CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-04 Medicare Claims Processing	Centers for Medicare & Medicaid Services (CMS)
Transmittal 1055	Date: SEPTEMBER 11, 2006
	Change Request 5079

Transmittal 953, dated May 19, 2006, is being rescinded and replaced by Transmittal 1055, dated September 11, 2006. This CR is being re-issued to correct the definition of the Medicare Summary Notice 16.34 in Business Requirements 5079.11.2 and 5079.12.3.1 to match the current CMS definition. All other information remains the same.

SUBJECT: 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 (RRB) Beneficiaries

I. SUMMARY OF CHANGES: This CR provides additional information and instructions for the implementation of the CAP pertaining to the CAP drug categories and fee schedule as outlined in CR 4064.

NEW/REVISED MATERIAL

EFFECTIVE DATE: October 1, 2006

IMPLEMENTATION DATE: October 2, 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

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
R	17/Table of Contents
R	17/100.2.4/CAP Claims Submitted with Only the No Pay Line
R	17/100.4.7/CAP Fee Schedule
N	17/100.8.2/Changes to the List of Drugs Supplied by Approved CAP Vendors

III. FUNDING:

No additional funding will be provided by CMS; contractor activities are to be carried out within their FY 2006 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: 1055	Date: September 11, 2006	Change Request: 5079

Transmittal 953, dated May 19, 2006, is being rescinded and replaced by Transmittal 1055, dated September 11, 2006. This CR is being re-issued to correct the definition of the Medicare Summary Notice 16.34 in Business Requirements 5079.11.2 and 5079.12.3.1 to match the current CMS definition. All other information remains the same.

SUBJECT: 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)

I. GENERAL INFORMATION

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 The term "carrier" used in this document will be superseded by the term "MAC" during the ongoing contractor reform process.

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 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.

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. 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.

It has come to our attention that contractors will have to manually enter the drugs the provider has chosen into each of the provider files. The purpose of this CR is to automate that process and the process of updating the list of drugs paid under the CAP. In 2006, the CAP will be implemented with one drug category and one geographic area, but this process must also take into account the possibility of multiple geographic areas and multiple drug categories. The process must also be compatible with the addition of drugs to the category based on vendor request beginning in October 2006. In addition, it has been determined that an expansion to the CAP fee schedule file layout is necessary as are additional requirements for CAP beneficiaries. Finally, disaster contingency business requirements have been added. These requirements are intended to address situations where an approved CAP vendor is unable to fill CAP orders, or is no longer supplying drugs under the CAP.

In addition, CMS clarifies here that the term "administration" may also include procedures when appropriate per the HCPCS designations. Carriers will each make their own determinations as to how to define "administration" as it applies to the drugs in the CAP program.

B. Policy:

CAP Drugs and Drug Categories

This CR provides additional information and instructions for the implementation of the CAP pertaining to the CAP drug categories and fee schedule as outlined in CR 4064. Federal law at Section 1847B(a)(1)(B) of the Social Security Act (the Act) states that for purposes of implementing the CAP, ''the Secretary shall establish categories of competitively biddable drugs and biologicals. The Secretary shall phase in the program with respect to those categories beginning in 2006 in such manner as the Secretary determines to be appropriate. " The Act also permits the creation of appropriate geographic regions established by the Secretary for contract award purposes.

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 NDCs in a HCPCS code supplied by the approved CAP vendor with one or more other NDCs.

- Add newly issued HCPCS Codes: Approved CAP vendor may request that CMS allow it to supply additional 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.

- 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, 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. 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. 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 two timelines for the submission of changes to the approved CAP vendor's drug list. In cases where a new HCPCS code will be added to the list, the approved CAP vendor will be required to submit the changes no later than one week after the beginning of a quarter. Approval of the changes by CMS and designated carrier will occur within three weeks of receipt. Updated tables listing the HCPCS codes under a specific vendor's drug categories will be available 60 days prior to the start of the following quarter. Physicians will be notified of these changes 30 days before the start of a quarter. Price files incorporating these changes will be available two weeks prior to the effective date for the corresponding changes. Requests for changes and substitutions to NDC codes supplied under a HCPCS code will be due three weeks after the start of a quarter. NDC number changes will not require associated table modifications and will not affect established payment amounts. Examples of the July – October 2006 timeline for HCPCS code changes and NDC code changes appear below.

