CMS Manual System	**Department of Health & Human Services (DHHS)**
Pub 100-04 Medicare Claims Processing	**Centers for Medicare & Medicaid Services (CMS)**
Transmittal 12067	**Date: June 2, 2023**
	Change Request 13056

SUBJECT: New Claims Modifier Requirement for Drugs and Biologicals from a Single-Dose Container or Single-Use Package

I. SUMMARY OF CHANGES: The purpose of this Change Request (CR) is to update Pub. 100-04 Medicare Claims Processing Manual, Chapter 17 – Drugs and Biologicals, Section 40 - Discarded Drugs and Biologicals to reflect revised provisions effective January 1, 2023, including requirements for the new JZ modifier beginning July 1, 2023. The CR also instructs contractors to conduct periodic audits of Part B claims beginning July 3, 2023.

EFFECTIVE DATE: January 1, 2023
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: July 3, 2023 - JZ Modifier

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 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:12067	Date: June 2, 2023	Change Request: 13056

SUBJECT: New Claims Modifier Requirement for Drugs and Biologicals from a Single-Dose Container or Single-Use Package

EFFECTIVE DATE: January 1, 2023
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IMPLEMENTATION DATE: July 3, 2023 - JZ Modifier

I. GENERAL INFORMATION

A. Background: When a provider or supplier must discard the amount of a Part B drug or biological (hereafter, drug) that was unused and discarded (that is, the discarded amount) from a single-dose container or a single-use package (hereafter, single-dose container) after administering a dose to a Medicare beneficiary, Medicare Part B provides payment for the discarded amount, as well as the dose administered, up to the amount of the drug indicated on the vial or package labeling. Pub. 100-04, Medicare Claims Processing Manual, Chapter 17, Section 40, provides policy for the reporting and billing of discarded drugs payable under Medicare Part B.

As stated in CR 9603, beginning January 1, 2017, the CMS requires uniform use of the JW modifier (Drug amount discarded/not administered to any patient) when processing Part B claims for drugs and biologicals from "single use vials or single use packages." Providers and suppliers are also required to document the amount of discarded drugs in the medical records of Medicare beneficiaries.

Section 90004 of the Infrastructure Investment and Jobs Act (Pub. L. 117-9, November 15, 2021) (Infrastructure Act) amended section 1847A of the Social Security Act (the Act) to require manufacturers to provide a refund to CMS for certain discarded amounts from a refundable single-dose container or single-use package drug. The refund amount is the amount of discarded drug that exceeds an applicable percentage, which is required to be at least 10 percent of total allowed charges for the drug in a given calendar quarter. This provision specifies that discarded amounts are to be determined using a mechanism such as the JW modifier or a successor modifier that includes discarded amount data.

Section 90004 of the Infrastructure Act also requires CMS to conduct periodic audits of claims submitted under Medicare Part B with respect to refundable single-dose container or single-use package drugs in accordance with the authority under section 1833(e) of the Act.

In the Calendar Year (CY) 2023 Physician Fee Schedule (PFS) final rule (87 FR 69710 – 69734), CMS finalized new requirements for submitting claims to Medicare under the PFS, Hospital Outpatient Prospective Payment System (OPPS), and Ambulatory Surgical Center (ASC) Payment System for separately payable Part B drugs from single-dose containers. We codified use of the JW modifier to identify discarded amounts of drugs from refundable single-dose containers or single-use packages.

Further, to align with the JW modifier reporting policy, the final rule established a requirement that providers and suppliers report the new JZ modifier (zero drug amount discarded/not administered to any patient) when there are no discarded amounts of such products. We stated that the JW and JZ modifier requirements would apply to separately payable drugs under Medicare Part B that are described as being supplied in a "single-dose" container or "single-use" package based on Food and Drug Administration (FDA)-approved labeling.

B. Policy:

- There are no changes regarding the reporting of the JW modifier.

- Note that CMS is using the terminology of "single-dose container" or "single-use package" instead of the terms used in CR 9603 (that is, "single use vials or single use packages").

- For dates of service on or after January 1, 2023, JW modifier data will be used to identify discarded amounts of a billing and payment code for the purpose of calculating the refund as described in section 1847A(h)(3) of the Act.

- Effective July 1, 2023, providers and suppliers are required to report the JZ modifier on all claims that bill for drugs separately payable under Medicare Part B when there are no discarded amounts from single-dose containers or single-use packages.

- Note that CMS is implementing the JZ modifier in phases:
    - Providers and suppliers may report the JZ modifier as early as January 1, 2023,
    - The JZ modifier is required on applicable claims beginning July 1, 2023, and
    - The contractor requirement to begin editing claims for correct use of the JW and JZ modifiers will be effective October 1, 2023, but claims editing will begin on October 2, 2023, which will be communicated in a future CR.

- In summary, providers and suppliers billing for drugs separately payable under Medicare Part B from single-dose containers are required to report on all claims either the JW or JZ modifier, to identify any discarded amounts or to attest that there are no discarded amounts, respectively.

- Claims that bill for separately payable drugs under Medicare Part B from single-dose containers that do not report the JW or JZ modifier on or after July 1, 2023 may be subject to audits, although the implementation date for audits is July 3, 2023.

