The Ohio Society of Health-System Pharmacists
Position Statement on White Bagging

The Ohio Society of Health-System Pharmacists (OSHP) is concerned regarding an emerging payer-driven practice called "white bagging." The practice of white bagging refers to a distribution method in which the payer purchases a medication on the patient's behalf through a specialty pharmacy. The specialty pharmacy is responsible for shipping the medication directly to the provider's office, a hospital, or a clinic which is often then further manipulated or processed for administration to the patient. White bagging may be preferred by payers as part of a cost-containment strategy that shifts the billing and payment for the medication from the medical benefit to the pharmacy's financial benefit. Unfortunately, changing the distribution method creates many risks for hospitals and health systems in Ohio, negatively impacts patient safety, and has a negative impact on the patient's access to care.

The OSHP Legal Affairs Division extensively researched the practice of white bagging and its impact on hospitals and their ability to provide safe and effective patient care. Feedback from members across the state of Ohio was also solicited and incorporated for consideration. To that end, the Ohio Society of Health-System Pharmacists opposes the practice of white bagging for the following reasons:

1. **Substantial risks and legal issues for hospitals and health-systems**

The language in the Ohio Administrative Code (OAC) 4729.43 prohibits non-self-injectable cancer medications from being distributed directly to a patient. This practice is known as "brown bagging." The OSHP firmly discourages this practice for both non-self-injectable cancer medications and non-self-injectable non-cancer medications due to the broken chain of custody. The OAC 4729.43 also outlines that hospitals must reach an agreement with payers for a medication to be distributed through the white bagging process. The OSHP cautions health systems considering such agreements and opposes the practice of white bagging for all medications due to the legal and quality implications for hospitals.

The Drug Supply Chain Security Act (DSCSA) was enacted by Congress on November 27, 2013 to protect consumers from exposure to drugs that may be counterfeit, stolen, contaminated, or otherwise harmful. The DSCSA requires transaction information, history, and statements to ensure suspect and illegitimate products do not enter the pharmaceutical supply chain. The practice of white bagging puts hospitals at risk of receiving suspect or illegitimate product as there is no way to track medications and ensure no tampering has occurred after the medication has left the manufacturer. Distributing medications through the practice of white bagging is effectively re-dispensing. Once a medication has a patient-specific label affixed and is dispensed and billed to a patient, it has been dispensed and should be possessed by the patient. Dispensing medications which then require further manipulation including compounding or reconstitution by a pharmacist who then must re-label the medication is re-dispensing the medication.

If a hospital receives a white bagged medication, the institution is responsible for storing and handling the medication under proper conditions to ensure product integrity. This creates a challenging scenario as hospitals must also take the necessary steps to segregate patient-specific

medication from hospital-owned stock. White bagging introduces several situations that may leave the hospital in possession of discontinued or expired patient-specific medications; this includes situations such as a change in therapy or failure of the patient to present to the clinic. The hospital would then be responsible for destroying patient-specific medications. All of these potential risks place an increased legal and financial burden on hospitals to ensure patients are treated in a safe manner. White Bagging is dispensing with compensation to the specialty pharmacy, without the preparation and administration risks. In receiving medications from the dispensing pharmacy, hospitals cannot guarantee product integrity as required by DSCSA and take on the preparation and administration risks without the financial compensation.

2. Medication and patient safety

The risk of patient harm is escalated by the unsafe practice of white bagging. This practice increases the risk of dispensing errors, medications administered without necessary lab work, and unintentional omissions of therapy. The practice of white bagging introduces a number of involved parties and each medication has the opportunity to be inappropriately stored or transported throughout the process. Many of the medications shipped through this practice are biologics, which are fragile and may require complex shipping instructions. To ensure product integrity is maintained throughout this process, verifying the chain of custody is essential. Medications move through each step of the pharmaceutical supply chain with minimal oversight when distributed through the white bagging practice. It is not uncommon for drugs to be shipped to a facility without knowledge of the pharmacy staff. These drugs may then sit at shipping docks or similar locations for extended periods of time, leading to excess drug waste. Each transfer places the medication at risk for adulteration, which is prohibited under the federal Food Drug and Cosmetic Act. Authoritative bodies hold traditional pharmacy settings to strict storage standards as defined by the Ohio Administrative Code and the Joint Commission. White bagging practices bypass these standards. Additionally, once a drug is dispensed by a pharmacy, it is considered adulterated and cannot be reused. With white bagging, medications are dispensed by a pharmacy and then shipped to another pharmacy or location. These drugs are adulterated once they have been dispensed and should not be re-dispensed.

A number of medications have lab parameters that are necessary to verify prior to dispensing. White bagging does not permit a clear process to verify the patient's clinical eligibility for the receipt of the medication being dispensed. The risk of dispensing a medication when a patient is not a candidate could lead to inappropriate medication administration, severe illness and hospitalization. Unsafe processes can mask medication errors. Electronic medical records do not effectively and completely interface with outside specialty pharmacies leading to communication lapses and errors that have the potential to jeopardize patient safety. Errors made when dispensing a product that is destined for an outside site are difficult to reconcile. Without access to all the necessary information, white bagging creates a lapse in dependable processes to ensure that dispensing errors have not occurred. However, some manufacturers selectively allocate their products to create distribution channels that are largely restricted, encouraging white bagging practices. Pharmacists and other healthcare professionals are placed in difficult positions when payers and/or drug companies restrict access to drug distribution channels. Pharmacists and providers are forced to make suboptimal patient care decisions for fear of entirely losing access

to the medication or further delaying care for a patient. Pharmacists in Ohio are trusted to ensure patients receive their medications in a safe and effective manner, and white bagging is a barrier to this duty.

3. **Patient access**

The practice of white bagging increases the likelihood of fragmented patient care. In the traditional process, hospitals purchase and manage inventory based on the volume and demand of patients scheduled for infusions or injections within their system. White bagging removes the practice site from appropriately managing inventory for patients they serve. This burden is transferred to the patient who must ensure their medication is ordered in a timely manner, so the treatment is available based on their next scheduled appointment. Medications shipped through the mail by specialty pharmacies may arrive late and outside of proper storage and handling conditions. If there are delays in medication arrival or arrival of medication that has been adulterated, there will be delays in patient care. There are currently no safeguards in place to assure the medication is being delivered to the appropriate practice site when distributed through the white bagging practice.

Additionally, poor customer service and increased patient dissatisfaction resulting from this process may cause patients to seek care elsewhere due to suboptimal experience. Specialty pharmacies need to contact the patient to procure the copay and arrange for the delivery of the medication, leading to an additional step in the treatment process. At times, this can prove to be very difficult, especially if there is patient contact and they arrive at the infusion center with no drug on site for them. Patients do not understand why the medication is missing or unavailable and hold the health-system accountable. Health-systems are then faced with making difficult decisions on whether or not to delay patient care or to use stock of medication knowing that it will likely not be reimbursed since the payer has mandated white bagging.

Conclusion

White bagging is a payer-driven distribution method used to maximize revenue for vertically integrated payers and to potentially mitigate the rising costs of medications. The Ohio Society of Health-System Pharmacists opposes the current practice of white bagging due to the increased legal risk for pharmacists and health-systems, addition of unnecessary cost to the health care system, negative impact on patient safety, and potential for ineffective or incomplete treatment resulting from fragmented patient care.

Adopted by the House of Delegates October 22, 2020