Optimizing Vial Strategy Under CMS Wastage Rules

A Financial and Commercial Imperative

Executive Summary

The Centers for Medicare & Medicaid Services (CMS) has introduced wastage refund rules for Medicare Part B drugs, fundamentally shifting how pharmaceutical manufacturers must approach vial configuration. Beginning in 2025, manufacturers will be financially responsible for discarded drug volumes exceeding predefined thresholds—10% for standard pharmaceuticals and 26% for orphan drugs.

These rules pose significant financial risks, particularly for weight-based dosing regimens in rare diseases, where patient variability can lead to unpredictable wastage. Manufacturers must now integrate vial optimization into early commercialization planning to mitigate refund liabilities and ensure sustainable market access.

This paper outlines the regulatory landscape, financial implications, and strategic steps manufacturers can take to optimize vial strategy, minimize wastage, and safeguard revenue.

Introduction: Why CMS Wastage Rules Demand a Strategic Approach

Historically, vial size selection was driven by Chemistry, Manufacturing, and Controls (CMC) considerations, with limited focus on financial impact. However, CMS's new wastage refund rules have elevated this decision to a critical commercial strategy issue.

Without proactive planning, manufacturers risk significant refund liabilities, particularly for high-cost therapies with weight-based dosing. This new financial burden requires organizations to rethink vial configuration strategies early in the development process, integrating clinical, operational, and financial considerations.

Regulatory Landscape: The Impact of CMS Wastage Rules

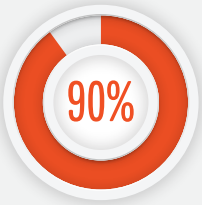
In 2023, CMS finalized regulations mandating that pharmaceutical manufacturers refund Medicare for drug wastage exceeding defined thresholds. These rules, taking effect in 2025, apply to all Medicare Part B drugs and will be enforced through healthcare-provider reported JW and JZ codes.

Categories of Refunds and Exclusions:

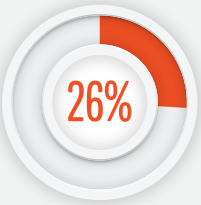
Max Allowed Wastage

Up to 10% of the Part B payment amount for a single-dose container

Drug that is reconstituted with a hydrogel



Drug with a low-volume dose contained within 0.1 mL or less



Drug designated as an orphan drug for a rare disease or condition for only 1 indication, not exceeding 100 patients

EXCLUDED is a drug or biological that:

- Is either a radiopharmaceutical or an imaging agent
- Requires filtration during the drug preparation process
- Payment has been made less than 18 months after drug approval; rebates become effective at 18 months

Key Regulatory Requirements:

- **Wastage Refund Mandate:** Refunds are required for discarded drug volumes exceeding 10% (26% for orphan drugs)
- **Reporting Mechanism:** Providers must document wastage using claim codes, allowing CMS to calculate refund obligations
- **Financial Timeline:** Refund calculations for 2024 wastage will be issued in September 2025, with quarterly payments starting in December 2025

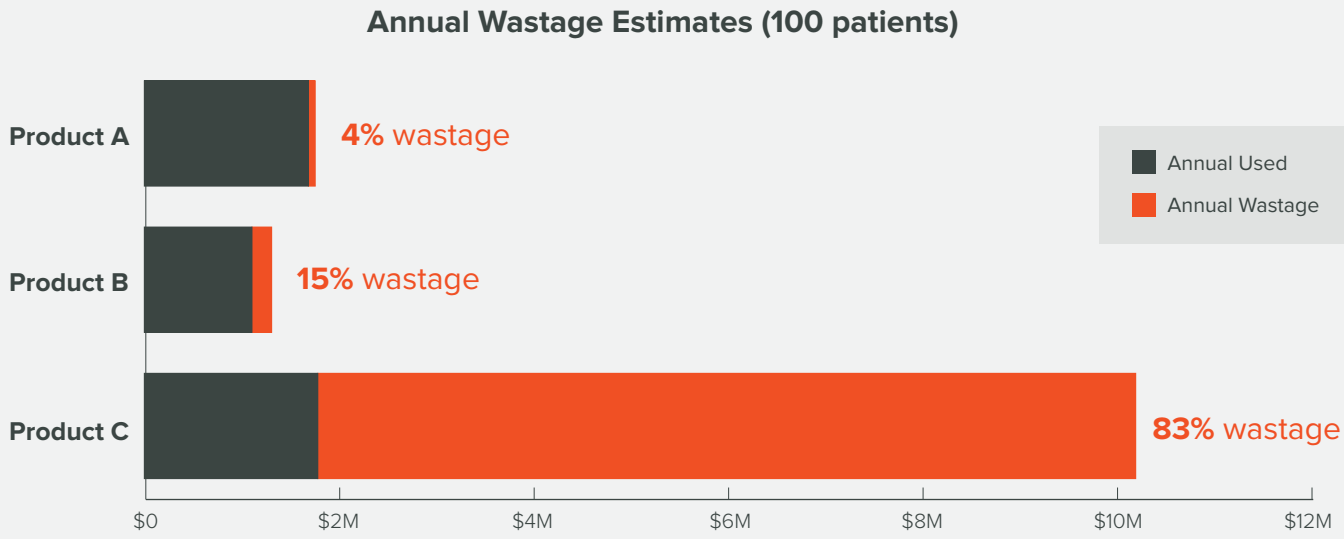
This retrospective refund process creates delayed financial liabilities that may not be immediately visible in a product's early commercial performance.

