CMS Manual System	**Department of Health & Human Services (DHHS)**
Pub 100-04 Medicare Claims Processing	**Centers for Medicare & Medicaid Services (CMS)**
Transmittal 1207	**Date: MARCH 19, 2007**
	Change Request 5546

SUBJECT: Competitive Acquisition Program (CAP) for Part B Drugs

I. SUMMARY OF CHANGES: This CR provides additional details, information and instructions for the implementation of the CAP as outlined in CRs 4064, 4306, 4404, 5079 and 5332.

New / Revised Material
Effective Date: April 1, 2007
Implementation Date: April 19, 2007

Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual is not updated)
R=REVISED, N=NEW, D=DELETED-*Only One Per Row.*

R/N/D	Chapter / Section / Subsection / Title
R	Chapter 17/Section 100 - The Competitive Acquisition Program (CAP) for Drugs and Biologicals Not Paid on a Cost or Prospective Payment Basis.

III. FUNDING:
No additional funding will be provided by CMS; contractor activities are to be carried out within their FY 2007 operating budgets.

IV. ATTACHMENTS:

Business Requirements

Manual Instruction

Unless otherwise specified, the effective date is the date of service.

Attachment - Business Requirements

Pub. 100-04	Transmittal: 1207	Date: March 19, 2007	Change Request: 5546

SUBJECT: Competitive Acquisition Program (CAP) for Part B Drugs

Effective Date: April 01, 2007

Implementation Date: April 19, 2007

I. GENERAL INFORMATION

A. Background: This CR provides additional details, information and instructions for the implementation of the CAP as outlined in CRs 4064, 4306, 4309, 4404, 5079, and 5332. Note: the term "carrier" used in this document will be superseded by the term "MAC" during the ongoing contracting reform process.

B. Policy: Section 303 (d) of the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003 established section 1847B of the Social Security Act requiring the implementation of a competitive acquisition program (CAP) for Medicare Part B drugs and biologicals not paid on a cost or prospective payment system basis. Beginning with drugs administered on or after July 1, 2006, physicians are given a choice between buying and billing these drugs for beneficiaries with Medicare as their primary insurer under the average sales price (ASP) system or obtaining these drugs from vendors selected through a competitive bidding process.

Under the MMA, payment for drugs supplied under the CAP was conditioned upon their administration to a beneficiary. This requirement led to the development of a claims payment system based on matching a physician's drug administration claim to a vendor's drug claim prior to making a payment for the claim. Title 2, Section 108(a) of the Tax Relief and Health Care Improvements Act of 2006 (TRCHA), strikes language used to develop the existing CAP claims matching process and furthermore requires the implementation of a post payment review process effective April 1, 2007. The post payment review process is required to assure that drugs supplied under the CAP have been administered to a beneficiary and the process must establish a mechanism to recoup, offset or collect any overpayments to the approved CAP vendor. CMS plans to implement CAP claims processing changes in order to comply with THRCA by April 1, 2007. Pending CAP claims submitted prior to April 1, 2007 and all new CAP claims submitted on or after April 1 will be subject to the post payment review process.

II. BUSINESS REQUIREMENTS TABLE

Use "Shall" to denote a mandatory requirement

Number	Requirement	Responsibility (place an "X" in each applicable column)										
		A/B MAC	DME MAC	FI	CARRIER	DMERC	RHHI	Shared-System Maintainers				OTHER
								FISS	MCS	VMS	CWF	
5546.1	Effective for claims processed on or after April 1, 2007, as under current processes, the CAP Designated Carrier shall continue to allow a claim from the CAP vendor to adjudicate to payment if an approved matching physician claim is found and the vendor claim passes all											CAP Designated Carrier

Number	Requirement	Responsibility (place an "X" in each applicable column)										
		A/B MAC	DME MAC	FI	CARRIER	DMERC	RHHI	Shared-System Maintainers				OTHER
								FISS	MCS	VMS	CWF	
	other current edits.											
5546.1.1	Effective for claims processed on or after April 1, 2007, the CAP Designated Carrier shall suspend for review claims from the CAP vendor if a matching, but denied, physician claim is found using the current matching process.											CAP Designated Carrier
5546.1.1.1	Effective for claims processed on or after April 1, 2007, the CAP Designated Carrier shall deny vendor claims that have a matching physician claim that was denied due to medical necessity, or as non-covered.											CAP Designated Carrier
5546.1.1.1.1	The Designated Carriers shall return the same denial messages as in BR 8.2 from CR 4064.											CAP Designated Carrier
5546.1.1.1.2	The Designated Carriers shall return the same denial messages for claims denied due to reasons other than medical necessity: Claims Adjustment Reason Code 96 – Non-covered service(s). Remittance Advice Remark Code N161 – This drug/service/supply is covered only when the associated service is covered.											CAP Designated Carrier
5546.1.1.2	Effective for claims processed on or after April 1, 2007, the CAP Designated Carrier shall approve vendor claims that have a matching physician claim that was denied due to other than medical necessity, or as non-covered and use the CWF override code as necessary.											CAP Designated Carrier
5546.2	Effective for claims processed on or after April 1, 2007, the CAP Designated Carrier shall use the CWF override code to allow claims from the CAP vendor to adjudicate to payment if no matching physician claim is received by the time the claim would be allowed to pay following the normal floor and claims processing timeliness standards.											CAP Designated Carrier
5546.2.1	Per BR 5546.2, the Designated Carrier shall no longer pend the claims for 90 days per BR 4064.8.4 and shall no longer follow any other instructions relating to the 90 day period.											CAP Designated Carrier
5546.3	Effective for pending claims with no matching											CAP

