

ASCO Position Statement on White Bagging

Approved by the ASCO Board of Directors August 24, 2023

Introduction

In recent years, the pharmacy benefit management industry has grown exponentially and become highly consolidated. Many of the largest insurance companies, pharmacy benefit managers (PBMs), and specialty pharmacies have combined, creating a more concentrated market.¹ According to an analysis by the American Medical Association (AMA), 69% of beneficiaries are covered by the commercial drug insurance market.²

Market consolidation—and the growing cost of drugs—has accelerated payer use of a mandated alternative drug delivery arrangement known as “white bagging.” White bagging occurs when payers cover necessary drugs contingent on their distribution from an owned or affiliated specialty pharmacy and shipped directly to the clinician. Part of this practice includes payers disallowing clinicians from procuring and managing the handling of drugs used in patient care.³ Instead, patients are directed to the payer’s preferred pharmacy.

The most common form of product sourcing remains “buy and bill,” in which providers acquire drugs and bill insurance for reimbursement. Although buy and bill remains the dominant form of product sourcing, white bagging continues to grow. A 2022 analysis from Drug Channels showed that white bagging for oncology products accounted for 27% of sourcing in physician offices (up from 18% in 2021).⁴ For non-oncology products, white bagging increased to 43% of sourcing by physician-affiliated clinics and 31% by hospital outpatient departments.⁵

Because white bagging commonly involves managing drugs through vertically integrated specialty pharmacies and pharmacy benefit managers (PBM), it is often managed under the pharmacy benefit, the patient out of pocket costs are often different and may be higher than they would be if the injectable or infusion drugs are covered under the medical benefit. Additionally, patients receive little or no support from PBM owned specialty pharmacies in way of co-pay assistance or foundation support.

Clear bagging occurs when a health system’s own specialty pharmacy voluntarily fulfills and transports a patient’s medication safely under streamlined and predictable drug delivery within their health system to the location of the clinician’s drug administration site. ASCO acknowledges there may be patient cost implications with clear bagging and subsequent shift to the pharmacy benefit, therefore it is crucial that clinicians – and their health system - are cognizant of the variation in plan sponsor benefits when taking into consideration such arrangements.

¹ <https://www.drugchannels.net/2022/10/mapping-vertical-integration-of.html>

² <https://www.ama-assn.org/system/files/prp-pbm-shares-hhi.pdf>

³ <https://www.aha.org/white-papers/2021-03-08-health-insurer-specialty-pharmacy-policies-threaten-patient-quality-care>

⁴ <https://www.drugchannels.net/2022/09/white-bagging-update-2022-hospitals.html>

⁵ <https://www.drugchannels.net/2020/09/specialty-pharmacy-keeps-disrupting-buy.html>

Current Model

Outpatient chemotherapy traditionally is administered in physician offices or hospital outpatient departments using drugs acquired and/or prepared by the physician's staff or the hospital's pharmacy. These offices and departments employ specialized pharmacy and nursing staff to manage toxic agents, which if handled improperly, can inflict serious injury to patients and clinicians.

Traditionally, the acquisition of anti-cancer drugs is managed in the independent practice or hospital setting. Practice or hospital pharmacies purchase, store, and administer these agents under strict handling and administration standards. Physicians rely on established procurement sources and processes to assure the safety and integrity of the product. Drugs do not leave the specified supply chain, and storage/handling requirements include meticulous tracking from the manufacturer until they are administered by clinicians. This process helps reduce risks, including tampering, dilution, mishandling, exposure to temperature changes, and waste that can render the drug ineffective.

Although clinicians prepare detailed treatment plans, drug regimens often change because of clinical circumstances on the day of treatment. Administration may be adjusted according to criteria, such as patient weight, comorbidities, lab reports, guidelines, and other clinical data. Frequently, chemotherapy dosages change on the day of treatment, based on lab results and other clinical considerations.⁶ Unlike a white bagging process, procuring and storing drugs within the treating practice—which means there is inventory immediately available—can accommodate changes in therapy on the day of treatment, allowing for careful patient management through timely, sometimes immediate, dose changes.

Payer-imposed White Bagging

Various media reports have highlighted patient and clinician concerns on the growing use of payer-mandated white bagging.⁷⁻¹³ Under such policies, payers require physicians to obtain drugs purchased and handled by payer-owned or affiliated pharmacies. White bagging requires additional coordination with patients and physicians and could delay or disrupt treatment plans and decisions.¹⁴

When prescribing and ordering medication, clinicians rely on electronic health records (EHRs) to activate comprehensive medication safety checks. Payer-owned specialty pharmacies that use white bagging may not have access to the patient's EHR, which introduces the potential for error and bypasses the health system's operational, system, and quality safeguards.

