CMS Manual System

Pub 100-04 Medicare Claims Processing

Transmittal 866

Department of Health & Human Services (DHHS)

Centers for Medicare & Medicaid Services (CMS)

Date: FEBRUARY 17, 2006

Change Request 4309

NOTE: Transmittal 839, dated February 6, 2006, is rescinded and replaced with Transmittal 866 dated February 17, 2006. In both the BR 4309.9 and the manual instructions we referenced a table in BR 4064.7.6. We are changing this reference in the business requirement and the manual instruction to be BR 4064.1.1.2.1. All other information remains the same.

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

I. SUMMARY OF CHANGES This CR provides new requirements that were identified both during the coding process of CR 4064 and the publication of the final rule for the Competitive Acquisition Program for Medicare Part B drugs.

NEW/REVISED MATERIAL

EFFECTIVE DATE: July 1, 2006

IMPLEMENTATION DATE: July 3, 2006, and for Requirements 4309.13 implementation date is March 24, 2006 and 4309.14 implementation date is April 17, 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	21/50/50.7 /Duplicates
R	21/50/50.38 /General Information Section
R	21/90/90.7 /Duplicados
R	21/90/90.38 /Seccion De Informacion General

R	17/Table of Content
N	17/100/ The Competitive Acquisition Program (CAP) of Outpatient Drugs and Biologicals Under Part B.
N	17/100/100.1/Physician Election and Information Transfer Between Carriers and the Designated Carrier for CAP Claims
N	17/100/100.1.1/Physician Information for the Designated Carrier
N	17/100/100.1.1.1/Quarterly Updates
N	17/100/100.1.2/Format for Data
N	17/100/100.1.3/Physician Information for the Vendors
N	17/100/100.2/Claims Processing Instructions for CAP Claims for the Local Carriers
N	17/100/100.2.1/CAP Required Modifiers
N	17/100/100.2.2/Submitting the Administration/Evaluation and Management Services and the No Pay Service Lines
N	17/100/100.2.3/Submitting the Prescription Order Numbers and No Pay Modifiers
N	17/100/100.2.4/CAP Claims Submitted With Only the No Pay Line
N	17/100/100.2.5/Only CAP Related Services on a Claim
N	17/100/100.2.6/Use of the ?Restocking? Modifier
N	17/100/100.2.7/Use of the ?Furnish as Written? Modifier
N	17/100/100.2.8/Monitoring of Claims Submitted With the J2 and/or J3 Modifiers
N	17/100/100.2.9/Claims Submitted for Only Drugs Listed on the Approved CAP Vendor?s Drug List
N	17/100/100.3/Application of Local Medical Review Policies
N	17/100/100.4/Claims Processing Instructions for the Designated Carrier
N	17/100/100.4.1/Creation of Internal Vendor Provider Files
N	17/100/100.4.2/Submission of Paper Claims by Vendors
N	17/100/100.4.3/Submission of Claims from Vendors With the J1 No Pay Modifier
N	17/100/100.4.4/Submission of Claims from Vendors Without a Provider Primary Identifier for the Ordering Physician
N	17/100/100.4.5/New MSN Message to Be Included on All Vendor Claims

N	17/100/100.4.6/Additional Medical Information
N	17/100/100.4.7/CAP Fee Schedule
N	17/100/100.5/Matching the Physician Claim to the Vendor Claim
N	17/100/100.5.1/Denials Due to Medical Necessity
N	17/100/100.5.2/Denials For Reasons Other Than Medical Necessity
N	17/100/100.5.3/Changes to Pay/Process Indicators
N	17/100/100.5.4/Post-Payment Overpayment Recovery Actions
N	17/100/100.5.5/Pending and Recycling the Claim When All Lines Do Not Have a Match
N	17/100/100.5.6/Creation of a Weekly Report for Claims That Have Pended More Than 90 Days and Subsequent Action
N	17/100/100.6/Coordination of Benefits
N	17/100/100.7/National Claims History
N	17/100/100.8/Adding New Drugs to CAP
N	17/100/100.8.1/Updating Fee Schedule for New Drugs in CAP
R	17/100/100.8.1/Non-Participating Physicians Who Elect the CAP
R	17/40/Discarded Drugs and Biologicals
R	1/80/80.3.2.1.3/Carrier Specific Requirements for Certain Specialties/Services

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: 866	Date: February 17, 2006	Change Request 4309

NOTE: Transmittal 839, dated February 6, 2006, is rescinded and replaced with Transmittal 866 dated February 17, 2006. In both the BR 4309.9 and the manual instructions we referenced a table in BR 4064.7.6. We are changing this reference in the business requirement and the manual instruction to be BR 4064.1.1.2.1. All other information remains the same.

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

I. GENERAL INFORMATION

A. Background: This CR provides additional instructions for the implementation of the CAP program as outlined in CR 4064. It is not a stand-alone CR. CR4309 builds on CR 4064 through the implementation of business requirements that were identified by the implementation process of CR 4064, and it supports business requirements in CR 4306 needed for the development of the final CAP rule and drug list, published on November 21, 2005. Both the CAP final rule and the CAP drug list can be found at the CAP website: http://www.cms.hhs.gov/CompetitiveAcquisforBios/ .

B. Policy: Section 303 (d) of the Medicare Prescription Improvement and Modernization Act (MMA) of 2003 mandates the implementation of a CAP for Part B drugs.

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	
4309.1	The designated carrier shall edit to determine if a UPIN (or NPI when implemented) of the ordering physician has been entered on every vendor 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	
4309.1.1	If the UPIN has not been entered on the claim, the designated carrier shall treat the claim as unprocessable.									Designated Carrier
4309.1.2	Along with any other appropriate reason and remark codes, the designated carrier shall return the following Remittance Advice Remark Code: N265 – Missing/incomplete/invalid ordering provider primary identifier.									Designated Carrier
4309.2	The designated carrier shall create an internal provider file for each vendor which includes the names, addresses, and UPINs (NPI when effective) of those physicians who have elected that vendor.						X			Designated Carrier
4309.2.1	The designated carrier shall treat as unprocessable claims received from vendors with ordering physician UPINs (NPI when effective) that do not match a physician's UPIN (NPI when effective) on the provider file for that vendor.									Designated Carrier
4309.2.2	For claims found unprocessable in 4309.2.1, the designated carrier shall return all of the following messages: For the Remittance Advice Messages: Reason Code 96 - Non-covered charge(s). and Remark Code N265 – Missing/incomplete/invalid ordering provider primary identifier. For the Medicare Summary Notice Messages: 17.11 This item or service can not be paid as billed. and 9.7 – We have asked your provider/supplier to resubmit the claim with the missing or correct information.									Designated Carrier

Requirement Number	Requirements	Responsibility ("X" indicates the columns that apply)								
		FI	RHHI	Carrier	DMERC	Shared System Maintainers				Other
						FISS	MCS	VMS	CWF	
	Spanish 17.11 -Este servicio no se puede pagar según facturado. 9.7 - Le hemos pedido a su proveedor que envíe la reclamación con la información omitida o incorrecta.									
4309.3	On all vendor claims for CAP drugs, in the general information section of the Medicare Summary Notice, whether paid or denied, only the designated carrier shall include the following: Your physician participates in the Competitive Acquisition Program for Medicare Part B drugs (CAP). The drug(s) you received in your physician's office were provided by an approved CAP vendor. You will receive two separate Medicare Summary Notices (MSNs). This MSN is from the Medicare carrier that processes claims for your drug(s) that came from the approved CAP vendor. You will receive another MSN from the Medicare carrier that processes claims for your physician, for the administration of the drug(s). If you appeal the determination for this drug vendor claim, you must send your appeal to the Medicare carrier address listed on the physician administration MSN, and not this vendor claim MSN. Spanish: Su médico participa en el Programa de Adquisición Competitiva para las medicinas cubiertas por la Parte B de Medicare (CAP, por sus siglas en inglés). Las medicinas que usted recibió en la oficina de su médico fueron									Designated Carrier

