Payer White-Bagging Requirements: Considerations for Access to Infusion Care

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In partnership with Avalere, the National Infusion Center Association (NICA), Infusion Providers Alliance (IPA), and The US Oncology Network (USON) commissioned primary research to understand the financial impact of specialty pharmacy acquisition models. Specifically, the research examined estimates of the financial effects of white bagging as a growing model for acquisition and delivery of provider-administered drugs and costs experienced by infusion practices, payers, and patients. Avalere surveyed a range of practices, from smaller community practices to multi-site systems.

The study's objectives were to assess the impact of specialty pharmacy acquisition as an alternative to buy-and-bill for medical benefit drugs and its implications for practice economics and patient experience across medical and pharmacy benefits. Insights from practices on how the existing infusion drug delivery systems impact patients and providers can inform stakeholders' evaluation of provider-administered drug acquisition methods and the policy debate around Part B drug reimbursement.

Executive Summary

Amid growing payer interest in using specialty pharmacy acquisition models as a mechanism to control costs for provider-administered drugs, Avalere conducted primary research that sheds light on the hidden expenses associated with white-bagging practices. The reported costs of discarded vials due to white bagging, borne primarily by payers, may pose a challenge to achieving the anticipated savings from reduced drug reimbursement through specialty pharmacy channels. Survey respondents reported average waste associated with white bagging to be $35,000 to $652,000 per site per year, depending on the number of patients served and types of drugs administered. These findings highlight the need for payers to better understand the potential full cost of discarded product across the full spectrum of infusion service providers.

Moreover, when payers implement white-bagging requirements, they change the reimbursement structure for providers and eliminate the add-on payment that is usually intended to cover overhead costs for storing and handling complex drugs. Survey respondents highlighted that practices face administrative costs associated with white-bagging waste ranging on average between $13,000 and $67,500 due to special requirements for handling and disposing of discarded products. Therefore, the elimination of the add-on payment may leave infusion providers with unreimbursed expenditures, which may jeopardize their sustainability and, consequently, raise concerns for patients. As these findings suggest, the impact extends beyond the economic realm, with patients facing potential out-of-pocket (OOP) costs and treatment delays contingent on healthcare coverage and payer policies. This underscores the

imperative for stakeholders to critically assess the hidden costs of white-bagging, considering both its financial ramifications and its broader implications for patient care and provider viability.

Background

Provider-administered drugs are complex therapies indicated for the treatment of a variety of disease states across multiple specialties, including gastroenterology, immunology, neurology, oncology, ophthalmology, and rheumatology. Under the medical benefit, provider-administered drug reimbursement comprises two parts: payment for the administration of service and payment for the drug itself. The drug payment under Medicare Part B fee-for-service is based on the average sales price (ASP) and a 6% add-on payment,[1] although the add-on is subject to a 2% sequestration cut. Other payers reimburse a negotiated amount for the drug, which also is often based on ASP with some add-on payment.[2]

There are two main methods for practices to acquire provider-administered drugs: (1) practices purchase drugs directly from a distributor under a "buy-and-bill" model, or (2) a treating provider orders a drug from a specialty pharmacy that is dispensed directly to the site of care for treatment.

1. **Buy-and-Bill:** This method describes the process by which the site of care administers the treatment purchases and maintains an inventory of medications. After a medication is administered to the patient, the provider submits a claim to the payer and receives reimbursement for the contracted rate of the drug as well as payment for administering that medication.
2. **Specialty Pharmacy Acquisition:** In some instances, organizations that furnish provider-administered medications are contracted through an insurer to utilize acquisition methods involving specialty pharmacies, which include white bagging, brown bagging, and clear bagging.
    - **White Bagging:** The specialty pharmacy ships the medication to the site of care, where it may only be administered to the intended patient.
    - **Brown Bagging:** This is similar to white bagging, but the specialty pharmacy ships the medication directly to the patient. The patient is then responsible for storing and transporting the medication to the site of care for administration.
    - **Clear Bagging:** This is a closed-circuit acquisition model in which an enterprise utilizes its internal specialty pharmacy to dispense patient-specific medication to the enterprise's site of care, furnishing the drug service.

