

MLN Matters Number: MM4064 **Revised**

Related Change Request (CR) #: 4064

Related CR Release Date: December 9, 2005

Effective Date: July 1, 2006

Related CR Transmittal #: R777CP

Implementation Date: July 3, 2006

MMA - Competitive Acquisition Program (CAP) for Part B Drugs - Coding, Testing, and Implementation

Note: This article was revised on May 8, 2006, to reflect that the election period for physicians to participate in the CAP this year will run from May 8, 2006, to June 2, 2006.

Provider Types Affected

Physicians billing Medicare carriers for Part B drugs and approved CAP vendors billing the designated carrier

Provider Action Needed



STOP – Impact to You

From May 8, 2006 to June 2, 2006, Medicare physicians will be given the opportunity to elect to participate in the Competitive Acquisition Program (CAP) for claims paid on or after July 1, 2006. Participating CAP physicians will obtain Medicare Part B covered drugs from selected drug categories through the CAP. Until further notice, there is only one drug category in the CAP. (**Note:** Exact dates of the physician election period will be announced on the comp bid web site (<http://www.cms.hhs.gov/CompetitiveAcquisforBios>) and via a list serv notice).



CAUTION – What You Need to Know

Participating CAP physicians will receive all of their Part B drugs from the approved CAP vendor for the drug category (ies) they have selected.

The only exception is the “**furnish as written**” situation, in which the participating CAP physician requires that, because of medical necessity, the beneficiary must have a certain brand of a drug or a particular product identified by the product’s National Drug Code (NDC) and that specific drug is not available for the HCPCS code listed on the approved CAP vendor’s drug list. This one exception will be identified with the use of the new CAP J3 modifier.

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Physicians participating in the CAP program should pay particular attention to the discussion in this article concerning the CAP J1, J2, and J3 modifiers.



GO – What You Need to Do

By May 1, the Centers for Medicare & Medicaid Services (CMS) will post on its web site a list of the CAP vendors and the drugs they will supply. Physicians wishing to participate in the CAP program in 2006 must elect to do so within 45 days of the date the election information is posted. The election agreement is effective on July 1, 2006. See the Background section of this article for further details regarding these changes.

Background

This article includes information from Change Request (CR) 4064, which provides instructions to Medicare carriers regarding the CAP program. This new CAP program applies to physician-injectable and infused drugs covered under Medicare's Supplemental Insurance (Part B) program that are commonly provided incident to a physician's service. This program does NOT apply to drugs included in the new Prescription Drug Benefit under Part D, which goes into effect on January 1, 2006.

Physicians (and other practitioners who provide physician services that include the authority to prescribe and order Medicare Part B drugs) wishing to participate in the CAP program in 2006 must elect to do within 45 days of the date that the election information is posted on the CMS website.

The election agreement is effective on July 1, 2006. Each subsequent year, the election period will be in the fall and physicians must make their participation decision within 45 days after CMS publishes the list of vendors and their drug list for the following year on the CMS web site. Election decisions will take effect on the following January 1.

How Drugs Are Selected For CAP

The 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 Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) gives CMS the authority to:

- Select drugs (or categories of drugs) that will be included in the CAP program,
- Establish geographic competitive acquisition areas, and
- Phase in these elements as appropriate.

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How Approved CAP Vendors Are Selected

A competition will be held every three years to award contracts to 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;
- Arrangements in effect for shipping at least 5 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.

Approved CAP vendors must qualify for enrollment as a Medicare supplier, and they will be enrolled as a new provider specialty type.

CMS will establish a single payment amount for each of the competitively bid drugs and areas. For this three year contract cycle there will be one drug category and one geographic area for CAP. After CAP drug prices are determined and vendor contracts are awarded, the information will be posted to a directory at <http://www.cms.hhs.gov/CompetitiveAcquisforBios> on the CMS web site.

Obtaining Drugs in the CAP

The Medicare Prescription Drug, 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 basis. You can review the MMA, Section 303(d) at <http://www.cms.hhs.gov/CompetitiveAcquisforBios/Downloads/303d.pdf> on the CMS web site.

Beginning with Part B drugs administered on or after July 1, 2006 incident to a physician service, Medicare 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 the CAP's competitive bidding process.

Physicians (and other practitioners who provide physician services that include the authority to prescribe and order Medicare Part B drugs) will be given the opportunity to participate in the CAP. Approved CAP vendors will supply the drugs and biologicals for the participants of this program.

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Physicians who elect to participate in CAP will continue to bill their local carrier for drug administration.

