



## Don't Let Money Go to Waste. Learn to Bill Discarded Drugs Correctly.

The Centers for Medicare & Medicaid Services (CMS) recently released Transmittal 1962 clarifying the use of modifier JW and how to bill Medicare for discarded drugs and biologicals.<sup>1</sup> According to CMS, hospitals are encouraged to schedule patients in such a way that drugs or biologicals are administered in an efficient yet, clinically appropriate manner. In order to minimize drug wastage, hospitals should schedule their patients requiring similar drugs or biologicals on the same day. This practice will allow hospitals to administer the unused portion of a single-use vial or drug package to another patient when clinically appropriate. CMS acknowledges that there are circumstances where such arrangements cannot be made and unused drugs or biologicals must be discarded. In that case, CMS will pay for both the administered and discarded drug and biological if specific criteria are met.

Failure to comply with CMS billing regulations can result in improper payments and have a substantial financial impact on an organization. Hospitals can lose income due to wasted drugs. Moreover, CMS contractors such as the Recovery Audit Contractors are auditing drug doses and billing units, including billing practices for discarded drugs. Therefore, hospitals may need to pay penalties for potential overpayments. As a result, hospitals must ensure that their billing staff is aware of and fully understands CMS billing rules with respect to discarded drugs and biologicals.

### A Refresher on Medicare's Coverage Policy on Drugs

Generally, Medicare covers drugs and biologicals administered during a Part A hospitalization or skilled nursing facility stay. Medicare also covers drugs that are furnished "incident to" a physician's service if the drug is not usually self-administered by the patient. According to the Benefits Improvement and Protection Act, Medicare will not pay for drugs that are self-administered by a Medicare beneficiary. Therefore, oral drugs, suppositories, and topical medications "are considered to be usually self-administered by the patient" and thus, not covered by Medicare.<sup>2,3</sup> CMS will, however, pay for drugs that are "not usually self-administered." This can include drugs administered intramuscularly (e.g.

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<sup>1</sup> Transmittal 1962 was issued on April 30, 2010.

<sup>2</sup> Medicare Benefit Policy Manual, Chapter 15, Section 50.2(B): Administered.

<sup>3</sup> Note that there are exceptions to the self-administered rule. Specifically, Medicare will cover Erythropoetin, drugs for patients with specific blood clotting factors, drugs used for immunosuppressive therapy, and some oral anti-cancer and anti-nausea drugs.

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injection), intravenously (e.g. IV drip with antibiotic to treat an infection), or subcutaneously provided that the drug and administration route are medically reasonable and necessary. Therefore, if a drug is available in both oral and injectable forms, “the injectable form of the drug must be medically necessary and reasonable as compared to the oral form.”<sup>4</sup>

## **An Update on Self-Administration**

CMS recently released revised instructions in Transmittal 123 to its contractors concerning the self-administration of a drug or biological. Specifically, CMS revised the language outlined in Medicare Policy Manual, Chapter 15 section 50.2, Determining Self Administration of Drug or Biological, to clarify the definition of injectable drugs. Prior to the issuance of Transmittal 123, “only” injectable drugs were eligible for Medicare coverage. CMS, however, now modified the language stating that “injectable drugs, including intravenously administered drugs are typically eligible” for Medicare coverage.<sup>5</sup>

CMS also updated the Medicare Benefit Policy Manual to include a broader range of drugs that are “not usually self-administered” and are covered by Medicare. According to CMS, the Food and Drug Administration (FDA) recently approved drugs administered through other routes than injection that can be considered as “not usually self-administered.” CMS did not provide specific examples of these FDA approved drugs; however, hospitals should refer to their contractors’ (i.e. Fiscal Intermediaries, Medicare Carriers, or A/B Medicare Administrative Contractors) website and local coverage determinations to determine whether a drug or biological is considered “usually self-administered” or “not usually self-administered” and their corresponding coverage status.

## **Billing Medicare for Discarded Drugs and Biologicals**

As noted above, CMS will provide payment for discarded drugs or biologicals when certain criteria are met. Specifically, CMS will reimburse discarded drugs or biologicals up to the dosage amount indicated on the vial or package label if:

- The hospital makes an effort to schedule patients to use drugs or biologicals in an efficient yet, clinically appropriate manner;
- The drug or biological is a single-use vial or single-use package;
- The amount billed to Medicare as discarded drug is not administered to another patient; and
- The drug or biological is initially administered to the patient to appropriately address the patient’s condition and any unused portion is discarded. A hospital cannot bill Medicare for

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<sup>4</sup> Medicare Benefit Policy Manual, Chapter 15, Section 50.2(A): Policy.