Timeline for HCPCS code changes

Date	**Action**
July 1, 2006	Begin CAP
July 7, 2006	Vendor requests for adding HCPCS codes due at CMS and designated carrier
August 1, 2006	CMS issues CR with approved HCPCS changes and tables that will become effective October 1, 2006
August 15, 2006	Designated Carrier adds HCPCS changes to table.
August 22, 2006	Local Carriers shall acquire HCPCS changes from Designated Carrier.
September 4, 2006	Physicians receive updated list of drugs from CAP vendor; list posted on CMS Web site
September 18, 2006	Price file with new codes posted
October 1, 2006	Effective date for additional HCPCS codes; beginning of next quarter

Timeline for NDC code changes

Date	**Action**
July 1, 2006	Begin CAP
July 21, 2006	Vendor requests for adding new NDCs under existing HCPCS code due at CMS and designated carrier
August 8, 2006	CMS approves NDC changes to become effective October 1, 2006
September 4, 2006	Physicians receive updated list of drugs from CAP vendor; list posted on CMS Web site
October 1, 2006	Effective date for additional HCPCS codes; beginning of next quarter

Payment amount. The payment amount for new HCPCS codes added to an approved CAP drug vendor's drug list will be ASP + 6 percent. 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.

The process for making changes to the CAP drug list is outlined in the attached manual language.

Additional Geographic Areas

The CAP will be implemented with one national geographic area and, as stated above, additional geographical areas may be created. Because CMS has not developed policy associated with additional geographic areas, the issue will not be addressed in the business requirements below. However, if such policy is developed in the future, additional business requirements will also be released.

Claims for Railroad Retirement Board (RRB) Beneficiaries

As claims for RRB beneficiaries can not be paid under the CAP, physicians should not order drugs for RRB beneficiaries under the program. However, should this occur, and the claim is sent to the carrier that processes claims for RRB beneficiaries, that carrier will treat the claim as unprocessable. The physician will have to resubmit the claim as a non-CAP claim with the drugs billed as ASP. The vendor will then have to look to the physician for reimbursement of the drugs that were mistakenly ordered under CAP.

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	
5079.1	Contractors shall expand the fee field in the CAP fee schedule, referenced in CR 4064.7.6, from 6 digits to 9 digits.						X			Designated Carrier
5079.1.1	Contractors shall expand the fee field to 6 dollar places and 3 cents places ($$$$$$¢¢) per the attached file layout.						X			Designated Carrier
5079.1.2	Contractors shall download a full file overlay upon notification from CMS of the file name.						X			Designated Carrier
5079.1.2.1	Contractors shall note that this file overlay shall include not only the current drugs with the expanded decimal places, but also any new drugs added to the category for October.						X			Designated Carrier
5079.2	Based on date of service, the contractor shall establish categories of drugs in tables by vendor in order to aid in the creation of the CAP provider files.						X			

Requirement Number	Requirements	Responsibility ("X" indicates the columns that apply)								
		FI	RHHI	Carrier	DMERC	Shared System Maintainers				Other
						FISS	MCS	VMS	CWF	
5079.2.1	Contractors shall develop a method whereby the tables of drug categories can be updated based on date of service by vendor in an automated fashion in order to avoid the current necessity of manual updates to each provider file at each carrier site.			X			X			Designated Carrier
5079.2.2	The Designated Carrier shall populate the appropriate tables with the appropriate drugs.									Designated Carrier
5079.3	Contractors shall receive notification of additions/deletions of drugs to categories by vendor by date of service through CMS Change Requests (CRs) on a quarterly basis.			X			X			Designated Carrier
5079.3.1	Per the timeline described in Section I.B, the Designated Carrier shall update the appropriate tables with the HCPCS codes.									Designated Carrier
5079.3.2	Per the timeline described in Section I.B, the contractors shall acquire the updated table from the Designated Carrier.									Designated Carrier
5079.4	Contractors shall code their systems to be able to add additional categories of CAP drug codes by vendor based on date of service that may be established at a later date.			X			X			
5079.4.1	Contractors shall code their systems to be able to end date entire categories of CAP drug codes by vendor based on date of service.			X			X			Designated Carrier
5079.4.2	Contractors shall receive notification of additions/end date of entire drug categories by vendor through CMS Change Requests (CRs).			X						Designated Carrier
5079.4.3	Contractors shall define the first category of drugs for CAP for all vendors as those found on the attached list until notified otherwise through a CMS CR.			X			X			Designated Carrier
5079.4.4	Contractors shall note that the CAP shall be implemented with one drug category.			X						Designated Carrier
5079.5	Contractors shall code their systems to allow for a particular drug to be part of more than one category.			X			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	
5079.6	For the table defined in 4064.1.1.2.1, when they receive the election forms from the providers, the contractors shall indicate for each provider which categories of drugs they have chosen to receive from which vendor.			X			X			
5079.7	Contractors shall find the Approved CAP Vendors' drug lists on the CMS Web site at: www.cms.hhs.gov/CompetitiveAcquisforBios/.			X						
5079.8	The contractor that processes RRB claims shall return as unprocessable claims it receives for RRB beneficiaries that include CAP services identified by the inclusion of the J1, J2, or J3 modifiers.									RRB Carrier
5079.8.1	The contractor shall return the following Remittance Advice messages: MA130 – 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.									RRB Carrier
5079.9	Carriers shall replace business requirement 4309.6.1 from CR 4309 with the following: Carriers shall return the following Claim Adjustment Reason Code and Remark Code messages when claims are received with invalid modifier combinations: Reason Code 4 - The procedure code is inconsistent with the modifier used or a required modifier is missing. Remark Code MA 130 - Your claim contains incomplete or invalid information, and no appeals rights are afforded because the claim is			X						

