CMS Manual System	**Department of Health & Human Services (DHHS)**
Pub 100-04 Medicare Claims Processing	**Centers for Medicare & Medicaid Services (CMS)**
Transmittal 1076	**Date: OCTOBER 13, 2006**
	Change Request 5207

Subject: Competitive Acquisition Program (CAP) – Instructions on Special CAP Appeals Requirements and Delivery of Dispute Resolution Services

I. SUMMARY OF CHANGES: This CR provides instruction for local carriers and the CAP designated carrier on how to execute the appeals process within the unique requirements of the CAP.

New / Revised Material
Effective Date: July 1, 2006
Implementation Date: November 13, 2006

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	17 – Table of Contents
N	17/101 - The Competitive Acquisition Program (CAP) for Drugs and Instructions on Special CAP Appeals Requirements and Delivery of Dispute Resolution Services
N	17/101.1-Dispute Resolution Services for Vendors
N	17/101.2-Dispute Resolution Services for Physicians
N	17/101.3-Dispute Resolution Services for Beneficiaries

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:

One-Time Notification

Manual Instruction

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

Attachment – One Time Notification

Pub. 100-04	Transmittal: 1076	Date: October 13, 2006	Change Request: 5207

SUBJECT: Competitive Acquisition Program (CAP) – Instructions on Special CAP Appeals Requirements and Delivery of Dispute Resolution Services

I. GENERAL INFORMATION

NOTE: This is not a stand-alone change request (CR). This CR provides additional information and instructions for the implementation of the CAP pertaining to the CAP appeals and dispute resolution process. Previously published, related CAP CRs include: CRs 4064, 4306, 4309, 4404, and 5079.

A. Background

Section 303 (d) of the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003, requires the implementation of a competitive acquisition program (CAP) for Medicare Part B drugs and biologicals ("drugs") 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. A participating CAP physician will submit a claim for drug administration to the local carrier. An approved CAP vendor will submit a claim for the drug product to the CAP designated carrier.

B. Policy: CAP Appeals

The CAP claims processing arrangement departs from the standard Part B claims processing routine. For the CAP a local carrier will make an initial determination on whether the participating CAP physician's claim for drug administration is payable by applying local coverage determinations (LCDs) to the administration and to the drugs billed as no-pay on the claim. If the local carrier finds the no-pay or administration lines are contrary to the LCDs, it will deny the administration and pass on a non-approved indicator on the no-pay lines. The local carrier sends a pay process indicator to common working file (CWF) for each of the no-pay lines. When the Designated Carrier enters the vendor claim into the system, CWF looks for a match. When CWF goes to find the match, it will not match against non-approved lines. If it finds a match among the approved lines, then it lets the designated carrier know and the claim is paid. If it doesn't find a match, the claim recycles for 90 days. Periodically during the 90 days, the Designated Carrier looks for a match again. If it finds one the claim pays. If after 90 days, it does not find a match, then the claim denies. The local carrier will notify CWF whether the approved CAP vendor's claim for the drug is payable. If the vendor's claim is not payable because of a determination of the local carrier, then the designated carrier will be notified. In turn, the designated carrier will deny the approved CAP vendor's claim. The claims processing requirements for this process have been described in more detail in previous CAP CRs.

Because of this unique situation, if the approved CAP vendor wants to appeal denial of the drug claim, then it must appeal to the local carrier rather than the designated carrier. There is one exception to this

rule. When the approved CAP vendor's drug claim has been denied because there was no participating CAP physician's claim to match it with, then the designated carrier will suppress appeal rights and offer the approved CAP vendor a reopening. When the approved CAP vendor requests a reopening, the designated carrier will be stimulated to call the participating CAP physician and encourage him or her to fulfill his or her CAP participation agreement obligations by filing the drug administration claim. If the participating CAP physician does not follow through, then the designated carrier will engage in dispute resolution activities potentially resulting in a recommendation to terminate the participating CAP physician's involvement in CAP.

The traditional Part B appeals process is the appropriate route for a beneficiary and a participating CAP physician seeking review of a drug administration claim that has been denied by the local carrier. The participating CAP physician has an obligation under his or her CAP participation agreement to appeal the denial of a denied drug administration claim to the local carrier. The approved CAP vendor is a party to that drug administration appeal.

The approved CAP vendor may also appeal a denied drug product claim adjudicated by the designated carrier by appealing to the local carrier, provided the approved CAP vendor's claim was not denied due to there being no matching participating CAP physician drug administration claim. However, if the approved CAP vendor's drug product claim was denied by the designated carrier because the participating CAP physician did not file the connected drug administration claim, then the approved CAP vendor should contact the participating CAP physician and ask him or her to file the claim. If the participating CAP physician does not file the claim within 15 days as required by the participating CAP physician's election agreement, then the approved CAP vendor should contact the designated carrier for assistance with dispute resolution services.