<sup>5</sup> Medicare Benefit Policy Manual, Chapter 15, Section 50.2(B): Administered.

discarded drugs if none of the drug was initially administered to a patient (e.g. Medicare beneficiary misses an appointment).

The billing rules for drug wastage depend on the hospital's contractor. For example, CMS does not mandate hospitals to report modifier JW on all claims with drug wastage. Rather, CMS defers to its contractors to determine if modifier JW should be reported on claims. CMS specifically states in Transmittal 1962 that "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."<sup>6</sup> As a result, providers are encouraged to visit their contractor's website and policy to ascertain the billing rules with respect to drug wastage.

## Modifier JW

Modifier JW is defined as "drug or biological amount discarded/not administered to any patient." This modifier is used on claims to indicate drug wastage. Modifier JW should not be used on claims for drugs or biologicals provided under the Competitive Acquisition Program (CAP).<sup>7</sup> If a hospital's contractor requires modifier JW, the hospital must report the amount administered and the amount wasted on separate line items but on the same claim. See examples below.

It should be noted that modifier JW is not used when the actual dose of the drug or biological administered is less than the billing unit defined in the HCPCS descriptor. For example, HCPCS J2175 descriptor states meperidine hydrochloride, per 100 mg. Therefore, one billing unit is equal to 100 mg. If 97 mg of J2175 is administered and 3 mg of J2175 is wasted, modifier JW should not be reported. This is because the amount administered, 97 mg, is less than the billing unit, which is 100 mg. Additional examples and other scenarios are provided below.

## Examples

CMS provided several examples of proper and improper billing of discarded drugs and biologicals. The following examples were extracted from CMS' transmittals and educational materials provided by CMS' contractors.

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<sup>6</sup> Medicare Claims Processing Manual Chapter 17, Section 40: Discarded Drugs and Biologicals.

<sup>7</sup> Section 303 (d) of the Medicare Modernization Act requires the implementation of CAP for Medicare Part B drugs and biologicals not paid on a cost or prospective payment system basis. The CAP is an alternative to the Average Sale Price payment methodology for acquiring certain Part B drugs which are administered incident to a physician's services.

### **Example 1: Single Patient with Modifier JW**

“[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. “

(Source: Transmittal 1962)

### **Example 2: Multiple Patients with Modifier JW**

“A physician schedules three Medicare patients to receive botulinum toxin type A (J0585, botulinum toxin type A, per unit) on the same day within the designated shelf life of the product. Currently Botox® is reconstituted in the physician’s office; it has a shelf life of only four hours. Often a patient receives less than a 100-unit dose. The physician administered 30 units to each patient. Your claim for these patients would indicate J0585 billed at quantity 30 (to indicate the amount administered to the patient). Billing J0585 JW is not appropriate for these patients.

Your claim for the last patient receiving the Botox® in those four hours is where the remaining 10 units are to be billed to Medicare. Your last patient’s claim would indicate J0585 billed at quantity 30 (to indicate the amount administered to the patient) on one detail line. The next detail line would indicate J0585 JW billed at quantity 10 (to indicate 10 units wasted from the 100-unit vial).”

(Source: TrailBlazer Health Enterprises, CMS Contractor, “Drug Wastage,” published May 2010)

### **Example 3: Single Patient Without Modifier JW**

“[O]ne billing unit for a drug is equal to 10mg of the drug in a [single-use] vial. A 7 mg 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 3 mg of drug is not permitted because it would result in overpayment. Therefore when the billing unit [in this case 10 mg] is equal to or greater than the total actual dose [7 mg] and the amount discarded [3mg], the use of JW modifier is not permitted.”

(Source: Transmittal 1962)

### **Example 4: Single Patient Without Modifier JW**

A physician administered 75 mg of meperidine HCL, (J2175, meperidine hydrochloride, per 100 mg) to a Medicare patient. The provider has only one patient who requires meperidine HCL. Thus, 25 mg of meperidine HCL is discarded. Furthermore, the provider’s contractor (First Coast Service Options Inc.) does not require modifier JW.

The provider will bill the drug wastage portion and actual administered portion on the same line item, i.e. J2175, 1 billing unit, without modifier JW. In the event the provider bills the drug wastage and actual

dose on separate line items and appends modifier JW to the drug wastage, First Coast Service Options will deny one of the line items as a duplicate. Note that First Coast Service Option chooses to delete one line item as a duplicate, not all contractors following this process. Therefore, failure to comply with your contractor's billing rules concerning discarded drugs can result in overpayment, a denied claim, or a delayed claim.