Requirement Number	Requirements	Responsibility ("X" indicates the columns that apply)								
		FI	RHHI	Carrier	DMERC	Shared System Maintainers				Other
						FISS	MCS	VMS	CWF	
	unprocessable. Please submit a new claim with the complete/correct information.									
5079.10	Upon notification from CMS that as of a particular date, a particular vendor is no longer operating due to a disaster/catastrophe, when contractors receive services on a claim with the modifier CR, Catastrophe/Disaster Related, from providers who have elected that vendor for the CAP program, contractors shall adjudicate the claim for the drug and the administration of that drug outside of the CAP and pay the drugs using the ASP methodology.			X			X			
5079.10.1	Contractors shall treat as unprocessable claim lines submitted with the CR modifier and the J1 or J2 modifiers.			X						
5079.10.1.1	Carriers shall return the following Remittance Advice messages: Reason Code 4 - The procedure code is inconsistent with the modifier used or a required modifier is missing. Remark Code MA130 – Your claim contains incomplete or invalid information, and no appeals rights are afforded because the claim is unprocessable, Please submit a new claim with the compete/correct information.			X						
5079.11	Should the Designated Carrier receive a claim from that vendor for a date of service after the date of the catastrophe/disaster, it shall deny the claim until further notice from CMS that the vendor is again available to provide drugs. CMS will provide the designated carrier with notification of a disaster and the appropriate dates for modification of relevant business requirements.									Designated Carrier

Requirement Number	Requirements	Responsibility ("X" indicates the columns that apply)								
		FI	RHHI	Carrier	DMERC	Shared System Maintainers				Other
						FISS	MCS	VMS	CWF	
5079.11.1	The Designated Carrier shall return the following Remittance Advice messages: 96 – Non-covered charges. Remark Code - M52 – Missing/incomplete/invalid "from" dates(s) of service.									Designated Carrier
5079.11.2	The Designated Carrier shall return the following Medicare Summary Notice messages: 21.21 – This service was denied because Medicare only covers this service under certain circumstances. 21.21 - Este servicio fue denegado porque Medicare solamente lo cubre bajo ciertas circunstancias. 16.34 – You should not be billed for this service. You are only responsible for any deductible and coinsurance amounts listed in the 'you may be billed' column. 16.34 - Usted no debería ser facturado por este servicio. Usted es responsable solamente por cualquier cantidad del deducible o coseguro que aparece bajo la columna titulada 'Podría Ser Facturado'.									Designated Carrier
5079.12	Upon notification from CMS that as of a particular date a particular vendor is no longer part of the CAP program for reasons other than a catastrophe/disaster, contractors shall end date the agreement on the provider file for that vendor.			X			X			
5079.12.1	Contractors shall adjudicate the claim for the drug and the administration of that drug outside of the CAP and pay the drugs using the ASP.			X						

Requirement Number	Requirements	Responsibility ("X" indicates the columns that apply)								
		FI	RHHI	Carrier	DMERC	Shared System Maintainers				Other
						FISS	MCS	VMS	CWF	
5079.12.2	Contractors shall treat as unprocessable claim lines received with the J1 or J2 modifiers from providers for vendors no longer in the CAP program with dates of service after the date the vendor has left the program.			X						
5079.12.2.1	Contractors shall return the following Remittance Advice messages: Reason Code 4 - The procedure code is inconsistent with the modifier used or a required modifier is missing. Remark Code MA130 – Your claim contains incomplete or invalid information, and no appeals rights are afforded because the claim is unprocessable, Please submit a new claim with the compete/correct information.			X						
5079.12.3	Should the Designated Carrier receive claims from vendors with dates of service after their end date with the program, the Designated Carrier shall deny the claims.									Designated Carrier
5079.12.3.1	The Designated Carrier shall return the following MSN and RA messages: Claim Adjustment Reason code 96 Non-covered charges. Claim Adjustment Reason Code 185 – The rendering provider is not eligible to perform the service billed. MSN 21.2 – The provider of this service is not eligible to receive Medicare Payments. 21.2 - El proveedor de estos servicios no es elegible para recibir pagos de Medicare. MSN 16.34 –You should not be billed for this									Designated Carrier

