Drug Waste: A Payable Service?

Robert M. Buell is Vice President, Patient & Provider Services, P4 Healthcare, LLC, and a recognized expert in oncology reimbursement.

In the late 1980s, when I first became a consultant to oncology practices, it was a common belief that practices and clinics would always get paid for waste. Why? Well, as my Medicare attorneys explained to me at the time, the Medicare program paid for all drugs provided “incident to” a physician’s service that were an expense to the billing physician. Back then, no payor minded picking up the tab for a little more 5-FU or leucovorin. Moreover, treatment in the community clinics or hospital outpatient setting was so economical compared to the hospital inpatient setting that paying for waste was considered a bargain.

However, with the increased approval and use of more-expensive drugs, waste has become an issue and begs the evaluation of several questions: What should be reimbursed and what should not? Do payors and manufacturers abuse the system? If so, how?

As will be outlined herein, Medicare has tightened their rules and many other payors are doing the same. For payors who have no written parameters on this issue, we will review the causes of waste, Medicare policies regarding waste, and the impact of these two factors on community oncology practices and other outpatient sites of service. In addition, we will present suggestions about payment policies that may prove fair to all stakeholders.

What is Waste and How Does It Happen?

There are actually several types of waste, and because Medicare treats these types of waste differently, we will define them as follows:

- **Waste after the patient uses the drug.** This can happen for several distinct reasons:
  - **The vial size.** Patients come in all sizes, so a single-dose vial may be too large for weight-based dosing. Furthermore, weight-based dosing drugs generally have very few units in their J-codes like 1 mg or 1 mcg (e.g., ARANESP) so that oncologists can more accurately reflect what was given to the patient. However, not every practice may have the patient volume to finish the vial. Thus, there are leftovers.
  - **Not enough patients for multi-dosing.** There are multidose vials that remain stable for enough time for multiple-patient utilization. However, not every practice may have the patient volume to finish the vial. Thus, there are leftovers.
  - **Inability to derive the proper units from the vial.** There have been problems with some drugs where, when drawing the drug from the vial, less than the advertised amount of drug can be extracted. These units are units that are paid for but are never used by a patient. This can show up in claims edits as overuse.
  - **Waste because the patient does not use the drug at all.** This can happen for several distinct reasons:
    - **The usual dose is 90 mg, leaving 20 mg (in a 30 mg vial) to be wasted—this does not always happen. That is why Medicare will only pay for single-dose vials.** 
    - **Patient cancellation.** Cancer patients cancel drug administration appointments. Patients dread the sickness and discomfort of chemotherapy. Other cancer patients would rather tend to personal issues than sit in the office with an intravenous drip. If drugs are mixed prior to cancellation, they are wasted.

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- **Spillage and breakage.** Accidents happen, and when they happen with chemotherapy drugs, it can be both environmentally hazardous and expensive. In any review of waste, some mention should be made regarding overfill.
  - Overfill is when, for some reason, a vial has more units than advertised on the box. Although all overfill is considered “free drug” and not wastage, it, too, is an area for discussion. This can range from 5 percent to as much as 16 percent. The fact is that manufacturers are keenly aware of the overfill and even adjust their manufacturing to make this happen, especially if the product is in a competitive category.

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How Medicare Deals with Waste

In the early days of office-based drug administration, Medicare allowed charges for any drug that was an expense to the practice or clinic. That caveat included any kind of waste except for overfill. However, again, as office- and hospital-based drugs have become more costly, stricter rules have been developed. Here is an overview of the current rules and some details about how they are handled in the Medicare program:

- **Medicare only pays for waste for single-dose vials.** Weight-based dosing drugs generally have very low units in their J-codes like 1 mg or 1 mcg (e.g., ARANESP) so that oncologists can more accurately reflect what was given to the patient. However, there are some drugs that still have higher dosing per J-code. For example, an oncologist may have to give a smaller patient 70 mg of TAXOL when the usual dose is 90 mg, leaving 20 mg (in a 30 mg vial) to be wasted—this does not always happen. That is why Medicare will only pay waste for single-dose vials. The theory behind this is that, if you use a multidose vial, you should have been drawn to use it by scheduling intelligently. For smaller practices, this may be easier said than done. In the past, it was acceptable to bill the multidose waste to the lampant on the vial. However, the Claims Processing Manual (Chapter 17, Section 40, which may be viewed at http://www.cms.hhs.gov/Manuals/10M/TermDetail.asp?filterType=otherOrder&ID=796068&ID= 145000&Order=ascend&ItemID=CM 5018912) makes a definitive statement outlining the fact that single-dose vial waste is the only billable kind. When a single-dose vial is the only size available, practices may schedule as many patients as possible to treat with that drug in an effort to maximize the wastage by mixing multiple doses out of a single-dose vial.
Medicare does not accept partial HCPCS codes as a rule. Over the years, there have been local Medicare contractors that have required decimal places in the drug Health Care Common Procedure Coding System (HCPCS) J-coding. However, with more standardization and a concerted effort to make J-codes compatible with dosing, this no longer happens. Now, there is a HCPCS modifier that may assist Medicare in tracking wasted drug costs better. Still, this modifier is only required in Medicare’s Competitive Acquisition Program, where Medicare purchases the drug and competitive Acquisition Program, where Medicare in tracking wasted drug costs better. Still, this modifier is only required in Medicare’s Competitive Acquisition Program, where Medicare purchases the drug and supplies it to the office-based clinic.

Medicare only covers a drug that is administered to a beneficiary. This means that a drug is not covered if the patient misses an appointment, the drug is inadvertently destroyed (e.g., a vial dropped on the floor and broken), or the doctor cancels a treatment for medical reasons. This is not a well-known fact in oncology practice circles because it is not explicitly stated anywhere. Still, implicitly, those are the rules. Here is the language from multiple Medicare manuals:

° “CMS will cover the amount of drug necessary for the patient’s condition. If a portion must be discarded after the patient is treated, Medicare will cover the discarded drug along with the amount administered.” This is published in the Medicare Claims Processing Manual, Chapter 17 – Drugs and Biologicals (Section 40 – Discarded Drugs and Biologicals).
° While not at all clearly stated in the waste section, I refer you to the Medicare Benefit Policy Manual, Chapter 15, Section 20: “Part B expenses for items and services are considered to be incurred the day the beneficiary RECEIVED the item or service, regardless of when it was paid for or ordered…”

° In the Medicare Benefit Policy Manual, Chapter 15, Section 30: “The physician must render the service for it to be covered.”

° The waste must be documented in a patient record. This is not explicitly in the rules, but practices must be able to substantiate the amount charged to the Medicare program. If waste is not recorded and the reason for the amount of drug wasted is not apparent, there may be a medical necessity issue down the road. Some Medicare contractors have insisted on stricter documentation requirements. For example, Empire Medical Services Part B Medicare (http://www.empiremedicare.com/news/rynnewse06/102406doc.htm) has the following requirements:
  ° “Recent reviews by Medicare contractors indicate that providers are not adequately documenting, in their medical records, the provision and administration of drugs in the office setting. Empire Medicare Services expects that providers adhere to the following guidelines:
    - Physicians and nonphysician providers should enter the drug ordered in their plan of care for the encounter. The dose and route should be included along with the name of the drug.
    - The encounter should be dated and signed in the medical record (or electronically if using EMR).
    - The person actually administering the drug should enter into the record that he/she administered the drug, include the dose, route, and site of administration, and sign/date that entry.