Requirement Number	Requirements	Responsibility ("X" indicates the columns that apply)								
		FI	RHHI	Carrier	DMERC	Shared System Maintainers				Other
						FISS	MCS	VMS	CWF	
	provistas por un suplidor autorizado del CAP. Usted recibirá dos Resúmenes de Medicare por separado. Este Resumen es de la empresa de seguros Medicare que procesa las reclamaciones de sus medicinas provistas por el suplidor autorizado del CAP. Usted recibirá otro Resumen de la empresa de seguros Medicare que procesa las reclamaciones de su médico, por el suministro de sus medicinas. Si usted apela la decisión de esta reclamación del suplidor de medicinas, debe enviar la apelación a la empresa de seguros Medicare que se menciona en el Resumen de la reclamación de su médico y no a la dirección que aparece en este Resumen.									
4309.4	Carriers shall not process CAP claims submitted for United Mine Worker, Railroad Retirement Board or Medicare Advantage beneficiaries.			X						Designated Carrier
4309.4.1	Carriers shall follow normal procedures for disposition of these claims.			X						Designated Carrier
4309.5	Any carrier that is currently applying any local unused drug (wastage) policy that requires a separate detail line with the unused drug modifier (JW) to indicate billing for the unused portion of a single-use drug product as per Chapter 17 Section 40-Discarded Drug and Biologicals, may continue to apply the policy for CAP.			X						
4309.5.1	These carriers shall accept the CAP J codes (either a J1- "no-pay" modifier or a J3 – "furnish as written") modifier on the same line as the JW modifier as required in 4064.2 to indicate that the claim for the unused drug is for a CAP drug as follows:			X						

Requirement Number	Requirements	Responsibility ("X" indicates the columns that apply)								
		FI	RHHI	Carrier	DMERC	Shared System Maintainers				Other
						FISS	MCS	VMS	CWF	
	J1 + JW J3 + JW									
4309.6.	For those claims identified in 4064.2 that include the no-pay, restocking, or furnish as written modifier, the carriers shall treat as unprocessable those CAP claim lines received with modifiers that include the following invalid modifier combinations: J1 + J3 – invalid J2 without J1 – invalid J2 + J3 – invalid			X						
4309.6.1	Carriers shall return any appropriate Remittance Advice Reason Codes and the following Remark Code messages when claims are received with invalid modifier combinations: 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 complete/correct information. and Remark Code MA78 – Missing/incomplete/invalid HCPCS modifier			X						
4309.7	Carriers shall return the following Claim Adjustment Reason Code along with the remark code specified in BR 4064.3.2.2.3.1: Claim Adjustment Reason Code 16: Claim/service lacks information which is needed for adjudication.			X						

Requirement Number	Requirements	Responsibility ("X" indicates the columns that apply)								
		FI	RHHI	Carrier	DMERC	Shared System Maintainers				Other
						FISS	MCS	VMS	CWF	
4309.8	When members in a group practice bill Medicare using the Group's PIN, they shall commit as a group practice to enroll in the CAP program. Carriers shall make an educational contact to verbally verify election information from any members of the practice for which they have not received that information.			X						
4309.8.1	Carriers shall only remove names from the table developed in BR 4064.1.1.2.1 when it has been determined that the physician is no longer a member of the group practice.			X						
4309.8.2	Carriers shall not allow a group practice, which is billing Medicare using the Group's PIN, to participate in the CAP program until all election information has been obtained for each eligible practice member within that group.			X						
4309.9	The carriers and the Designated Carrier shall develop the capacity to manually add new vendor specific HCPCS codes and identify to which vendor lists these have been added for the table developed in 4064.1.1.2.1 on a quarterly basis upon notification by CMS.			X						Designated Carrier
4309.9.1	Carriers shall add these codes to their table by 7 calendar days after receipt of notification from CMS.			X						
4309.10	The Designated Carrier shall develop the capacity to add the prices for the new vendor specified HCPCS codes to the pricing table. Prices will be available on the CMS website for the quarterly update of prices to the of new drug prices.									Designated Carrier

Requirement Number	Requirements	Responsibility ("X" indicates the columns that apply)								
		FI	RHHI	Carrier	DMERC	Shared System Maintainers				Other
						FISS	MCS	VMS	CWF	
4309.11	Business Requirement 4064.3.5 shall be deleted. CAP and non-CAP services may be processed on the same claim.			X						
4309.11.1	Carriers shall pay all HCPCS codes for the administration of CAP drugs on an assigned basis.			X						
4309.12	For any address created in 4064.1.1.2.1, the carriers shall obtain the physical address for delivery of the CAP drugs from each physician or group who has elected to participate in CAP.			X						
4309.13	The designated carrier shall forward the 4 position alphanumeric vendor identification number (VIN) from 4064.7.1 to CMS by March 24, 2006 for this first CAP year. For subsequent CAP years, this date will be by 14 days after new CAP vendor contracts have been announced by CMS.									Designated Carrier
4309.14	CMS will post the 4-position alphanumeric vendor identification number (VIN) on the CMS website. Carriers shall download these identification codes from the CMS website and added them to the Carriers table by April 17, 2006.			X						
4309.15	CWF shall read the CAP's Aux file for all adjustments submitted without a prescription order number on Part B records with Specialty Code '95' to match based on the Document Control Number(DCN).								X	
4309.16	CWF shall bypass the MSP edits on Physician claim when the 'J1' modifier is present								X	
4309.17	For claims rejected in 4064.3.3, for paper			X						

Requirement Number	Requirements	Responsibility ("X" indicates the columns that apply)								
		FI	RHHI	Carrier	DMERC	Shared System Maintainers				Other
						FISS	MCS	VMS	CWF	
	claims only, the carriers shall return the following message at the return reject level: RA 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 complete/correct information.									

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	
4309.18	A provider education article related to this instruction will be available at www.cms.hhs.gov/medlearn/matters shortly after the CR is released. You will receive notification of the article release via the established "medlearn 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 Medlearn Matters articles with localized information that would benefit their provider community in									

Requirement Number	Requirements	Responsibility ("X" indicates the columns that apply)								
		FI	RHHI	Carrier	DMERC	Shared System Maintainers				Other
						FISS	MCS	VMS	CWF	
	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. This CR rescinds and fully replaces CR 4000

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:** July 3, 2006 and for Requirements 4309.11 and 4309.13 implementation date is April 17, 2006 **Pre-Implementation Contact(s):** Lia Prela at Cecilia.Prela@cms.hhs.gov; Leslie Trazzi at leslie.trazzi@cms.hhs.gov **Post-Implementation Contact(s):**	**No additional funding will be provided by CMS; contractor activities are to be carried out within their FY 2006 operating budgets.**

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

80.3.2.1.3 - Carrier Specific Requirements for Certain Specialties/Services

(Rev.866, Issued: 02-17-06, Effective: 07-01-06, Implementation: 07-03-06)

Carriers must return the following claim as unprocessable to the provider of service/supplier:

a. For chiropractor claims:
   1. If the x-ray date is not entered in item 19 for claims with dates of service prior to January 1, 2000. Entry of an x-ray date is not required for claims with dates of service on or after January 1, 2000.
   2. If the initial date "actual" treatment occurred is not entered in item 14. (Remark code MA122 is used.)

