CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-04 Medicare Claims Processing	Centers for Medicare & Medicaid Services (CMS)
Transmittal 1478	Date: MARCH 14, 2008
	Change Request 5923

SUBJECT: Additional Clarification to Chapter 17, Section 40, Regarding Processing of Drug Claims with the JW Modifier

I. SUMMARY OF CHANGES: This manual update is to clarify the use of the JW modifier when processing all drugs except Competitive Acquisition Program (CAP) drugs.

New / Revised Material Effective Date: January 1, 2008 Implementation Date: April 14, 2008

Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual is not updated) R=REVISED, N=NEW, D=DELETED-*Only One Per Row.*

R/N/D	Chapter / Section / Subsection / Title
R	17/40/Discarded Drugs and Biologicals

III. FUNDING:

SECTION A: For Fiscal Intermediaries and Carriers:

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

SECTION B: For Medicare Administrative Contractors (MACs):

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

IV. ATTACHMENTS:

Business Requirements

Manual Instruction

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

Attachment - Business Requirements

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SUBJECT: Additional Clarification to Chapter 17, Section 40, Regarding Processing of Drug Claims with the JW Modifier

Effective Date: January 1, 2008

Implementation Date: April 14, 2008

I. GENERAL INFORMATION

A. Background:

This manual update is to clarify the use of the JW modifier when processing all drugs except Competitive Acquisition Program (CAP) drugs.

B. Policy:

When processing all drugs except those provided under the Competitive Acquisition Program for Part B drugs and biologicals (CAP), local contractors may require the use of the modifier JW to identify unused drug or biologicals from single use vials or single use packages that are appropriately discarded. This modifier will provide payment for the discarded drug or biological. The JW modifier is not used on claims for CAP drugs.

II. BUSINESS REQUIREMENTS TABLE

Use "Shall" to denote a mandatory requirement

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A	D	F	C	R	í Ó	Shai	ed-		OTH
		/	Μ	Ι	A	Η		Syst	em		ER
		B	Е		R	Η	Maintainers				
					R	Ι	F	Μ	V	С	
		M	Μ		Ι		Ι	С	М	W	
		A	А		E		S	S	S	F	
		C	С		R		S				
5923.1	Contractors may require the use of the modifier JW to	Χ	Х	Х	Х						
	identify unused drug or biologicals from single use vials										
	or single use packages that are appropriately discarded										
	when processing all drugs except those provided under										
	the Competitive Acquisition Program for Part B drugs										
	and biologicals (CAP). This modifier will provide										
	payment for the discarded drug or biological. The JW										
	modifier is not used on claims for CAP drugs.										

III. PROVIDER EDUCATION TABLE

Number	Requirement		Responsibility (place an "X" in each applicable column)									
		A	A D F C R Share					OTH				
		/	Μ	Ι	Α	Η	System	ER				
		В	E		R	Η	Maintainers					

						F I S S	M C S	V M S	C W F	
5923.2	A provider education article related to this instruction will be available at <u>http://www.cms.hhs.gov/MLNMattersArticles/</u> 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 one week of the availability of the provider education article. In addition, the provider education article shall be included in your next regularly scheduled bulletin. Contractors are free to supplement MLN Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly.	X	X	X	X					

IV. SUPPORTING INFORMATION

Section A: For any recommendations and supporting information associated with listed requirements, use the box below:

Use "Should" to denote a recommendation.

X-Ref	Recommendations or other supporting information:
Requireme	
nt	
Number	

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

V. CONTACTS

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Post-Implementation Contact(s): Glenn McGuirk, (410) 786-5723, Glenn.McGuirk@cms.hhs.gov

VI. FUNDING

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

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

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

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

40 - Discarded Drugs and Biologicals

(Rev. 1478, issued: 03-14-08 Effective: 01-01-08; Implementation: 04-14-08)

The CMS encourages physicians, hospitals and other providers to schedule patients in such a way that they can use drugs or biologicals most efficiently, in a clinically appropriate manner. However, if a physician, hospital or other provider must discard the remainder of a single use vial or other single use package after administering a dose/quantity of the drug or biological to a Medicare patient, the program provides payment for the amount of drug or biological discarded along with the amount administered, up to the amount of the drug or biological as indicated on the vial or package label.

When processing all drugs except those provided under the Competitive Acquisition Program for Part B drugs and biologicals (CAP), local contractors may require the use of the modifier JW to identify unused drug or biologicals from single use vials or single use packages that are appropriately discarded. This modifier will provide payment for the discarded drug or biological. The JW modifier is not used on claims for CAP drugs.

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

NOTE: Multi-use vials are not subject to payment for discarded amounts of drug or biological.

EXAMPLE 1:

A provider 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, it has a shelf life of only four hours. Often, a patient receives less than a 100 unit dose. The provider administers 30 units to each of the three patients. The remaining 10 units that must be discarded 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 provider had to discard 10 units at that point.

EXAMPLE 2:

A provider administers 15 units of Botulinum Toxin Type A to a Medicare patient, and it is not practical to schedule another patient who requires Botulinum Toxin. The remaining 85 units are discarded. For example, the provider may have only one patient who requires Botulinum Toxin, or the patient requiring treatment may be previously unknown to the provider, thereby precluding consideration of the treatment modality in scheduling the new patient. The provider bills for 100 units on behalf of the patient and Medicare pays for 100 units.