

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-04 Medicare Claims Processing	Centers for Medicare & Medicaid Services (CMS)
Transmittal 1506	Date: MAY 16, 2008
	Change Request 6010

SUBJECT: Competitive Acquisition Program (CAP): Updating Submission Deadlines for Quarterly Drug List Updates

I. SUMMARY OF CHANGES: Approved CAP vendors may request approval for changes to the lists of drugs that they supply under the CAP. In order to ensure that these requests are processed in a timely manner, the deadlines explicated in the Internet Only Manual (IOM) must be updated.

New / Revised Material

Effective Date: October 1, 2008

Implementation Date: October 6, 2008

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	17/100.8.2/Changes to the List of Drugs Supplied by Approved CAP Vendors

III. FUNDING:

SECTION A: For Fiscal Intermediaries and Carriers:

No additional funding will be provided by CMS; Contractor activities are to be carried out within their operating budgets.

SECTION B: For Medicare Administrative Contractors (MACs):

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. 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.

IV. ATTACHMENTS:

Business Requirements

Manual Instruction

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

Attachment - Business Requirements

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SUBJECT: Competitive Acquisition Program (CAP): Updating Submission Deadlines for Quarterly Drug List Updates

Effective Date: October 1, 2008

Implementation Date: October 6, 2008

I. GENERAL INFORMATION

A. Background:

Section 303 (d) of the Medicare Prescription Improvement and Modernization Act (MMA) of 2003 mandates the implementation of a CAP for Part B drugs and biologicals not paid on a cost or prospective payment basis. The CAP was implemented with a single category of drugs and one geographic area. Approved CAP vendors are able to request approval for changes to the lists of drugs that they supply under the CAP. Regulatory text at 42 CFR 414 subpart K describes the process used to amend an approved CAP vendor's drug list.

B. Policy:

This CR updates information for the CAP pertaining to requests for changes to a CAP drug list by an approved CAP vendor as outlined in CR 4309 and CR 5079. An approved CAP vendor may request approval for changes to the list of drugs that it supplies under the CAP. In order to ensure that these requests are processed in a timely manner, the deadlines explicated in the Internet Only Manual (IOM) must be updated. Approved CAP vendors may request that CMS (or its designee) approve the following types of changes.

Substitution: Approved CAP vendor may request approval to replace one or more drug products as identified by national drug codes (NDCs) in a Healthcare Common Procedure Coding System (HCPCS) code supplied by the approved CAP vendor with one or more NDCs.

Add newly issued HCPCS Codes: Approved CAP vendor may request that CMS allow it to supply additional drug products with new HCPCS codes under the CAP.

Additional NDCs: Approved CAP vendor may request that CMS allow it to supply additional NDCs under a HCPCS code that the approved CAP vendor already supplies under the CAP.

Newly approved drugs without HCPCS codes ("NOC" drugs): Approved CAP vendor may request that CMS allow it to supply a newly approved drug under the CAP before a permanent HCPCS code is assigned to the drug.

Orphan Drugs: Approved CAP vendor may request that CMS allowed it to supply single indication orphan drugs under the CAP.

Changes to the drug list: Written requests for changes to the approved CAP vendor's drug list must be submitted to CMS or the CAP designated carrier. The requests 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, routine changes will become effective at the beginning of the following quarter. CMS will post the changes on the CMS Web site (www.cms.hhs.gov/CompetitiveAcquisforBios/) and notify the carriers and participating CAP physicians of any changes on a quarterly basis via a recurring Change Request (CR).

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B MA C	D M E M A C	F I	C A R R I E R	R H I	Shared-System Maintainers				OTHER
							F I S S	M C S	V M S	C W F	
	changes has been updated.										ted Carrier

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B MA C	D M E M A C	F I	C A R R I E R	R H I	Shared-System Maintainers				OTH ER
							F I S S	M C S	V M S	C W F	
	None.										

IV. SUPPORTING INFORMATION

Section A: Other related instructions

X-Ref Requirement Number	Recommendations or other supporting information:
CR 4309	Additional Requirements for the Competitive Acquisition Program (CAP) for Part B Drugs

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

V. CONTACTS

Pre-Implementation Contact(s): Bonny Dahm, Bonny.Dahm@cms.hhs.gov or at 410-786-4006, or Edmund Kasaitis, Edmund.Kasaitis@cms.hhs.gov or 410-786-0477

Post-Implementation Contact(s): Bonny Dahm, Bonny.Dahm@cms.hhs.gov or at 410-786-4006, or Edmund Kasaitis, Edmund.Kasaitis@cms.hhs.gov or 410-786-0477

VI. FUNDING

Section A: For *Fiscal Intermediaries (FIs), Carriers, and Regional Home Health Carriers (RHHIs)* use only one of the following statements:

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

Section B: For *Medicare Administrative Contractors (MACs)*, use the following statement:

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. 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.