b. For certified registered nurse anesthetist (CRNA) and anesthesia assistant (AA) claims, if the CRNA or AA is employed by a group (such as a hospital, physician, or ASC) and the group's name, address, ZIP code, and PIN (or NPI when effective) number is not entered in item 33 or their personal PIN (or NPI number when effective) is not entered in item 24K. (Remark code MA112 is used.)

c. For durable medical, orthotic, and prosthetic claims, if the name, address, and ZIP code of the location where the order was accepted were not entered in item 32. (Remark code MA 114 is used.)

d. For physicians who maintain dialysis patients and receive a monthly capitation payment:
   1. If the physician is a member of a professional corporation, similar group, or clinic, and the attending physician's PIN (or NPI when effective) is not entered in item 24K. (Remark code MA112 is used.)
   2. If the name, address, and ZIP code of the facility other than the patient's home or physician's office involved with the patient's maintenance of care and training is not entered in item 32. (Remark code MA114 is used.) Effective for claims received on or after April 1, 2004, the name, address, and ZIP code of the service location for all services other than those furnished in place of service home – 12 must be entered.

e. For routine foot care claims, if the date the patient was last seen and the attending physician's PIN (or NPI when effective) is not present in item 19. (Remark code MA104 is used.)

f. For immunosuppressive drug claims, if a referring/ordering physician, physician's assistant, nurse practitioner, clinical nurse specialist was used and their name and/or UPIN (or NPI when effective) is not present in items 17 or 17A. (Remark code M33 or MA102 is used.)

g. For all laboratory services, if the services of a referring/ordering physician, physician's assistant, nurse practitioner, clinical nurse specialist are used and his or her name and/or UPIN (or NPI when effective) is not present in items 17 or 17A. (Remark code M33 or MA102 is used.)

h. For laboratory services performed by a participating hospital-leased laboratory or independent laboratory in a hospital, clinic, laboratory, or facility other the patient's home or physician's office (including services to a patient in an institution), if the name, address, and ZIP code of the location where services were performed is not entered in item 32. (Remark code MA114 is used.) Effective for claims received on or after April 1, 2004, the name, address, and ZIP code of the service location for all services other than those furnished in place of service home – 12 must be entered.

i. For independent laboratory claims:
   1. Involving EKG tracing and the procurement of specimen(s) from a patient at home or in an institution, if the claim does not contain a validation from the prescribing physician that any laboratory service(s) performed were conducted at home or in an

institution by entering the appropriate annotation in item 19 (i.e., “Homebound”). (Remark code MA116 is used.)

2. If the name, address, and ZIP code where the test was performed is not entered in item 32, if the services were performed in a location other than the patient’s home or physician’s office. (Remark code MA114 is used.) Effective for claims received on or after April 1, 2004, the name, address, and ZIP code of the service location for all services other than those furnished in place of service home – 12 must be entered.

j. For mammography “diagnostic” and “screening” claims, if a qualified screening center does not accurately enter their 6-digit, FDA-approved certification number in item 32 when billing the technical or global component. (Remark code MA128 is used.)

k. For parenteral and enteral nutrition claims, if the services of an ordering/referring physician, physician assistant, nurse practitioner, clinical nurse specialist are used and their name and/or UPIN (or NPI when effective) is not present in items 17 or 17A. (Remark code MA102 is used.)

l. For portable x-ray services claims, if the ordering physician, physician assistant, nurse practitioner, clinical nurse specialist’s name, and/or UPIN (or NPI when effective) are not entered in items 17 or 17A. (Remark code MA102 is used.)

m. For radiology and pathology claims for hospital inpatients, if the referring/ordering physician, physician assistant, nurse practitioner, clinical nurse specialist’s name, and/or UPIN (or NPI when effective) if appropriate are not entered in items 17 or 17A. (Remark code MA102 is used.)

n. For outpatient services provided by a qualified, independent physical, or occupational therapist:

1. If the UPIN (or NPI when effective) of the attending physician is not present in item 19. (Remark code MA104 is used.)
2. If the 6-digit (MM | DD | YY) or 8-digit (MM | DD | CCYY) date patient was last seen by the attending physician is not present in item 19. (Remark code MA104 is used.)

o. For all laboratory work performed outside a physician’s office, if the claim does not contain a name, address, and ZIP code, and PIN (or NPI when effective) where the laboratory services were performed in item 32, if the services were performed at a location other than the place of service home – 12. (Use Remark code MA114.)

p. For all physician office laboratory claims, if a 10-digit CLIA laboratory identification number is not present in item 23. This requirement applies to claims for services performed on or after January 1, 1998. (Remark code MA51 is used.)

q. For investigational devices billed in an FDA-approved clinical trial if an Investigational Device Exemption (IDE) number is not present in item 23. (Remark code MA50 is used.)

r. For physicians performing care plan oversight services if the 6-digit Medicare provider number of the home health agency (HHA) or hospice is not present in item 23. (Remark code MA49 is used.)

s. For Competitive Acquisition Program drug and biological claims, in accordance with the instructions found in the Medicare Claims Processing Manual, Chapter 17, Section 100.4.2 through 100.4.4.

Medicare Claims Processing Manual

Chapter 17 - Drugs and Biologicals

Table of Contents

(Rev. 866, 02-17-06)

40 - Discarded Drugs and Biologicals

(Rev.866, Issued: 02-17-06, Effective: 07-01-06, Implementation: 07-03-06)

The CMS encourages physicians to schedule patients in such a way that they can use drugs most efficiently. However, if a physician must discard the remainder of a vial or other package after administering it to a Medicare patient, the program covers the amount of drug discarded along with the amount administered.

Please see subsection 100.2.9 - Submission of Claims With the Modifier JW, "Drug Amount Discarded/Not Administered to Any Patient", for additional discussion of the discarded remainder of a vial or other packaged drug in the CAP.

NOTE: The coverage of discarded drugs applies only to single use vials. Multi-use vials are not subject to payment for discarded amounts of drug.

EXAMPLE 1:

A physician schedules three Medicare patients to receive Botulinum Toxin Type A on the same day within the designated shelf life of the product. Currently, Botox is available only in a 100-unit size. Once Botox is reconstituted in the physician's office, it has a shelf life of only four hours. Often, a patient receives less than a 100 unit dose. The physician administers 30 units to each patient. The remaining 10 units are billed to Medicare on the account of the last patient. Therefore, 30 units are billed on behalf of the first patient seen and 30 units are billed on behalf of the second patient seen. Forty units are billed on behalf of the last patient seen because the physician had to discard 10 units at that point.

EXAMPLE 2:

A physician must administer 15 units of Botulinum Toxin Type A to a Medicare patient, and it is not practical to schedule another patient who requires Botulinum Toxin. For example, the physician has only one patient who requires Botulinum Toxin, or when the physician sees the patient for the first time and did not know the patient's condition. The physician bills for 100 units on behalf of the patient and Medicare pays for 100 units.

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

(Rev.866, Issued: 02-17-06, Effective: 07-01-06, Implementation: 07-03-06)

Section 303 (d) of the Medicare Prescription Improvement and Modernization Act (MMA) of 2003 requires the implementation of a competitive acquisition program (CAP) for Medicare Part B drugs and biologicals not paid on a cost or prospective payment system basis. Beginning with drugs administered on or after July 1, 2006, physicians will be given a choice between buying and billing these drugs under the average sales price (ASP) system, or obtaining these drugs from vendors selected in a competitive bidding process. For purposes of the CAP, the term "a physician" includes individuals defined under §1861(s) of the Social Security Act who are authorized to provide physician services under §1861(s) of the Act and who can, within their State's scope of practice, prescribe and order drugs covered under Medicare Part B.