In response to increasing costs for specialty medications, employers, plans, and pharmacy benefit managers (PBMs) continue to evolve their strategies for controlling drug spend. Traditional management of products has been tied to formulary placement, but that is typically

[1] 42 CFR § 414.904 - Average sales price as the basis for payment. Available here.
[2] The add-on payment aims to cover a range of fixed and variable overhead provider costs (e.g., clinical labor, inventory management, IT infrastructure, patient bad debt, compliance with medication storage and handling requirements, preparation, and disposal).

more effective for pharmacy benefit drugs than therapies administered by clinicians and reimbursed through the medical benefit. Instead, payers deploy strategies such as limitations to site of care and drug acquisition channels, although these approaches may be in tension with one another.

Large health plans, many of whom own PBMs and specialty pharmacies, increasingly require that drugs previously purchased directly by practices be filled by a PBM-owned specialty pharmacy, bypassing buy-and-bill. They do so because of the expectation that they would be better positioned to negotiate drug acquisition costs and drug reimbursement rates through the specialty pharmacy channel. From 2020 through 2022, major insurers such as Blue Cross Blue Shield, Anthem, Cigna, Aetna, UnitedHealthcare and others require providers to acquire provider-administered medications from specialty pharmacies, which are often owned by the insurer, suggesting a potential conflict of interest and misaligned incentives.[3]

The practice of white bagging is increasingly viewed as an innovative cost-control lever, especially for payers with an ownership stake in a preferred specialty pharmacy, but others flag that the policy only adds cost to the healthcare system overall. Patient groups and providers express concern that mandated white bagging poses operational and financial burdens to practices and may create barriers to supporting patient safety and optimal health outcomes. Provider groups have also raised safety issues over the implementation of white bagging, such as delays in shipping and delivery of medication, storage concerns, and medication integrity due to unreliable shipping procedures. In addition, delays in accessing care if the medication is not readily on hand at a provider's office can affect the patient's overall health, disease state, and potentially add financial stress to the payer and patient in the event of a disease flare-up.

While white bagging has been in place for some time, the number of health plans requiring white bagging and the scope of the drugs included in the policies is increasing. Therefore, the challenges experienced by providers, such as negative financial pressures, increased administrative burden, and adverse impacts on the quality of care they can provide for their patients may be placing their viability at risk. Moreover, payers themselves may not be fully aware of how some operational issues with mandated specialty pharmacy drug acquisition may be eroding any savings from lower drug reimbursement because of errors, delays, and waste.

Buy-and-bill allows providers to purchase drugs in bulk and have them in stock for "just in time" administration to patients. Providers favor the practice as the most immediate and efficient way to provide access to personalized care and offer necessary dosing adjustments at the point of care. Patients with complex conditions treated with specialty medications often require adjustments to their treatments, such as changes to dosage, strength, or class of medication, based on changes in patients' weight, lab values, and overall treatment tolerance. As such, with white bagging, the product mailed to the treating provider may no longer be appropriate for the patient when it arrives; if any adjustments to dose or strength are needed, the clinic cannot use its own inventory for a replacement but must obtain a new, patient-specific supply from the

[3] UnitedHealthcare. Specialty pharmacy requirements for UnitedHealthcare commercial plan members. January 2023. Available here.

designated specialty pharmacy. This can lead to treatment delays and waste as the previously dispensed prescription can neither be returned nor administered to another patient.

One study found that 92% of respondents reported experiencing problems with products obtained through white bagging, including issues such as wrong drug, damaged product, delays, and the inability to make necessary dose adjustments at the point of care.[4] The cost of specialty medications could range from $3,000 to $16,000 or more per administration.[5] As a result, payers and other stakeholders should seek to understand the hidden costs of white bagging waste and the extent to which they offset any purported savings from lower drug reimbursement through the specialty pharmacy channel.

White bagging may also be placing undue financial pressure on practices by altering the payment structure around provider-administered drugs. As the complexity of specialty medical benefit drugs grows, the current reimbursement framework has been viewed as increasingly insufficient to cover all practice costs associated with furnishing those products. Moreover, white bagging may place further financial pressures on practices and infusion centers, as organizations that acquire drugs through specialty pharmacy acquisition lose the add-on payment intended to offset practice expenses, such as separate inventory management and staff costs to manage variable payer policies. This not only impacts the financial sustainability of practices but also forces clinicians to rely more heavily on drug administration reimbursement codes, which are often insufficient. Additionally, clinicians are expected to prepare all doses of white-bagged medications in accordance with various sterile and nonsterile compounding practices; they are often unable to bill for that work when they receive shipments of product through white bagging.