Requirement Number	Requirements	Responsibility ("X" indicates the columns that apply)								
		FI	RHHI	Carrier	DMERC	Shared System Maintainers				Other
						FISS	MCS	VMS	CWF	
	service. You are only responsible for any deductible and coinsurance amounts listed in the 'you may be billed' column. 16.34 - Usted no debería ser facturado por este servicio. Usted es responsable solamente por cualquier cantidad del deducible o coseguro que aparece bajo la columna titulada 'Podría Ser Facturado'.									
5079.13	Contractors shall continue to adjudicate the services outside of CAP and pay the drugs using the ASP until the physician has chosen a new vendor and submitted a new CAP election form.			X						
5079.14	BR 4064.1.2.0 in CR 4064 required contractors to forward to the Designated Carrier the information in BR 4064.1.1.2.1. Due to the changes implemented in this CR, contractors need only submit to the Designated Carrier the category of drugs that the provider has chosen from that vendor rather than the whole list of drugs.			X			X			Designated Carrier
5079.15	The contractor shall code the vendor table created in BR 4309.2 to be able to add a mailing/correspondence address for the physicians if different from the practice address.									Designated Carrier
5079.16	The contractor shall code the vendor table created in BR 4309.2 to be able to add multiple addresses for additional practice locations for the physicians.									Designated Carrier
5079.17	Contractors shall replace BR 4064.3.4 from CR 4064 with this BR and BR 5079.17.1. Physicians and practitioners shall be required to submit the claim line for the administration of the drug and the no-pay claim line for the drug on the same claim.			X						

Requirement Number	Requirements	Responsibility ("X" indicates the columns that apply)								
		FI	RHHI	Carrier	DMERC	Shared System Maintainers				Other
						FISS	MCS	VMS	CWF	
5079.17.1	Should contractors receive claim lines for drugs submitted with the no-pay modifier without a related claim line on the claim for the administration of that drug, they shall treat the no-pay claim line as unprocessable using the RA messages provided in BR4064.3.4.1 in CR 4064.			X						
5079.18	Carriers shall note that this business requirement clarifies that for BRs 4404.2.1, 4404.2.2, and 4404.5 from CR 4404 that the term "remove" or "delete" should be "end date" in order to allow for claims with prior dates of service to appropriately pay after a physician leaves the CAP program.			X						

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	
5079.19	A provider education article related to this instruction will be available at 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 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.			X						

Requirement Number	Requirements	Responsibility ("X" indicates the columns that apply)								
		FI	RHHI	Carrier	DMERC	Shared System Maintainers				Other
						FISS	MCS	VMS	CWF	
	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.									

IV. SUPPORTING INFORMATION AND POSSIBLE DESIGN CONSIDERATIONS

A. Other Instructions:

X-Ref Requirement #	Instructions
CR 4064	Competitive Acquisition Program (CAP) for Part B Drugs
CR 4309	Additional Requirements for the Competitive Acquisition Program (CAP) for Part B Drugs

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*: October 1, 2006 **Implementation Date:** October 2, 2006 **Pre-Implementation Contact(s):** For CAP Policy, Cassie Black, cassandra.black@cms.hhs.gov; For Claims Processing, Leslie Trazzi, leslie.trazzi@cms.hhs.gov.	**No additional funding will be provided by CMS; contractor activities are to be carried out within their FY 2006 operating budgets.**

Post-Implementation Contact(s): Appropriate Medicare carrier. www.medicare.gov/Contacts/Include/DataSection/Questions/SearchCriteria.asp#astep2	

*__Unless otherwise specified, the effective date is the date of service.__

Attachments (2)

Attachment

COMPETITIVE ACQUISITION PROGRAM FEE SCHEDULE FILE RECORD DESCRIPTION

Field Name	Position	Length	Format	Description
HCPCS	1-5	5	Character	Healthcare Common Procedure Coding System
Filler	6-7	2		Space Filled
State	8-9	2	Character	Alpha Abbreviation
Filler	10-11	2		Space Filled
Current Year	12-15	4	Character	YYYY
Filler	16-17	2		Space Filled
Current Quarter	18	1	Character	Calendar Quarter – value 1-4
Filler	19-20	2		Space Filled
Fee	21-29	9	Numeric	Fee to Pay For Drug $$$$$$¢¢ (Pic9(6)v999)
Filler	30-80	51	Character	Space Filled

CMS will upload the CAP Part B Drug file to the Direct Connect each calendar quarter. Approximately two weeks prior to the beginning of each calendar quarter (i.e., approximately 2 weeks prior to January 1, April 1, July 1, and October 1) an email will be sent out providing notification of the availability of the updated file.