For 2006, the first CAP year will run from July 1, 2006 through December 31, 2006. In subsequent years, it will run annually on a calendar year basis.

The Secretary may exclude drugs from the CAP if competitive pricing will not result in significant savings, or is likely to have an adverse impact on access to such drugs. The statute gives CMS the authority to select drugs, or categories of drugs, that will be included in the program, to establish geographic competitive acquisition areas, and to phase in these elements as appropriate.

A competition will be held every three years to award contracts to approved CAP vendors that will supply drugs and biologicals for the program. A three year contract will be awarded to qualified approved CAP vendors in each geographic area who have and maintain: 1) Sufficient means to acquire and deliver competitively biddable drugs within the specified contract area; 2) Arrangements in effect for shipping at least 5 days each week for the competitively biddable drugs under the contract and means to ship drugs in emergency situations; 3) Quality, service, financial performance, and solvency standards; and 4) A grievance and appeals process for dispute resolution. A vendor's contract may be terminated during the contract period if they do not abide by the terms of their contract with CMS. CMS will establish a single payment amount for each of the competitively bid drugs and areas, for this three year cycle there will be one drug category and one geographic area. After CAP drug prices are determined and vendor contracts are awarded the information will be posted to a directory on the Medicare Web Site.

Medicare physicians will be given an opportunity to elect to participate in the CAP on an annual basis. Physicians who elect to participate in CAP will continue to bill their local carrier for drug administration. The participating CAP physicians will receive all of their drugs from the approved CAP vendor for the drug categories they have selected, with only one exception. The exception will be for "furnish as written" situations where the participating CAP physician requires that, due to medical necessity, the beneficiary must have a specific drug, defined by it's National Drug Code (NDC), for one of the HCPCS codes within the approved CAP vendor's drug list if that specific drug NDC is not available on the CAP drug list. The participating CAP physician may buy the drug,

administer it to the beneficiary and bill Medicare using the ASP system. The local carrier will monitor drugs obtained using the "furnish as written" provision to ensure that the participating CAP physician is complying with Medicare payment rules.

The CAP will also allow a participating CAP physician to provide a drug to a Medicare beneficiary from his or her own stock and obtain the replacement drug from the approved CAP vendor when certain conditions are met. The local carrier will monitor drugs ordered under the replacement provision to ensure that the participating CAP physician is complying with Medicare payment rules.

Approved CAP vendors must qualify for enrollment in Medicare as a supplier, and will be enrolled as a new provider specialty type. The approved CAP vendor's claims for the drugs will be submitted to one designated Medicare carrier. The approved CAP vendor will bill the Medicare designated carrier for the drug and the beneficiary for any applicable coinsurance and deductible. Payment to the approved CAP vendor for the drug is conditioned on verification that the drug was administered to the Medicare beneficiary. Proof that the drug was administered shall be established by matching the participating CAP physician's claim for drug administration with the approved CAP vendor's claim for the drug in the Medicare claims processing system by means of a prescription number on both claims. When they are matched in the claims processing system, the approved CAP vendor will be paid in full. Until drug administration is verified, the approved CAP vendor may not bill the beneficiary and/or his third party insurance for any applicable coinsurance and deductible. For more information on the CAP claims processing seeFR70251.

100.1 – Physician Election and Information Transfer Between Carriers and the Designated Carrier for CAP Claims

(Rev.866, Issued: 02-17-06, Effective: 07-01-06, Implementation: 07-03-06)

Prior to each annual election period, CMS will post on its Web site a list of the vendors that have been selected to participate in the CAP, the categories of drugs they will be providing, and the geographic areas within which each vendor will operate. Physicians will then elect the approved CAP vendors they choose to receive drugs from under the CAP. The election period will end each year approximately 45 days after the list of vendors is posted on the CMS Web site.

100.1.1 – Physician Information for the Designated Carrier

(Rev.866, Issued: 02-17-06, Effective: 07-01-06, Implementation: 07-03-06)

10 Calendar days after the end of the annual election period, the 2006 election period, by May 25, 2006 carriers shall create a table and forward it to the designated carrier. The table will indicate which physicians have elected to participate in CAP, for which drugs, and with which vendors. When carriers receive applications, they shall verify that the chosen vendor is valid per the CMS Web site. If an invalid vendor has been chosen, an educational contact shall be made to resolve the issue.

Carriers shall forward this table each year to the designated carrier by 7calender days after the end of the election period. Should that date fall on a weekend, it shall be extended to the following Monday.

The table shall include the physician's name, the street address, city, state, zip code, and phone number of each practice address/shipping address (the physical location where the drugs will be administered and the CAP drugs shipped to), PIN, UPIN (or NPI when effective), e-mail address (if available). If the mailing/correspondence address (where the participating CAP physician can be contacted directly) is different from the practice/shipping address, the mailing/correspondence shall be included. If the group or individual practice has more than one practice location where drugs are administered, each practice address/shipping location where drugs will be administered shall also be included. For group practices that elect to participate in CAP, the group PIN as well as the individual PINs and UPINs (NPI when effective) shall be included.

The carriers shall manually add any additional practice/shipping addresses and the mailing/correspondence address to the spreadsheet provided to them by the standard system before sending the information to the designated carrier. Carriers shall also remove any members of a group practice who do not qualify to provide services under the CAP. In order to qualify to provide services under the cap the providers must have prescriptive authority in their state to prescribe medications. Examples of provider types that may or may not have prescriptive authority in their states are nurse practitioners and physician's assistants.

Since group practices must commit as a practice to enroll in the CAP program if they bill using the group's PIN, if the carrier receives from the standard system names of providers in a group for whom an election form has not been received, they shall contact the group practice to verbally request the required election form information. Carriers shall only remove names from the CAP provider table when it has been determined that the physician is no longer a member of a group practice. Carriers shall not allow a group practice to participate in the CAP until all election information has been obtained for each eligible practice member within that group who bills using the group's PIN.

The designated carrier shall transmit information to each vendor on the physicians and practitioners who have elected that particular vendor 30 days prior to the start of the CAP year.

100.1.1.1 – Quarterly Updates

(Rev.866, Issued: 02-17-06, Effective: 07-01-06, Implementation: 07-03-06)

On a quarterly basis, CMS may provide updates to the HCPCS codes that the participating CAP physician must accept for the CAP. Carriers must add these HCPCS codes to the table created in 100.1.1 by 7 days after receipt of the changes from CMS.

100.1.2 – Format for Data

(Rev.866, Issued: 02-17-06, Effective: 07-01-06, Implementation: 07-03-06)

In order to simplify the transfer of physician election information, prior to end of the

election period, the carriers and the designated carrier shall determine a common format in which to send the information to the designated carrier. This format shall remain constant for subsequent years unless CMS issues instructions that it is to be changed.

100.1.3 – Physician Information for the Vendors

(Rev.866, Issued: 02-17-06, Effective: 07-01-06, Implementation: 07-03-06)

One month before the beginning of the calendar year, the designated carrier shall transmit the following information to each vendor on the physicians who have elected that particular vendor: the name, the street address, city, state, zip code, and phone number of each practice address/shipping address (physical location where the drugs will be administered), UPIN (or NPI when effective), e-mail address (if available) of the physicians who have elected to participate in CAP with that vendor and the drugs they have chosen. If the mailing/correspondence address (where the participating CAP physician can be contacted directly) is different from the practice/shipping address, the mailing/correspondence shall be included. If the group or individual practice has more than one practice location where drugs are administered, each practice address/shipping location where drugs will be administered shall also be included. (Note: For the 2006 claims processing period, the information must be sent by June 1, 2006)

For group practices that elect to participate in CAP, the individual UPINs (NPI when effective) shall be included.

