



**White Bagging, Brown Bagging, and
Site of Service Policies:
Best Practices in Addressing Provider Markup in
the Commercial Insurance Market**

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Introduction

For people with conditions like autoimmune disease, cancer, and multiple sclerosis, clinician-administered specialty drugs represent positive, sometimes lifesaving innovation. Payers and policymakers recognize these advances but also see these products as leading drivers of increased drug spending. While use of specialty drugs is concentrated in less than 5% of the population, they now account for about half of total drug spend.¹ And that proportion of cost growth is accelerating - the overall spending on specialty drugs has increased 8.4% between 2019 and 2020, driven by a combination of price increases and expanded utilization.²³ In the commercial insurance market, overall prescription drug costs grew 7% per employee in 2020, driven by specialty drug costs that increased 11.4% per employee.⁴ With health care insurance premiums for employers and other plan sponsors poised to increase substantially again in 2022-2023, ripples of concern emanate outward from those areas of fastest cost increases. Specialty pharmaceuticals have occupied the center of attention for many years.⁵

In response to these pressures, employers, other plan sponsors, and the commercial health plans and pharmacy benefit managers (PBMs) who manage health benefits and create formularies, have all deployed a variety of strategies intended to control drug spending while maintaining appropriate access for patients. Traditional management of drug spending by health plans and PBMs has emphasized price negotiation linked to formulary placement, and evidence-based utilization management, including prior authorization and step therapy when equivalent or more effective treatment options are available at lower cost. However, these approaches are more readily implemented for drugs administered through the pharmacy benefit component of health insurance coverage, and may not be easily applied to specialty drugs. Notably, 45% of specialty spend is on drugs that are administered by clinicians and reimbursed through the medical benefit. For these specialty drugs, formulary tiering is not usually feasible, and payers often have more limited data with which to track and manage utilization in real time through prior authorization and step therapy.⁶

Given the high costs of specialty drugs and the limitations of traditional utilization management, many commercial payers are increasing efforts to reduce the “markup” on specialty drug acquisition and administration that is charged by providers who buy drugs directly from drug wholesalers and then bill payers for the drug at a higher price. The intent of markup is to cover the administrative infrastructure costs to the provider of storing and managing a large number of specialty drugs so that the right drug at the right dose can be selected at the time the patient is seen by the provider. Under this “buy and bill” approach, however, markups can be more than the price of the drug itself. For example, markups charged to payers by hospitals when clinicians administer drugs in the hospital setting have been found to be as high as 200-300% of the base price of the drug.⁷ For many specialty drugs with an annual base cost of \$300,000 or more, this

level of markup can represent hundreds of thousands of dollars per patient, every year. These added costs create real pressure on insurance premiums and are viewed by payers and plan sponsors as an outgrowth of an outdated contracting approach that was more suited to an environment when very few patients required specialty drugs and the cost of specialty drugs was far lower. The goal of reducing these substantial costs without adversely affecting patient access to appropriate treatment has spurred many payers to make important changes in their coverage policies in recent years.

Payers have developed two primary strategies for managing drug markups. The first involves bypassing the buy and bill approach by providing the drug to the clinician directly through a payer-affiliated specialty pharmacy. With this approach payers avoid provider markup while also leveraging the negotiation power of specialty pharmacies, which can often obtain a lower price for the drug from drug wholesalers. This practice is often called “white bagging” since the drug is envisioned as being delivered in a white bag to the provider. Another approach used to supersede the buy and bill model is called “brown bagging” when the payer’s specialty pharmacy delivers the drug directly to the patient, either to take to the provider at the time of administration or for use at home through a home infusion program. In both white and brown bagging, the common theme is that the traditional buy and bill approach is replaced with some approach through which the drug is provided to the clinician by another entity and reimbursed with a drug administration fee but without any markup on the cost of the drug itself.

In addition to these “bagging” policies, the second main approach payers are using to avoid the markups associated with buy and bill reimbursement is to require patients to receive treatment at a lower-cost site of care, either at a clinician’s office outside of a hospital-based system, at a stand-alone infusion center, or at home. Requirements for patients to have their drug administered in specific locations are called “site of service” policies. While in practice white and brown bagging and site of service policies seem to overlap in intent, and often in implementation, each presents distinct incentives and challenges.