Attachment

List of CAP Drugs at CAP Implementation

Effective for the CAP program July 1, 2006.

The following HCPCS codes will be supplied under the CAP in the single national geographic area. The list of CAP drugs consists of a single drug category.

HCPCS	Long Description
J0150	INJECTION, ADENOSINE FOR THERAPEUTIC USE, 6 MG
J0152	INJECTION, ADENOSINE FOR DIAGNOSTIC USE, 30 MG
J0170	INJECTION, ADRENALIN, EPINEPHRINE, 1 ML AMPULE
J0207	INJECTION, AMIFOSTINE, 500 MG
J0215	INJECTION, ALEFACEPT, 0.5 MG
J0280	INJECTION, AMINOPHYLLIN, 250 MG
J0290	INJECTION, AMPICILLIN SODIUM, 500 MG
J0475	INJECTION, BACLOFEN, 10 MG
J0540	INJECTION, PENICILLIN G BENZATHINE AND PENICILLIN G PROCAINE, 1,200,000 UNITS
J0550	INJECTION, PENICILLIN G BENZATHINE AND PENICILLIN G PROCAINE, 2,400,000 UNITS
J0570	INJECTION, PENICILLIN G BENZATHINE, 1,200,000 UNITS
J0585	BOTULINUM TOXIN TYPE A, PER UNIT
J0587	BOTULINUM TOXIN TYPE B, PER 100 UNITS
J0600	INJECTION, EDETATE CALCIUM DISODIUM, 1000 MG
J0637	INJECTION, CASPOFUNGIN ACETATE, 5 MG
J0640	INJECTION, LEUCOVORIN CALCIUM, PER 50 MG
J0670	INJECTION, MEPIVACAINE HYDROCHLORIDE, PER 10 ML
J0690	INJECTION, CEFAZOLIN SODIUM, 500 MG
J0692	INJECTION, CEFEPIME HYDROCHLORIDE, 500 MG
J0696	INJECTION, CEFTRIAXONE SODIUM, PER 250 MG
J0698	INJECTION, CEFOTAXIME SODIUM, PER GM
J0702	INJECTION, BETAMETHASONE ACETATE & BETAMETHASONE SODIUM PHOSPHATE, PER 3 MG
J0704	INJECTION, BETAMETHASONE SODIUM PHOSPHATE, PER 4 MG
J0735	INJECTION, CLONIDINE HYDROCHLORIDE, 1 MG
J0800	INJECTION, CORTICOTROPIN, 40 UNITS
J0881	INJECTION, DARBEPOETIN ALFA, 1 MCG (NON-ESRD USE)

J0885	INJECTION, EPOETIN ALPHA, (FOR NON ESRD USE), PER 1000 UNITS
J0895	INJECTION, DEFEROXAMINE MESYLATE, 500 MG
J1000	INJECTION, DEPO-ESTRADIOL CYPIONATE, 5 MG
J1020	INJECTION, METHYLPREDNISOLONE ACETATE, 20 MG
J1030	INJECTION, METHYLPREDNISOLONE ACETATE, 40 MG
J1040	INJECTION, METHYLPREDNISOLONE ACETATE, 80 MG
J1051	INJECTION, MEDROXYPROGESTERONE ACETATE, 50 MG
J1094	INJECTION, DEXAMETHASONE ACETATE, 1 MG
J1100	INJECTION, DEXAMETHASONE SODIUM PHOSPHATE, 1MG
J1190	INJECTION, DEXRAZOXANE HYDROCHLORIDE, PER 250 MG
J1200	INJECTION, DIPHENHYDRAMINE HCL, 50 MG
J1212	INJECTION, DMSO, DIMETHYL SULFOXIDE, 50%, 50 ML
J1245	INJECTION, DIPYRIDAMOLE, PER 10 MG
J1250	INJECTION, DOBUTAMINE HYDROCHLORIDE, PER 250 MG
J1260	INJECTION, DOLASETRON MESYLATE, 10 MG
J1335	INJECTION, ERTAPENEM SODIUM, 500 MG
J1440	INJECTION, FILGRASTIM (G-CSF), 300 MCG
J1441	INJECTION, FILGRASTIM (G-CSF), 480 MCG
J1450	INJECTION FLUCONAZOLE, 200 MG
J1580	INJECTION, GARAMYCIN, GENTAMICIN, 80 MG
J1600	INJECTION, GOLD SODIUM THIOMALATE, 50 MG
J1626	INJECTION, GRANISETRON HYDROCHLORIDE, 100 MCG
J1631	INJECTION, HALOPERIDOL DECANOATE, PER 50 MG
J1642	INJECTION, HEPARIN SODIUM, (HEPARIN LOCK FLUSH), PER 10 UNITS
J1644	INJECTION, HEPARIN SODIUM, PER 1000 UNITS
J1645	INJECTION, DALTEPARIN SODIUM, PER 2500 IU
J1650	INJECTION, ENOXAPARIN SODIUM, 10 MG
J1655	INJECTION, TINZAPARIN SODIUM, 1000 IU
J1720	INJECTION, HYDROCORTISONE SODIUM SUCCINATE, 100 MG
J1745	INJECTION INFLIXIMAB, 10 MG
J1756	INJECTION, IRON SUCROSE, 1 MG
J1885	INJECTION, KETOROLAC TROMETHAMINE, PER 15 MG
J1940	INJECTION, FUROSEMIDE, 20 MG
J1956	INJECTION, LEVOFLOXACIN, 250 MG
J2001	INJECTION, LIDOCAINE HCL FOR INTRAVENOUS INFUSION, 10 MG
J2010	INJECTION, LINCOMYCIN HCL, 300 MG
J2150	INJECTION, MANNITOL, 25% IN 50 ML
J2260	INJECTION, MILRINONE LACTATE, 5 MG
J2300	INJECTION, NALBUPHINE HYDROCHLORIDE, PER 10 MG
J2325	INJECTION, NESIRITIDE, 0.1 MG
J2353	INJECTION, OCTREOTIDE, DEPOT FORM FOR INTRAMUSCULAR INJECTION, 1 MG
J2354	INJECTION, OCTREOTIDE, NON-DEPOT SUBCUTANEOUS OR INTRAVENOUS INJECTION, 25 MCG