Each year the date the designated carrier shall transmit information to each vendor on the physicians who have elected that particular vendor shall be 7 calendar days after the final date the carriers forward to the designated carrier the list of all the physicians who have elected to participate in CAP. Should that date fall on a weekend, it shall be extended to the following Monday.

The designated carrier shall not send a vendor any information pertaining to other vendors.

100.2 - Claims Processing Instructions for CAP Claims for the Local Carriers

(Rev.866, Issued: 02-17-06, Effective: 07-01-06, Implementation: 07-03-06)

The carrier shall not process CAP claims submitted for United Mine Worker or Medicare Advantage or Railroad Board beneficiaries. Carriers shall follow normal procedures for the disposition of these claims.

Carriers shall pay for the administration of the drugs for which physicians have elected to receive under CAP. The local carriers shall processing CAP claims from physicians per the following instructions.

100.2.1 – CAP Required Modifiers

(Rev.866, Issued: 02-17-06, Effective: 07-01-06, Implementation: 07-03-06)

The carrier shall identify physicians who have elected CAP and will no longer pay the physician for drugs under the ASP system that were obtained through CAP. Carriers shall continue to pay physicians for the administration of CAP drugs. Unless claims for the CAP drugs include the no-pay (J1) or furnish as written (J3) modifier, the claim will be treated as unprocessable.

Carriers shall return the following Medicare Summary Notice (MSN) messages and Remittance Advice (RA) messages when physicians submit a claim for a drug they have provided under the CAP without the J1 or J3 modifiers:

MSN 7.7 – Your physician has elected to participate in the Competitive Acquisition Program for these drugs. Claims for these drugs must be billed by the appropriate drug vendor rather than your physician.

Spanish Version 7.7 - Su médico eligió participar en el Programa de Adquisición Competitiva para estas medicinas. Las reclamaciones para estas medicinas deben ser facturadas por el distribuidor de medicinas adecuado y no por su médico.

Claim Adjustment Reason Code 96 – Non-covered charges.

RA Remark Code N348 - You chose that this service/supply/drug would be rendered/supplied and billed by a different practitioner/supplier.

Carriers shall treat as unprocessable CAP claims with the following invalid modifier combinations on CAP claims:

J1 + J3 – invalid

J2 without a J1 – invalid

J2 + J3 – invalid

Carriers shall treat as unprocessable claims received with invalid modifier combinations. Carriers shall return any appropriate Remittance Advice Reason Codes and the following Remark Code messages when claims are received with invalid modifier combinations:

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 complete/correct information.

and

Remark Code MA78 – Missing/incomplete/invalid HCPCS modifier

100.2.2 – Submitting the Charges for the Administration of a CAP Drug and the No Pay Service Lines

(Rev.866, Issued: 02-17-06, Effective: 07-01-06, Implementation: 07-03-06)

No pay service lines are identified by the modifier code: J1 – Competitive Acquisition Program, no-pay submission for a prescription number.

On both paper and electronic claims, the physician must submit their charges for the administration of the CAP drug and an additional no-pay service line for each prescription number. Each no-pay service line shall include the no-pay modifier J1, a HCPCS drug code, and a prescription number. The J1 modifier should always be entered in the first modifier position.

The no-pay service lines shall be submitted with the regular billed charges for the administration of these drugs. No payment shall be made for services received with the CAP no-pay modifier and they shall bypass the MSP Pay module.

100.2.3 –Submitting the Prescription Order Numbers and No Pay Modifiers

(Rev.866, Issued: 02-17-06, Effective: 07-01-06, Implementation: 07-03-06)

On paper claims the prescription numbers must be entered in Item 19. On electronic claims the prescription number must be entered at the line level in the ANSI X12 837P LOOP 2410 REF02 (REF01=XZ) of the 4010A1 version. As the Implementation Guide requires the entry of the National Drug Code (NDC) number in the LIN segment in order to enter the prescription number, the NDC will be required as well. The NDC must be submitted in LOOP 2410 LIN03 (LIN02=N4).

The prescription number will consist of the vendor identification (ID) number, the HCPCS code, and the vendor controlled prescription number. Each vendor controlled prescription number shall be a unique number and shall not consist of all zero's.

The standard system shall add the prescription number received on either paper or electronic claims to the claims screen and retain the information in history. Carriers shall forward the prescription number on both paper and electronic claims to CWF.

For paper claims, the carriers shall return as unprocessable paper claims submitted with the J1 modifier, but no prescription number. The carriers shall return the following messages:

Claim Adjustment Reason Code 16 – Claim/service lacks information which is needed for adjudication.

Additional information is supplied using Remittance advice remark codes where ever appropriate.

RA 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 complete/correct information.

The standard system shall create a pre-pass edit to reject claims from physicians or practitioners submitted with a no-pay modifier on a line, but without a prescription number on that same line. The carriers shall return the following message:

RA 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 complete/correct information.

100.2.4 – CAP claims submitted With Only the No Pay Line

(Rev.866, Issued: 02-17-06, Effective: 07-01-06, Implementation: 07-03-06)

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.

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

100.2.5 – Use of the "Restocking" Modifier

(Rev.866, Issued: 02-17-06, Effective: 07-01-06, Implementation: 07-03-06)

The restocking modifier is: J2 – Competitive Acquisition Program, (CAP) restocking of emergency drugs after emergency administration.

Under certain circumstances, physicians will be permitted to administer a drug they have on hand and go through the CAP program to restock it. Once the participating CAP physician orders and receives the restocking drug from the approved CAP vendor, the physician will bill for the administration fee. The physician will also include no-pay lines on the claim for each of the drugs as usual. These lines will include the restocking

modifier in addition to the no-pay modifier (in the first modifier position), the procedure code for the drug, the prescription number and all other elements normally required.

Carriers shall consider "restocking" drug claims for payment when the following requirements are met:

a) The physician has elected to receive the drug under CAP;

b) The physician has submitted the claim with the "restocking" modifier;

c) The physician received the drug from the CAP vendor to replace a drug he or she used from pre-existing stock.

d) The claim was submitted with the "restocking" modifier:

J2 – Competitive Acquisition Program, (CAP) restocking of emergency drugs after emergency administration.

By including the "restocking" modifier on the claim, the physician is asserting that:

a) The drug was required immediately;

b) The need couldn't be anticipated;

c) The vendor couldn't deliver in time;

d) The drug was administered in an emergency situation; and

e) Documentation is being maintained in the file to validate the information in a – d and will be made available to the carrier at their request.

100.2.6 – Use of the "Furnish as Written" Modifier

(Rev.866, Issued: 02-17-06, Effective: 07-01-06, Implementation: 07-03-06)

The "furnish as written" modifier is: J3 – Competitive Acquisition Program,(CAP) drug not available through CAP as written, reimbursed under average sales price methodology.

When the J3 modifier is used, the physician will be allowed to bill Medicare for a CAP drug in addition to the claim for the administration of that drug.

Carriers shall consider "furnish as written" drug administration claims for payment outside of the CAP program when the new "furnish as written" modifier is used.

By using only the J3 modifier on the claim, the physician is asserting that:

a) A specific drug product was medically necessary;

b) The selected drug vendor could not provide that specific brand and/or NDC for the CAP HCPCS code;

and

c) Documentation is being maintained on file to validate the information in a) and b) and will be made available to the carrier at their request.

100.2.7 – Monitoring of Claims Submitted With the J2 and/or J3 Modifiers

(Rev.866, Issued: 02-17-06, Effective: 07-01-06, Implementation: 07-03-06)

As part of their normal data analysis, carriers shall monitor these claims submitted with the J2, "restocking" modifier, or J3, the "furnish as written" modifier, for patterns of abuse and follow the Progressive Corrective Action (PCA) process described in the Program Integrity Manual, Chapter 3, Section 11.