II. BUSINESS REQUIREMENTS

"Shall" denotes a mandatory requirement
"Should" denotes an optional requirement

Requirement Number	Requirements	Responsibility ("X" indicates the columns that apply)								
		FI	RHHI	Carrier	DMERC	Shared System Maintainers				Other
						FISS	MCS	VMS	CWF	
5207.1	All redeterminations of denied drug administration claims shall be adjudicated by the local carrier, with one exception. Even though the drug product line of the claim is a no pay line, the local carrier's LCD/NCD shall apply. (See CMS CR 4064.6.0 – 4064.6.0.3.)			X						

Requirement Number	Requirements	Responsibility ("X" indicates the columns that apply)								
		FI	RHHI	Carrier	DMERC	Shared System Maintainers				Other
						FISS	MCS	VMS	CWF	
5207.1.1	The local carrier shall comply with the requirements of the Internet Only Manual (IOM), Chapter 29 in adjudicating redeterminations on CAP initial determinations.			X						
5207.2	The one exception is a claim that has been denied because there is no matching claim on file with the local carrier. The designated carrier shall deny the claim and suppress appeal rights if there is still no matching drug administration claim or contractor ID after 90 days.									Designated Carrier
5207.3	The Designated Carrier shall use group code CO for claims denied because the participating CAP physician has not filed his/her claim.									Designated Carrier
5207.3.1	The Designated Carrier shall return the following messages: MSN – 16.34 – You should not be billed for this service. You do not have to pay this amount. Remark code N211 – You may not appeal this decision.									Designated Carrier
5207.3.1.1	These messages are in addition to BR 4064.9.2.1 which also provides MSN message 21.21 and RA reason code 107 for these claim denials.									Designated Carrier
5207.4	The Designated Carrier shall assist the approved CAP vendor to complete a reopening if contacted about a N211 denial following the instructions outlined in IOM Chapter 29, section 90.									Designated Carrier
5207.4.1	The designated carrier shall then commence delivering dispute resolution services by calling the participating CAP physician to encourage him or her to comply with his or her contractual CAP obligations and file the drug administration claim.									Designated Carrier

Requirement Number	Requirements	Responsibility ("X" indicates the columns that apply)								
		FI	RHHI	Carrier	DMERC	Shared System Maintainers				Other
						FISS	MCS	VMS	CWF	
5207.4.2	If the participating CAP physician has instructed the approved CAP vendor that the drug administration claim has been filed, then the approved CAP vendor may request that the designated carrier reopen and reprocess the drug product claim									Designated Carrier
5207.5	July – September 2006: The local carrier shall document it in the MCS ICN comment screen when a reopening is performed on the physician administration/drug claim to correct the prescription number.			X						
5207.5.1	The local carrier shall alert the designated carrier by phone-and by fax if requested-that a reopening to correct the prescription number has occurred with in five business days of performing the MCS documentation in BR5207.5.			X						
5207.5.1.1	Prior to the implementation date of this change request, the designated carrier shall provide point of contact(s) to the local carriers and each local carrier shall provide point of contact(s) to the designated carrier for the purposes of these business requirements via the weekly Functional Workgroup call. The designated carrier shall be responsible for initiating contact with any carrier(s) they have not exchanged point of contact information with during the weekly Functional Workgroup call.			X						Designated carrier
5207.5.2	The local carrier shall indicate the state, contact name and phone number.			X						
5207.5.2.1	The local carrier shall be required to pass the Privacy Act requirements.			X						
5207.5.2.2	The local carrier shall provide the following information: Beneficiary HIC, date of service, drug HCPC code, physicians UPIN/NPI, billed amount, the incorrect prescription number and the correct prescription number.			X						