- Further details regarding the JW and JZ modifiers are found in the Frequently Asked Questions (FAQ) available at https://www.cms.gov/medicare/medicare-fee-for-service-part-b-drugs/mcrpartbdrugavgsalesprice

II. BUSINESS REQUIREMENTS TABLE

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

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
13056.1	Effective July 1, 2023, contractors shall require the use of the JZ modifier on claims for drugs and biologicals from single-dose containers or single-use packages when no amount is discarded. The	X	X		X					

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	implementation date for this requirement is July 3, 2023.									
13056.2	Contractors shall be aware of recent legislation (SSA section 1847A(h)(6)(A)(ii)) requiring periodic audits of the JW modifier and conduct medical review, at their discretion and as driven by data mining/findings, within their normal medical review constructs.	X	X		X					

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
13056.3	Medicare Learning Network® (MLN): CMS will market provider education content through the MLN Connects® newsletter shortly after CMS releases the CR. MACs shall follow IOM Pub. No. 100-09 Chapter 6, Section 50.2.4.1 instructions for distributing the MLN Connects newsletter information to providers and link to relevant information on your website. You may supplement MLN content with your local information after we release the MLN Connects newsletter. Subscribe to the "MLN Connects" listserv to get MLN content notifications. You don't need to separately track and report MLN content releases when you distribute MLN Connects newsletter content per the manual section referenced above.	X	X		X	

IV. SUPPORTING INFORMATION

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

"Should" denotes a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:
	Contractors shall note that the JZ modifier was issued in the January 1, 2023 HCPCS Alpha-Numeric HCPCS File. Therefore, Medicare claims processing systems can accept and process this modifier.
	Contractors shall note that the JW modifier was issued in the 2003 Alpha-Numeric HCPCS File and later clarified in CRs 5520, 5923, 6711, 7095, and 9603. Therefore, Medicare

X-Ref Requirement Number	Recommendations or other supporting information:
	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): Laura Kennedy, 410-786-3377 or laura.kennedy@cms.hhs.gov (Policy)

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

Medicare Claims Processing Manual
Chapter 17 - Drugs and Biologicals

40 - Discarded Drugs and Biologicals
(Rev: 12067; Issued: 06-02-23; Effective: 01-01-23; Implementation: 07-03-23)

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 *billing* provider or supplier must discard the remainder of a single-*dose container* or single-use package after administering a dose 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 local contractors shall require the use of the *JW* modifier to identify unused *and discarded amounts (hereafter, discarded amounts) of* drugs or biologicals from single-*dose containers* or single-use packages.

The discarded amount is any amount that is not part of the prescribed dose and not intended to have a therapeutic effect in the patient. Even if certain amounts are extracted from the vial or are required to be in the vial to administer the prescribed dose, we do not consider them to be used if they are not intended for therapeutic effect as part of the prescribed dose. Generally, the discarded amount is the labeled amount on the single-dose container (or containers if more than one is required) minus the dose (the dose being the prescribed amount of drug administered to the patient).

The JW modifier, billed on a separate line, provide*s* payment for the amount of discarded drug or biological. *For the administered amount, one claim line shall include the billing and payment code (such as a HCPCS code) describing the given drug, no modifier, and the number of units administered in the unit field. For the discarded amount, a second claim line shall include the same billing and payment code as used for the administered amount, the JW modifier, and the number of units discarded in the unit's field.*

For example, *if a provider or supplier uses* a single-*dose container* that is labeled to contain 100 units of a drug *to administer* 95 units to the patient and 5 units *are* discarded. The 95-unit dose is billed on one line, while the discarded 5 units shall be billed on another line *with* 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.

Effective July 1, 2023, local contractors shall require the use of the modifier JZ to attest that there are no amounts of drugs or biologicals from single-dose containers or single-use packages were unused and discarded. For the administered amount, the claim line should include the billing and payment code (such as HCPCS code) describing the given drug, the JZ modifier (attesting that there were no discarded amounts), and the number of units administered in the unit's field.

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. *For dates of service beginning July 1, 2023, the JZ modifier shall be used in this circumstance.*

In general, the JW and JZ modifier policy applies to all drugs separately payable under Medicare Part B that are described as being supplied in a "single-dose" container or "single-use" package based on FDA-approved labeling. The use of these modifiers is not appropriate for drugs that are from multiple-dose containers. The JW and JZ modifier policy does not apply for drugs that are not separately payable, such as packaged OPPS or ASC drugs, or drugs administered in the FQHC or RHC setting.

The JW and JZ modifiers are not required for vaccines described under section 1861(s)(10) of the Act that are furnished from single-dose containers. Since the influenza, pneumococcal, and COVID–19 vaccines specified in section 1861(s)(10) of the Act are often roster billed by mass immunizers, and roster billing cannot accommodate modifiers, it would be impractical to require the JW and JZ modifiers for such vaccines. Such a requirement would likely result in substantial operational issues for mass immunizers and impair patient access to these vaccines.

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 that the CAP is postponed effective January 1, 2009.*