100.2.8 –Claims Submitted for Only Drugs Listed on the Approved CAP Vendor's Drug List

(Rev.866, Issued: 02-17-06, Effective: 07-01-06, Implementation: 07-03-06)

The carrier shall edit to verify that the no-pay lines (lines with the CAP drug HCPCS code and the J1modifier) that the participating CAP physician has billed is for a drug included in the CAP and is from the particular CAP vendor they have chosen to receive drugs from.

If the carrier determines that the physician has billed no-pay lines along with the codes for the payment of the administration for drug HCPCS code(s) that are not provided by the approved CAP vendor that the physician had selected, it shall return as unprocessable those no-pay lines along with the lines for the codes for the payment of the administration for these drugs. The carrier shall return the following messages:

Remittance Advice Messages:

Claim Adjustment Reason Code 96 – Non-covered charges.

Remark Code N348 – You chose that this service/supply /drug would be rendered/supplied and billed by a different practitioner/supplier.

MSN Message 7.8 - Your physician has elected to participate in the Competitive Acquisition Program (CAP) for Medicare Part B drugs. Medicare cannot pay for the administration of the drug(s) being billed because these drug(s) are not available from the CAP vendor

Spanish version 7.8: Su médico ha elegido participar en el Programa de Adquisición Competitiva (CAP, por sus siglas en inglés) para las medicinas cubiertas por la Parte B de Medicare. Medicare no puede pagar por el suministro de las medicinas cobradas porque estas medicinas no están disponibles del vendedor CAP.

100.2.9 - Submission of Claims With the Modifier JW, "Drug Amount Discarded/Not Administered to Any Patient"

(Rev.866, Issued: 02-17-06, Effective: 07-01-06, Implementation: 07-03-06)

Chapter 17, Section 40 – Discarded Drug and Biologicals, provides Medicare payment policy for the discarded remainder of a single-use drug product after administering it to a Medicare patient. This policy will apply equally in both the ASP and the CAP. If the CAP physician has made good faith efforts to minimize the unused portion of the CAP drug in how he or she scheduled patients and how he or she ordered, accepted, stored, and used the drug, and only if the approved CAP vendor has made good faith efforts to minimize the unused portion of the drug in how it supplied the drug to the participating CAP physician, then the program will cover the amount of drug discarded along with the amount administered.

Any carrier that is currently applying any local unused drug (wastage) policy that requires a separate detail line with the unused drug modifier (JW) to indicate billing for the unused portion of a single-use drug product as per Chapter 17 Section 40-Discarded Drug and Biologicals, may continue to apply the policy for CAP. These carriers shall accept the CAP J codes on the same line as the JW modifier as required in Section 100.2.1 to indicate that the claim for the unused drug is for a CAP drug. Each line with a JW modifier must have either a J1- "no-pay" modifier or a J3 –"furnish as written" modifier:

J1 + JW

J3 + JW

100.3 - Application of Local Medical Review Policies

(Rev.866, Issued: 02-17-06, Effective: 07-01-06, Implementation: 07-03-06)

Carriers and/or Program Safeguard Contractors shall apply all Local Coverage Determination (LCD) policies and National Coverage Determination (NCD) policies to the administration and no-pay drug code lines on the CAP claims.

Should it be determined that a drug administration or drug code service line does not meet the requirements of the LCD, the carrier shall follow current processes to determine how to adjudicate the related services.

If appropriate, the carriers shall include messages on the MSN and RA to indicate which LCD was applied.

The carriers shall also apply all regular edits to the administration and no-pay drug lines and send appropriate denial messages.

100.4 - Claims Processing Instructions for the Designated Carrier

(Rev.866, Issued: 02-17-06, Effective: 07-01-06, Implementation: 07-03-06)

The designated carrier shall follow normal procedures to enroll the Drug Vendors as provider specialty type, 95, Competitive Acquisition Program (CAP) for Part B Drug Vendors.

A separate 4 position, alpha-numeric vendor identification number (VIN) shall be assigned to be used in the prescription number and a master list of which numbers are assigned to which vendors shall be kept.

The designated carriers shall forward the VIN to the carriers and to CMS 14 days after new CAP vendor contractors have been announced by CMS. CMS will post the VIN on the CMS website. Carriers shall download these identification codes from the CMS website and added them to the Carriers table.

For subsequent CAP years, this date will be the first Monday in November

These codes shall be added to the Carriers table by 14 days after receipt.

The designated carrier shall track the name, the address, zip code, and phone number of each practice location/shipping address (location where the drugs will be administered), PIN, UPIN, (or NPI when effective), and e-mail (if available) of the physicians and physician groups and which vendors and which drugs they have chosen. In addition, the mailing/correspondence address (where the participating CAP physician can be contacted directly) for each physician shall also be tracked. This information shall be made available to CMS upon request.

On a quarterly basis, the designated carrier shall manually add additional HCPCS codes to the information above when received from the carriers. They shall add this information by 14 days after its receipt from the carriers.

The designated carrier shall only process CAP claims from approved drug vendors submitted in a HIPAA-compliant standard electronic format 4010A1 version (or later). All vendor claims shall be processed by the designated carrier. These will not include claims for United Mine Worker, Railroad or Medicare Advantage beneficiaries.

100.4.1 – Creation of Internal Vendor Provider Files

(Rev.866, Issued: 02-17-06, Effective: 07-01-06, Implementation: 07-03-06)

The designated carrier shall create an internal provider file for each vendor which includes the names, addresses, and UPINs, (NPI when effective), of those physicians who have elected that vendor.

The designated carrier shall edit incoming vendor claims to verify that the UPIN number on the claim for the ordering physician is one of the UPINs on the provider file for that vendor. The designated carrier shall treat the claim as unprocessable when it receives claims from vendors with ordering physician UPINs that do not match a physician UPIN on the provider file and return the following messages:

Remittance Advice Messages:

Reason Code 96 - Non-covered charge(s).

Remark Code: N265 – Missing/incomplete/invalid ordering provider primary identifier.

Medicare Summary Notice Messages:

17.11 This item or service can not be paid as billed.

and

9.7 – We have asked your provider/supplier to resubmit the claim with the missing or correct information.

Spanish:

17.11 -Este servicio no se puede pagar según facturado.

and

9.7 - Le hemos pedido a su proveedor que envíe la reclamación con la información omitida o incorrecta.

100.4.2 – Submission of Paper Claims by Vendors

(Rev.866, Issued: 02-17-06, Effective: 07-01-06, Implementation: 07-03-06)

The designated carrier shall treat as unprocessable paper claims submitted by vendors and return the following RA messages:

Claim Adjustment Reason Code 96 – Non-covered charge(s).

Remark Code M117 – Not covered unless submitted via electronic format.

100.4.3 – Submission of Claims from Vendors With the J1 No Pay Modifier

(Rev.866, Issued: 02-17-06, Effective: 07-01-06, Implementation: 07-03-06)

The designated carrier shall treat as unprocessable claims submitted by vendors with a no-pay modifier and return the following RA messages:

Claim Adjustment Reason Code 96 – Non-covered charge(s).

RA 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 complete/correct information.

100.4.5 - Submission of Claims from Vendors Without a Provider Primary Identifier for the Ordering Physician

(Rev.866, Issued: 02-17-06, Effective: 07-01-06, Implementation: 07-03-06)

The designated carriers shall edit to determine if a UPIN, (or NPI when effective), of the ordering physician has been entered on the claim. If the UPIN, (or NPI when effective), has not been entered on the claim, the designated carrier shall treat the claim as unprocessable.