Large payers report significant cost savings with both white and brown bagging policies and site of service policies.⁸ Internal data and independent reports also have shown stable or improved patient satisfaction with the care process.⁹ However, the data to perform independent evaluations of these policies are not available publicly, and while payers have touted their effectiveness and positive effects for patients, hospitals and provider groups have argued that there are important risks and underappreciated negative consequences for both patients and providers.¹⁰ Providers we interviewed cite examples when patient outcomes have suffered due to poor coordination of information across care settings, disruptions in care due to treatment delays, and risks for vulnerable patients who may face access challenges as a result of these policies.¹¹ Clinicians claim that bagging and site of service policies also add burdens on clinicians and patients—with clinicians having to manage separate sources for medications they deliver, and encountering more questions

and calls from patients and families who are trying to understand these new drug delivery models.¹² For patients, it is claimed that brown bagging can create anxiety about handling the drug properly, and, although some patients may appreciate the option of home administration for a chronically administered drug, some site of service policies may force patients to arrange for travel from their doctors' offices to another site on the same day, or make a separate visit to receive a medication.¹³

This paper accepts the premise that payers have a legitimate reason to consider policies that can maintain appropriate access while reducing the scale of markups that has been seen within the traditional buy and bill reimbursement system. Our purpose in this paper is to describe the specifics behind how white bagging, brown bagging, and site of service policies have been designed and implemented, to analyze the respective potential benefits and harms that these policies may cause, and to highlight safeguards and other types of design or implementation best practices through which it will be most likely that reduced costs can be achieved with the lowest risk of adverse consequences for patients and clinicians. Finally, the paper will also present an analysis of potential broader policy reform options that may help improve the design and implementation of these policies and other efforts to control costs for clinician-administered drugs. We will frequently note throughout this paper that publicly available evidence on the impact of white bagging, brown bagging, and site of service policies is very limited. Many of the purported benefits and drawbacks of these policies are supported solely by anecdote or internal analyses not subject to public examination or peer review. We therefore acknowledge the potential for bias within the views of different stakeholders whose experience and views are reported in this paper, and are sensible that our own analyses and conclusions are vulnerable to the selective information provided to us by sources with varying conflicts of interest.

Structure of This Paper

To understand why payers are shifting drug distribution channels and sites of care, it is important to analyze the current policy landscape and other market trends driving the high cost of specialty drugs. It is also critical to understand purchasing and reimbursement models that currently dominate drug sourcing channels. This information is presented in the background section of this paper.

We then examine the efforts of payers to implement white bagging and brown bagging policies to shift the drug purchasing channel from providers to specialty pharmacies. We look at how these policies may affect patient safety and equitable access to care, and we explore the financial implications of these policies and additional consequences across the specialty drug supply chain.

In turn we then examine site of service policies and the potential advantages and disadvantages of different approaches to design and implement these policies. The impact on patient outcomes, on equitable access to care, and the finances of payers, providers, and patients are explored.

Following an outline of current legislation proposed at the state level to address concerns about white bagging, brown bagging, and site of service policies, we analyze in the concluding section of this paper a series of potential best practices and the pros and cons of a variety of policy reforms that may support the best balance between reducing markup and maintaining equitable access that ensures that individualized needs of patients are recognized and fulfilled.

Methods

This paper relies on information, data, and perspectives gathered from a targeted literature review, as well as interviews with patient advocacy groups, provider groups, and with a sample of organizations participating in the ICER Policy Leadership Forum.

We used a structured discussion guide to collect input during these interviews with 19 experts from large and small pharmaceutical manufacturers, health plans, PBMs, specialty pharmacies, comprehensive cancer centers and physicians about their views on the challenges around the shifts in drug delivery and site of service for clinician-administered drugs. Furthermore, we conducted extensive literature review which included keyword and hand searches for peer-reviewed and gray literature to understand the impact of changes in drug delivery and site of service has on patients, providers and payers. We tracked legislation regarding these issues that was introduced in state assemblies across the country to inform our understanding of how the legislation will impact drug delivery and site of service model. To understand the various stakeholder's perspectives, we also tracked the comment letters submitted to FTC's request for information about PBMs and their practices.

Based on the primary and secondary research, the ICER research team analyzed a set of potential policy solutions and highlighted best practices that respond to identified themes and challenges associated with maintaining access and controlling costs. Representatives from provider groups joined senior policy leaders from 30 payer and life science companies at a two-day meeting in December 2022 to deliberate on the potential policy solutions and best practices and provide suggestions for revisions to a draft version of this paper. The participants in this meeting are shown in Appendix A. None of these participants or their organizations should be considered as having approved of any element of this paper. The perspectives and recommendations in this paper are those of the editorial team at ICER and NORC alone.