  ° It is recommended that providers include the drug lot number when documenting the administration of the drug.
  ° If the drug was administered by the ordering provider, it would be sufficient for that person to enter ‘given’ next to the order in the plan of care (and also include the site of administration and lot number).
  ° A provider may indicate that the drug will be administered over a number of dates in the future, in a single plan of care. However, each subsequent administration of the drug must be separately documented as noted above.
    - Signatures should be legible (you may want to print your name under the signature, if necessary).
    - If the full amount of a single-use vial is not administered, the provider or staff administering the drug should enter a note in the patient’s medical record indicating the amount not administered (discarded) as waste.
    - These guidelines are intended to document the provision and administration of drugs that are covered under the Medicare ‘incident to’ benefit (the drug is administered by the physician/nonphysician provider or staff in the office). Use of these documentation guidelines will not extend Medicare coverage to any drug not otherwise covered (e.g., drugs that are usually self-administered, drugs that are not Food and Drug Administration (FDA)-approved, drugs provided for indications that are not considered medically necessary, etc.). Drugs provided in the physician office may not be billed to Medicare unless they are also administered by or incident to the same physician/group.
  ° Providers should retain drug invoice records to document the purchase of the drug, if requested by a Medicare contractor.”

° While the above guidelines are stricter than CMS has dictated nationally, recent CMS audits have indicated that adherence to guidelines like these might protect providers in cases where Medicare wants to know the sources of waste.

A lack of policies concerning drug waste can cause losses for both office managers and private insurers.

- Medicare provisions prohibit providers from billing overfill. In the pharmaceutical world, overfill is basically more drug than the vial size specifies. Part B Medicare covers injectable drugs only if they “represent an expense to the physician or billing entity” (Medicare Benefit Policy Manual, Chapter 15, Section 60.1.A). If the drug units were not explicitly purchased, this does not constitute an expense to the physician and should not be billed. For pharmaceutical manufacturers, it is probably a more egregious problem in that overfills can (unless accurately reflected as a discount) represent a reduction to list price that is not reported to CMS as part of the Average Selling Price (ASP) calculation. This could cause sanctions from the Medicare and Medicaid programs.

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Allow payment for wastage if patients cannot be scheduled in a way to absorb waste regardless of vial size. The Medicare Part B distinction between single- and multidose vials often discriminates against smaller, rural practices. However, if such a policy is instituted at any level, it might be a good idea to have an in-house expert who is charged with understanding vial sizes and average dosing to assure that provisions are followed without abuse.

Allow payment for wastage of unused drugs upon appeal if it is unavoidable. Medicare and Medicaid pay many practices below cost for some drugs. As a result, losses of entire doses of drugs are expensively disastrous. Unavoidable waste includes breakage, spillage, and cancelled treatments for medical reasons. Some pharmaceutical manufacturers do have programs for broken vials. Payors should guard against being billed if there is a pharmaceutical program in place or if a practice mixed the drug prior to the patient’s arrival in the office or clinic.

My Internet searches and interviews with office managers have revealed little about how private insurers manage drug wastage. However, a lack of policies can cause losses for both parties. Therefore, payors would be wise to publish guidelines or have contracts that at least have these simple provisions:

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• Put a max-dosage rule in place. Ceiling dosing would help save money and would ensure that leakage does not occur. However, the question arises as to whether there should be reimbursement for drugs with very short half-lives that must be wasted. Currently, there are edits called the medically unbelievable edits (MUEs) that do have ceiling doses for many drugs. The problem with these MUEs is that the average weight of population is increasing daily. As a result, claims get kicked out, and there need to be medical necessity appeals each time a claim is submitted. It is certainly worthwhile for plans to use ceiling dosing, and it probably saves plans some money; however, plans should check their max-doses against the average weight in the population and the number of successful appeals relative to denials to ensure that the max-doses are reasonable.

• Be cautious about paying for overfill. The Attorneys General of states and the federal government call attention to these cases. It is hard to detect, but it can be an unjustified expense for insurers. Drug waste has become a significant issue in managed care oncology with the increased approval and use of more-expensive pharmacologic agents and the advent of more-stringent Medicare policies regarding waste. Understanding these policies, as well as the underlying causes of waste, will benefit both Medicare and non-Medicare payors alike in developing reimbursement strategies that will likely be fair for all stakeholders.

• Be careful about waste if you, the payor, are financing the drug. Oncologists and other physician providers generally charge erroneously for accidental waste specialty pharmacy providers can also erroneously bill for waste, but these providers are operationally easier to manage. Make sure contracts specify that supplies are in the smallest vial size available or pre-packaged in a traceable size so that audits can obviate overcharging.

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