Along with any other appropriate reason and remark codes, the following remark code shall be returned:

Remark Code N265 – Missing/incomplete/invalid ordering provider primary identifier.

100.4.6 – New MSN Message to Be Included on All Vendor Claims

(Rev.866, Issued: 02-17-06, Effective: 07-01-06, Implementation: 07-03-06)

On all vendor claims, whether paid or denied, the designated carriers shall include the following new Medicare Summary Notice Message:

Your physician participates in the Competitive Acquisition Program for Medicare Part B drugs (CAP). The drug(s) you received in your physician's office were provided by an approved CAP vendor. You will receive two separate Medicare Summary Notices (MSNs). This MSN is from the Medicare carrier that processes claims for your drug that came from the approved CAP vendor. You will receive another MSN from the Medicare carrier that processes claims for your physician, for the administration of the drug(s). If you appeal the determination for this drug vendor claim, you must send your appeal to the Medicare carrier address listed on the physician administration MSN, and not this vendor claim MSN.

Spanish:

Su médico participa en el Programa de Adquisición Competitiva para las medicinas cubiertas por la Parte B de Medicare (CAP, por sus siglas en inglés). Las medicinas que usted recibió en la oficina de su médico fueron provistas por un suplidor autorizado del CAP. Usted recibirá dos Resúmenes de Medicare por separado. Este Resumen es de la empresa de seguros Medicare que procesa las reclamaciones de sus medicinas provistas por el suplidor autorizado del CAP. Usted recibirá otro Resumen de la empresa de seguros Medicare que procesa las reclamaciones de su médico, por el suministro de sus medicinas. Si usted apela la decisión de esta reclamación del suplidor de medicinas, debe enviar la apelación a la empresa de seguros Medicare que se menciona en el Resumen de la reclamación de su médico y no a la dirección que aparece en este Resumen.

100.4.7 – Additional Medical Information

(Rev.866, Issued: 02-17-06, Effective: 07-01-06, Implementation: 07-03-06)

The designated carrier shall reserve the right to solicit, at any time, medical information to support adjudication of the drug vendor's claim.

100.4.8 – CAP Fee Schedule

(Rev.866, Issued: 02-17-06, Effective: 07-01-06, Implementation: 07-03-06)

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*	*Numeric*	*YYYY*
Filler	*16-17*	*2*		*Space Filled*
Current Quarter	*18*	*1*	*Numeric*	*Calendar Quarter – value 1-4*
Filler	*19-20*	*2*		*Space Filled*
Fee	*21-26*	*6*	*Numeric*	*Fee to Pay For Drug $$$$$$*
Filler	*27-80*	*62*	*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.

100.5 - Matching the Physician Claim to the Vendor Claim

(Rev.866, Issued: 02-17-06, Effective: 07-01-06, Implementation: 07-03-06)

CWF shall match physician submitted claim lines with prescription numbers and no-pay modifiers to vendor submitted claim lines with prescription numbers.

The local carrier shall send to CWF a pay/process indicator for each line of the claim, (including the lines with HCPCS codes for the administration of the CAP drug and the lines for the CAP drug HCPCS code), to indicate whether it is approved, not-payable due to medical necessity, or not payable due to a reason other than medical necessity.

When CWF finds a prescription number that matches a prescription number on the claim, it shall notify the designated carrier. The designated carrier shall make payment for the drug lines that have a pay/process indicator of approved. It shall deny any lines not approved.

100.5.1 – Denials Due to Medical Necessity

(Rev.866, Issued: 02-17-06, Effective: 07-01-06, Implementation: 07-03-06)

If the lines are not approved due to medical necessity, the designated carrier shall return the following messages:

Claim Adjustment Reason Code 96 – Non-covered charge(s).

MSN -16.48 – Medicare does not pay for this item or service for this condition.

100.5.2 – Denials For Reasons Other Than Medical Necessity

(Rev.866, Issued: 02-17-06, Effective: 07-01-06, Implementation: 07-03-06)

If the designated carrier denies the lines due to other reason, it shall use the following messages:

Claim Adjustment Reason Code 96 – Non-covered charge(s).

MSN 16.10 – Medicare does not pay for this item or service.

100.5.3 – Changes to Pay/Process Indicators

(Rev.866, Issued: 02-17-06, Effective: 07-01-06, Implementation: 07-03-06)

Should local carriers make adjustments to the physician claims, they shall forward any changes in the pay/process indicators to CWF and CWF shall make any changes to the pay/process indicator as necessary to keep it current. CWF shall notify the designated

carrier of any changes to the pay/process indicators so that they may respond accordingly.

100.5.4 – Post-Payment Overpayment Recovery Actions

(Rev.866, Issued: 02-17-06, Effective: 07-01-06, Implementation: 07-03-06)

If it is determined on a post-pay basis that based on a change to the pay-process indicator the designated carrier has now made an overpayment, the designated carrier shall initiate an overpayment recovery action. If it is determined that they have made an underpayment, they shall also take appropriate action. Carriers and the designated carrier shall follow the instructions in the Program Integrity Manual, Chapter 3 and the Medicare Financial Management Manual, Chapter 3, for overpayment recovery.

100.5.5 – Pending and Recycling the Claim When All Lines Do Not Have a Match

(Rev.866, Issued: 02-17-06, Effective: 07-01-06, Implementation: 07-03-06)

If the designated carrier receives a claim from the vendor and CWF determines some or all of the lines on the claim do not have a match, the designated carrier shall pend the claim for 90 days. However, prior to the end of the 90 day period, if at the vendor's request the designated carrier can determine that a matching paper physician claim is on file, the designated carrier shall allow payment of the approved services on the claim.

The designated carrier may also recycle the claim back to CWF at their discretion to determine if a matching electronic claim has been received prior to the end of the 90 day period. No interest shall be paid on the pending claim.

100.5.6 – Creation of a Weekly Report for Claims That Have Pended More Than 90 Days and Subsequent Action

(Rev.866, Issued: 02-17-06, Effective: 07-01-06, Implementation: 07-03-06)

The standard system shall create a weekly report for the designated carrier providing information on claims that have pended for more than 90 days. The designated carrier shall review the weekly report to identify and deny claim lines for which the 90 day time period has expired. Before denying the claim lines, the designated carrier shall determine if the physician claim had been submitted as a paper claim. If there is an approved physician paper claim for the beneficiary with the same HCPCS code and a date of service within 7 days of the date of service of the vendor drug claim posted at CWF and the details are not denied, the designated carrier shall pay the claim lines. If there is no claim on file that matches these criteria, or some details are denied, the designated carrier shall deny the corresponding claim lines.

The designated carrier shall return the following messages:

RA Claim Adjustment Reason Code - 107 – Claim/service denied because the related or qualifying service was not previously paid or identified on this claim.

MSN – 21.21 – This service was denied because Medicare only covers this service under certain circumstances.

Spanish: 21.21 - Este servicio fue denegado porque Medicare solamente lo cubre bajo ciertas circunstancias.

100.6 – Coordination of Benefits

(Rev.866, Issued: 02-17-06, Effective: 07-01-06, Implementation: 07-03-06)

CWF and the designated carrier shall submit claims for full payment of drug claims to the Coordination of Benefits Contractor (COBC) for crossover to trading partners, in accordance with the requirements specified in Transmittal 138 (Change Request 3218).

100.7 – National Claims History

(Rev.866, Issued: 02-17-06, Effective: 07-01-06, Implementation: 07-03-06)

CWF shall pass the prescription number to National Claims History (NCH) where it will be stored.