J2405	INJECTION, ONDANSETRON HYDROCHLORIDE, PER 1 MG
J2430	INJECTION, PAMIDRONATE DISODIUM, PER 30 MG
J2505	INJECTION, PEGFILGRASTIM, 6 MG
J2550	INJECTION, PROMETHAZINE HCL, 50 MG
J2680	INJECTION, FLUPHENAZINE DECANOATE, 25 MG
J2765	INJECTION, METOCLOPRAMIDE HCL, 10 MG
J2780	INJECTION, RANITIDINE HYDROCHLORIDE, 25 MG
J2820	INJECTION, SARGRAMOSTIM (GM-CSF), 50 MCG
J2912	INJECTION, SODIUM CHLORIDE, 0.9%, PER 2 ML
J2916	INJECTION, SODIUM FERRIC GLUCONATE COMPLEX IN SUCROSE INJECTION, 12.5 MG
J2920	INJECTION, METHYLPREDNISOLONE SODIUM SUCCINATE, 40 MG
J2930	INJECTION, METHYLPREDNISOLONE SODIUM SUCCINATE, 125 MG
J2997	INJECTION, ALTEPLASE RECOMBINANT, 1 MG
J3260	INJECTION, TOBRAMYCIN SULFATE, 80 MG
J3301	INJECTION, TRIAMCINOLONE ACETONIDE, PER 10MG
J3302	INJECTION, TRIAMCINOLONE DIACETATE, PER 5MG
J3303	INJECTION, TRIAMCINOLONE HEXACETONIDE, PER 5MG
J3315	INJECTION, TRIPTORELIN PAMOATE, 3.75 MG
J3370	INJECTION, VANCOMYCIN HCL, 500 MG
J3396	INJECTION, VERTEPORFIN, 0.1 MG
J3410	INJECTION, HYDROXYZINE HCL, 25 MG
J3420	INJECTION, VITAMIN B-12 CYANOCOBALAMIN, UP TO 1000 MCG
J3475	INJECTION, MAGNESIUM SULFATE, PER 500 MG
J3480	INJECTION, POTASSIUM CHLORIDE, PER 2 MEQ
J3487	INJECTION, ZOLEDRONIC ACID, 1 MG
J7030	INFUSION, NORMAL SALINE SOLUTION , 1000 CC
J7040	INFUSION, NORMAL SALINE SOLUTION, STERILE (500 ML=1 UNIT)
J7042	5% DEXTROSE/NORMAL SALINE (500 ML = 1 UNIT)
J7050	INFUSION, NORMAL SALINE SOLUTION , 250 CC
J7060	5% DEXTROSE/WATER (500 ML = 1 UNIT)
J7070	INFUSION, D5W, 1000 CC
J7120	RINGERS LACTATE INFUSION, 1000 CC
J7317	SODIUM HYALURONATE, PER 20 TO 25 MG DOSE FOR INTRA-ARTICULAR INJECTION
J7320	HYLAN G-F 20, 16 MG, FOR INTRA ARTICULAR INJECTION
J9000	DOXORUBICIN HCL, 10 MG
J9001	DOXORUBICIN HYDROCHLORIDE, ALL LIPID FORMULATIONS, 10 MG
J9031	BCG (INTRAVESICAL) PER INSTILLATION
J9040	BLEOMYCIN SULFATE, 15 UNITS
J9045	CARBOPLATIN, 50 MG
J9050	CARMUSTINE, 100 MG
J9060	CISPLATIN, POWDER OR S0LUTION, PER 10 MG
J9062	CISPLATIN, 50 MG

