

## "Brown Bagging" and "White Bagging" of Chemotherapy Drugs

Outpatient chemotherapy traditionally has been administered in physician offices or hospital outpatient departments using drugs prepared by the physician's staff or the hospital pharmacy. This is because many chemotherapy agents are extremely toxic drugs capable of causing death or serious injury to patients if prepared, handled, or administered improperly.

The American Society of Clinical Oncology (ASCO) is concerned about a trend amongst payers, which are advancing an alternative arrangement that requires the oncologist to administer chemotherapy agents prepared outside the physician's office by an entity under contract with the payer. These so-called "brown bagging" and "white bagging" arrangements may increase the potential for waste, medication errors and other mishaps, with potential adverse effects on patient health, including toxic reactions and ineffective treatment. "Brown bagging" means the drug is purchased through a specialty pharmacy and shipped directly to the patient, who takes it to the provider's office for administration. "White bagging" means the drug is purchased through a specialty pharmacy and shipped to the provider's office for administration.

Removing the ability for a physician to control the preparation of the drugs is problematic for a number of reasons. It is fairly common for a patient's cancer treatment regimen to need adjustments on the planned day of treatment. The causes of this include patient response and tolerance to specific drugs, idiosyncratic reactions, drug-drug interactions, symptoms and complications from comorbidities, adverse events, and patient preference. In either a brown bagging or white bagging arrangement, treatment is delayed in this clinical scenario while the physician and patient either await delivery of the appropriate drugs or wait while the patient obtains the appropriate drug and brings it to the physician's office.

Within the context of ongoing treatments, it is unclear what the arrangements are for drug delivery and storage, and what provisions are made regarding the waste that would result from changing treatments or drug expiration.

There may be a greater risk to patients if an oncologist administers chemotherapy drugs prepared by an outside entity rather than if the drugs are prepared within the oncologist's own office. The identity and dosage of the drug are not known to the oncologist unless the outside entity has properly prepared and labeled the drug. Additionally, there are questions such as whether the drug:

- was properly mixed
- is within the manufacturer's labeled expiration date
- has been properly handled before and after preparation

- has become contaminated
- may be the product of deliberate counterfeiting
- is available to the oncologist on a schedule that meets treatment needs
- is being furnished to the oncologist soon enough after mixing to comply with the preparation instructions in the FDA-approved labeling or other applicable requirements

In contrast to physicians maintaining practice-based inventories of drugs for immediate administration and treatment as necessary for their patients, there is no assurance that a needed drug will be available in a timely fashion through the payer-directed distribution channels.

ASCO opposes "brown bagging" and strongly urges payers and policymakers to give consideration to these points and consult with oncologists prior to enforcing "white bagging" policies.

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