp on the CMS website.

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- As related in CR6119, 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.

Important Previously Issued Capped Rental Instructions

All suppliers should pay attention to the new Chapter 36, Sections 20.6.4 (Transfer of Title for Oxygen Equipment and Capped Rental DME) and 20.6.5 (Capped Rental DME Furnished Prior to January 1, 2006). Previously, CR5010 detailed the changes in the payment for oxygen equipment and capped rental equipment as a result of the Deficit Reduction Act (DRA) of 2005. The MLN Matters article on that issue, MM5010, is available at

<http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM5010.pdf> on the CMS website.

CR5461 covered changes in maintaining and servicing capped rental DME and oxygen equipment as a result of the DRA, especially requirements for maintenance of **capped rental DME furnished PRIOR TO January 1, 2006**. These items are subject to the capped rental payment rules in effect prior to the changes made by the DRA. For such items, the supplier that provides the item in the 15th month of the rental period is responsible for supplying the equipment and its maintenance and servicing after the 15-month period. This requirement is not eliminated by the competitive bidding program and applies to contract and noncontract suppliers whether or not the noncontract supplier is a grandfathered supplier. The MLN Matters article related to CR5461 is available at <http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM5461.pdf> on the CMS website.

Additional Information

You can find more information about the payment changes for DMEPOS items as a result of the DMEPOS competitive bidding program and the Deficit Reduction Act of 2005 by going to CR 5978, located at <http://www.cms.hhs.gov/Transmittals/downloads/R1502CP.pdf> on the CMS website. You will find the updated *Medicare Claims Processing Manual* Chapter 36 (Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program) as an attachment to that CR. CR6119 is also available at <http://www.cms.hhs.gov/Transmittals/downloads/R1532CP.pdf> on the CMS website.

Additional information regarding this program, including tip sheets for specific Medicare provider audiences, can be found at <http://www.cms.hhs.gov/DMEPOSCompetitiveBid/> on the CMS dedicated

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If you have any questions, please contact your carrier, FI, RHHI, A/B MAC, or DME MAC at their toll-free number, which may be found at

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