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Health Insurer Specialty Pharmacy Policies Threaten Patient Quality of Care

Health insurers are driving significant change in the drug supply chain to the detriment of patient care. Under new policies being implemented by a number of large private insurance companies, 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 these providers accept drugs purchased and handled by their owned or affiliated pharmacies to use in patient care. In some cases, the providers are barred entirely from administering drug therapies to their critically ill patients and instead must direct their patients to seek care at unknown specialty pharmacies owned or affiliated by the health plan. These actions pose significant risks to quality of care as providers have inadequate control in ensuring patient access to high quality drugs, as well as the appropriate storage and handling of those drugs. These policies simply serve to drive more revenue to health insurers through their pharmacy benefit management and specialty pharmacy lines of business.

Traditionally, the acquisition of and payment for drugs administered in a hospital setting was managed using the "buy and bill" model, which requires a provider to purchase, store and administer drugs, after which payers reimburse providers for both the cost of the drug and the administration of the drug. Health insurers are upending the traditional system, potentially sacrificing patient safety and quality care to benefit their profit margins. Specifically, the health insurers increasingly are implementing policies known as "white bagging" and "brown bagging" in their health plan products:

- **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.

- **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.

White and brown bagging policies present a number of challenges for patients and providers that warrant closer scrutiny by regulators.

- **Patient Care.** White bagging has implications for the safe care of patients requiring certain drug therapy treatments. The difficulties that white bagging policies place on cancer patients are a prime example of the potential harm. Specifically, many cancer patients are seen the same day as their scheduled infusion. Depending on a patient's lab results and clinical presentation, initial treatment plans may be amended or cancelled altogether. Similarly, when oncologists use CT scans, infusion regimens may need same-day adjustments depending on the progression of the disease shown in the CT scan results. When either of these situations occur, not having the new infusion regimen immediately available at the hospital can cause delays in treatment, ultimately increasing risk for the patient and potentially adversely impacting cancer patients' recovery.

- **Patient Access to Medication.** White and brown bagging policies have the potential to directly delay or disrupt the administration of a particular drug to a patient. For example, as the purchasers of pharmaceutical

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products under these policies, payers, not providers, are responsible for ensuring delivery of the product. However, this practice, especially in brown bagging situations, places significant reliance on the on-time delivery of product. 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. In addition, brown bagging situations, in particular, could result in drug diversion.

Moreover, changing the distribution of outpatient drugs has implications for the 340B Drug Pricing Program. This program allows providers that care for a large number of low-income and uninsured patients to stretch their scarce federal resources to provide better access to care, including, but not limited to, improved access to outpatient prescribed pharmaceuticals. Contract or community pharmacy arrangements under the 340B program have allowed hospitals to improve access to prescription drugs for their communities. White or brown bagging drugs allows the insurer to control the distribution of the drug and would eliminate the role of 340B community pharmacy arrangements as well as undermine the intent of the 340B program to allow hospitals to use savings from discounted drugs to improve access to care for the vulnerable communities they serve.

- **Planning and Preparedness.** 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. White bagging and brown bagging remove providers from this process, creating significant, avoidable challenges that directly impact patient safety protections. For example, under the "buy and bill" 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. White and brown bagging policies interrupt that process and require hospitals to receive and store product that is not their own with little-to-no notice. As a result, these policies have 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.

- **Quality of Handling.** More complex medications require increased care and attention to ensure product quality control. When hospitals control and own medications, they can guarantee the point of origin of the drug and are responsible for and can demonstrate a clear chain of custody to ensure the highest quality product. White bagging and brown bagging, however, interrupt that process, disrupting a hospital's ability to guarantee the safety of such drugs firsthand. For example, when a payer implements a white bagging 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, further complicating matters and adding to concerns around excessive product waste.

- **Information on Drug Shortages.** 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. Further, removing hospitals from this juncture 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.** Providers have primary responsibility for the safety of their patients. 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. This shift represents an inappropriate distribution of responsibility to be shouldered by providers, who no longer own or manage the acquisition of certain pharmaceutical products. For example, 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.

Policy Recommendations

We urge policymakers to take action to ensure that access to quality care and drug therapies is not compromised through white or brown bagging policies. **Specifically, regulators should ensure that health insurers comply with the following policies:**

- **No Brown Bagging.** Brown bagging should be prohibited. Shipping pharmaceutical products that require provider administration directly to patients presents significant and serious patient safety issues. Specifically, there is no method to guarantee proper storage of these drugs and the risk of drug diversion increases.

- **Prohibitions on Certain White Bagging.** There are some situations where white bagging poses significant risks to patient care. For example, drug doses for certain patients are dependent upon the results of lab tests and, therefore, dosing levels could change over the course of a treatment based on those test results. White bagging policies severely hinder a provider's ability to adapt and change dosing as necessary, at best, delaying needed patient care. In order to eliminate this potential harm, policies should be implemented that prohibit white bagging when the dosage or compounding of a pharmaceutical product is dependent upon the results of a patient's lab tests.

- **Safety Criteria for When White Bagging Can Apply.** In instances where white bagging is not prohibited, it should be restricted, allowing the practice only when certain criteria are met. Specifically, the practice should be restricted to the following situations. First, the practice only should be permissible in instances where the provider and health plan agree through their standard negotiations that such arrangements are in the clinical best interests of the patient. For example, certain providers, such as smaller or more rural facilities, may prefer to partner on some pharmacy operations in which case white bagging may present a reasonable solution. However, providers must be a joint partner in setting the terms of the agreement, including the quality and safety criteria, and have shared oversight of the specialty pharmacy arrangement. Second, there may be instances where white bagging policies are necessary to ensure patient access to a medication. In those cases, specific safety criteria should be satisfied before any white bagging policy is permissible. Finally, at no point should providers be required to accept these arrangements when they are unilaterally forced upon them by payers. Providers should be permitted to decline any such arrangements based on quality of care concerns.

- **Provider Notice.** Oftentimes, providers learn about the payer implementation of these policies with little-to-no notice. When permitted to use white bagging, payers should be required to give sufficient and advance notice to providers to mitigate any gaps in critical information and secure the type of agreement referenced above.