

<b>CMS Manual System</b>	<b>Department of Health &amp; Human Services (DHHS)</b>
<b>Pub 100-04 Medicare Claims Processing</b>	<b>Centers for Medicare &amp; Medicaid Services (CMS)</b>
<b>Transmittal 1034</b>	<b>Date: AUGUST 18, 2006</b>
	<b>Change Request 5259</b>

**SUBJECT: Competitive Acquisition Program (CAP) – Claim Processing for Not Otherwise Classified (“NOC”) 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, 4309 and 5079.

**Effective Date: January 1, 2007**

**Implementation Date: January 2, 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
N	17/100.8.3/CAP Not Otherwise Classified (NOC) Drugs
N	17/100.8.3.1/Editing for CAP NOC Drugs

**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: 1034	Date: August 18, 2006	Change Request: 5259
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**SUBJECT: Competitive Acquisition Program (CAP) – Claim Processing for Not Otherwise Classified (“NOC”) Drugs**

## **I. GENERAL INFORMATION**

**NOTE:** This is not a stand-alone Change Request (CR). This CR provides additional details, information and instructions for the implementation of the CAP as outlined in CRs 4064, 4306, 4309 and 5079. The term “carrier” used in this document will be superseded by the term “MAC” during the ongoing contractor reform process.

### **A. Background:**

A basic background on CAP has been provided in the aforementioned CRs. The CAP has been implemented with a single category of drugs and one geographic area, however as the program evolves, additional geographic areas and additional drug categories may be created. Approved CAP vendors will also be able to request approval for changes to the lists of drugs that they supply under the CAP. CR 4064 described requirements for carriers to develop provider files that list physicians who have enrolled with an approved CAP vendor and the category (or categories) of drugs that the CAP vendor will furnish under the CAP. CR 5079 described the use of automated tables for provider information and the expansion of the CAP fee schedule file layout associated with adding drugs that are available through the CAP. CR 5079 specifically outlined several methods for making changes to the list of drugs that an approved CAP vendor supplies under the CAP. This CR describes the process for adding NOC Drugs to the CAP beginning in 2007. The CAP still operates under one drug category.

### **B. Policy:**

Medicare Part B claims for NOC drugs may be submitted under several HCPCS codes, including J3490, J3590 and J9999. CMS publishes a list of NOC drugs and provides quarterly updates on the ASP website (See the downloads section of [http://www.cms.hhs.gov/McrPartBDrugAvgSalesPrice/02\\_aspfiles.asp#TopOfPage](http://www.cms.hhs.gov/McrPartBDrugAvgSalesPrice/02_aspfiles.asp#TopOfPage) ). The ASP NOC drug list contains a variety of drugs, but also includes drugs that have been recently introduced to the market and are awaiting approval of specific HCPCS codes. Currently, drugs not identified in an approved CAP vendor’s drug list, including NOC drugs, may be purchased and billed through the Average Sales Price (ASP); “buy and bill”) process. As discussed in the November 2005 CAP final rule and in response to public comments about beneficiary access to new medications, CMS provided for the addition of “NOC” drugs to the CAP beginning in 2007. CMS believes that the addition of “NOC” drugs to the CAP will improve beneficiaries’ access to newly marketed drugs that have a national sales price, will decrease the reliance on buy and bill acquisition and will further simplify the drug acquisition process for physicians who have elected to participate in the CAP.

The process for adding NOC drugs to the CAP will basically follow the process for adding other drugs to the CAP as described in CR5079. An approved CAP vendor will be required to submit a written request to add specific NOC drugs to the CAP designated carrier. The request must include a rationale for the proposed change, and a discussion of the impact on the CAP, including safety, waste, and potential for

cost savings. If approved, changes will become effective at the beginning of the following quarter. CMS will post the changes on the CMS website ( [www.cms.hhs.gov/CompetitiveAcquisforBios/](http://www.cms.hhs.gov/CompetitiveAcquisforBios/) ) and notify the carriers and participating CAP physicians of any changes on a quarterly basis. Participating CAP physicians will be notified of changes to their approved CAP vendor’s CAP drug list on a quarterly basis and at least 30 days before the approved changes are due to take effect. Physicians who participate in the CAP are required to obtain all CAP drugs on the updates from the approved CAP vendor unless medical necessity requires the use of a formulation not supplied by the vendor. Approvals apply only to the CAP vendor who submitted the request and to the category identified on the request. Therefore, each vendor’s drug list may contain different drugs after changes to the initial drug list are approved. The timeline for adding NOC drugs to the vendor’s drug list and dissemination of corresponding updated information to physicians and carriers will be the same as the timeline for HCPCS code changes listed in CR5079.