Requirement Number	Requirements	Responsibility ("X" indicates the columns that apply)								
		FI	RHHI	Carrier	DMERC	Shared System Maintainers				Other
						FISS	MCS	VMS	CWF	
5207.5.3	The designated carrier shall evaluate the information to determine if a reopening is warranted on the vendor claim.									Designated Carrier
5207.6	The local carrier shall check for duplicate CAP appeals by comparing the ICNs, DOS and prescription numbers connected with each CAP appeal.			X						
5207.6.1	The local carrier shall remove the subsequent request(s) after combining with the original request if duplicate appeal requests are received.			X						
5207.6.2	The local carrier shall send a notification letter to all parties upon completion of the original request after combining requests. The term "party" refers to the applicable Medicare beneficiary, CAP physician, and the CAP vendor.			X						
5207.6.3	The local carrier shall use the One-Time Representative (OTR) record to generate additional letters.			X						
5207.7	The local carrier shall include the approved CAP vendor on the provider OTR screen.			X						
5207.7.1	The local carrier shall determine the approved CAP vendor's name and address from the VIN appearing as part of the prescription number on the claim. Positions 1-4 of the prescription number will indicate the VIN. See CMS CR 4064.3.2.0.1 for the breakdown of the prescription number.			X						
5207.7.2	The local carrier shall determine the approved CAP vendor's address by consulting the CAP web page at http://www.cms.hhs.gov/CompetitiveAcquisforBios/01_overview.asp#TopOfPage .			X						
5207.8	The designated carrier shall educate the approved CAP vendor that supporting									Designated Carrier

Requirement Number	Requirements	Responsibility ("X" indicates the columns that apply)								
		FI	RHHI	Carrier	DMERC	Shared System Maintainers				Other
						FISS	MCS	VMS	CWF	
	documentation must accompany the request for a redetermination. Supporting documentation, as identified in the IOM Chapter 29, Section 310.4, is defined as: • The remittance notice; • Medical records; • Certifications; and • Any other information that will verify that administration of the drug was a covered benefit and within the scope of current medical review policy.									
5207.9	The designated carrier shall assist the approved CAP vendor in locating supporting documentation and obtaining it from the local carrier if necessary in its role as the provider of dispute resolution services under CAP.									Designated Carrier
5207.10	The Designated Carrier shall review relevant facts and provide dispute resolution services designed to address all CAP service, quality, health, safety and billing issues within two business days (48 hours). If the designated carrier foresees the inability to meet the predetermined timeframes for completion the designated carrier shall request an extension by e-mail to the CMS Project Officer and the Director of the Division Ambulatory Services copying the relevant local carrier. The request should include a brief explanation of the need for an extension and an estimate time for completion. CMS will reply to all with a decision on the request for an extension.									Designated Carrier
5207.10.1	The designated carrier shall identify specific issues and develop solutions that will satisfy both parties.									Designated Carrier

Requirement Number	Requirements	Responsibility ("X" indicates the columns that apply)								
		FI	RHHI	Carrier	DMERC	Shared System Maintainers				Other
						FISS	MCS	VMS	CWF	
5207.11	The designated carrier shall accept reports of emergent drug safety issues from any member of the Medicare community including, but not limited to, providers, local carriers and other Medicare contractors, and beneficiaries. An emergent safety issue is one that directly affects a beneficiary's ability to safely and appropriately receive a scheduled drug administration. Emergent safety issues may be a one time isolated event or may be the result of chronic, ongoing and unresolved routine issues. These issues may include, but are not limited to, drug quality issues such as contamination, counterfeit drugs, drug shortage and other ongoing, unresolved issues.									Designated Carrier
5207.11.1	The designated carrier shall notify the CMS CAP Project Officer and the Director of the Division of Ambulatory Services (Center for Medicare Management, Hospital and Ambulatory Policy Group) immediately upon receipt of any such notice.									Designated Carrier
5207.12	The local carrier shall provide information and records to the designated carrier and CMS, within two working days (48 hours), upon request, when an investigation is underway into whether a physician's or vendor's CAP participation should be terminated. If the local carrier foresees the inability to meet the predetermined timeframes for completion, the local carrier shall contact the designated carrier by e-mail to request an extension. The request should include a brief explanation of the need for an extension and an estimate time for completion. The designated carrier shall request an extension by e-mail to the CMS Project Officer and the Director of the Division Ambulatory Services copying the relevant local carrier. CMS will reply to all with a decision on			X						

