CMS Manual System	**Department of Health & Human Services (DHHS)**
Pub 100-04 Medicare Claims Processing	**Centers for Medicare & Medicaid Services (CMS)**
Transmittal 1962	**Date: April 30, 2010**
	Change Request 6711

SUBJECT: Discarded Drugs and Biologicals Updates

I. SUMMARY OF CHANGES: This document furnishes the contractor with updates and additions to language relating to discarded drugs and biologicals.

EFFECTIVE DATE: July 30, 2010
IMPLEMENTATION DATE: July 30, 2010

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:

For Fiscal Intermediaries (FIs), Regional Home Health Intermediaries (RHHIs) and/or Carriers:
No additional funding will be provided by CMS; Contractor activities are to be carried out within their operating budgets.

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

Pub. 100-04	Transmittal: 1962	Date: April 30, 2010	Change Request: 6711

SUBJECT: Discarded Drugs and Biologicals Updates

Effective Date: July 30, 2010

Implementation Date: July 30, 2010

I. GENERAL INFORMATION

A. Background: This document furnishes you with updates and additions to language relating to discarded drugs and biologicals. These updates and additions are found in Publication 100-04, Medicare Claims Processing Manual, Chapter 17, section 40.

B. Policy: Publication 100-04, Medicare Claims Processing Manual, Chapter 17, section 40, provides policy on the appropriate use of the JW modifier for discarded drugs.

II. BUSINESS REQUIREMENTS TABLE

Use"Shall" to denote a mandatory requirement

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
6711.1	Contractors shall recognize the updated and new guidelines established in Chapter 17, §40 of the Medicare Claims Processing Manual stating that the JW modifier may only be applied to the amount of drug units not used.	X	X	X	X						

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
6711.2	A provider education article related to this instruction will be available at http://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	X	X	X	X						

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
	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.										

IV. SUPPORTING INFORMATION

A. For any recommendations and supporting information associated with listed requirements, use the box below:
Use "Should" to denote a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:

V. CONTACTS

Pre-Implementation Contact(s): Glenn McGuirk, (410) 786-5723, Glenn.McGuirk@cms.hhs.gov
Post-Implementation Contact(s): Cheryl Gilbreath, (410) 786-5919, Cheryl.Gilbreath@cms.hhs.gov

VI. FUNDING

A. For *Fiscal Intermediaries and Carriers,* 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.

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

The contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the Statement of Work (SOW). 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.1962, Issued: 04-30-10, Effective: 07-30-10, Implementation: 07-30-10*)

The CMS encourages physicians, hospitals and other providers *and suppliers* to care for and administer to patients in such a way that they can use drugs or biologicals most efficiently, in a clinically appropriate manner.

When a physician, hospital or other provider *or supplier* 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 *as well as* the *dose* administered, up to the amount of the drug or biological as indicated on the vial or package label.

When processing *claims for drugs and biologicals (*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, billed on a separate line, will provide payment for the *amount of* discarded drug or biological. *For example, a single use vial that is labeled to contain 100 units of a drug has 95 units administered to the patient and 5 units discarded. The 95 unit dose is billed on one line, while the discarded 5 units may be billed on another line by using the JW modifier. Both line items would be processed for payment.*

The JW modifier is only applied to the amount of drug or biological that is discarded. A situation in which the JW modifier is not permitted is when the actual dose of the drug or biological administered is less than the billing unit. For example, one billing unit for a drug is equal to 10mg of the drug in a single use vial. A 7mg dose is administered to a patient while 3mg of the remaining drug is discarded. The 7mg dose is billed using one billing unit that represents 10mg on a single line item. The single line item of 1 unit would be processed for payment of the total 10mg of drug administered and discarded. Billing another unit on a separate line item with the JW modifier for the discarded 3mg of drug is not permitted because it would result in overpayment. Therefore, when the billing unit is equal to or greater than the total actual dose and the amount discarded, the use of the JW modifier is not permitted.

The JW modifier is not used on claims for CAP drugs. For CAP drugs, 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.