CMS Delays JW Modifier Reporting Requirement

During a Hospitals Open Door Forum on June 7, 2016 representatives from CMS announced that the requirement for reporting single-use drug or biological wastage with the JW modifier would be delayed at least 6 months from the previously announced 7/1/16 effective date. Then, on June 9, CMS released transmittal 3530 officially changing the effective date to 01/01/2017:

https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2016-Transmittals-Items/R3538CP.html?DLPage=1&DLEntries=10&DLSort=1&DLSortDir=descending

Transmittal 3530, dated May 24, 2016, is being rescinded and replaced by Transmittal 3538 to update the Effective and Implementation dates.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.

During the same Open Door Forum, CMS promised to soon provide additional guidance on the JW modifier requirement. Representatives explained that the requirement was intended to apply to separately payable drugs assigned to OPPS status indicators G and K. This limitation in scope has not yet been finalized in transmittal form, however.

In late April 2016, Medicare had announced that Part B providers (including both physicians and hospitals) must report the JW modifier (Drug Amount Discarded/Not Administered to Any Patient) on a second claim line to separately report the wasted/unused units of HCPCS coded drugs or biologicals from single use vials or single use packages on Medicare outpatient claims. At that announcement, the effective date for compliance was July 1, 2016:

https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM5923.pdf

Provider Action Needed

The Centers for Medicare & Medicaid Services (CMS) issued Change Request (CR) 9603 to alert MACs and providers of the change in policy regarding the use of the JW modifier for discarded Part B drugs and biologicals.

Effective July 1, 2016, providers are required to:

- Use 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 (CAP) for Part B drugs and biologicals) and
- 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

Make sure that your billing staffs are aware of these changes. Remember that the JW modifier is not used on claims for CAP drugs and biologicals.

With this announcement, CMS changes the Medicare Claims Processing Manual, Chapter 17 - Drugs and Biologicals. Previously, the Manual allowed that "contractors may require the use of the modifier JW…" The new language is in red font below:

> https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R3508CP.pdf
>
> Effective July 1, 2016 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.

In requiring the JW modifier, Medicare intends to monitor wastage to ensure that providers use the most appropriate available single-use vial size, particularly for separately payable drugs and biologicals (OPPS status K and G HCPCS). Critical Access Hospitals (CAHs) are paid for all line items on a cost basis. For separately payable drugs, both the administered and the discarded units of a drug or biological will be reimbursed.

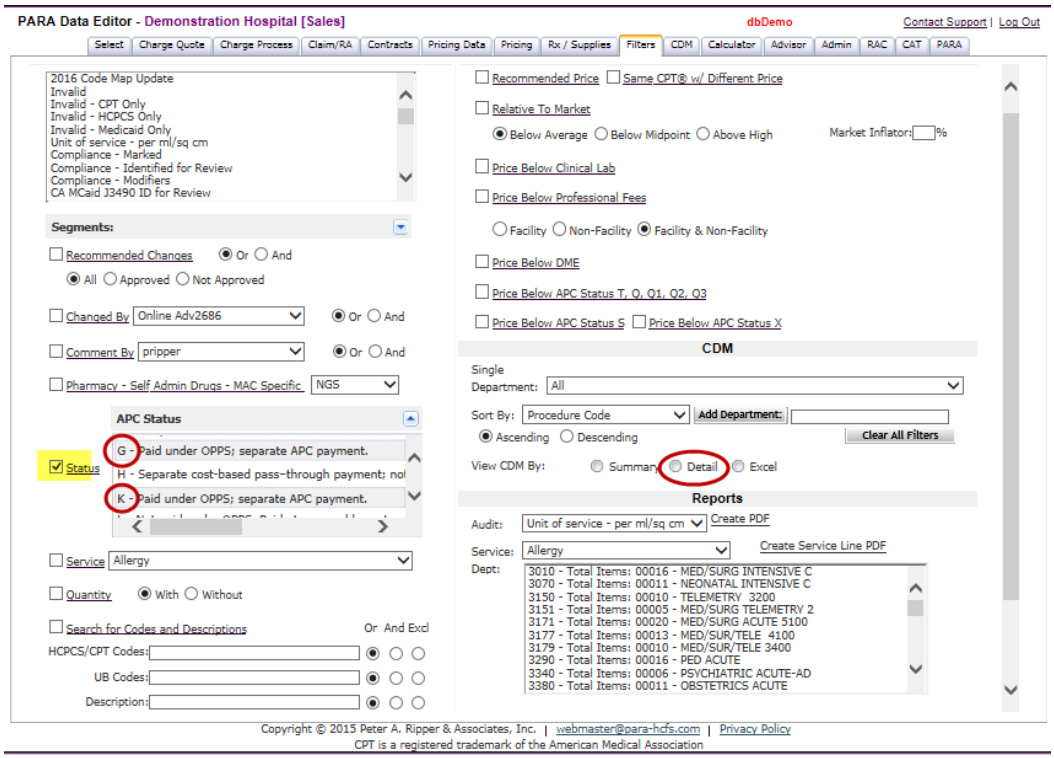
In a MedLearn publication revised in 2013, Medicare explains its expectation that the smallest available vial should be used to meet the dose required to treat the patient:

> https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/SE1316.pdf
>
> - If the provider must discard the remainder of a single-use vial or other package after administering the prescribed dosage of any given drug, Medicare may cover the amount of the drug discarded along with the amount administered. The following elements must be followed in order for the discarded amount to be covered.
>
> 1. The vial must be a single-use vial. Multi-use vials are not subject to payment for any discarded amounts of the drug.
>
> 2. The units billed must correspond with the smallest dose (vial) available for purchase from the manufacturer(s) that could provide the appropriate dose for the patient.