Requirement Number	Requirements	Responsibility ("X" indicates the columns that apply)								
		FI	RHHI	Carrier	DMERC	Shared System Maintainers				Other
						FISS	MCS	VMS	CWF	
	the request for an extension.									
5207.13	The local carrier shall provide, by fax to the number provided by the designated carrier at the point of contact, information and records to the designated carrier and CMS, within two working days, upon request, when a participating CAP physician or an approved CAP vendor has requested a reconsideration of a termination decision.			X						
5207.14	CMS may suspend a vendor while considering a termination decision. Under a vendor suspension scenario CMS will invoke the disaster instructions established in CR5079 in BRs5079.10-12.3.1. Thus, the local carrier shall accept drug product claims from physicians during the period the vendor's termination decision is under reconsideration by CMS, and pay those claims pursuant to ASP and the designated carrier shall reject claims from the suspended vendor for the period of the suspension CMS will notify both the local carrier and the designated carrier of the suspension period by a Joint Signature Memo (JSM).			X						Designated Carrier
5207.15	The designated carrier shall inform the local carrier when the dispute resolution process stimulates the designated carrier to make a determination that the local carrier processed a claim incorrectly causing an overpayment for the claims filed by both the participating CAP physician and the approved CAP vendor.									Designated Carrier
5207.16	Medicare Contractors shall retroactively apply the business requirements in this change request to any claims erroneously adjudicated between July 1, 2006 and September 1, 2006 brought to			X						Designated Carrier

Requirement Number	Requirements	Responsibility ("X" indicates the columns that apply)								
		FI	RHHI	Carrier	DMERC	Shared System Maintainers				Other
						FISS	MCS	VMS	CWF	
	their attention. Contractors need not proactively search their files to retroactively apply these requirements. However, contractors shall retroactively apply the requirements for claims brought to their attention.									

III. PROVIDER EDUCATION

Requirement Number	Requirements	Responsibility ("X" indicates the columns that apply)								
		FI	RHHI	Carrier	DMERC	Shared System Maintainers				Other
						FISS	MCS	VMS	CWF	
5207.17	An appeals and dispute resolution article related to this instruction will be available at www.cms.hhs.gov/MLNMattersArticles shortly after the CR is released. Notification of the article release will be distributed 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 1 week of the availability of the provider education article. In addition, the provider education article shall be included in your next regularly scheduled bulletin and incorporated into any educational events on this topic. 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.			X						

IV. SUPPORTING INFORMATION AND POSSIBLE DESIGN CONSIDERATIONS

A. Other Instructions:

X-Ref Requirement #	Instructions

B. Design Considerations: N/A

X-Ref Requirement #	Recommendation for Medicare System Requirements

C. Interfaces: N/A

D. Contractor Financial Reporting /Workload Impact: N/A

E. Dependencies: N/A

F. Testing Considerations: N/A

V. SCHEDULE, CONTACTS, AND FUNDING

Effective Date*: July 1, 2006 **Implementation Date:** November 13, 2006 **Pre-Implementation Contact(s):** For CAP Policy, Mark Newsom, mark.newsom@cms.hhs.gov. **Post-Implementation Contact(s):** Appropriate Medicare Administrative Contractor	**No additional funding will be provided by CMS; contractor activities are to be carried out within their FY 2007 operating budgets.**

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

Medicare Claims Processing Manual
Chapter 17 - Drugs and Biologicals

Table of Contents
(Rev. 1076, 10-13-06)

101 - The Competitive Acquisition Program (CAP) for Drugs and Instructions on Special CAP Appeals Requirements and Delivery of Dispute Resolution Services

(Rev. 1076, Issued: 10-13-2006; Effective: 07-01-06; Implementation: 11-13-06)

All appeals of denied CAP claims will be processed by the local carrier. This includes an appeal for the denial of an approved CAP vendor's drug product claim. This break from the traditional administrative appeals process is necessitated by the arrangement whereby the CAP designated carrier pays the approved CAP vendor claim only after a match is found in the central claims processing system indicating the corresponding participating CAP physician's drug administration claim was paid by the local carrier. As a result, the only appealable issues attach to the decision of the local carrier.

The CAP claims processing arrangement departs from the standard Part B claims processing routine. The local carrier will make an initial determination on whether the participating CAP physician's claim for drug administration is payable by applying local coverage determinations (LCDs) to the administration and to the drugs billed as no-pay on the claim. If the local carrier finds the no-pay or administration lines are contrary to the LCDs, it will deny the administration and pass on a non-approved indicator on the no-pay lines. The local carrier sends a pay process indicator to CWF for each of the no-pay lines. When the designated carrier enters the vendor claim into the system, CWF looks for a match. When CWF goes to find the match, it will not match against non-approved lines. If it finds a match among the approved lines, then it lets the designated carrier know and the claim is paid. If it doesn't find a match, the claim recycles for 90 days. Periodically during the 90 days, the designated carrier looks for a match again. If it finds one, the claim pays. If after 90 days it doesn't find a match, then the claim denies. The local carrier will notify CWF whether the approved CAP vendor's claim for the drug is payable. If the vendor's claim is not payable because of a determination of the local carrier, then the designated carrier will be notified. In turn, the designated carrier will deny the approved CAP vendor's claim. The claims processing requirements for this process have been described in previous CAP Change Requests.