The process to approve CAP NOC drugs differs from the process for other CAP drug approvals in two significant ways. First, CMS will define a list of CAP NOC drugs that the approved CAP vendor must use when requesting the addition of NOC drugs to the CAP. The CAP NOC drug list will be based on the ASP NOC list, but will include only drugs that are both likely to fit the existing CAP drug category (or categories) and drugs that have a single national ASP-based payment amount. The CAP NOC drug list will be posted on the CMS CAP website and updated quarterly. Second, CMS will require the use of a CAP-specific Q code for CAP NOC drug claims in order to distinguish CAP NOC drug claims from ASP NOC claims and to prevent the CAP claims from being paid outside the Medicare Part B drug CAP. Physician and vendor claims for CAP NOC drugs shall be required to use this code and to identify the specific NOC drug that had been administered; all other claim parameters will remain the same. The CAP NOC Q code and descriptor will be released in October 2006; additional guidance will be provided at that time. Note that physicians who have elected to participate in the CAP may still use ASP NOC codes when billing for NOC drugs that are outside the CAP.

The CAP NOC drug payment amount will be at the same rate as published on the ASP NOC file consistent with the next quarterly update; the payment amount will be updated annually as for other CAP drugs. Applicable regulation text describing the CAP NOC codes may be found at 42 CFR 414 Subpart K.

## II. BUSINESS REQUIREMENTS

*“Shall” denotes a mandatory requirement*

*“Should” denotes an optional requirement*

Requirement Number	Requirements	Responsibility (“X” indicates the columns that apply)								
		F	R	C	D	Shared System Maintainers				Other
		I	H	a	M	F	M	V	C	
			H	r	E	I	C	M	W	
			I	r	R	S	S	S	F	
				e	C					
				r						

Requirement Number	Requirements	Responsibility (“X” indicates the columns that apply)								
		F I	R H I	C a r r i e r	D M E R C	Shared System Maintainers				Other
						F I S S	M C S	V M S	C W F	
5259.1	Contractors shall process and pay CAP NOC Drug claims in a manner consistent with CRs 4064, 4306, 4309 and 5079, other pertinent CMS guidance, and updates to existing guidance.			X			X			
5259.1.2	Contractors shall require CAP modifiers with the CAP NOC HCPCS code as for any other CAP drugs.			X						
5259.1.3	Contractors shall pay for new CAP drugs approved for inclusion in the approved CAP vendor’s CAP drug list before they are assigned a HCPCS code at the price published in the ASP’s “not otherwise classified” (NOC) price file consistent with the next quarterly update.									Designated Carrier
5259.1.4	Contractors shall begin processing CAP NOC claims effective with claims with dates of service on or after January 1, 2007.			X			X		X	Designated Carrier
5259.2	Contractors shall accept and identify CAP NOC claims by a CAP-specific Q Code. The Q code and descriptor will be released in Fall 2006.			X			X			Designated Carrier
5259.2.1	Contractors shall apply the same edits to CAP NOC drug claims that they currently apply to other NOC drugs.			X						Designated Carrier
5259.2.2	Contractors shall verify per the description of the drug submitted on the claim, that the drug is part of the approved CAP drug category for that vendor.			X						Designated Carrier
5259.3	Contractors shall receive the descriptions of the acceptable CAP NOC drug additions and updates along with other CAP drug updates.			X			X			Designated Carrier

Requirement Number	Requirements	Responsibility (“X” indicates the columns that apply)								
		F I	R H I	C a r r i e r	D M E R C	Shared System Maintainers				Other
						F I S S	M C S	V M S	C W F	
5259.3.1	Contractors shall note that more than one drug description may correspond to the CAP NOC Q code and the Q code may represent a different group of drugs for each vendor for each category.			X			X			Designated Carrier
5259.3.2	Timeline for information associated with CAP NOC drugs shall correspond to the timeline for adding new HCPCS codes to the CAP described in CR5079.			X			X			Designated Carrier
5259.4	The designated carrier shall update the files identified in BR 4064.1.3.1 and BR 4064.7.1.1 with CAP NOC drug additions and updates.									Designated Carrier
5259.5	<p>Should the carrier receive a CAP NOC code, but the description does not match a CAP NOC drug on the approved list, carriers shall treat the claim as unprocessable and return the following RA messages:</p> <p>Reason Code 16 – Claim/service lacks information which is needed for adjudication. Additional information is supplied using the remittance codes whenever appropriate.</p> <p>Remark Codes</p> <p>MA 130 – Your claims contains incomplete and/or invalid information, and no appeals rights are afforded because the claim is unprocessable. Please submit a new claim with the complete/correct information.</p> <p>N350 – Missing/incomplete/invalid description of a service for a Not Otherwise Classified (NOC) code or an Unlisted procedure.</p>			X						Designated Carrier