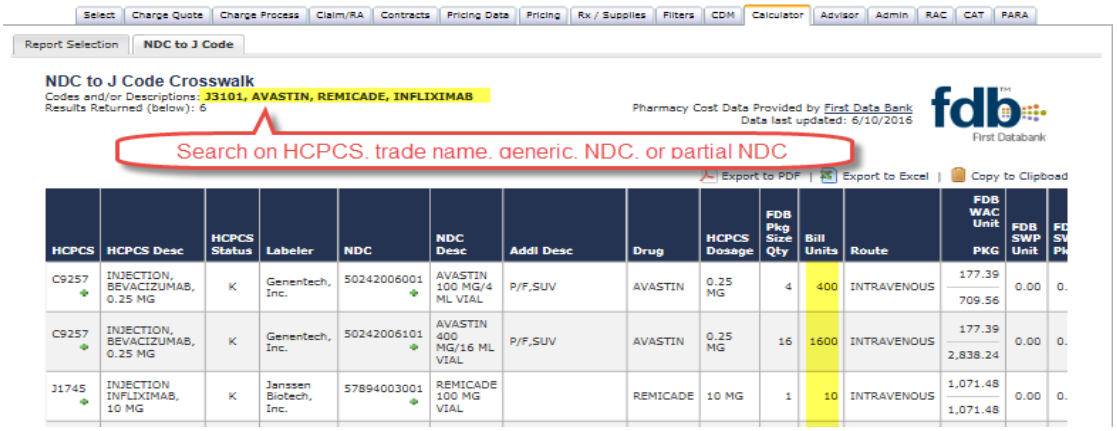
For example, if a patient is to receive a dose of 44 units (440 milligrams) of Avastin, Medicare would expect that one 40-unit vial and one 10-unit vial would be used, resulting in wastage of only 6 units. If two vials of the 40-unit size vial were consumed, the wastage reported would be 36 units. The documentation should include an affirmation that the excess drug was discarded; since some pharmacies may split a single vial between two patients for scheduled services on the same day (i.e.

macular degeneration injections), CMS requires documentation that the drug was wasted and not reallocated.

Hospitals which are paid under Medicare's OPPS system can determine which drugs and biological items are separately payable using the **PARA Data Editor** Filters tab. In the status section, highlight status indicators G (Pass-Through Drugs and Biologicals) and K (Nonpass-Through Drugs and Nonimplantable Biologicals, Including Therapeutic Radiopharmaceuticals):



Furthermore, the **PARA Data Editor** Calculator features an NDC to HCPCS report, which provides convenient access to details of HCPCS reporting and the quantity of bill units in any one vial. The NDC to HCPCS crosswalk will return results when the drug trade name, generic name, NDC, HCPCS, or partial NDC are entered in the search field:



HCPCS	HCPCS Desc	HCPCS Status	Labeler	NDC	NDC Desc	Addl Desc	Drug	HCPCS Dosage	FDB Pkg Size Qty	Bill Units	Route	FDB WAC Unit PKG	FDB SWP Unit
C9257	INJECTION, BEVACIZUMAB, 0.25 MG	K	Genentech, Inc.	50242006001	AVASTIN 100 MG/4 ML VIAL	P/F,SUV	AVASTIN	0.25 MG	4	400	INTRAVENOUS	177.39 / 709.56	0.00
C9257	INJECTION, BEVACIZUMAB, 0.25 MG	K	Genentech, Inc.	50242006101	AVASTIN 400 MG/16 ML VIAL	P/F,SUV	AVASTIN	0.25 MG	16	1600	INTRAVENOUS	177.39 / 2,838.24	0.00
J1745	INJECTION INFLIXIMAB, 10 MG	K	Janssen Biotech, Inc.	57894003001	REMICADE 100 MG VIAL		REMICADE	10 MG	1	10	INTRAVENOUS	1,071.48 / 1,071.48	0.00

As clients work to meet the new reporting requirement, **PARA** offers the following recommendations:

- **Confer with your information system software vendor** for a billing solution; all hospitals doing business with Medicare are faced with the same requirement, therefore the software vendors are under pressure to deliver a solution. Many have a solution developed which has not been used; some Medicare administrative contractors have required the JW modifier years ago, but none presently require it.
- **Ensure both billing and documentation requirements are met** – In addition to the daunting requirement that the JW modifier should be reported on the claim, Medicare requires that "Providers must record the discarded amounts of drugs and biologicals in the patient's medical record." **PARA** recommends incorporating an affirmative statement in the supporting documentation that the unused portion of a vial of expensive medication was truly discarded, and was not reallocated to another patient receiving the same medication.
- **Test claims** – be sure to look at the actual claim lines produced, not just the detail charges. For example, if the hospital does not apply a price to the wasted units, verify whether the line with the JW modifier is actually produced on the claim. Hospitals have learned in the past that a zero-priced line item will not appear on the claim, even though the "charge" appears in the transaction detail.
- **Prioritize OPPS Status G and K drugs which are in single-use vials or packages and have a multiplier of more than one**. Since it is not possible to report waste on those NDC codes which contain only one bill unit of the assigned HCPCS code, vials containing only one unit of the reported HCPCS will not require a separate JW line.