Background

Specialty drugs[†] are used to treat serious conditions, including cancer, multiple sclerosis, and rheumatoid arthritis.¹⁴ Many specialty drugs are also now available to treat rare conditions for which there had been few, if any, treatment options.¹⁵ These drugs have improved patients' quality of life and, in some cases, provided a cure.¹⁶ However, the multitude of benefits from specialty drugs come with high prices, and spending on specialty drugs now constitutes a significant and growing portion of total prescription drug spending. According to IQVIA data, in 2020, spending on specialty drugs was \$265.3 billion, which constituted 49.6% of total prescription drug expenditure. That spending represents an increase of 8.4% between 2019 and 2020.²

Many specialty drugs are biologics, which often have unique and specialized handling requirements, such as temperature-controlled storage. More complex handling and distribution requirements means that many specialty products are not distributed through standard retail pharmacies, but are purchased directly and stored by providers to have on hand when needed by patients. Alternatively, specialty pharmaceuticals can be managed by specialty pharmacies, which are set up to manage the complexity of the entire process of drug delivery and tracking of patients including managing FDA-imposed Risk Evaluation and Mitigation Strategies (REMS) program requirements for certain drugs.

Traditional Buy and Bill Reimbursement. While some specialty drugs can be self-administered by a patient (e.g., orally or by sub-cutaneous injection), many specialty drugs are administered by clinicians via an infusion or intramuscular injection. Traditionally, products administered by physicians or other providers are reimbursed under a health plan's medical benefit through a "buy-and-bill" payment system. Under a buy and bill mechanism, providers purchase drugs directly from a wholesaler and are then responsible for storing and administering the drugs to patients.

Buy-and-bill remains by far the most common form of reimbursement for clinician-administered drugs, but the proportion of specialty pharmaceuticals reimbursed through buy-and-bill varies across settings and, particularly, by physician specialty. For instance, oncologists and rheumatologists who administer a significant number of specialty products to their patients are more likely to maintain their own drug inventory and participate in buy-and-bill. By contrast, specialties like cardiology, which have not traditionally had many clinician-administered treatments, may not have the office infrastructure or interest in running a buy-and-bill process for a small volume of drugs.

[†]Specialty drugs encompass a range of medications that require special handling, closer patient monitoring, are either infusion based or self-administered, are more expensive and can require reimbursement assistance.

Reimbursement Rates and Markup by Insurance Source. The reimbursement rates for drugs purchased via buy-and-bill can vary by provider type (e.g., hospitals, independent providers), payer, and line of business (e.g., commercial, Medicare, Medicaid). Medicare pays 106 percent of the average sales price (ASP), which is intended to fully reimburse the providers' for the acquisition cost of the drug and overhead costs for storage and other related office expenses. A separate administration fee is paid to providers. Medicaid fee-for-service reimburses providers at their acquisition cost (as defined by the state) and most pay a separate fee for administering the drug.

In the commercial insurance system, reimbursement levels are set through negotiations with providers which, until recently, largely followed Medicare's 106 percent reimbursement arrangement.¹⁷ In the commercial market, the markup on the cost of the drug and the reimbursement for administering the drug are also two separate payments, but may be reflected differently depending on the plan's design contracting terms with the provider. For purposes of this paper, discussion around reimbursement and markup will focus only on the commercial market.

Providers suggest that markup charged to commercial payers is scaled appropriately to cover the storage, quality assurance, other costs of maintaining an adequate inventory to provide same-day treatment options for a wide variety of patients. However, the amount of markup can vary significantly across providers and payers for the same drug.^{18, 19} Recent research has found that markup charged to different payers can even vary widely at the same hospital, suggesting markup reflects broader negotiation and contracting issues.²⁰ Payers argue that markup can vary as a result of number of factors, including relative market dominance of the provider and health plan, and purchasing mechanism (e.g., group purchasing organization or GPO) used.