Requirement Number	Requirements	Responsibility (“X” indicates the columns that apply)								
		F I	R H I	C a r r i e r	D M E R C	Shared System Maintainers				Other
						F I S S	M C S	V M S	C W F	
5259.6	<p>Should a non-CAP physician submit the CAP NOC code, the carriers shall treat the claims as unprocessable and return the following RA messages:</p> <p>Reason Code 16 – Claim/service lacks information which is needed for adjudication. Additional information is supplied using the remittance codes whenever appropriate.</p> <p>Remark Codes</p> <p>MA 130 – Your claims contains incomplete and/or invalid information, and no appeals rights are afforded because the claim is unprocessable. Please submit a new claim with the complete/correct information.</p> <p>N56 – Procedure code billed is not correct/valid for the services billed or the date of service billed.</p>			X						
5259.7	<p>Should a CAP physician submit a J NOC code with a description of a CAP approved NOC drug, the carriers shall treat the claim as unprocessable and return the following RA messages:</p> <p>Reason Code 16 – Claim/service lacks information which is needed for adjudication. Additional information is supplied using the remittance codes whenever appropriate.</p> <p>MA 130 – Your claims contains incomplete and/or invalid information, and no appeals rights are afforded because the claim is unprocessable. Please submit a new claim with</p>			X						

Requirement Number	Requirements	Responsibility (“X” indicates the columns that apply)							
		F I	R H I	C a r r i e r	D M E R C	Shared System Maintainers			
F I S S	M C S					V M S	C W F		
	the complete/correct information.  N56 – Procedure code billed is not correct/valid for the services billed or the date of service billed.								

### III. PROVIDER EDUCATION

Requirement Number	Requirements	Responsibility (“X” indicates the columns that apply)							
		F I	R H I	C a r r i e r	D M E R C	Shared System Maintainers			
F I S S	M C S					V M S	C W F		
5259.8	A provider education article related to this instruction will be available at <a href="http://www.cms.hhs.gov/MLNMattersArticles">www.cms.hhs.gov/MLNMattersArticles</a> 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 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:**

<b>X-Ref Requirement #</b>	<b>Instructions</b>
CR 4064	Competitive Acquisition Program (CAP) for Part B Drugs
CR 4309	Additional Requirements for the Competitive Acquisition Program (CAP) for Part B Drugs
CR 5079	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 (RRB)

**B. Design Considerations: N/A**

<b>X-Ref Requirement #</b>	<b>Recommendation for Medicare System Requirements</b>

**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**

<p><b>Effective Date*:</b> January 1, 2007</p> <p><b>Implementation Date:</b> January 2, 2007</p> <p><b>Pre-Implementation Contact(s):</b> For CAP Policy, Edmund Kasaitis, edmund.kasaitis@cms.hhs.gov; For Claims Processing, Leslie Trazzi, leslie.trazzi@cms.hhs.gov.</p> <p><b>Post-Implementation Contact(s):</b> Appropriate Medicare carrier.  <a href="http://www.medicare.gov/Contacts/Include/DataSection/Questions/SearchCriteria.asp#astep2">www.medicare.gov/Contacts/Include/DataSection/Questions/SearchCriteria.asp#astep2</a></p>	<p><b>No additional funding will be provided by CMS; contractor activities are to be carried out within their FY 2007 operating budgets.</b></p>
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**\*Unless otherwise specified, the effective date is the date of service.**

## Chapter 17 - Drugs and Biologicals (Rev. 1034, 08-18-06)

### Table of Contents

*100.8.3- CAP Not Otherwise Classified (NOC) Drugs  
100.8.3.1 – Editing for CAP NOC Drugs*

### ***100.8.3- CAP Not Otherwise Classified (NOC) Drugs (Rev. 1034, Issued: 08-18-06; Effective: 01-01-07; Implementation: 01-02-07)***

*As described in Section 100.8.2, approved CAP vendors are able to request approval for changes to the list of drugs that they supply under the CAP. In an effort to improve beneficiary access to newly marketed drugs, approved CAP vendors will be able to request the addition of certain NOC drugs as defined by CMS to their drug lists for claims with dates of service on or after January 1, 2007.*