Avalere surveyed practices to evaluate the impacts of provider-administered drug acquisition models and explore provider concerns that drug waste, patient costs and financial pressures on practices may add costs to the broader health system.

Survey Results

Characteristics of Practice Respondents

Survey participants included a range of non-hospital infusion providers. Many respondents represent providers that serve as alternative sites of care (ASOC) for infusion services (e.g., non-hospital outpatient infusion departments, provider office-based infusion suites). These practices, or ASOCs, provide chronic infusion care for patients using specialty drugs where self-administered injections or oral therapy are not an option. Infusion providers are likely to be a less costly setting of care compared to hospitals and, their ability to utilize a particular drug acquisition method depends on practice economics, state laws, or payer contracts. The

[4] Vizient. Survey on the Patient Care Impact and Additional Expense of White/brown Bagging. Available here
[5] Local Infusion. How Much Does the Infusion Therapy Cost? Available here

respondents included in this primary research represented practices in a range of sizes, many with multiple sites, that provided infusion services for multiple specialty conditions. Figures 1 and 2 summarize key characteristics.

Figure 1: Overview of Infusion Services Provided by Practice Respondents

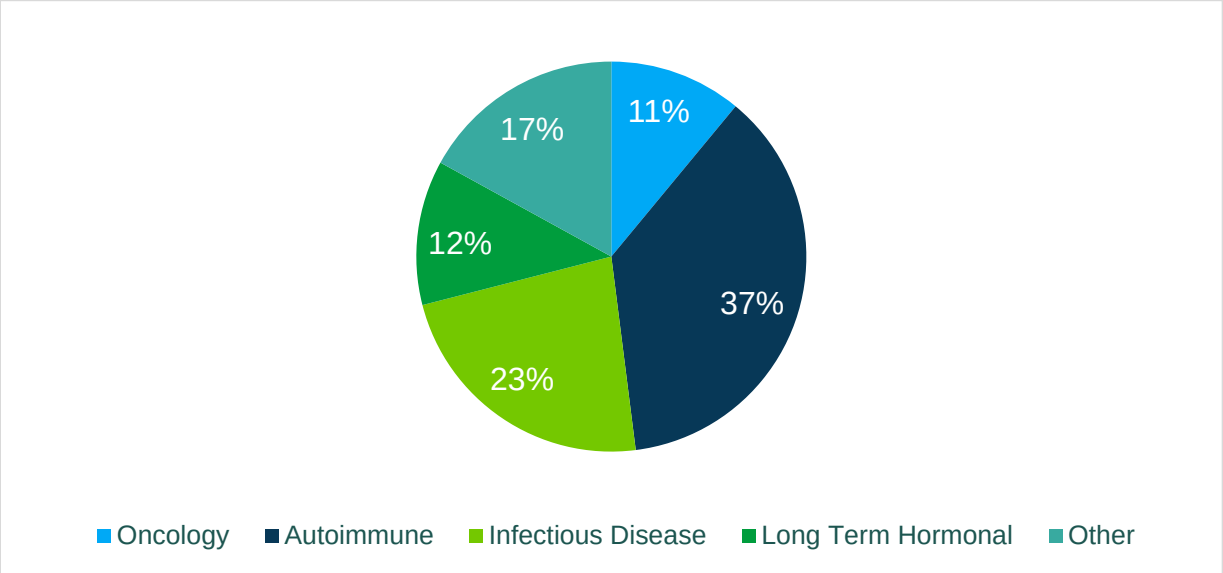
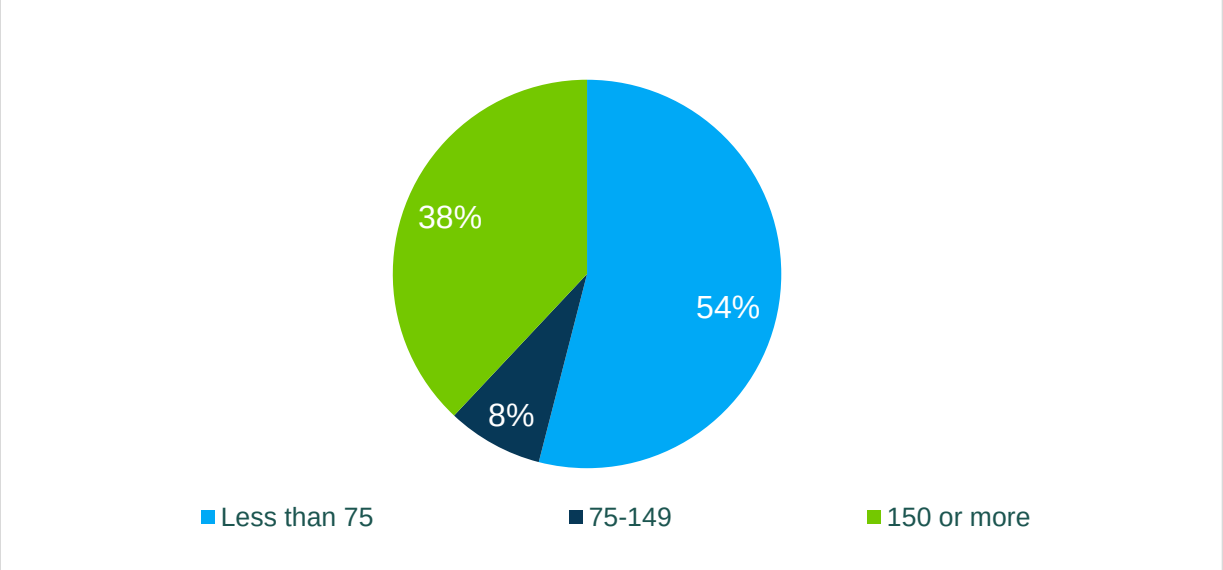