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 in which the participating CAP physician specifies that, because of medical necessity, the beneficiary must have a certain brand of a drug or a particular product defined by the product’s National Drug Code (NDC) and that drug is not available for the HCPCS codes listed on the approved CAP vendor’s drug list.

In those cases, the participating CAP physician may:

- Buy the drug;
- Administer it to the beneficiary; and
- Using the appropriate modifier (see below discussion of modifiers), bill Medicare using the average sales price (ASP) methodology.

In addition, 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 under the emergency replacement provision when certain conditions are met as follows:

- The drug was required immediately;
- The need for the drug could not be anticipated;
- The CAP vendor could not deliver the drug in time;
- The drug was administered in an emergency situation; and
- Documentation is maintained on file to validate these conditions.

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.

Physician Billing

Physicians will be given the opportunity to participate in the CAP on an annual basis, and those who elect to participate in CAP will continue to bill their local carrier for the drug’s administration. They will agree to submit a claim to Medicare within 14 days of the administration of the CAP drug.

The carrier will deny any physician Part B claims for drugs included in the CAP unless the CAP modifier codes are appropriately included. CAP has three

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modifier codes that will need to be used when physicians submit claims to their carriers for the administration of CAP drugs. The new CAP modifier codes are:

- J1 – Competitive Acquisition Program, no-pay submission for a prescription number
- J2 – Competitive Acquisition Program (CAP), restocking of emergency drugs after emergency administration and a prescription number
- J3 – Competitive Acquisition Program (CAP), drug not available through CAP as written, reimbursed under average sales price (ASP) methodology.

Participating CAP physicians will also use a prescription/order number to identify each CAP drug administered. This number will be matched to the prescription/order number(s) on the approved CAP vendor's claim as verification that the beneficiary received the drug(s) and that the approved CAP vendor may now be paid by Medicare.

When physicians submit claims for the administration of CAP drug (s) to their carriers, they should include:

- A prescription/order number for each CAP drug administered;
- The HCPCS code for each CAP drug administered along with the new "J1" no-pay modifier;
- The HCPCS code(s) that include the administration of each CAP drug on separate lines.

Note: On paper claims, the prescription numbers will be in Item 19.

When physicians submit claims for the administration of CAP drug(s) that have been administered in an emergency situation and required "emergency restocking" from the approved CAP vendor, the claim should be submitted with the:

- Prescription/order number for each CAP drug administered;
- HCPCS code for each administered CAP drug along with the new "J1" no-pay modifier and also on that same line, the new "J2" modifier denoting "Competitive Acquisition Program, (CAP) restocking of emergency drugs after emergency administration;" and
- HCPCS code(s) that include the administration of each CAP drug on separate lines.

When physicians submit claims for "**furnish as written**" drugs to be paid outside the CAP program:

- Physicians should use only the new "J3" modifier denoting "Competitive Acquisition Program (CAP), drug not available through CAP as written, reimbursed under the average sales price methodology."

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Physicians who elect CAP should note:

- The administration services and the no-pay lines must be on the same claim or your carrier will return the claim as unprocessable and you will see a remittance advice reason code of 16 denoting claim lacks information which is needed for adjudication.
- The Medicare carrier will identify them as physicians who elected to participate in CAP and who will not be paid for the drugs obtained from the approved CAP vendor.

Additionally, unless claims for CAP administration do not include the CAP drug no-pay, restocking, or "furnish as written" modifier, the claim will be denied and you will see a remittance advice, N348, stating that "You chose that this service/supply/drug be rendered/supplied and billed by a different practitioner/supplier."

Note: The physician's local carrier will monitor drugs that are:

- Obtained using the "furnish as written" provision to ensure that the participating CAP physician is complying with Medicare payment rules; and
- Ordered under the replacement provision to ensure that the participating CAP physician is complying with Medicare payment rules.

Vendor Billing

The approved CAP vendor will bill the:

- Medicare designated carrier for the drug; and
- Beneficiary for any applicable coinsurance and deductible.

The approved CAP vendor will also include a prescription/order number on the claim to identify each CAP drug administered.

Note: Payment to the approved CAP vendor for the drug is conditioned on verification that the drug was administered to the Medicare beneficiary.

Proof that the drug was administered shall 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 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.

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Implementation

The implementation date for this instruction is July 3, 2006.

Additional Information

For complete details, please see the official instruction issued to your carrier regarding this change. That instruction may be viewed by going to <http://www.cms.hhs.gov/Transmittals/downloads/R777CP.pdf> on the CMS web site.

Also, additional information on the CAP program is available at <http://www.cms.hhs.gov/CompetitiveAcquisforBios/> on the CMS web 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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