

Pharmacy White Bagging: Growth And Countermeasures

Executive Summary And Outline

White bagging, a pharmacy management tool increasingly utilized by vertically integrated health insurers, threatens to disrupt not only the economics of traditional buy-and-bill, but the growing trend of provider-integrated pharmacies. Herein, we define payor alternatives to buy-and-bill, including white bagging, present emerging payor policies and discuss provider concerns that have mobilized pushback at both the state and federal level.

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I. Introduction

Over the last several years, the nation's largest insurers have vertically integrated with pharmacy benefits managers (PBMs) and specialty pharmacies. Beyond strategic efficiencies of scale, these vertical business entities have channeled drugs that were previously purchased by the provider via "buy-and-bill" and required that they be filled by a PBM-owned specialty pharmacy and shipped to either the provider "white-bagged" or to the patient "brown-bagged". However, these are often intravenous (IV) drugs, requiring support by the provider for administration, wherein the provider is left with only the professional component of reimbursement.

II. Distinguishing White, Brown and Clear Bagging From Buy-and-bill

In the buy-and-bill process, the provider purchases (buys) and administers the drug, after which the medical claim is submitted (billed). The provider is thus charged with purchase, storage and administration of the product to the patient, upon which they are reimbursed not only for their time administering the drug, but capture the spread (average sales price (ASP)+X%) between what they paid for the drug from the wholesaler and how much they are reimbursed.

With the rise of high-cost specialty drugs, payors have become aware of the growing spread, in absolute dollars, of buy-and-bill covered under a patient's medical benefit. Payors have therefore permitted or mandated a role for captive or associated specialty pharmacies in managing and distributing provider-administered drugs through several channels, most notably white bagging:

- **White bagging:** A specialty pharmacy, predominantly at the discretion of the provider, ships the patient's prescription directly to the provider, which holds the product until the patient arrives for treatment.

- **Brown bagging:** The patient picks up a prescription at a pharmacy and takes it to the provider's office for administration. Due to chain-of-custody considerations, brown bagging is more limited in application.
- **Clear bagging:** A provider's internal specialty pharmacy (ex. Hospital-owned specialty pharmacy) dispenses the patient's prescription and transports the product to the location of drug administration. Given involvement of provider's system in the drug's acquisition, this is less of a provider concern.

In neither white nor brown bagging does the provider either purchase the drug or seek reimbursement for the drug from the payor; the provider still files for reimbursement for the professional component of the drug's administration, which is sent directly to them. The specialty pharmacy adjudicates the claim and collects any copayment or coinsurance from the patient before treatment and reimbursement for the drug.

III. Health Plan Payor Policies

Whereas buy-and-bill is reimbursed under the medical benefit, white bagging is typically reimbursed under the pharmacy benefit. Over the last several years, several of the nation's largest insurers have instituted white bagging to differing degrees although policies predominantly focus on the hospital outpatient setting.

- **United Healthcare's** policy "Requirements to Use a Participating Specialty Pharmacy Provider For Certain Medications", which took effect on April 1, 2020 requires participating hospitals to obtain certain specialty medications from participating in-network specialty pharmacy providers, except where separately payor authorized. However, April 2020 saw postponement of its white bagging policy due to the COVID-19 public health emergency. In March 2021, United announced an expansion of its Specialty Pharmacy Policy to 12 additional "oncology supportive medications" beginning on June 7, 2021.
- **Anthem Blue Cross**, through CVS Caremark, has indicated CVS Specialty as its designated pharmacy for specialty medications administered in the office or outpatient hospital setting, effective July 1, 2020. Among others, the policy impacts oncology practices, hematology practices and ophthalmology practices ,that routine administer medication to their patients in-office. This policy appears to apply to all specialty drugs covered through commercial HMO members' medical benefits. Furthermore, the notice suggests that drugs could be delivered to any destination of the patient's choice, which may indicate "brown bagging as an option.
- **Cigna**, through Express Scripts, has indicated certain specialty medical injectables must be dispensed and their claims must be submitted by a specialty pharmacy with which Cigna has a reimbursement arrangement. Cigna indicated it will not reimburse "facilities" that purchase these injectables directly from specialty pharmacies, manufacturers, or wholesalers. It does not apply when the specialty medical injectable is administered in a provider's office, non-hospital affiliated ambulatory infusion suite, or home setting.
- **Aetna**, owned by CVS Health, through CVS Caremark, has noted effective July 1, 2020 that it is moving several oncology in-office therapies to a "Site of Care Management List" including Opdivo, Yervoy, and Enhertu. The patients will be required to choose in-network options, predominantly outside of the hospital outpatient setting, including independent infusion centers, home infusion, infusion within a physician's office, or, when those options are not possible, Aetna will coordinate

with the hospital facility to deliver patient-specific medication from a specialty pharmacy. While this policy does not prohibit physician practices from engaging in buy-and-bill, it does require white/brown bagging for outpatient hospital centers.