Figure 2: Breakdown by Total Number of Active Infusion Chairs Across All Practices' Sites



Infusion Practice Drug Acquisition Methods

Infusion providers often receive patient referrals from specialists in other care settings, and they are committed to preserving the integrity of the provider-patient relationship. Due to their business models and focus on timely drug delivery, they rely heavily on the buy-and-bill model for drug acquisition; consequently, white bagging made up the minority of overall volume for most infusion providers. Among practices that acquire at least some drugs via white bagging, 81% responded that this drug acquisition approach was due to payer contract restrictions, while another 19% indicated it was an operational/financial decision.

Among practices that acquire drugs via white bagging through a specialty pharmacy, 76% indicated that payers mandate the specific specialty pharmacy used for acquisition, while 24% may choose the specialty pharmacy of their choice.

Among the practices that chose to utilize white bagging to manage financial risk, the main reason reported was insufficient demand to justify the overhead expense and opportunity cost to buy and bill a particular drug. For example, there are instances where a single patient is being treated with a product, like a rare disease product, that is not typically stocked.

Impact of White Bagging on Payers Infusion Practice Economics

Under a white bagging drug acquisition model, infusion products are sent directly from the specialty pharmacy to the facility for preparation and administered to a specific patient. Should the drug be unsuitable to treat the indicated patient for a number of factors like dose adjustments related to changes in weight, treatment tolerance, side effects, or a complete alteration in treatment, the drug must be discarded and deemed waste. There are strict constraints prohibiting a drug's dispensation to another patient or return to the specialty pharmacy. Specialty pharmacy policy explicitly prohibits the return of dispensed prescriptions. Notably, some of these considerations intersect with pharmacy law and drug pedigree within the channel.

Through the Avalere survey, respondents engaged in white bagging quantified their estimated costs due to waste associated with white bagging. Figure 3 shows the average costs among surveyed providers by relative practice size, approximate estimated cost of discarded product, and overhead costs carried by practices associated with storing and eventually disposing of drug wastage. The estimates raise considerations around the hidden costs of white bagging, since the estimates around discarded vials are often borne by payers, while the estimates on overhead for handling wastage are costs paid by providers.