Influence of 340B and the Inflation Reduction Act (IRA). The 340B drug discount program serves to amplify provider incentives to capture additional revenue through markup as part of the buy and bill reimbursement mechanism. For example, a 2021 report by the Community Oncology Alliance (COA) found that 340B hospitals markup the price of drugs 3.8 times the acquisition cost of the drugs.²¹ Providers eligible to participate in the 340B program[‡] have lower net acquisition costs for outpatient drugs because they receive discounts that allow them to purchase drugs at Medicaid prices. These lower acquisition prices can significantly increase the margin that a provider earns with markup on a clinician-administered drug. Many argue that this extra margin has enhanced incentives for 340B entities to purchase the practices of clinicians with high rates of specialty drug utilization, including oncologists and rheumatologists.

The recent passage of the Inflation Reduction Act (IRA) will have differential effects on hospitals depending on whether they are eligible for 340B. The IRA will shift Medicare reimbursement for

[‡]Eligible providers, also known as covered entities, include disproportionate share hospitals, sole community hospitals, rural referral centers, children's hospitals, or free standing cancer hospitals. Further information can be found at <https://www.hrsa.gov/opa/eligibility-and-registration>.

drugs subject to negotiation from 106% of ASP to 106% of the negotiated maximum fair price (MFP).²² This means that the drugs will be reimbursed at a lower rate than before, narrowing the profit margin under buy and bill reimbursement. However, the IRA allows for 340B providers to purchase drugs at the lower of the 340B ceiling price and the MFP, retaining greater opportunity for markup revenue for 340B entities relative to other institutions.²³

Market Dynamics and Variation in Markup by Site of Service. The markup on the price of drugs varies significantly based on the site of service where the drug is administered. If a drug is administered in a hospital-based outpatient department (HOPD), the prices are significantly higher than if it is administered at a provider office or at the patient’s home. Payers point out that HOPDs should, in theory, be better equipped to store and manage specialty products at scale and would thus need less markup to cover these costs. But according to Magellan, buy-and-bill costs for drugs administered in HOPD settings are often twice as high as costs under buy and bill in independent physician offices.²⁴ This differential can be seen in Table 1 below which shows that Blue Cross Blue Shield health plan costs for biologics, chemotherapies, and other infused cancer drugs delivered in HOPDs were up to double (99%-104% higher) the cost of the same drugs administered in physicians’ offices.²⁵

Table 1: Price Differences to Payers for Infused Cancer Drugs Administered at HOPD vs Physician Office²⁶

Infused Cancer Drugs	Cost Increase for HOPD vs. Physician Office (%)
All infused drugs	100.2
Biologics	99.6
Chemotherapies	103.6
Hormonal therapies	68.2
Other drugs	98.6

The relationship of site of service to size of markups is largely based on the relative negotiating power of any given provider.²⁷ For instance, providers in highly concentrated markets may command higher reimbursement from payers, which extends to markup. Similarly, individual health systems that are dominant players (e.g., leading academic medical centers) may be harder for plans to exclude from their networks and, thus, are able to command higher payment rates, including higher markup.

Given the lucrative nature of drug mark-ups in HOPDs, recent research has shown that markets with strong integrated hospitals or systems have a higher share of infusions occurring at HOPDs (63%) compared to other sites of care (37%).²⁸ The differences in mark-ups and administration fees motivates integrated health system providers to administer drugs in more profitable settings within

their system. As noted earlier, this is also believed to be a major factor driving hospital acquisitions of physician practices and infusion centers with high volumes of clinician-administered drugs. Over 700 oncology practices were acquired by hospitals between 2008 and 2020²⁹, allowing hospitals and health systems to increase payment rates from specialty drugs.

In markets where physicians tend to be more independent and less likely to be employed by a hospital system, the share of infusions occurring at HOPDs (33%) is smaller than in hospital-dominating markets.²⁸ In these markets, hospitals have reduced incentives to guide expensive infusions to HOPDs since they are less likely to qualify for 340B and thus would not be capturing as much markup as in other markets.

In “middle ground” markets where neither integrated delivery systems nor independent physicians have incentives to strategically drive site of care decisions, the share of infusions at HOPDs (47%) falls somewhere in the middle between what hospital-dominating (63%) or independent physician-dominating (33%) markets tend to see (see Table 2 below).