*The process for adding NOC drugs to an approved CAP vendor's drug list will generally follow the process for adding new drugs to the CAP. An approved CAP vendor is required to submit a written request to add specific NOC drugs to the CAP designated carrier. The request must include a rationale for the proposed change, and a discussion of the impact on the CAP, including safety, waste, and potential for cost savings. The CAP designated carrier will review the application and forward the information to CMS along with a recommendation for approval or denial. CMS will make a final decision upon review of the application and the designated carrier's recommendation. If approved, changes will become effective at the beginning of the following quarter. CMS will post the approved NOC additions along with other changes to the CAP Drug List on the CMS Web site ([www.cms.hhs.gov/CompetitiveAcquisforBios/](http://www.cms.hhs.gov/CompetitiveAcquisforBios/)).*

*Additions of NOC drugs apply only to the approved CAP vendor and the CAP category identified on the request. Therefore, each vendor's drug list may contain different drugs after changes to the initial drug list are approved. The timeline for this process follows the timeline for HCPCS code changes described in Manual Section 100.8.2. CMS will also continue to notify local carriers of any changes to the CAP drug list on a quarterly basis. Participating CAP physicians will also be notified of changes at least 30 days before the approved changes will become effective.*

*The process to approve CAP NOC drugs differs from the process for other CAP drug approvals in two significant ways. First, CMS will define a list of CAP NOC drugs that the approved CAP vendor must use when requesting the addition of NOC drugs to the CAP. The CAP NOC drug list is based on the current ASP NOC list and is limited to drugs that are likely to fit the existing CAP drug category (or categories) and drugs that*

*have a single national ASP-based payment amount. The list of CAP NOC drugs will be posted on the CMS CAP Web site ([www.cms.hhs.gov/CompetitiveAcquisforBios/](http://www.cms.hhs.gov/CompetitiveAcquisforBios/)) and updated quarterly. The CAP NOC drug payment amount is set at the rate published on the ASP NOC file consistent with the next quarterly update; the CAP NOC payment amount will be updated annually.*

*Second, physician administration claims and vendor drug claims for services related to CAP NOC drugs are required to use the CAP-specific Q-code for all CAP NOC drug claims along with the appropriate CAP modifiers. This code is necessary to distinguish CAP NOC drug claims from ASP NOC claims and to provide payment for CAP NOC drugs within the CAP. In addition to the use of the CAP NOC Q-code, CAP NOC claims must identify the specific NOC drug that had been administered. All remaining requirements concerning the proper submission of a claim continue to be effective, and claims processing for CAP NOC drug claims will follow procedures described in previous CAP CRs and applicable Manual sections. All current editing for other NOC codes shall also be applied to the CAP NOC code.*

*Participating CAP physicians will continue to use ASP NOC codes when billing for NOC drugs that are not included in the CAP category they have chosen. Participating CAP physicians are required to obtain all CAP drugs from the approved CAP vendor including any drugs added to the CAP drug list under this process, unless medical necessity requires the use of a formulation not supplied by the vendor.*

### ***100.8.3.1 – Editing for CAP NOC Drugs***

***(Rev. 1034, Issued: 08-18-06; Effective: 01-01-07; Implementation: 01-02-07)***

*Should the carrier receive a CAP NOC code, but the description does not match a CAP NOC drug on the approved list, carriers shall treat the claim as unprocessable and return the following RA messages:*

*Reason Code 16 – Claim/service lacks information which is needed for adjudication. Additional information is supplied using the remittance codes whenever appropriate.*

#### ***Remark Codes***

*MA 130 – Your claim contains incomplete and/or invalid information, and no appeals rights are afforded because the claim is unprocessable. Please submit a new claim with the complete/correct information.*

*N350 – Missing/incomplete/invalid description of a service for a Not Otherwise Classified (NOC) code or an Unlisted procedure.*

*Should a non-CAP physician submit the CAP NOC code, the carrier shall treat the claims as unprocessable and return the following RA messages:*

*Reason Code 16 – Claim/service lacks information which is needed for adjudication. Additional information is supplied using the remittance codes whenever appropriate.*

*Remark Codes*

*MA 130 – Your claim contains incomplete and/or invalid information, and no appeals rights are afforded because the claim is unprocessable. Please submit a new claim with the complete/correct information.*

*N56 – Procedure code billed is not correct/valid for the services billed or the date of service billed.*

*Should a CAP physician submit a J NOC code with a description of a CAP approved NOC drug, the carriers shall treat the claim as unprocessable and return the following RA messages:*

*Reason Code 16 – Claim/service lacks information which is needed for adjudication. Additional information is supplied using the remittance codes whenever appropriate.*

*MA 130 – Your claim contains incomplete and/or invalid information, and no appeals rights are afforded because the claim is unprocessable. Please submit a new claim with the complete/correct information.*

*N56 – Procedure code billed is not correct/valid for the services billed or the date of service billed.*