Number	Requirement	Responsibility (place an "X" in each applicable column)										
		A/B MAC	DME MAC	FI	CARRIER	DMERC	RHHI	Shared-System Maintainers				OTHER
								FISS	MCS	VMS	CWF	
	physician claim processed on or after April 1, 2007 with dates of service prior to April 1, 2007, the CAP Designated Carrier shall resend the claims to CWF so that the CWF override code may be used to allow the claims to adjudicate to payment.											Designated Carrier
5546.4	Effective for pending claims with a matching physician claim processed on or after April 1, 2007 with dates of service prior to April 1, 2007, the CAP Designated Carrier shall follow the processes described above in 5546.1 – 5546.2.1.											CAP Designated Carrier

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility (place an "X" in each applicable column)										
		A/B MAC	DME MAC	FI	CARRIER	DMERC	RHHI	Shared-System Maintainers				OTHER
								FISS	MCS	VMS	CWF	
5546.5	A provider education article related to this instruction will be available at http://www.cms.hhs.gov/MLNMattersArticles/ shortly after the CR is released. You will receive notification of the article release via the established "MLN Matters" listserv. Contractors shall post this article, or a direct link to this article, on their Web site and include information about it in a listserv message within one week of the availability of the provider education article. In addition, the provider education article shall be included in your next regularly scheduled bulletin. Contractors are free to supplement MLN Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly.											CAP Designated Carrier

IV. SUPPORTING INFORMATION

A. For any recommendations and supporting information associated with listed requirements, use the box below:
Use "Should" to denote a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:

B. For all other recommendations and supporting information, use this space:

V. CONTACTS

Pre-Implementation Contact(s): Cassandra Black, Cassandra.black@cms.hhs.gov or on 410-786-4545 or Leslie Trazzi, leslie.trazzi@cms.hhs.gov or on 410-786-7544

Post-Implementation Contact(s): Leslie Trazzi, leslie.trazzi@cms.hhs.gov or on 410-786-7544 or Cassandra.black@cms.hhs.gov or on 410-786-4545

VI. FUNDING

A. *For Fiscal Intermediaries, Carriers, and the Durable Medical Equipment Regional Carrier (DMERC),* use only one of the following statements:
No additional funding will be provided by CMS; contractor activities are to be carried out within their FY 2007 operating budgets.

B. *For Medicare Administrative Contractors (MAC),* use the following statement:

The contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the Statement of Work (SOW). The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

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

(Rev. 1207, Issued: 03-19-07; Effective Date: 04-01-07; Implementation Date: 04-19-07)

Section 303 (d) of the Medicare Prescription Improvement and Modernization Act (MMA) of 2003 requires the implementation of a competitive acquisition program (CAP) for Medicare Part B drugs and biologicals not paid on a cost or prospective payment system 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 §1861(s) of the Social Security Act who are authorized to provide physician services under §1861(s) of the Act and who can, within their State's scope of practice, prescribe and order drugs covered under Medicare Part B.

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 Secretary 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.

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: 1) Sufficient means to acquire and deliver competitively biddable drugs within the specified contract area; 2) 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; 3) Quality, service, financial performance, and solvency standards; and 4) 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.

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 it's National Drug Code (NDC), for one of the HCPCS

codes within the approved CAP vendor's drug list if that specific drug NDC is not available on the CAP drug list. The participating CAP physician may buy the drug, administer it to the beneficiary and bill Medicare using the ASP system. 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.

The CAP will also 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 replacement provision to ensure that the participating CAP physician is complying with Medicare payment rules.

Approved CAP vendors must qualify for enrollment in Medicare as a supplier, and will be enrolled as a new provider specialty type. 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 *under the MMA, for CAP claims submitted after July 1, 2006 but before April 1, 2007,* payment to the approved CAP vendor for the drug *was* conditioned on verification that the drug was administered to the Medicare beneficiary. Proof that the drug was administered *was* 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 *the claims* matched in the claims processing system, the approved CAP vendor was paid in full.

Title II, section 108(a) of the Tax Relief and Health Care Act of 2006 (TRHCA), struck language used to develop the existing CAP claims matching process and furthermore required the implementation of a post payment review process effective April 1, 2007. The post payment review process is required to assure that drugs supplied under the CAP have been administered to a beneficiary and the process must establish a mechanism to recoup, offset or collect any overpayments to the approved CAP vendor. The CMS is implementing CAP claims processing changes in order to comply with THRCA by April 1, 2007. Pending CAP claims submitted prior to April 1, 2007 and all new CAP claims submitted on or after April 1 will be subject to the post payment review process.

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. For more information on the CAP claims processing see **FR70251**.