Table 2. Concentration of HOPD Infusions by Market Archetype²⁸

Market Archetype	Number of Markets	HOPD Share Within Market	% of All Infusions	% of HOPD Infusions	Market Examples
Hospital Dominating	114	63%	25%	33%	Cleveland, OH; Minneapolis, MN
Physician Dominating	114	33%	25%	17%	Orlando, FL; Nashville, TN
Middle ground	172	47%	50%	50%	Salt Lake City, UT; Austin, TX
All Markets	400	48%	100%	100%	

Payer Policies to Address Markup

White Bagging, Brown Bagging, and Clear Bagging

In response to ongoing concerns about specialty drug spending, high markups by some providers, and the financial incentive that buy-and-bill creates to administer higher-cost drugs, payers have developed several strategies to achieve savings for plan sponsors, plan members, and themselves. One strategy is to mandate that products be dispensed through a specialty pharmacy, instead of directly from the physician’s buy-and-bill supply. This approach is known as white bagging or brown bagging depending on who receives the drug from the specialty pharmacy.

White bagging policies deliver drugs from specialty pharmacies directly to providers at the site of service where the drug will be administered (typically a physician’s office, HOPD, or home infusion provider). Providers are responsible for receiving the drug delivery from the specialty pharmacy, unboxing it, and storing it until the patient is on site and ready for administration. The moniker “white bagging” arises from the “white coats” of the providers who receive the drug from the specialty pharmacy. Analysis of the impact of white bagging on payers and patients will be discussed later in this paper.

Brown bagging policies require patients to pick up their prescribed clinician-administered drugs at a specialty pharmacy or have these drugs delivered directly to patients, after which patients are responsible for storing these drugs appropriately until the time of their appointment with a clinician, at which time patients bring their drug with them to hand over to a clinician for administration. The term “brown bagging” comes from the analogy to a “brown bag” lunch carried by an individual.

Clear bagging involves a provider, typically a hospital, creating a formal program through which its internal specialty pharmacy can dispense the drug and deliver it to the site of service. Clear bagging thus serves as a provider strategy to offer an alternative to white bagging and brown bagging, thereby retaining the revenue associated with specialty drug delivery. Clear bagging also avoids some of the logistical and safety challenges associated with white bagging. For instance, if a patient’s drug dosage needs to be adjusted, the hospital specialty pharmacy can dispense the new dosage and have it delivered to the on-site hospital suite or clinic without having to reschedule the patient’s appointment as can be the case with white bagging.³⁰

There has been a recent proliferation of hospital-owned specialty pharmacies, with estimates from 2019 showing that 26% of hospitals owned a specialty pharmacy.³¹ Some stakeholders suggest that clear bagging is also on the rise due to hospital acquisition of independent physician practices, which allow hospitals to dispense a larger volume of clinician-administered drugs through their specialty pharmacy.³² If they cannot be paid under buy-and-bill, hospitals that participate in the 340B program have strong incentives to shift prescription volumes to clear bagging to maintain access to 340B discounts for these products.

Because many of the conflicts over the risks and benefits of bagging policies have focused on white bagging and brown bagging, the remaining analysis in this paper will focus on these policies and will not include further commentary on clear bagging.

Insurer Payment Policy Definitions

Buy-and-bill: Specialty drugs that are clinician-administered are purchased in bulk by a provider who then stores and administers them to patients. Once the provider administered the drug, they then submit a claim to the payer for reimbursement for the cost of the drug. Under this system, the physician is also responsible for maintaining the inventory of the drug.

Brown bagging: When a patient is required to fill a clinician-administered drug through a specialty pharmacy. The patient takes possession of the drug and then brings it to their provider to be administered. Patients may pick up a prescription from a designated pharmacy or the product may be drop-shipped to the patients' home. Similar to a brown lunch bag, the patient is responsible for physically transporting and handling the drug from the time of pick up to administration.

White bagging: When a specialty pharmacy ships a patient's prescription directly to the provider (e.g., physician office, HOPD) and the provider is responsible for handling and storing the drug in anticipation of using it for an individual patient.

Clear bagging: A provider, usually a hospital, uses its internal specialty pharmacy to fulfill a patient's specialty drug prescription and transports it to the site of administration. The payment for the drug flows through the provider-owned specialty pharmacy, as opposed to the provider themselves (i.e., buy-and-bill).

Site of Service:

Physician Office: An independent clinic that is owned by a physician, equipped with capability to provide routine diagnostic and therapeutic services including administering infusion based drugs.

Hospital-based Outpatient Department (HOPD): An HOPD is owned by and usually attached to a hospital. Services such as imaging and laboratory tests are provided at HOPDs.

Infusion Center: An infusion center is an outpatient clinic where infusion therapy is administered. The cost of infusion therapy to a payer is typically less at an infusion center compared to physician office or HOPD.

