

Health Insurer-Mandated Pharmacy Practices Threaten Patient Care and Medication Safety

State Policymakers Can Protect Patient Choice, Maintain Access to Care

WHA POSITION

Health insurance companies are implementing new policies limiting patient choice and reducing access to care for critical specialty medications that are necessarily administered by health care professionals.

One practice known as “white bagging” is having significant detrimental effects on patient safety and is delaying care for patients.

According to a recent report from Vizient Health, **83% of hospitals** surveyed said that specialty medications delivered to them for patient administration through white bagging **did not arrive on time**, and another **66% of hospitals** said that they have received the **wrong dose**.

Lawmakers can stop this dangerous practice.

For more information, visit: PatientsFirstWI.com

ASK: Support legislation prohibiting insurance company-mandated white bagging policies. Protect patient choice and access to specialty medications.

WHA Staff Contacts

Joanne Alig
SVP Public Policy
jalig@wha.org

Kyle O'Brien
SVP Government Relations
kobrien@wha.org

Revised: October 2021

Some health insurers are driving significant change in the drug supply chain to the detriment of care for patients with multiple sclerosis, cancer, rheumatoid arthritis, Crohn's disease and a host of other life-threatening and debilitating conditions. Medications for these patients often must be administered by a clinician through infusion. Under new policies being implemented by some health insurance companies in Wisconsin, providers are no longer permitted to acquire and store a variety of drugs needed to treat their patients. Instead, the health insurers are demanding that providers accept drugs purchased and handled by the insurer's selected pharmacy to use in patient care.

These actions pose significant risks to patient treatments, quality of care and quality of life. Under these policies, providers have inadequate control in ensuring patient access to high-quality drugs or ensuring appropriate storage and handling of those drugs.

Traditionally, the acquisition of and payment for drugs administered in a hospital setting is managed using a model where the provider purchases, stores and administers drugs, after which payers reimburse the provider for both the cost of the drug and the administration of the drug. Health insurers are upending this traditional system, potentially sacrificing patient safety and quality of care.

Specifically, health insurers increasingly are implementing policies known as “white bagging” and “brown bagging” in their health plan products, or requiring patients get their medications at home through home infusion.

- **White Bagging.** The practice of disallowing a provider from procuring and managing the handling of a drug used in patient care. Instead, a third-party specialty pharmacy dispenses the drug and sends it to a hospital or physician office on a one-off basis. The hospital pharmacy or physician office must still receive and store the medications.
- **Brown Bagging.** Similar to white bagging, the provider is not permitted to procure and manage the handling of the drug used in patient care. However, in this instance, the third-party specialty pharmacy dispenses the drug directly to a patient who then brings the drug to the hospital or a physician's office for administration.
- **Home Infusion.** Payers require that the patient receive the drug from a clinician in the patient's home. Drugs and associated supplies are often shipped directly to the patient's home.

Patient Treatment Delays and Interruptions

Delayed Shipments. Under the traditional model, the hospital pharmacy buys in bulk and has ample storage to meet the needs of patients and to ensure supply is available at the time of the patient's scheduled treatment. In a white bagging scenario, providers must order a dosage of the medication specific for an individual patient.

- Since these products are ordered on a patient-by-patient basis, as opposed to in bulk by hospitals, the potential for delay in care due to late or mistaken delivery of a product is a realistic outcome.

- Providers have reported numerous instances when a drug shipped for specific patient didn't arrive on time for the patient's appointment, either because it was never shipped, was delivered to an alternate location, or was simply delayed in the mail. Providers also have reported that this has occurred so often for some patients that the patient has given up on treatment altogether.

Incorrect Dosage at time of Appointment. Not having the new infusion regimen immediately available at the hospital can cause delays in treatment, ultimately increasing risk for the patient and potentially causing harm to the patient's recovery.

