

Medlearn Matters Number: MM4309 **Revised**

Related Change Request (CR) #: 4309

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Effective Date: July 1, 2006

Related CR Transmittal #: R866CP

Implementation Date: July 3, 2006, except as otherwise specified in the article.

MMA - Additional Requirements for the Competitive Acquisition Program (CAP) for Part B Drugs and Biologicals

Note: This article was revised on February 21, 2006, to reflect a new CR Transmittal number, CR Web address, and CR release date. The changes were made to reflect revisions made by CMS to CR4309. All other information in the article remains the same.

Provider Types Affected

Physicians and suppliers billing Medicare carriers for Part B drugs and biologicals not paid on a cost or prospective payment system basis

Provider Action Needed



STOP – Impact to You

This article is based on Change Request (CR) 4309, which provides additional requirements for the CAP for Part B drugs and biologicals.



CAUTION – What You Need to Know

CR4309 provides additional instructions for the implementation of the CAP program. It builds on CR4064 through business requirements that were identified through the implementation process of CR4064 and the development of the final CAP rule recently published on November 21, 2005.



GO – What You Need to Do

See the *Background* section of this article for further details regarding these additional requirements.

Background

Change Request (CR) 4309 provides new requirements that were identified both during the coding process of CR4064 (<http://new.cms.hhs.gov/transmittals/downloads/R777CP.pdf>) and the publication of the final rule for the CAP for Medicare Part B drugs. It provides

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additional instructions for the implementation of the CAP program as outlined in CR4064, and it is tied to the business requirements in CR4064. CR4309 is not a stand-alone CR and needs to be understood in conjunction with CR4064.

The Competitive Acquisition Program (CAP) for Drugs and Biologicals Not Paid on a Cost or Prospective Payment Basis

The Medicare Prescription Improvement and Modernization Act of 2003 (MMA, Section 303 (d)), requires the implementation of a CAP for Medicare Part B drugs and biologicals not paid on a cost or prospective payment system (PPS) basis. Beginning with drugs administered on or after July 1, 2006, physicians will be given a choice between buying and billing these drugs under the average sales price (ASP) system, or obtaining these drugs from vendors selected in a competitive bidding process.

For purposes of the CAP, the term “a physician” includes individuals defined under the Social Security Act, §1861(s) who are authorized to provide physician services under §1861(s) of the Social Security Act and who can, within their State’s scope of practice, prescribe and order drugs covered under Medicare Part B.

Note: For 2006, the first CAP year will run from July 1, 2006, through December 31, 2006. In subsequent years, it will run annually on a calendar year basis.



MMA, Section 303 (d) may be found at <http://www.cms.hhs.gov/MMAUpdate/> on the CMS web site.
Social Security Act, Section 1861(s) is available at http://www.ssa.gov/OP_Home/ssact/title18/1861.htm.

The Centers for Medicare & Medicaid Services (CMS) may exclude drugs from the CAP if competitive pricing will not result in significant savings, or is likely to have an adverse impact on access to such drugs.

The statute gives CMS the authority to select drugs, or categories of drugs, that will be included in the program, to establish geographic competitive acquisition areas, and to phase in these elements as appropriate.

Award Competition

A competition will be held every three years to award contracts to approved CAP vendors that will supply drugs and biologicals for the program. A three-year contract will be awarded to qualified approved CAP vendors in each geographic area who have and maintain:

- Sufficient means to acquire and deliver competitively biddable drugs within the specified contract area;

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- Arrangements in effect for shipping at least five days each week for the competitively biddable drugs under the contract and means to ship drugs in emergency situations;
- Quality, service, financial performance, and solvency standards; and
- A grievance and appeals process for dispute resolution.

A vendor's contract may be terminated during the contract period if they do not abide by the terms of their contract with CMS. CMS will establish a single payment amount for each of the competitively bid drugs and areas; for this three-year cycle there will be one drug category and one geographic area. After CAP drug prices are determined and vendor contracts are awarded, the information will be posted to a directory on the Medicare Web Site.

Participation in the CAP

Medicare physicians will be given an opportunity to elect to participate in the CAP on an annual basis. Physicians who elect to participate in CAP will continue to bill their local carrier for drug administration. The participating CAP physicians will receive all of their drugs from the approved CAP vendor for the drug categories they have selected, with only one exception.