Moreover, while these rules currently apply to Medicare Part B, industry experts anticipate that commercial insurers will adopt similar policies within the next 12–18 months, particularly for high-cost therapeutic areas such as oncology, rare diseases, and rheumatology.

Financial Implications: The Hidden Cost of Wastage

The financial impact of CMS wastage rules is particularly pronounced for weight-based dosing regimens, which introduce variability in drug utilization and wastage.

A recent analysis of 3 weight-based products with orphan designation demonstrated the potential severity of refund liabilities:



The products shown above illustrate distinct wastage profiles based on their vial configuration, each with unique financial and operational implications:

- **Product A** is projected to experience 4% wastage per 100 patients annually—well below the 26% maximum threshold permitted under current guidelines. This level of wastage poses minimal financial risk
- **Product B** has an anticipated wastage rate of 15% per 100 patients, which remains under the 26% cap. However, 2 potential factors could significantly increase exposure:
  - — The product is currently in clinical development for a second indication. If a second indication is approved, the product will lose the variance for 26% wastage and move to the 10% allowable wastage, thereby increasing liability for any excess between 10% and the current 15%
  - — Patients in the 50–75 kg weight range generate approximately 35% wastage. Should patient distribution trend toward this cohort, the overall average could quickly approach or exceed the 26% limit, resulting in significant financial impact
- **Product C** is projected to have an 83% wastage rate per 100 patients, driven by its current vial configuration. For Medicare Part B alone, this translates to an estimated $2.2 million in annual losses that apply directly to GTN. Due to the timing of the wastage rebates, the GTN impact will not become evident for at least 18 months, resulting in significant loss of revenue

These varying scenarios underscore the importance of early wastage modeling during product development. Manufacturers should evaluate dosing and vial strategies proactively to mitigate financial risk, plan for potential GTN impacts, and ensure compliance with payer requirements.

Key Risk Factors for High Wastage Exposure:

- **Injected or Infused Products –** Particularly those administered intravenously or subcutaneously
- **Weight-Based Dosing –** Drugs requiring individualized dosing based on patient weight
- **Wide Patient Weight Variability –** Greater demographic spread increases wastage likelihood
- **Limited Vial Size Options –** Lack of flexible vial configurations exacerbates wastage

With wastage refunds becoming a reality, failing to optimize vial configurations could lead to millions in unexpected costs.

Strategic Approaches: Minimizing Wastage, Maximizing Market Viability

Manufacturers can mitigate the financial risks posed by CMS wastage rules through proactive vial strategy optimization. Key considerations include

- **Early-Stage Wastage Risk Assessment –** Model potential wastage scenarios using real-world patient data
- **Flexible Vial Configuration Strategies –** Explore alternative vial sizes or multidose packaging solutions
- **Ongoing Policy Monitoring and Advocacy –** Understand changes driven by CMS and adoption by commercial payers to determine the impact on your product
- **Operational and Supply Chain Readiness –** Ensure vial strategies align with provider workflows to reduce unnecessary wastage

By integrating these strategies into clinical development and commercialization planning, pharmaceutical companies can protect revenue while ensuring compliance.

The Time to Act Is Now

Vial selection is no longer just a technical decision—it is a financial and strategic necessity. With CMS wastage refund rules, manufacturers must proactively integrate wastage considerations into their commercialization strategies to understand the long-term impact on their GTN, which can be significant throughout the product's life cycle.

At **PX3 AXS**, we specialize in helping pharmaceutical companies optimize their vial strategies to minimize financial risk and enhance market access. Our team provides:

- Custom wastage risk assessments
- Strategic vial configuration planning
- Policy and reimbursement landscape insights

Contact us today to discuss how we can help you stay ahead of evolving payer policies and safeguard your product's commercial success.

Contact:

Renata Reis, Managing Director — rreis@px3axs.com

Roderick Cavin, Executive Director and Partner — rcavin@px3axs.com

PX3AXS® transforming access