- Many patients are seen the same day as their scheduled infusion. Depending on a patient's lab results, weight and overall clinical presentation, initial treatment plans may be amended. Infusion regimens may need same-day adjustments depending on the progression of the disease.
- Providers have reported instances where a patient needed a different dosage than what was sent by the insurer's pharmacy. When the provider requested special permission to use its own supply, the insurer refused.

Patient-Provider Relationship Interrupted. Insurers implementing these policies are creating unnecessary disruption in a patient's care and treatment at a time when the patient needs his or trusted provider the most.

- To ensure the highest quality of care and patient safety, providers must have a clear line of sight into the acquisition, storage and administration of medications. Insurer policies remove providers from this process, directly impacting patient safety protections. As a result of these challenges, some hospitals have decided they cannot accept drugs through a white bagging process.
- Unfortunately, this means patients are caught in the middle, having to find an alternate provider or accept an unknown clinician into their home, even though their provider of choice is in-network for their insurance plan.
- The choice of home infusion, in particular, should be made between a patient and his or provider, not by the insurance company.

Medication Safety Compromised Through Insurance-Mandated White Bagging

Quality Control Disrupted. More complex medications require increased care and attention. White bagging and brown bagging interrupt a hospital's ability to ensure product quality control.

- Under the traditional model, hospitals are the purchasers and owners of medications necessary for patient care. This purchaser/ownership role allows providers to manage inventory; monitor dispensing, compounding, and dosing; and ensure proper preparation and storage of drugs from purchase through administration. Insurer policies requiring white bagging or brown bagging interrupt that process and require hospitals to receive and store product that is not their own with little-to-no notice.
- When hospitals control and own medications, they can guarantee the point of origin of the drug. The hospital is responsible for and can demonstrate a clear chain of custody to ensure the highest quality product.
- White bagging has the potential to overwhelm hospital storage capacity or surprise hospital supply chain and pharmacy personnel as product is delivered, which has the potential to violate individual hospital supply acquisition guidelines. Further, because these drugs are ordered for specific patients, tracking and keeping record of each patient-specific product presents an unreasonable and resource-intensive challenge.
- When a payer implements a white bagging, brown bagging, or home infusion policy for a specific drug, the hospital is unable to dictate where the product is manufactured or if it met storage requirements, like refrigeration, prior to delivery to the facility. In addition, certain drugs have very limited windows for use once mixed or compounded. This results in excessive product waste, and possibly unnecessary costs for patients.

Patient Outcomes Jeopardized. Under the traditional model, hospital pharmacists are able to help physicians better manage patient outcomes.

- Prior to the utilization of white and brown bagging policies, hospitals were armed with more information to manage, address and navigate drug shortages because they had clear line of sight into the medications their patients required. With the implementation of these new policies, hospitals are no longer responsible for the purchasing of pharmaceutical products, but still are left with the real consequences that drug shortages present, like alternative medication options and potential delay of receiving a specific drug.

- The same is true in the event the Food and Drug Administration recalls a specific medication. It is critically important that a patient be advised of any such recalls immediately, so that alternative treatments can quickly be considered by the physician. Removing hospitals from this point in the acquisition process limits provider access to critical data and information necessary to adapt to unanticipated challenges that may arise.

Inappropriate Shift in Liability. As white and brown bagging policies continue to expand, the primary onus for patient safety remains with providers, despite health plans stripping those providers of their control over the quality and handling of drug therapies.

- Providers have primary responsibility for the safety of their patients. This shift represents an inappropriate distribution of responsibility to providers who no longer own or manage the acquisition of certain pharmaceutical products.
- As drug therapies become more complex, they require significant resources and focus when it comes to storage, dispensing, compounding and administration. Given the significant liability attached to any error in preparation or administration, and without appropriate provider opportunity to oversee the acquisition process due to white and brown bagging, hospitals are more likely to feel compelled to refuse to administer products under these conditions because they cannot guarantee their safety or efficacy.