Home Infusion: When a clinician provides an infusion at the home of a patient.

Rationale for White Bagging and Brown Bagging. One reason for the move to white and brown bagging is that it allows payers to take advantage of lower negotiated prices for drugs that specialty pharmacies are able to obtain because they are associated with large national payers who have greater market leverage. Using their own specialty pharmacies also keeps all the associated fees associated with drug delivery. For example, Aetna touts that its savings associated with their movement away from buy and bill to specialty-based pharmacy drug management may exceed 50%.³³

A second reason why payers can favor white bagging or brown bagging is that these policies give payers more control over which drugs are utilized. Under buy-and-bill it can be harder to influence clinician and patient drug selection, so specialty pharmacies can generate savings both by eliminating markup costs and by shifting utilization to lower priced products, many of which have substantial rebates that may enhance the payer's overall revenue.

White and brown bagging also allows payers to leverage the expertise of specialty pharmacies to treat complex and rare conditions. By virtue of how rare some diseases are, some providers may have limited experience with these medications. Specialty pharmacies, in contrast, treat significantly more patients and have clinical staff with experience providing overall drug and condition support (e.g., help managing side effects, adherence, and patient out of pocket costs).

Lastly, payers argue that white bagging can improve continuity of care in the face of supply chain shortages and disruptions. Large specialty pharmacies have strong purchasing power and are usually one of the last to be impacted by drug shortages. For example, Express Scripts noted that its specialty pharmacy, Accredo, was able to successfully manage nearly 500 backordered drugs and supplies between 2021 and 2022.

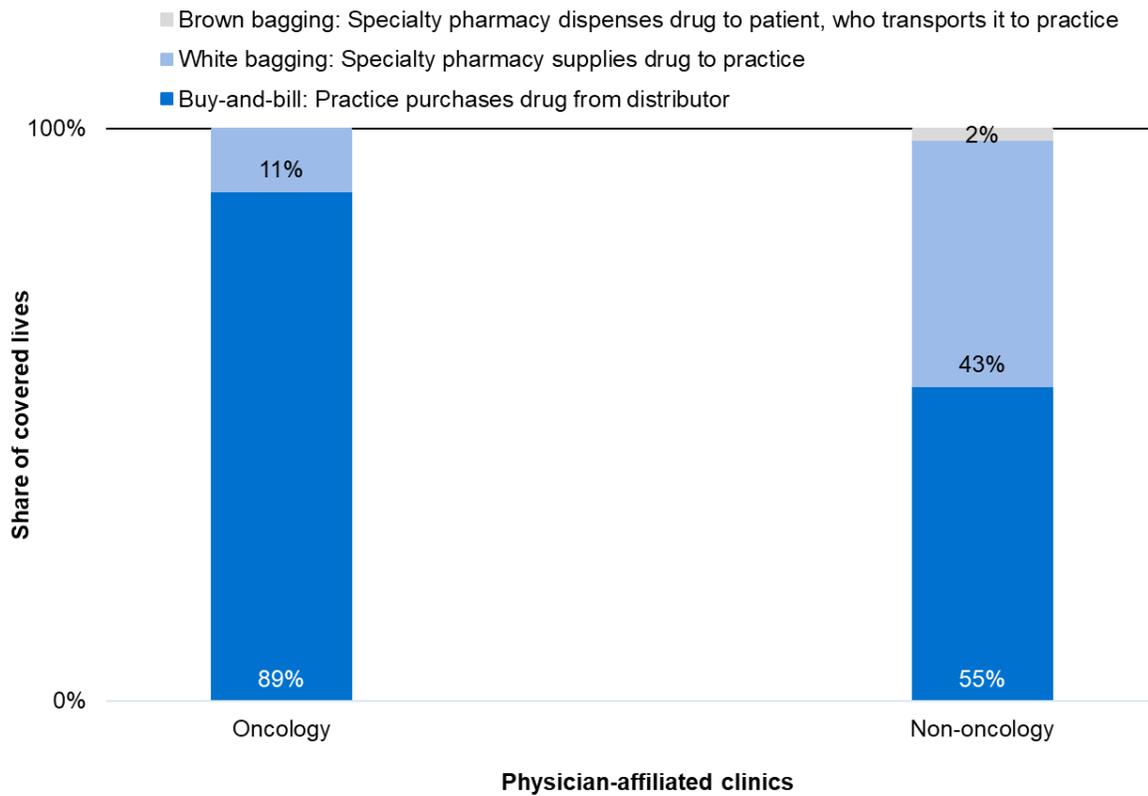
The relative benefits of brown bagging have been viewed as less certain by many payers due to concerns about the safety of sending specialty drugs directly to a residential address for management by the patient, further detailed below. Nonetheless, the convenience of brown bagging when twinned with home infusion is viewed by payers as providing important advantages for many patients. Some payers report very high levels of satisfaction among patients shifted to home infusion with brown bagging, and also argue that employers have asked for more services to be provided at home in an attempt to meet employee requests for greater flexibility in care options, particularly during the pandemic.