The exception will be for "furnish as written" situations where:

- The participating CAP physician requires that, due to medical necessity, the beneficiary must have a specific drug, defined by its National Drug Code (NDC), for one of the Healthcare Common Procedure Coding Systems (HCPCS) code within the approved CAP vendor's drug list; and
- That specific drug NDC is not available on the drug list.

In cases where the drug is not available from the approved CAP vendor, the participating CAP physician may buy the drug, administer it to the beneficiary, and bill Medicare using the ASP system using the CAP J3-"furnish as written" modifier. The local carrier will monitor drugs obtained using the "furnish as written" provision to ensure that the participating CAP physician is complying with Medicare payment rules.



Note: Physicians will still be able to continue to purchase and bill Medicare under the Average Sales Price (ASP) system those drugs that are covered under Medicare Part B but whose HCPCS codes are not provided by the chosen approved CAP vendor.

Providing a Drug from Physician's Stock

Under emergency situations, the CAP will allow a participating CAP physician to provide a drug to a Medicare beneficiary from his or her own stock and obtain the replacement drug from the approved CAP vendor when certain conditions are met. The local carrier will monitor drugs ordered under the emergency replacement

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provision to ensure that the participating CAP physician is complying with Medicare payment rules.

Approved CAP Vendor Requirements

- Approved CAP vendors must qualify for enrollment in Medicare, and will be enrolled as a new provider specialty.
- The approved CAP vendor's claims for the drugs will be submitted to one designated Medicare carrier.
- The approved CAP vendor will bill the Medicare-designated carrier for the drug and the beneficiary for any applicable coinsurance and deductible.
- Payment to the approved CAP vendor for the drug is conditioned on verification that the drug was administered to the Medicare beneficiary:
 - Proof of administration must be established by matching the participating CAP physician's claim for drug administration with the approved CAP vendor's claim for the drug in the Medicare claims processing system by means of a prescription order number on both claims.
 - When they are matched in the claims processing system, the approved CAP vendor will be paid in full.
 - Until drug administration is verified, the approved CAP vendor may not bill the beneficiary and/or his third party insurance for any applicable coinsurance and deductible.

Physician Election and Information Transfer between Carriers and the Designated Carrier for CAP Claims

For this first CAP year, by April 3, 2006, CMS will post on its website:

- A list of the vendors that have been selected to participate in CAP for 2006,
- The categories of drugs they will be providing, and
- The geographic areas within which each vendor will operate.

Physicians can then elect the vendors and the categories of drugs they choose to receive drugs from under the CAP program.

For this first CAP cycle, there will be one category of drugs and one geographic area.



Note: The election process for 2006 will end May 18, 2006.

In subsequent years the CAP election will take place in the fall of each year and CMS will post on its website the updated list of vendor information. The election

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process will end each year approximately 45 days after the list of vendors is posted on the CMS Web site.

Additional Requirements Regarding the CAP

Additional instructions and more complete details about the CAP requirements for Part B Drugs can be found in Change Request (CR) 4309 and its attachments. Some of these important requirements to remember are as follows:

- The CAP is only available to physicians billing Medicare on a fee-for-service basis;
- Vendors can only submit claims for drugs provided by physicians who selected that vendor;
- Members of a group must elect to participate in the CAP as a whole group when billing as a group;
- Only members of a group who have prescriptive authority are eligible to participate in the CAP;
- The J1 modifier must be on every physician claim for a CAP drug; and
- All HCPCS codes for the administration of CAP drugs must be billed as assigned.

Implementation

The implementation date for this instruction is July 3, 2006, except where otherwise indicated in this article.

Additional Information

For complete details, please see the official instruction issued to your carrier regarding this change. That instruction may be viewed at <http://www.cms.hhs.gov/Transmittals/downloads/R866CP.pdf> on the CMS web site. In addition, you may wish to review CR4064 at <http://www.cms.hhs.gov/Transmittals/downloads/R777CP.pdf> and its related article at <http://www.cms.hhs.gov/MedlearnMattersArticles/downloads/MM4064.pdf> on the CMS site.

If you have any questions, please contact your carrier at their toll-free number, which may be found at <http://www.cms.hhs.gov/apps/contacts/> on the CMS web site.

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