J9065	INJECTION, CLADRIBINE, PER 1 MG
J9070	CYCLOPHOSPHAMIDE, 100 MG
J9080	CYCLOPHOSPHAMIDE, 200 MG
J9090	CYCLOPHOSPHAMIDE, 500 MG
J9091	CYCLOPHOSPHAMIDE, 1.0 GRAM
J9092	CYCLOPHOSPHAMIDE, 2.0 GRAM
J9093	CYCLOPHOSPHAMIDE, LYOPHILIZED, 100 MG
J9094	CYCLOPHOSPHAMIDE, LYOPHILIZED, 200 MG
J9095	CYCLOPHOSPHAMIDE, LYOPHILIZED, 500 MG
J9096	CYCLOPHOSPHAMIDE, LYOPHILIZED, 1.0 GRAM
J9097	CYCLOPHOSPHAMIDE, LYOPHILIZED, 2.0 GRAM
J9098	CYTARABINE LIPOSOME, 10 MG
J9100	CYTARABINE, 100 MG
J9110	CYTARABINE, 500 MG
J9130	DACARBAZINE, 100 MG
J9140	DACARBAZINE, 200 MG
J9150	DAUNORUBICIN, 10 MG
J9170	DOCETAXEL, 20 MG
J9178	INJECTION, EPIRUBICIN HCL, 2 MG
J9181	ETOPOSIDE, 10 MG
J9182	ETOPOSIDE, 100 MG
J9185	FLUDARABINE PHOSPHATE, 50 MG
J9190	FLUOROURACIL, 500 MG
J9200	FLOXURIDINE, 500 MG
J9201	GEMCITABINE HCL, 200 MG
J9202	GOSERELIN ACETATE IMPLANT, PER 3.6 MG
J9206	IRINOTECAN, 20 MG
J9208	IFOSFAMIDE, 1 GM
J9209	MESNA, 200 MG
J9211	IDARUBICIN HYDROCHLORIDE, 5 MG
J9213	INTERFERON, ALFA-2A, RECOMBINANT, 3 MILLION UNITS
J9214	INTERFERON, ALFA-2B, RECOMBINANT, 1 MILLION UNITS
J9219	LEUPROLIDE ACETATE IMPLANT, 65 MG
J9245	INJECTION, MELPHALAN HYDROCHLORIDE, 50 MG
J9250	METHOTREXATE SODIUM, 5 MG
J9260	METHOTREXATE SODIUM, 50 MG
J9263	INJECTION, OXALIPLATIN, 0.5 MG
J9265	PACLITAXEL, 30 MG
J9268	PENTOSTATIN, PER 10 MG
J9280	MITOMYCIN, 5 MG
J9290	MITOMYCIN, 20 MG
J9291	MITOMYCIN, 40 MG
J9293	INJECTION, MITOXANTRONE HYDROCHLORIDE, PER 5 MG
J9310	RITUXIMAB, 100 MG
J9320	STREPTOZOCIN, 1 GM
J9340	THIOTEPA, 15 MG
J9350	TOPOTECAN, 4 MG
J9355	TRASTUZUMAB, 10 MG

J9360	VINBLASTINE SULFATE, 1 MG
J9370	VINCRISTINE SULFATE, 1 MG
J9375	VINCRISTINE SULFATE, 2 MG
J9390	VINORELBINE TARTRATE, PER 10 MG
J9395	INJECTION, FULVESTRANT, 25 MG
J9600	PORFIMER SODIUM, 75 MG
Q3025	INJECTION, INTERFERON BETA-1A, 11 MCG FOR INTRAMUSCULAR USE
J0128	ABARELIX INJECTION, 10 MG
J0180	AGALSIDASE BETA INJECTION, 1 MG
J0278	AMIKACIN, 100MG
J0878	DAPTOMYCIN INJECTION, 1 MG
J1751	IRON DEXTRAN 165, 50MG
J1752	IRON DEXTRAN 267, 50MG
J1931	LARONIDASE INJECTION, 0.1 MG
J2357	OMALIZUMAB INJECTION, 5 MG
J2469	PALONOSETRON HCL, 25MCG
J2503	PEGAPTANIB, 0.3MG
J2794	RISPERIDONE, LONG ACTING, 0.5MG
J9035	BEVACIZUMAB INJECTION, 10MG
J9041	BORTEZOMIB INJECTION, 0.1MG
J9055	CETUXIMAB INJECTION, 10MG
J9225	HISTRELIN IMPLANT, 50MG
J9264	PACLITAXEL PROTEIN BOUND PARTICLES, 1MG
J9305	PEMETREXED INJECTION, 10MG

