

<b>CMS Manual System</b>	<b>Department of Health &amp; Human Services (DHHS)</b>
<b>Pub 100-04 Medicare Claims Processing</b>	<b>Centers for Medicare &amp; Medicaid Services (CMS)</b>
<b>Transmittal 3538</b>	<b>Date: June 9, 2016</b>
	<b>Change Request 9603</b>

**Transmittal 3530, dated May 24, 2016, is being rescinded and replaced by Transmittal 3538 to update the Effective and Implementation dates. All other information remains the same.**

**SUBJECT: JW Modifier: Drug amount discarded/not administered to any patient**

**I. SUMMARY OF CHANGES:** Effective January 1, 2017, claims for discarded drug or biological amount not administered to any patient, shall be submitted using the JW modifier. Also, effective January 1, 2017, providers must document the discarded drugs or biologicals in patient's medical record. This CR updates the Section 40 - Discarded Drugs and Biologicals of Chapter 17 of the Claims Processing Manual 100-04.

**EFFECTIVE DATE: January 1, 2017**

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

**IMPLEMENTATION DATE: January 3, 2017**

*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.

<b>R/N/D</b>	<b>CHAPTER / SECTION / SUBSECTION / TITLE</b>
R	17/40/Discarded Drugs and Biologicals

**III. FUNDING:**

**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**

# Attachment - Business Requirements

Pub. 100-04	Transmittal: 3538	Date: June 9, 2016	Change Request: 9603
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**IMPLEMENTATION DATE: January 3, 2017**

## I. GENERAL INFORMATION

**A. Background:** Pub. 100-04, Medicare Claims Processing Manual, chapter 17, section 40, provides policy on the use of the JW modifier for discarded Part B drugs and biologicals. The current policy allows contractors the discretion to determine whether to require the JW modifier for any claims with discarded drugs or biologicals, and the specific details regarding how the discarded drug or biological information should be documented. In order to more effectively identify and monitor billing and payment for discarded drugs and biologicals, CMS is revising this policy to require the uniform use of the JW modifier for all claims with discarded Part B drugs and biologicals.

With this manual update, effective January 1, 2017, contractors shall require the use of the JW modifier to identify discarded drugs and biologicals when processing Part B claims for drugs and biologicals, except Competitive Acquisition Program (CAP) drugs and biologicals.

**B. Policy:** Effective January 1, 2017, when processing claims for Part B drugs and biologicals (except those provided under CAP), the use of the JW modifier to identify unused drugs or biologicals that are appropriately discarded is required.

Also, effective January 1, 2017, providers are required to document the discarded drug or biological in the patient's medical record. CMS is removing the contractors' discretion to determine whether the JW modifier is required for claims with discarded drugs and biologicals.

The JW modifier is not used on claims for CAP drugs and biologicals.

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

## II. BUSINESS REQUIREMENTS TABLE

*"Shall" denotes a mandatory requirement, and "should" denotes an optional requirement.*

Number	Requirement	Responsibility								
		A/B MAC			D M E	Shared-System Maintainers				Other
		A	B	H H H		F M V C	I C M W	S S S F		
9603.1	Effective January 1, 2017, contractors shall require the use of the JW modifier for claims with unused drugs or biologicals from single use vials or single use packages that are appropriately discarded (except those provided under the Competitive Acquisition Program for Part B drugs and biologicals (CAP)).	X	X		X					
9603.2	Effective January 1, 2017, contractors shall also require providers to document the discarded drug or biological in the patient's medical record when submitting claims with unused Part B drugs or biologicals from single use vials or single use packages that are appropriately discarded.	X	X		X					
9603.3	Effective January 1, 2017, contractors shall no longer have discretion to determine whether the JW modifier is required for claims with discarded Part B drugs and biologicals.	X	X		X					

**III. PROVIDER EDUCATION TABLE**

Number	Requirement	Responsibility					
		A/B MAC			D M E	C	I
		A	B	H H H			
9603.4	MLN Article: A provider education article related to this instruction will be available at <a href="http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/">http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/</a> 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 sites and include information about it in a listserv message within 5 business days after receipt of the notification from CMS announcing the availability of the article. In addition, the provider education article shall be included in the contractor's 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		

**IV. SUPPORTING INFORMATION**

**Section A: Recommendations and supporting information associated with listed requirements:**

"Should" denotes a recommendation.

<b>X-Ref Requirement Number</b>	<b>Recommendations or other supporting information:</b>
9603.1	Contractors shall note that the JW modifier was issued in the 2003 Alpha-Numeric HCPCS File and later clarified in CRs 5520, 5923, and 7095. Therefore, Medicare claims processing systems can accept and process this modifier.

**Section B: All other recommendations and supporting information:** N/A

## V. CONTACTS

**Pre-Implementation Contact(s):** Felicia Eggleston, 410-786-9287 or Felicia.Eggleston@cms.hhs.gov , Prabath Malluwa-Wadu, 410-786-4620 or prabath.malluwa-wadu@cms.hhs.gov

**Post-Implementation Contact(s):** Contact your Contracting Officer's Representative (COR).

## VI. FUNDING

### **Section A: 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.

**ATTACHMENTS: 0**

## 40 - Discarded Drugs and Biologicals

**(Rev.3538, 06-09-16, Effective: 01-01-17, Implementation: 01-03-17)**

The CMS encourages physicians, hospitals and other providers and suppliers to care for and administer **drugs and biologicals** 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.

**Effective January 1, 2017** when processing claims for drugs and biologicals (except those provided under the Competitive Acquisition Program for Part B drugs and biologicals (CAP)), local contractors **shall** require the use of the modifier JW to identify unused **drugs** 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 **shall** be billed on another line by using the JW modifier. Both line items would be processed for payment. **Providers must record the discarded amounts of drugs and biologicals in the patient's medical record.**

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.