Rates of Adoption of Bagging and Site of Service Policies. White bagging is now a common and growing practice. In 2022, 27% of oncology therapy products administered in physician offices under commercial insurance were subject to white bagging policies.³⁴ Representatives of specialty pharmacy networks told us that the dollar amount flowing through white bagging policies has been increasing in recent years, and hospital sources suggest that the number of products purchased via

white bagging have also been increasing. Recent 2022 data, however, show a substantial increase in buy-and-bill purchases at HOPDs, representing an outlier in recent trends. Experts have speculated that this increase may be a result of hospitals acquiring physician practices, including the drive by 340B hospitals to expand their networks through which they can capture the additional margin that buy-and-bill can generate when drugs are purchased at 340B prices.³⁴

As shown in Figure 1 below, white bagging was less common for cancer products than non-cancer products (11% for oncology vs 43% for other drugs), likely because cancer drug selection and dosing is more likely to shift in the course of a single office visit, concerns about managing and storing the medication, or perhaps because of the greater contract negotiating leverage of large oncology provider groups.³⁵

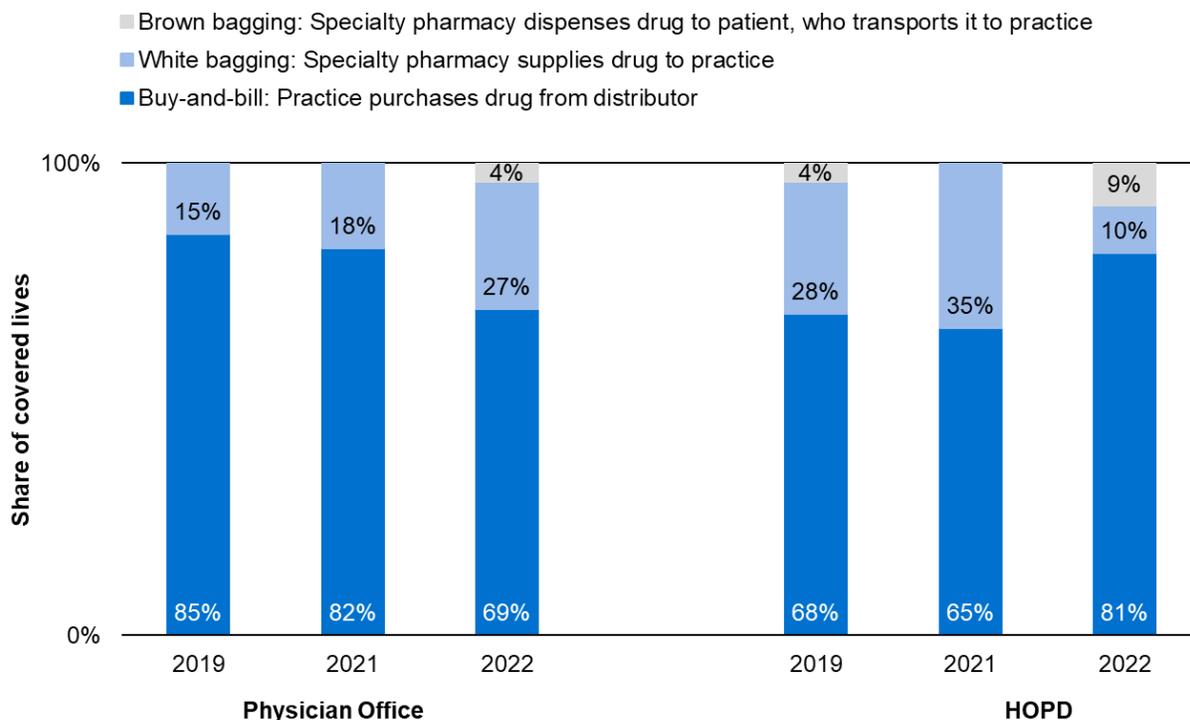
Figure 1: Prevalence of Different Distribution Channels for Oncology vs. Non-oncology Infused Therapies for Commercial Payers (2019)³⁵