100.8 – Adding New Drugs to CAP

(Rev.866, Issued: 02-17-06, Effective: 07-01-06, Implementation: 07-03-06)

The carriers and the Designated Carrier shall develop the capacity to manually add new vendor specific HCPCS codes and identify to which vendor lists these have been added for the table developed in 4064.1.1.2.1 on a quarterly basis upon notification by CMS. Carriers shall add these codes to their table by 7 days after receipt of notification from CMS.

100.8.1- Updating Fee Schedule for New Drugs in CAP

(Rev.866, Issued: 02-17-06, Effective: 07-01-06, Implementation: 07-03-06)

The Designated Carrier shall develop the capacity to add the prices for the new vendor specified HCPCS codes to the pricing table. Prices will be available on the CMS website for the quarterly update of prices to the of new drug prices.

100.8.2- Non-Participating Physicians Who Elect the CAP

(Rev.866, Issued: 02-17-06, Effective: 07-01-06, Implementation: 07-03-06)

Participating CAP physicians must appeal drug administration denials. For a non-participating physician that elects to participate in the CAP, he or she must agree to accept assignment for all CAP drug administration charges to allow for the Medicare beneficiary's and approved CAP vendor's appeal rights.

Carriers shall pay all HCPCS codes that provide payment for the administration of CAP drugs on an assigned basis.

50.38 - General Information Section

(Rev.866, Issued: 02-17-06, Effective: 07-01-06, Implementation: 07-03-06)

38.3 - If you change your address, please contact the Social Security Administration by calling 1-800-772-1213.

38.4 - You are at high risk for complications from the flu and it is very important that you get vaccinated. Please contact your health care provider for the flu vaccine.

38.5 - If you have not received your flu vaccine it is not too late. Please contact your health care provider about getting the vaccine.

38.6 - January is cervical cancer prevention month

38.7 - The Pap test is the most effective way to screen for cervical cancer.

38.8 - Medicare helps pay for screening Pap tests once every two years.

38.9 - Colorectal cancer is the second leading cancer killer in the United States. However, screening tests can find polyps before they become cancerous. They can also find cancer early when treatment works best. Medicare helps pay for screening tests. Talk to your doctor about the screening options that are right for you.

38.10 - Compare the services you receive with those that appear on your Medicare Summary Notice. If you have questions, call your doctor or provider. If you feel further investigation is needed due to possible fraud or abuse, call the phone number in the Customer Service Information Box.

38.12- Your physician participates in the Competitive Acquisition Program for Medicare Part B drugs (CAP) . The drug(s) you received in your physician's office were provided by an approved CAP vendor. You will receive two separate Medicare Summary Notices (MSNs). This MSN is from the Medicare carrier that processes claims for your drug that came from the approved CAP vendor. You will receive another MSN from the Medicare carrier that processes claims for your physician, for the administration of the drug(s). If you appeal the determination for this drug vendor claim, you must send your appeal to the Medicare carrier address listed on the physician administration MSN, and not this vendor claim MSN.

50.7 - Duplicates

(Rev.866, Issued: 02-17-06, Effective: 07-01-06, Implementation: 07-03-06)

7.1 - This is a duplicate of a charge already submitted.

7.2 - This is a duplicate of a claim processed by another contractor. You should receive a Medicare Summary Notice from them.

7.3 - This service/item is a duplicate of a previously processed service. No appeal rights are attached to the denial of this service except for the issue as to whether the service is a duplicate. Disregard the appeals information on this notice unless you are appealing whether the service is a duplicate.

7.7 – Your physician has elected to participate in the Competitive Acquisition Program for these drugs. Claims for these drugs must be billed by the appropriate drug vendor rather than your physician.

7.8 - Your physician has elected to participate in the Competitive Acquisition Program (CAP) for Medicare Part B drugs. Medicare cannot pay for the administration of the drug(s) being billed because these drug(s) are not available from the CAP vendor

90.7 - Duplicados

(Rev.866, Issued: 02-17-06, Effective: 07-01-06, Implementation: 07-03-06)

7.1 - Este es un duplicado de un cargo previamente sometido.

7.2 - Este es un duplicado de una reclamación procesada por otro contratísta de Medicare. Usted debe recibir un Resumen de Medicare de ellos.

7.3 - Este servicio/articulo es un duplicado de otro servicio procesado previamente. No tiene derechos de apelación por la denegación de este servicio, excepto si cuestiona que este servicio es un duplicado. Haga caso omiso a la información sobre apelaciones en esta notificatión, en relación a sus derechos de apelación, a menos que esté apelando si el servicio fue duplicado.

7.7 - Su médico eligió participar en el Programa de Adquisición Competitiva para estas medicinas. Las reclamaciones para estas medicinas deben ser facturadas por el distribuidor de medicinas adecuado y no por su médico.

7.8 –Su médico ha elegido participar en el Programa de Adquisición Competitiva (CAP, por sus siglas en inglés) para las medicinas cubiertas por la Parte B de Medicare. Medicare no puede pagar por el suministro de las medicinas cobradas porque estas medicinas no están disponibles del vendedor CAP.

90.38 - Sección De Información General

(Rev.866, Issued: 02-17-06, Effective: 07-01-06, Implementation: 07-03-06)

38.3 - Si usted cambia de dirección, *por* favor *comuníquese con* la *Administración* del Seguro Social al 1-800-772-1213.

38.4 - Usted está en alto riesgo para complicaciones de la influenza y es muy importante que usted se vacune. Favor de comunicarse con su proveedor del cuidado de la salud para la vacuna contra la influenza.

38.5 - Si usted no ha recibido su vacuna contra la influenza no es demasiado tarde. Favor de comunicarse con su proveedor del cuidado de la salud sobre recibir la vacuna contra la influenza.

38.6 - El cáncer colorectal es el segundo cáncer principal que ataca en los E.E.U.U. Sin embargo, pruebas de investigación pueden encontrar pólipos antes de que lleguen a ser cancerosos. También pueden encontrar el cáncer temprano cuando el tratamiento trabaja lo mejor posible. Medicare ayuda a pagar por pruebas de investigación. Comuníquese con su doctor sobre las opciones de pruebas de investigación que son apropiadas para usted.

38.7 - Medicare cubre las pruebas de investigación del cáncer colorectal que pueden encontrar pólipos precancerosos en el colon y recto. Los pólipos pueden ser removidos antes de que sean cancerosos. Comuníquese con su doctor sobre hacerse la prueba.

38.8 - Enero es el mes de la prevención del cáncer cervical.

38.9 - La prueba de papanicolao (o prueba pap) es la manera más efectiva de examinar el cáncer cervical.

38.10 - Compare los servicios que usted recibe con los que aparecen en su Resumen de Medicare. Si tiene preguntas, llame a su doctor o proveedor. Si usted cree que se necesita investigar más debido a un posible fraude o abuso, llame al teléfono que aparece en la sección Información de Servicios al Cliente.

38.12 – Su médico participa en el Programa de Adquisición Competitiva para las medicinas cubiertas por la Parte B de Medicare (CAP, por sus siglas en inglés). Las medicinas que usted recibió en la oficina de su médico fueron provistas por un suplidor autorizado del CAP. Usted recibirá dos Resúmenes de Medicare por separado. Este Resumen es de la empresa de seguros Medicare que procesa las reclamaciones de sus medicinas provistas por el suplidor autorizado del CAP. Usted recibirá otro Resumen de la empresa de seguros Medicare que procesa las reclamaciones de su médico, por el suministro de sus medicinas. Si usted apela la decisión de esta reclamación del suplidor de medicinas, debe enviar la apelación a la empresa de seguros Medicare que se menciona en el Resumen de la reclamación de su médico y no a la dirección que aparece en este Resumen.