Based on the responses, the highest average costs for discarded drugs due to white bagging waste are among medium-sized practices and clinics, possibly because small providers handle a lower volume of product, while the largest and most complex practices have more robust inventory tracking processes. At the same time, the administrative burden of drug wastage associated with white bagging was highest among large practices.

Figure 3: Survey Respondent White Bagging Wastage Estimates

Practice Size and Type	Average Estimated Annual Cost of Wasted Vials per Respondent	Average Estimated Annual Overhead Costs for Wasted Drug per Respondent
Large/Multi Specialty	$565,000	$67,500
Medium	$662,000	$13,000
Small/Single Provider Offices	$35,000	$20,000

Payers are often responsible for the cost of vials wasted because of white bagging. When aggregated across all infusion sites across the United States, these costs could offset any savings that plans hope to achieve from lower reimbursement to specialty pharmacies. The estimated averages shown by practice type in Figure 3 cannot be directly extrapolated across the market, given variability in practice characteristics and types of drugs, but these findings highlight the need for further analysis of the hidden costs of white bagging. Collectively, the study sponsors (NICA, IPA, and The US Oncology Network) represent over 10,000 sites of care for infusion services all with varying degrees of white bagging utilization, so as payer and employer interest in white bagging grows, the burden of drug waste could become significant.

Moreover, under specialty pharmacy drug acquisition, practices receive reimbursement only for drug administration. When a white-bagged product must be discarded due to errors or point of care changes, the provider does not bear financial risk for the drug itself. However, the disposal of any wastage resulting from white bagging may require special handling in compliance with federal requirements, which can be costly. The added variable of costs from drugs that are not administered can further add to practice's financial pressures. White bagging also necessitates that practices differentiate buy-and-bill drugs from specialty pharmacy drugs, adding administrative burden and infrastructure and software costs to organizations. These financial pressures are further accentuated by the loss of the add-on payment and will in turn put the viability of infusion providers at risk and carry significant implications for patients. Without access to lower cost sites for infusion, patients may require care in the hospital outpatient setting, which would be costlier and might require more travel time.[6]

[6] Journal of Oncology Practice. Cost Differences Associated With Oncology Care Delivered in a Community Setting Versus a Hospital Setting: A Matched-Claims Analysis of Patients With Breast, Colorectal, and Lung Cancers. October 2018. Available here.

Impact of Infusion Drug Acquisition Model on Patients

Beyond the implications for infusion practices and payers, it is important to note that patients may incur additional OOP costs and treatment delays due to infusion care center utilization of white bagging, depending on their healthcare coverage and payer type. With white bagging, the prescription is filled by a contracted specialty pharmacy that collects needed copayments or coinsurance and settles the claim with the payer.

46%

of surveyed providers report that patients had out-of-pocket costs for drugs that were not administered

Practice respondents reported patients experiencing additional OOP costs attributed to white bagging procedures. These arise for several reasons, including pharmacy-specific deductibles, replacement of wasted treatment (e.g., shipment delays, change in dosing), and administrative costs of logistical coordination (e.g., additional visits and burdensome coordination of drug shipments). Furthermore, the tier in which the PBM places a drug can significantly influence the OOP costs for patients. Depending on the tiering system, patients may encounter different copayment structures, adding another layer of complexity to the financial aspects of their treatment.

Treatment delays and the resulting pharmacy-related OOP costs are frequently identified as critical issues. These delays not only impact the financial well-being of patients but also have direct implications on the patient's disease state. Untimely treatments can lead to disease progression or acute flares, resulting in heightened costs for both the patient and payers alike. Across all practice respondents, 46% indicated that they have experienced instances where patients paid a copay for a regimen/dosage that was not administered due to complications from white bagging.[4]

Discussion

White bagging at provider offices continues to grow for provider-administered drugs, with the share of covered lives for which white bagging is the most common scheme of product sourcing growing to 27% in 2022 (up from 15% of covered lives in 2019).[7] Pressures for white bagging are mounting as payers become more vertically integrated with specialty pharmacies and PBMs and seek to generate more revenue and income from their owned assets. The three largest payer-PBM-specialty pharmacy organizations (CVS/Aetna, Optum/UnitedHealthcare, Express Scripts/Cigna) accounted for over 77% of all drug claims in 2020.[8] Payers may also favor white bagging as it allows them to influence the selection of provider-administered drugs via utilization management.