IV. Disrupting A Growing Trend In Provider-Integrated Pharmacy

Specialty pharmacies owned by hospitals, health systems, physician practices, and provider group purchasing organizations have more than doubled as a share of accredited specialty pharmacy locations over the last several years. Hospitals can often earn extraordinary profits by acquiring discounted specialty drugs under the 340B Drug Pricing Program. In **Figure 1**, we illustrate the growth of the hospital outpatient setting for infusion, through Medicare Part B utilization trend data. This data does not reflect the discussed payor policies that commercial and managed care payors are increasingly implementing, as white bagging does not exist in Medicare Part B. In effect, the data reflects a control group of pharmaceutical utilization that serves as impetus behind private payor policies.

Figure 1: Payor white bagging policies are targeting the hospital outpatient setting where utilization has increased with vertical integration of health systems and specialty groups over the past several years

Marwood conducted an analysis of CMS Standard Analytics Files looking at Medicare utilization trends in the physician office versus hospital outpatient settings for certain classes of drugs. Hospital outpatient utilization of select oncology drugs far exceed that of the physician office setting and have grown nearly twice as fast over the past 3 years. Similarly, Medicare utilization of immune globulin therapies are performed most often in the hospital setting as opposed to the physician office. As a point of comparison, Medicare utilization physician-administered asthma medications are primarily performed in the physician office setting. *Note that Medicare utilization data does not reflect the discussed payor policies that commercial and managed care payors are increasingly implementing. Thus, this data reflects a control group of pharmaceutical utilization that serves as impetus behind private payors policies.*

Table 1 - Medicare Utilization Trends of Oncology Drugs By Site Of Care

Units	2017	2018	2019	2020	CAGR
Physician Office	1,934,654	2,632,909	3,155,251	3,215,511	18.5%
Hospital Outpatient	2,341,274	3,606,610	4,584,059	5,267,863	31%

Source: CMS Standard Analytics File

Note: Data reflects units of the J-codes cited by payors in specialty pharmacy policies

Table 2 - Medicare Utilization Trends of Immune Globulin Drugs By Site Of Care

Units	2017	2018	2019	2020	CAGR
Physician Office	541,652	606,108	587,023	618,019	4.5%
Hospital Outpatient	1,108,168	1,171,053	1,206,218	1,229,220	3.5%

Source: CMS Standard Analytics File

Note: Data reflects units of the J-codes cited by payors in specialty pharmacy policies

Table 3 - Medicare Utilization Trends of Asthma Drugs By Site Of Care

Units	2017	2018	2019	2020	CAGR
Physician Office	332,347	420,185	520,584	579,852	20.4%
Hospital Outpatient	404,106	487,496	529,318	519,128	8.7%

Source: CMS Standard Analytics File

Note: Data reflects units of the J-codes cited by payors in specialty pharmacy policies

Similarly, outpatient ambulatory infusion companies often utilize integrated pass-through situations with integrated specialty pharmacy function, rather than buy-and-bill. In these pass-through situations, a specialty pharmacy delivers the drug— and possibly infusion equipment & supplies to the ambulatory center upon which the pharmacy bills the insurer directly. The pharmacy is also responsible for the authorization and collection of co-pays. White bagging has the potential to disrupt these integrated pharmacy margins, either by 1) directly restricting pharmacy channels to specific payor-integrated or payor-aligned pharmacies or 2) requiring provider-associated pharmacies to accept margins which may be untenable. For example, an ambulatory infusion center's integrated pharmacy may not be able to secure the volume discounts of a PBM-aligned captive pharmacy of a national plan.

V. Provider Concerns

The most tangible provider opposition to white bagging is grounded in lost revenue and reduced profit from the loss of margin from drug buy-and-bill. While supplemental to the professional component of reimbursement, it is often seen as covering the order, dose and sterile room preparation of infused therapies, the latter which has a significant fixed cost of facility. Outside of these financial considerations, white bagging does not mitigate, and may actually increase, handling costs associated with the drug. Providers incur costs for handling and storage in separate, patient-specific, inventory of product and associated assurance that the product is available and accessible (ex. associated disposable medical equipment (DME)), when the patient arrives for treatment. Beyond financial considerations, the logistical aspects have called into question the viability of white bagging and has been a point to ground consensus in opposition across provider and patient stakeholders:

- Therapeutics are patient-specific, wherein treatment regimen changes that exclude or minimize its use or in situations where the entire vial is not used, the medication must be discarded. The provider and patient (copay) bears the burden, similar to picking up a prescription which is then not used. Disposal may require costly special handling at the expense of the provider.
- Not only is storage still required, but must be separate from buy-and-bill drugs as they are patient-specific. Even among hospital pharmacies, white bagging can be a storage and logistics issue.
- As these drugs are processed as the patient's-specific medication, they do not go through the checks and balances of the order-entry system. Thus pharmacy errors, from dosage to strength, may be more difficult to catch.
- As with any mail-order service, drugs are not always delivered to the right place or in-time for the patient's appointment. This can leave providers racing to institute alternative treatment plans. A point seized upon by legislators, as detailed below, this contrasts with buy-and-bill where the pharmacy has the drugs or ensures the distributor delivers the drugs in time.
- Additional handling costs may be incurred to comply with state laws; track-and-trace and drug pedigree laws, including the Drug Supply Chain Security Act, and other state laws

VI. Provider Advocacy Pushback Through State And Federal Channels

National associations including the American Pharmacists Association (APhA), Hematology/Oncology Pharmacy Association (HOPA), the American Hospital Association (AHA) and American Society of Health-System Pharmacists (ASHP) are banding together to advocate with policymakers to prohibit health plans and pharmacy benefit managers from requiring white bagging of clinician-administered drugs. Earlier this year, the AHA asked CMS to prohibit the UnitedHealthcare white bagging policies

described above. AHA wrote to CMS to “express deep concerns” about UnitedHealthcare’s white bagging policies for provider-administered specialty drugs. Similarly, ASHP says it officially “stands opposed to payer-mandated white bagging.”

In addition, as part of a national effort, ASHP and AHA expressed concern over white bagging in a joint letter to the Acting FDA Commissioner Dr. Janet Woodcock. Together, both organizations encouraged the FDA to “consider the patient safety and supply chain security risks of white bagging, and take appropriate enforcement action to protect patients” and requested a meeting with the FDA to discuss these concerns in greater detail. From the FDA standpoint, the appeals to the FDA are valid from a Drug Supply Chain Security Act (DSCSA) standpoint, but the complaints seem to raise more of a risk than an outright violation. The issue at hand would be safety and maintaining a track-and-trace system, which providers are complaining "is hard to do" or "presents risks."

Efforts to restrict white bagging have found traction at the state level. Among examples presented in **Figure 2**, a Louisiana law (LA SB191) that prohibits insurers from implementing white bagging policies.

Figure 2: An increasing number of states have moved to prohibit or curtail white and/or brown bagging	
CA	The California Board of Pharmacy met in February 2020 to discuss the challenges presented by white bagging policies including the dangers posed to drug security and patient safety.
GA	White bagging mandates could run afoul of state patient steering laws (GA. Code Ann. § 26-4-119) which generally prohibit health care providers from agreeing to send prescriptions to a particular pharmacy.
IN	The Indiana Department of Health note white bagging should be regulated, in a report issued in July of 2021 to the Indiana General Assembly; however, they do not call for a ban.
LA	Many hospitals supported a bill that would block the practice of white bagging. The bill passed the Louisiana House and Senate nearly-unanimously, and was signed by Governor Edwards on June 1, 2021 (LA SB191).
MA	Massachusetts identifies white bagging as “redispensing” which is prohibited. (247 CMR 09.01(4)).
NJ	White bagging mandates could run afoul of state patient steering laws (N.J.A.C. 13:39-3.10) which generally prohibit health care providers from agreeing to send prescriptions to a particular pharmacy.
TX	The Texas Senate is currently considering HB 1586, which would amend the Insurance Code to address health benefit plan coverage of clinician-administered drugs for patients with cancer or a cancer-related diagnosis. If enacted, the law would prevent health benefit plan issuers from (1) requiring clinician-administered drugs to be dispensed by a pharmacy selected by the health benefit plan issuer, (2) requiring that the drug or administration of the drug be covered as a pharmacy benefit rather than a medical benefit, (3) limiting or excluding coverage for the clinician-administered drug when not dispensed by a pharmacy selected by the health benefit plan issuer, and (4) prohibiting a physician or provider from obtaining or administering a clinician-administered drug that the physician or provider is otherwise permitted to obtain or administer by law.
WI	A bipartisan group of 10 lawmakers led by Sen. Alberta Darling and Rep. Tony Kurtz began circulating a bill in October of 2021 (21-4440/1) banning insurers requiring that specialty drugs be white bagged.

VII. Future Considerations

Marwood continues to evaluate the regulatory, legislative, payor and provider impact of white bagging on the industry, as payor pressure mounts to shift infusion from a hospital outpatient to a home and ambulatory setting. Marwood is also following trends hospital/health system consolidation and growth which may impact outpatient infusion and associated 340B pharmacy considerations, as well as growth and consolidation in the home infusion and ambulatory infusion center space. As Marwood explores the strategic impact of these developments to the infusion market, we continue to follow federal impacts to the sector, associated healthcare plan payor dynamics and market trends attributable to the COVID-19 pandemic.

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