



Related MLN Matters Article #: MM4309

Date Posted: February 14, 2006

Related CR #: 4309

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

Key Words

MM4309, CR4309, R866CP, R777CP, CR4064, MMA, Competitive, Acquisition, Program, CAP, Drugs, Biologicals

Provider Types Affected

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

Key Points

- The effective date of the instruction is July 1, 2006.
- The implementation date is July 3, 2006, except as otherwise specified in MLN Matters article MM4309.
- 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 CAP for Drugs and Biologicals Not Paid on a Cost or PPS 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 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 system or obtaining these drugs from vendors selected in a competitive bidding process.
- 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.
- 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.

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, CMS will post on its website:
 - A list of the vendors selected to participate in CAP for 2006 and their websites;
 - The categories of drugs they will provide; and
 - The geographic areas where each vendor will operate.
- Physicians can then elect the categories of drugs and the vendors from whom they choose to receive drugs under the CAP program.
- For the 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 website.

Additional Requirements Regarding the CAP

- 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 may only submit claims for drugs provided by physicians who select 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.
- 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. (See Note below for update on use of the JW modifier.)

- 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, or
 - 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 Unique Physician Identification Number (UPIN) or National Provider Identifier (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.
- All Healthcare Common Procedure Coding System codes for the administration of CAP drugs must be billed as assigned.

Note: For claims processed after August 23, 2007, CR5658 (<http://www.cms.hhs.gov/Transmittals/downloads/R1313CP.pdf>) rescinded 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. 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.

Important Links

The related MLN Matters article can be found at <http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM4309.pdf> on the CMS website.

The official instruction (CR4309) regarding this change may be viewed at <http://www.cms.hhs.gov/Transmittals/downloads/R866CP.pdf> on the CMS website.

For additional information about the implementation of the CAP program, providers may want to review the following MLN Matters articles on the CMS website.

- MM4404 (MMA Competitive Acquisition Program (CAP) for Part B Drugs Physician Election) at <http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM4404.pdf> on the CMS website.
- MM5079 (Competitive Acquisition Program (CAP) - Creation of Automated Tables for Provider Information, Expansion of CAP Fee Schedule File Layout, and Additional Instructions for Claims Received from Railroad Retirement Board Beneficiaries) at <http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM5079.pdf> on the CMS website.
- MM5332 (Instructions for the Coordination of Medicare Secondary Payer (MSP) claims for the Competitive Acquisition Program (CAP)) at <http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM5332.pdf> on the CMS website.
- MM4064 (MMA - Competitive Acquisition Program (CAP) for Part B Drugs - Coding, Testing, and Implementation) may be found at <http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM4064.pdf> on the CMS website.

If providers have any questions, they may contact their carrier or FI at their toll free number, which is available at <http://www.cms.hhs.gov/MLNProducts/downloads/CallCenterTollNumDirectory.zip> on the CMS website.