Medicare Claims Processing Manual

Chapter 17 - Drugs and Biologicals

Table of Contents

(Rev. 1055, 09-11-06)

100.2.4 – CAP Claims Submitted with Only the No Pay Line

(Rev. 1055, Issued: 09-11-06; Effective: 10-01-06; Implementation: 10-02-06)

Physicians must submit their charges for the administration of CAP drugs and the no-pay lines on the same claim. Carriers shall treat as unprocessable claims received that only have services submitted with the no-pay modifier. Carriers shall return the following RA messages:

Claim Adjustment 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.

Remark Code M67 – Missing/incomplete/invalid other procedure code(s).

100.4.7 – CAP Fee Schedule

(Rev. 1055, Issued: 09-11-06; Effective: 10-01-06; Implementation: 10-02-06)

CMS will provide a fee schedule for the payment of CAP drugs to the designated carrier and MCS. The fees will be provided in a file on the CMS mainframe at a later date. The file layout is attached.

CAP PROGRAM FEE SCHEDULE FILE RECORD DESCRIPTION

Field Name	Position	Length	Format	Description
HCPCS	1-5	5	Character	Healthcare Common Procedure Coding System
Filler	6-7	2		Space Filled
State	8-9	2	Character	Alpha Abbreviation
Filler	10-11	2		Space Filled
Current Year	12-15	4	*Character*	YYYY
Filler	16-17	2		Space Filled
Current Quarter	18	1	*Character*	Calendar Quarter – value 1-4
Filler	19-20	2		Space Filled
Fee	*21-29*	*9*	Numeric	Fee to Pay For Drug $$$$$$*¢¢¢(Pic9(6)v999)*
Filler	*30-80*	*51*	Character	Space Filled

CMS will upload the CAP Part B Drug file to the Direct Connect each calendar quarter. Approximately six weeks prior to the beginning of each calendar quarter (i.e., approximately 6 weeks prior to January 1, April 1, July 1, and October 1) an email will be sent out providing notification of the availability of the updated file. The updated file will be available in the early November for the January 1 release, early February for the March 1 release, early May for the July 1 release, and early August for the September 1 release.

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

(Rev. 1055, Issued: 09-11-06; Effective: 10-01-06; Implementation: 10-02-06)

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 NDCs in a HCPCS code supplied by the approved CAP vendor with one or more other NDCs.*

- *Add newly issued HCPCS Codes: Approved CAP vendor may request that CMS allow it to supply additional 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.*

- *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, 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. 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. 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 two timelines for the submission of changes to the approved CAP vendor's drug list. In cases where a new HCPCS code will be added to the list, the approved CAP vendor will be required to submit the changes no later than one week after the beginning of a quarter. Approval of the changes by CMS and designated carrier will occur within three weeks of receipt. Updated tables listing the HCPCS codes under a specific vendor's drug categories will be available 60 days prior to the start of the following quarter. Physicians will be notified of these changes 30 days before the start of a quarter. Price files incorporating these changes will be available two weeks prior to the effective date for the corresponding changes. Requests for changes and substitutions to NDC codes supplied under a HCPCS code will be due three weeks after the start of a quarter. NDC number changes will not require associated table modifications and will not affect established payment amounts. Examples of the July – October 2006 timeline for HCPCS code changes and NDC code changes appear below.

Timeline for HCPCS code changes

Date	*Action*
July 1, 2006	*Begin CAP*
July 7, 2006	*Vendor requests for adding HCPCS codes due at CMS and designated carrier*
August 1, 2006	*CMS issues CR with approved HCPCS changes and tables that will become effective October 1, 2006*
August 15, 2006	*Designated Carrier adds HCPCS changes to table.*
August 22, 2006	*Local Carriers shall acquire HCPCS changes from Designated Carrier.*
September 4, 2006	*Physicians receive updated list of drugs from CAP vendor; list posted on CMS Web site*
September 18, 2006	*Price file with new codes posted*
October 1, 2006	*Effective date for additional HCPCS codes; beginning of next quarter*

Timeline for NDC code changes

Date	*Action*
July 1, 2006	*Begin CAP*
July 21, 2006	*Vendor requests for adding new NDCs under existing HCPCS code due at CMS and designated carrier*
August 8, 2006	*CMS approves NDC changes to become effective October 1, 2006*
September 4, 2006	*Physicians receive updated list of drugs from CAP vendor; list posted on CMS Web site*
October 1, 2006	*Effective date for additional HCPCS codes; beginning of next quarter*

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.