(Sources: TrailBlazer Health Enterprises, CMS Contractor, "Drug Wastage," published May 2010; First Coast Service Option Inc., CMS Contractor, "Medicare Update A Newsletter for Florida Medicare Part B Providers," published May 2008)

## Do's and Don'ts when Billing for Drug Wastage

The following table summarizes the do's and don'ts regarding billing for drug wastage. Hospitals may wish to use the table as educational material for their billing staff.

**Table 1: Billing Drug Wastage**

Do's	Don'ts
<ul style="list-style-type: none"><li>Do refer to your CMS contractor to verify appropriate billing of discarded drugs.</li></ul>	<ul style="list-style-type: none"><li>Do not use modifier JW when the billing unit is equal to or greater than the total actual dose and the amount discarded.  For example, if 1 billing unit is equal to 10 mg and 7 mg of a drug was administered to a patient and 3 mg of the drug was discarded, modifier JW cannot be used to report the discarded drug. As the sum of the administered dose (7mg) and discarded dose (3mg) is equal to the billing unit of 10 mg.</li></ul>
<ul style="list-style-type: none"><li>Do bill Medicare for discarded drugs and biologicals up to the amount indicated on the single-use vial or package label when appropriate.</li></ul>	<ul style="list-style-type: none"><li>Do not bill Medicare the extra amount of drug manufacturers provide to account for wastage in syringe hubs. Many manufacturers provide an extra drug in each vial to account for the wastage in the syringe hubs. This extra amount should not be billed to Medicare because it is not an expense to the provider and it exceeds the amount on the vial or package label.</li></ul>
<ul style="list-style-type: none"><li>Do make good-faith effort to schedule patient appointments for similar single-use vial or packages on the same day to reduce drug wastage. Note that this practice should only be used when clinically appropriate.</li></ul>	<ul style="list-style-type: none"><li>Do not bill Medicare for drug wastage if none of the drug was initially administered. CMS will not reimburse unused drugs or biologicals that result from a missed patient appointment.</li></ul>

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- Do use modifier JW when single-use vials or single-use packages are appropriately discarded.
  - Do not bill Medicare for discarded drugs or biologicals for multi-use vials.
- Do not use modifier JW for drugs or biologicals provided under the CAP.

## Take Home Message

As indicated above, failure to comply with CMS billing regulations can result in improper payments. Hospitals must review their contractor's websites and policies for appropriate billing rules concerning discarded drugs and biologicals. In the current regulatory environment, hospitals face increased government and public scrutiny with respect to compliance. Thus, hospitals must be cautious about billing for drug wastage and ensure internal policies and procedures are updated based on regulatory changes.

## Resources

- "Discarded Drugs and Biologicals Updates." Transmittal: 1962. 30 Apr. 2010.
- "Medicare Benefits Policy Manual Update-Determining Self-Administration of Drug or Biological." Transmittal: 123. 30 April. 2010.
- "Discarded Drugs and Biological Updates." Medicare Learning Network Matters: MM6711 Revised. 27 May 2010.
- "Discarded Drugs and Biological Updates." Medicare Learning Network Provider Inquiry Assistance: JA6711 Revised. 6 May 2010.
- "Medicare Benefits Policy Manual Update-Determining Self-Administration of Drug or Biological." Medicare Learning Network Provider Inquiry Assistance: JA6950 Revised. 13 May 2010.
- "Medicare Benefits Policy Manual Update-Determining Self-Administration of Drug or Biological." Medicare Learning Network Matters: MM6950. 4 May 2010.
- Medicare Claims Processing Manual Chapter 17, Section 40: Discarded Drugs and Biologicals.
- Medicare Benefit Policy Manual Chapter 15, Section 50.2: Determining Self-Administration of Drug or Biological.
- Competitive Acquisition Program for Drugs & Biologicals. 2010. CMS Website 11 Jun. 2010. <<https://www.cms.gov/CompetitiveAcquisforBios/>>.
- Drug Waste. 2010. TrailBlazer Health Enterprise (CMS Contractor). 9 Jun. 2010. <<http://www.trailblazerhealth.com/Publications/Job%20Aid/Drug%20Wastage.pdf>>.
- Manual update regarding billing for discarded drugs or biologicals. 2010. First Coast Service Options Inc. (CMS Contractor). 9 Jun. 2010. <[http://medicare.fcso.com/Claim\\_submission\\_guidelines/169677.asp](http://medicare.fcso.com/Claim_submission_guidelines/169677.asp)>.

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- Birkenshaw, Claudia. UD-04 Handbook for Hospital Billing a Reference and Training Tool for Efficient Operations in Health Care Facilities. Chicago: Health Forum, Inc. 2007.