



Pharmacists Optimizing Cancer Care®

## White Bagging Issue Brief

The recent growth in payer mandated white has shifted the delivery of medications so that specialty injectable medications are often required to be dispensed from a third party, who is not affiliated with the provider. In a 2021 survey by Vizient, a health care performance improvement company, 92 percent of respondents reported experiencing problems with the medication received from white bagging and brown bagging.<sup>1</sup> In a 2023 study published by The Journal of the American Medical Association (JAMA), white bagging in oncology lowered payers' costs, but raised patients' out-of-pocket obligation.<sup>2</sup>

- White bagging: Distribution of a patient-specific injectable drug from a specialty pharmacy that is shipped directly to the provider's office or infusion clinic for preparation and administration.
- Clear bagging: Similar to white bagging, except the drug is obtained through a health system's own specialty pharmacy and delivered to the provider's office or infusion site for preparation and administration.

### Benefits of White Bagging

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Insurers prefer white bagging as the drug is processed via the prescription benefit of portion of the patient's insurance, which may reduce the cost paid by the insurer due to higher coinsurance or patient out of pocket responsibility. Generally, the drug is obtained from a payer owned or affiliated specialty pharmacy. Institutions may save money as well since they will not have to buy the drugs directly.

### Drawbacks of White Bagging

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White bagging policies jeopardize patient safety and exacerbate supply chain security challenges. The provider/infusion center is responsible for all aspects of a patient's treatment, which includes care of the patient, development of a treatment plan, execution of the treatment, and frequent monitoring of treatment efficacy and toxicity. The introduction of white bagging requirements threatens a well-developed and robust care model.

HOPA is concerned that white bagging will remove a patient's autonomy to choose the care team that is best for them. If an institution does not accept white bagging when mandated by insurance, the patient may need to leave their care team for a new site or clinic. Patient safety is also a concern, as any prescription sent to a specialty pharmacy bypasses health-system EHR safety checks, which can result in a wrong medication or wrong dose being sent and given to a patient. This could happen if the product is not on the formulary, or if the staff is unfamiliar with the drug that they receive. White bagging can lead to delays in care if an insurer-designated pharmacy does not send the drug on time. If the drug delivery is delayed, providers may be forced to adjust the entire care plan. Such disruptions may place additional burdens on patients and/or caregivers, including then need to reschedule or find alternative transportation for appointments or to readjust work schedules. This may disproportionately impact disadvantaged patient populations.

In the event of errors with reconstitution and/or preparation or dosage adjustments, replacement medication may not be available. This delay in care may compromise patient outcomes, particularly in oncology. Combination therapies pose a challenge since drugs could be coming from multiple sources. If a provider modifies the drug regimen, a new medication supply must be obtained. The previously dispensed medication cannot be added back into inventory for use with another patient, like supplies in a traditional infusion pharmacy model which can actually lead to drug waste. HOPA is also concerned about the impact of white bagging on supply chain integrity and proper storage of drugs. Once the product leaves the pharmacy, accountability for proper handling, including temperature control, storage conditions, and expiration monitoring, becomes unclear. Shipped medications may not be integrated into site-based technology systems that support safety checks and verification processes. In addition, medications may arrive late due to logistical bottlenecks or be left unattended on shipping docks or outside facility entrances without appropriate notification or security. Under the Drug Supply Chain Security Act, documentation of the complete chain of custody is required, and white bagging may pose challenges to meeting these requirements. Furthermore, storage of the product requires

additional space for patient-specific doses in the pharmacy, which can necessitate buying additional medical-grade refrigerators or freezers.

White bagging shifts the work and liability onto administering pharmacies without offering reimbursement for these services. It is challenging to coordinate scheduling, and to track drugs to ensure that they arrive on time for administration to the patient. Facilities can bill an administration fee, but there is no additional reimbursement. Without a corresponding drug charge, the administration fee may be denied by insurance payors. The drug fee also pays for the pharmacy review, preparation, and dispensing of the medication. Currently, there is no mechanism available to charge a dispensing fee in an infusion center, thus the infusion center pharmacy is preparing the product with no reimbursement for the supplies or personnel time. While there is an argument that these issues can be addressed through contracting, this will be a larger burden for smaller institutions who do not have the resources and opportunities to negotiate favorable contracts.

### **Impact on Cancer Patients**

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Due to the high proportion of anticancer medications that fall under specialty pharmacy distribution, HOPA's primary concern is that cancer patients are disproportionately at risk from negative outcomes when the white bagging process does not work effectively. Patients can be treated with the same drug and receive two different levels of care depending on the use of white bagging. If there are issues with receiving the drug from the specialty pharmacy, then a patient cannot start treatment; since anticancer drugs follow a scheduled regimen, this can delay the care schedule by several weeks. When the drug has a curative intent, any delay could lead to worse patient outcomes. Delays may also have a negative impact on the patient's mental well-being. Patients do not need the added stress of dealing with the administrative burden of white bagging, including increased co-pays, specialty pharmacy ordering, and restrictions from their insurance company.

### **Recommendations**

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While HOPA acknowledges that there are positive aspects to white bagging, we oppose the components identified in this issue brief that have a negative impact on patient care. Specifically, we are concerned with the following areas:

- Additional burden to the patient, including both financial burden and additional time spent coordinating care.
- Delays in care that are caused by changes in medication regimen, supply chain issues, or delays in shipment of the drug.
- Patient safety issues caused by medication errors in supply chain disruption, unsafe handling, and/or improper storage of the drug.
- Requirements to use a specific pharmacy that favors the insurance payor but is not the preferred choice by the patient.
- Lack of reimbursement for pharmacy services, preparation, and dispensing when white bagging is required.

These issues must be addressed to ensure that white bagging does not negatively impact patient care.

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1. Vizient. Survey on the patient care impact and additional expense of white/brown bagging. *Vizient, Inc.* 2021. [https://assets.senate.mn/committees/2021-2022/3095\\_Committee\\_on\\_Health\\_and\\_Human\\_Services\\_Finance\\_and\\_Policy/Vizient%20white%20bagging%20report%202021.pdf](https://assets.senate.mn/committees/2021-2022/3095_Committee_on_Health_and_Human_Services_Finance_and_Policy/Vizient%20white%20bagging%20report%202021.pdf)
  2. Shih YT, Xu Y, Yao JC. Financial Outcomes of "Bagging" Oncology Drugs Among Privately Insured Patients With Cancer. *JAMA Netw Open.* 2023;6(9):e2332643. doi:10.1001/jamanetworkopen.2023.32643