

MLN Matters Number: MM4309

Related Change Request (CR) #: 4309

Related CR Release Date: February 17, 2006

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 August 27, 2007 to show that effective August 23, 2007, CR 5658 (<http://www.cms.hhs.gov/Transmittals/downloads/R1313CP.pdf>) rescinded from CR 4309 the instructions that addressed applying the unused drug modifier (JW) to indicate billing for the unused portion of a single-use drug product under the CAP (see page 3). Claims for drugs provided under CAP submitted with the JW modifier will be treated as unprocessable. This CR does not affect the use of the JW modifier for non-CAP claims. The related MLN Matters article (<http://www.cms.hhs.gov/MLNMattersArticles/downloads/mm5658.pdf>) may be found on the CMS website.

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 requirement 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 published on November 21, 2005.

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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://www.cms.hhs.gov/transmittals/downloads/R777CP.pdf>) and the publication of the final rule for the CAP for Medicare Part B drugs. It provides 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 a complete overview of the program, see the MLN Matters article at

<http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM4064.pdf> on the CMS website.

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 website. 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.

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

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

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

For this first CAP year, by May 1, 2006, CMS will post on its website:

- A list of the vendors that have been selected to participate in the CAP for 2006 and their websites,
- 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.

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 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 and is not applicable to United Mine Worker, Railroad Retirement Board, or Medicare Advantage beneficiaries;
- Vendors can only submit claims for drugs provided by physicians who selected that vendor;
- Every claim from a vendor will indicate that all appeals on CAP claims must be adjudicated by the physician's carrier;
- 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;

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- Any carrier that is currently applying a local billing policy for unused drug (waste) that requires a separate detail line with the unused drug modifier (JW) may continue to apply that policy under the CAP, but they must require the addition of the CAP modifier to the line;
- Claims that include the no-pay, restocking, or furnished as written modifier (as noted in CR4064) will be treated as unprocessable if they contain one of the following invalid modifier combinations:
 - J1 and J3
 - J2 without J1
 - J2 and J3
- The J1 modifier must be on every physician claim for a CAP drug;
- Vendors may petition CMS to add new drugs to their vendor specific drug list on a quarterly basis;
- The UPIN (or NPI) of the ordering physician must be entered on every vendor claim and match the UPIN (or NPI) of a physician that has elected that vendor; and
- All HCPCS codes for the administration of CAP drugs must be billed as assigned.

When physicians or practitioners submit a paper claim with a no-pay modifier on a line, but without a prescription number on that line, the claim will be rejected and returned with remittance advice remark code MA130, indicating "Your claim contains incomplete information, and no appeals rights are afforded because the claim is unprocessable. Please submit a new claim with the complete/correct information."

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 website. In addition, you may wish to review CR4064 at <http://www.cms.hhs.gov/Transmittals/downloads/R777CP.pdf> and its related article at

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<http://www.cms.hhs.gov/MLNMattersArticles/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/MLNProducts/downloads/CallCenterTollNumDirectory.zip> on the CMS website.

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