Several features of the Inflation Reduction Act (IRA) may further contribute to this trend, including increasing plan liability and financial pressures on providers for drugs that are subject

[7] Drug Channels: White Bagging Update 2022: Hospitals Battle to Boost Buy-and-Bill
[8] Drug Channels: The Top Pharmacy Benefit Managers of 2020: Vertical Integration Drives Consolidation

to Medicare negotiations. Specifically, Medicare Advantage Prescription Drug Plans may turn to white bagging as they look to manage overall financial liability across both the pharmacy and medical benefit. Additionally, the maximum fair price of drugs selected for Medicare price negotiation under the IRA will lead to substantially lower add-on payments and overall reimbursement for providers who administer the selected products. The increased financial pressure will be especially salient for independent providers who have less negotiating power.

The proliferation of white bagging for Part B drugs is occurring at a time when PBM reform is at the forefront of state and federal legislative agendas. A growing number of state legislatures and boards of pharmacy are considering ways to limit white bagging and add various safeguards. Several states are focused on bills that would prohibit PBMs and plans from restricting a patient's coverage, reducing a provider's payments, or requiring additional fees for covered clinician-administered drugs dispensed by an entity not selected by an issuer. Since 2021, legislation to prohibit the use of payer-mandated white bagging has been enacted in at least five states (Arkansas, Louisiana, North Dakota, Tennessee, and Virginia) while three states have enacted statutory protections (Minnesota, Texas, Virginia).

As policymakers consider Medicare provider reimbursement reforms and legislation to address white bagging, the impact to the quality of patient care is a consideration. There is the possibility that practices that provide infusion services are not able to maintain their standards of care or patient support services due to financial losses from inadequate reimbursement. This in turn could impact the availability of infusion services for patients and potentially force them to receive care in higher-cost settings, like hospitals. Additionally, hospitals are purchasing infusion clinics and community-based sites of care, which also increases the total cost of care for infusion services.

White bagging also has patient cost implications, as white-bagged drugs are reimbursed under the pharmacy benefit compared to the medical benefit. Depending on the pharmacy and medical benefit coverage of an individual patient, they may have a higher OOP cost for treatment under the pharmacy benefit compared to what they would experience under the medical benefits. The higher patient OOP costs that white bagging may lead to can translate into lower treatment adherence rates for patients and, consequently, increased healthcare consumption.[9] A 2020 study found that higher patient OOP costs were associated with lower treatment adherence in three common neurologic conditions.[10] Lower treatment adherence can mean suboptimal disease control for many patients, which can lead to increased costs for patients, providers, and payers.[11]

[9] Alimentary Pharmacology & Therapeutics. Real-world assessment of therapy changes, suboptimal treatment and associated costs in patients with ulcerative colitis or Crohn's disease. May 2014. Available here.
[10] Neurology. Association of OOP costs on adherence to common neurologic medications. March 2020. Available here.
[11] Alimentary Pharmacology & Therapeutics. Real-world assessment of therapy changes, suboptimal treatment and associated costs in patients with ulcerative colitis or Crohn's disease. May 2014. Available here.

Stakeholders should continue to evaluate which drug acquisition models provide the most flexibility and efficiency for providers, reduce administrative burden and waste, while also allowing for the most effective and efficient patient care.

Survey Methodology

Avalere conducted a survey among members of NICA, IPA, and USON, three organizations that collectively represent over 10,000 practice locations in the United States. The survey was fielded among 35 organizations, many with multiple sites. Avalere conducted the study via the Alchemer platform and initiated outreach for supplemental primary interviews. These supplementary 30-minute interviews were conducted with practices from the selected respondent pool to gain additional insights and anecdotes on the impact of specialty pharmacy acquisition on infusion practice economics and care coordination.

Diversity in survey respondents based on organizational characteristics (i.e., infusion services provided, organization size, and location) ensured a holistic sample of data and organization perspectives on infusion drug administration dynamics. Most respondents were in senior-level leadership roles (e.g., CEO, executive director) within their organizations. The remaining respondents were typically in business operations roles (e.g., revenue control manager, provider operations). Respondents in these positions could aggregate necessary practice financial information to answer survey questions and provide additional anecdotes on patient experience and practice economics.

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