⁶ <https://www.texasoncology.com/who-we-are/legislation-public-policy/safe-drug-delivery>

⁷ <https://www.managedhealthcareexecutive.com/view/how-white-bagging-affects-patients-physicians-and-340b-funding>

⁸ <https://www.minnpost.com/community-voices/2022/03/white-bagging-a-cost-savings-strategy-but-for-whom/>

⁹ <https://www.medpagetoday.com/meetingcoverage/ashp/96064>

¹⁰ <https://www.healthcarefinancenews.com/news/hospitals-and-health-system-pharmacists-urge-fda-take-closer-look-white-bagging>

¹¹ <https://www.virginiamercury.com/2021/05/21/specialty-drugs-are-sparking-the-latest-battle-between-virginia-hospitals-and-health-insurers/>

¹² <https://www.georgiahealthnews.com/2021/04/white-bagging-insurers-shift-drugs-raises-alarm/>

¹³ <https://www.weau.com/2021/10/22/new-bill-would-ban-white-bagging-wisconsin/>

¹⁴ <https://www.aha.org/system/files/media/file/2022/05/aha-white-bagging-infographic.pdf>

White bagging can also lead to significant waste, as unused portions of a previously dispensed drug—which can occur when treatment plans are modified—cannot be used for a different patient.¹⁵ A change in drug or dosage requires physicians to place new orders, meaning patients often must return on a later date—when the updated drug is delivered—to receive their treatment. This process of introducing a new intermediary can delay treatment. Incorrectly shipped or damaged drugs are wasted. Clinicians also report they frequently are not notified of shipping delays, nor of the expected date and time of arrival of the drug, which leads to uncertainty regarding treatment schedule.

Many anti-cancer drugs are highly toxic and thus require special handling when discarded. The burden of unnecessary waste related to white bagging falls to practices and hospitals, which must dispose of the drugs according to state and federal requirements overseen by environmental authorities.¹⁶ Payers are not required to comply with individual state boards of pharmacy or environmental protection agencies.

White bagging creates the potential for increased waste, additional administrative burden, and—most important—discontinuity and delays of care. The loss of clinician control over procurement processes can delay and disrupt care, which for some patients can be life-threatening.¹⁷

Conclusion

Although white bagging may be necessary in some settings, mandatory white bagging can jeopardize the delivery of high-value, high-quality care, and requires additional steps to protect patient safety. For these reasons, ASCO opposes the mandatory imposition of white bagging and strongly urges payers and policymakers to consider the recommendations set forth below.

Recommendations

Federal and state governments should strengthen oversight of white bagging:

- Enact legislation to prohibit the mandatory use of white bagging.

Payers should take steps to protect the delivery of high-quality care within voluntary white bagging programs:

- Implement a white bagging bypass that accommodates changes in drug or dose on the day of treatment.
- Notify the treating clinician of the expected date and time of arrival of the drug within 72 hours of when the order is placed. For urgent circumstances, if any delay occurs and delivery cannot be achieved within 48 hours of the scheduled administration date, allow a white bagging bypass.
- Integrate the white bagging processes into electronic health records within 24 hours of a submitted claim.

¹⁵ <https://www.managedhealthcareexecutive.com/view/how-white-bagging-affects-patients-physicians-and-340b-funding>

¹⁶ https://nabp.pharmacy/wp-content/uploads/2018/04/White-Bagging-and-Brown-Bagging-Report-2018_Final-1.pdf

¹⁷ <https://www.ashp.org/news/2021/03/22/white-bagging-a-growing-concern-for-health-systems?loginreturnUrl=SSOCheckOnly>

- Do not allow white bagging policies to delay necessary care, including providing compensation when physicians must use their inventory for emergent care or continuation of care under an authorized treatment plan.

Regulatory Agencies should:

- Apply appropriate enforcement action on payers violating supply chain security protections which negatively impact patient safety.
- Prohibit the use of drug reimportation in the delivery of specialty medications unless otherwise permitted under federal and state law.
- Enforce the Centers for Medicare and Medicaid Services “Any Willing Provider” provision in Medicare Part D. Clinicians should not be prevented from using qualified in-office dispensing or clinician-led pharmacies from its networks.
- Ensure safety and transparency by requiring payers to provide clinicians with detailed delivery, quality, and safety protocols, including track and trace policies, used by their contracted specialty pharmacies.
- Monitor and prevent predictable, adverse consequences that individuals with cancer may experience from barriers or delays in receiving preferred oncology therapies as a result of white bagging, including suboptimal clinical outcomes, increases in adverse events, increases in emergency department visits, and disparities in treatment or outcomes.
- Enforce reporting requirements for payers to document sources and cost of waste.

ASCO and other Stakeholders should:

- Promote implementation and compliance with accepted standards for the administration of hazardous drugs and treatments in all treatment settings.