Medicare Claims Processing Manual

Chapter 17 - Drugs and Biologicals

100.8.2 - Changes to the List of Drugs Supplied by Approved CAP Vendors

(Rev. 1506; Issued: 05-16-08; Effective Date: 10-01-08; Implementation Date: 10-06-08)

The CAP will be 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.

As CMS continues to develop the CAP, additional geographical areas and additional drug categories may be created. If additional drug categories are created, certain drugs may appear in more than one drug category.

Approved CAP vendors will be permitted to request certain changes to the list of drugs that they supply under the CAP. Beginning in July 2006 with changes to be effective October 1, 2006, approved CAP vendors may request that CMS (or its designee) approve the following types of changes:

Substitution: Approved CAP vendor may request approval to replace one or more *drug products as identified by national drug codes (NDCs)* in a *Healthcare Common Procedure Coding System (HCPCS) code* supplied by the approved CAP vendor with one or more NDCs.

Add newly issued HCPCS Codes: Approved CAP vendor may request that CMS allow it to supply additional *drug products with new HCPCS codes* under the CAP.

Additional NDCs: Approved CAP vendor may request that CMS allow it to supply additional NDCs under a HCPCS code that the approved CAP vendor already supplies under the CAP.

Newly approved drugs without HCPCS codes (“NOC” drugs): Approved CAP vendor may request that CMS allow it to supply a newly approved drug under the CAP before a permanent HCPCS code is assigned to the drug.

Orphan Drugs: Approved CAP vendor may request that CMS allowed it to supply single indication orphan drugs under the CAP.

Regulation text describing the above may be found at 42 CFR 414 Subpart K.

Changes to the drug list. Written requests for changes to the approved CAP vendor's drug list must be submitted to CMS and the CAP designated carrier. The requests 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, *routine* changes will become effective at the beginning of the following quarter. CMS will post the changes on the CMS Web site (www.cms.hhs.gov/CompetitiveAcquisforBios/) and notify the carriers and participating CAP physicians of any changes on a quarterly basis *via a recurring Change Request (CR)*. 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. Please note that approved changes will apply only to the list of drugs supplied by the approved CAP vendor who submitted the request; therefore, each vendor's drug list may contain different drugs after changes to the initial drug list are approved.

Timeline for changes. *There will be one timeline for the submission of changes to the approved CAP vendor's drug list. For new HCPCS and/or NDC codes, and substitutions or changes to NDC codes supplied under an existing HCPCS code, the approved CAP vendor will be required to submit requests for drug list changes no later than four months before the beginning of the quarter in which the changes will take effect. Updated tables listing the HCPCS codes under a specific vendor's drug categories will be available 30 days prior to the start of the following quarter. NDC number changes will not require associated table modifications and will not affect established payment amounts. Physicians will be notified of these changes 30 days before the start of a quarter. Price files incorporating these changes will be available 7-14 days prior to the effective date for the corresponding changes. An example of the timeline for the July 1, 2008 HCPCS and NDC code changes appears below.*

Example of Timeline for HCPCS and NDC Additions

<i>Date</i>	<i>Action</i>
<i>3/1/2008</i>	<i>Vendor deadline to submit request for new HCPCS and/or NDCs</i>
<i>3/12/2008</i>	<i>CMS begins approval process to evaluate vendor request</i>
<i>5/24/2008</i>	<i>HCPCS and/or NDC changes approved to become effective July 1, 2008</i>
<i>5/30/2008</i>	<i>Per the approval of all clearance processes, CMS issues a CR regarding approved drug list changes and tables that will become effective July 1, 2008</i>
<i>6/2/2008</i>	<i>Designated carrier downloads HCPCS changes to the drug table. List posted onto the CMS web site. Physicians receive updated list of drugs from the CAP vendor.</i>
<i>6/5/2008</i>	<i>Local Carriers shall acquire HCPCS changes from the Designated Carrier</i>
<i>6/17-6/24/2008</i>	<i>Price file with new codes posted</i>
<i>7/1/2008</i>	<i>Effective date for additional HCPCS codes; beginning of next quarter</i>

Payment amount. The payment amount for new HCPCS codes added to an approved

CAP drug vendor's drug list will be ASP + 6%. Addition or substitution of NDC numbers under an existing HCPCS code supplied by an approved CAP vendor will not change the CAP single payment amount for that HCPCS code. CMS will update the single payment amount based on the approved CAP vendor's reported net acquisition costs for the category of drugs on an annual basis.