Because the local carrier's initial determination on the drug administration claim decides the outcome of the of the approved CAP vendor's drug product claim, CMS interprets the initial determination to be an initial determination of the approved CAP vendor's drug product claim for the purposes of the Part B appeals regulations found at 42 CFR 405.801 Accordingly, the approved CAP vendor shall not file its appeal with the CAP designated carrier. Rather, the approved CAP vendor shall file its appeal with the local carrier, with one exception.

That exception is the case where the approved CAP vendor's drug product claim was denied because there was no matching claim filed by the participating CAP physician after 90 days of recycling. In this instance, the designated carrier will deny the approved CAP vendor's drug product claim and suppress appeal rights. The remittance notice will instruct the approved CAP vendor that it may request a reopening. Upon receipt of a reopening request, the designated carrier will contact the participating CAP physician

and request that he or she fulfill his or her CAP participation agreement by filing the drug administration claim. If the participating CAP physician does not follow through as required, then the designated carrier will initiate the dispute resolution track discussed below.

In the role of the furnishing Medicare supplier, the approved CAP vendor is a party to any appeal of a denied drug administration claim filed by a participating CAP physician with the local carrier. The balance of the rules pertaining to the local carrier's adjudication of Part B appeals applies (See Pub. 100-04, Chapter 29), with the following exceptions:

a) *The local carrier will check for duplicate appeals. If the participating CAP physician and the approved CAP vendor filed independent appeals connected with the same service, then the local carrier will merge the two files.*

b) *The local carrier will ensure the approved CAP vendor is copied on all correspondence connected with the participating CAP physician's appeal of the denied drug administration claim.*

101.1-Dispute Resolution Services for Vendors

(Rev. 1076, Issued: 10-13-2006; Effective: 07-01-06; Implementation: 11-13-06)

The CAP designated carrier has responsibility to deliver dispute resolution services to the approved CAP vendor when the approved CAP vendor's drug product claims are not paid because the participating CAP physician has either failed to file a payable drug administration claim or has failed to file a successful appeal of the denied drug administration claim.

The approved CAP vendor may file its drug product claim on the day it delivers the drug to the participating CAP physician. The participating CAP physician is contractually obligated to file his or her CAP drug administration claim within 14 days of administering the drug.

The approved CAP vendor may determine its own threshold for financial exposure. If the approved CAP vendor does not receive payment within 14 days, then the approved CAP vendor may request assistance from the CAP designated carrier in encouraging the participating CAP physician to fulfill his or her contractual obligations. If the CAP designated carrier's dispute resolution services do not yield adequate results for the approved CAP vendor, then the approved CAP vendor may request that the CAP designated carrier investigate the participating CAP physician's performance and recommend that the participating CAP physician's CAP election agreement be terminated. If the CAP designated carrier does recommend termination, then a suspension, hearing, and final termination process set forth in 42 CFR 414.916 will be employed by CMS.

101.2-Dispute Resolution Services for Physicians

(Rev. 1076, Issued: 10-13-2006; Effective: 07-01-06; Implementation: 11-13-06)

If a participating CAP physician has an issue concerning the quality or safety of the services and/or drug delivered by the approved CAP vendor, then the participating CAP physician should address that issue through the approved CAP vendor's grievance process. If the participating CAP physician is not satisfied with the results of the approved CAP vendor's grievance process, then the participating physician may ask the CAP designated carrier to review the situation and encourage the approved CAP vendor to comply with its contractual obligations. If the approved CAP vendor refuses to comply with its contractual CAP obligations, then the CAP designated carrier may recommend to CMS that the approved CAP vendor's participation in CAP be terminated. If the CAP designated carrier does recommend termination, then a suspension, hearing, and final termination process set forth in 42 CFR 414.917 will be employed by CMS.

101.3-Dispute Resolution Services for Beneficiaries

(Rev. 1076, Issued: 10-13-2006; Effective: 07-01-06; Implementation: 11-13-06)

The approved CAP vendor is not permitted to bill the beneficiary for any coinsurance or deductible until the approved CAP vendor's drug product claim has been paid by the designated carrier. If the approved CAP vendor does bill the beneficiary before payment on the drug claim has been received, or if the approved CAP vendor bills the beneficiary too much after the drug product claim has been paid, then the beneficiary may use the approved CAP vendor's grievance process to challenge the inappropriate billing. If the approved CAP vendor's grievance process does not yield satisfactory results for the beneficiary, then the beneficiary may ask the CAP designated carrier to counsel the approved CAP vendor on its contractual CAP obligations.