One possible driver for the increase in white bagging practices prior to 2022 may be the growing consolidation between payers and PBMs. In 2020, the three biggest PBMs aligned with payers – CVS/Aetna, Optum/UnitedHealthcare, and Express Scripts/Cigna -- accounted for 77% of all prescription claims.^{36,37} Some providers assert that bagging policies are motivated by the health plan’s desire to drive volume to their own specialty pharmacies. This concern has gained national attention, with a recent FTC investigation launched in June 2022 looking specifically into PBM methods steering patients to PBM-owned specialty pharmacies.³⁸ Growth of white bagging could also be a response to increased consolidation of providers, which drives higher reimbursement rates and more use of HOPD for infusions.

As opposed to white bagging, brown bagging occupies a very small place in current insurance coverage policies. As of 2022, brown bagging policies were applied to only 4% of oncology drugs administered in physicians’ offices and 9% of drugs administered in HOPDs (Figure 2 below).³⁴ In some states, legislatures have even outlawed the practice entirely. Notably, brown bagging is somewhat more common in a home infusion setting (12% in 2019), since the patient’s home is also the site of service.³⁵

Figure 2: Prevalence of Different Distribution Channels for Infused Oncology Therapies by Practice Type and Source for Commercial Payers (2022)³⁴

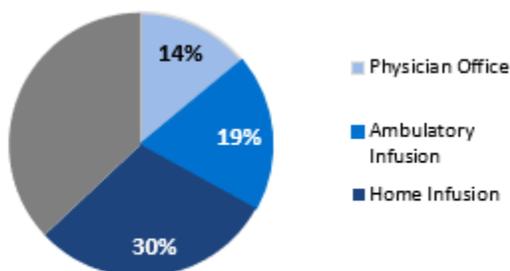


Site of Service Policies

In addition to white bagging and brown bagging policies, health plans and PBMs have also worked to reduce spending on clinician-administered specialty drugs by shifting site of service to lower-cost settings. For example, according to United HealthCare’s site of service policies, patients cannot receive coverage for certain drugs in hospital outpatient settings, and instead must be administered treatment at alternative sites such as non-hospital outpatient infusion centers, independent physician offices, or at home.³⁹ The UnitedHealthcare policies do not steer patients towards any one specific alternative site but do highlight clinical evidence on the safety of home infusion specifically, likely because home infusion is the cheapest alternative site of administration. Patients meeting exception criteria may receive their drugs at hospital outpatient departments, but they will be reassessed every six months to determine whether they can be safely transitioned to receive treatment at an alternative site.

A Magellan survey showed that by 2020 almost 70% of commercial plans had site-of-service programs, of which 34% were mandatory and 32% were voluntary.²⁴ That same survey found that across all site-of-service strategies, commercial payers had shifted 30% of members into home infusion, 19% to ambulatory infusion suites, and 14% to independent physician offices in 2019 (Figure 3).⁴⁰ Twelve of these commercial plans reported that site-of-service programs had saved them an average of 23% of the medical benefit drug spending.²⁴

Figure 3: Payers Report Shifting Member Site of Service to Home, Ambulatory Infusion, Provider Office, 2020⁴⁰



Payers often apply clinical criteria to their site of service requirements to limit the policies to certain populations or drugs. Many plans report that site of service policies typically begin after the first dose is administered to ensure that the patient can tolerate the medicine and has no adverse events or severe side effects. After the first dose, subsequent doses are expected to be lower risk and more easily shifted to other sites of service. For instance, CVS has a site of care policy that requires subsequent doses (after the first dose) of a clinician-administered drug to be provided at home unless the medical necessity criteria for an exception are met.⁴¹

Some payers also align patient cost sharing with efforts to shift utilization to lower-cost sites, though cost sharing varies widely by benefit design and policy. According to a 2016 Magellan Rx report, 24% of private payers reported having policies varying patient cost sharing by site of service, although we heard in payer interviews that many payers seek policies that keep cost sharing unchanged across different settings, with savings flowing to help keep premiums down rather than shared directly with patients.⁴²

Criticisms of White Bagging and Brown Bagging

Despite the potential for reducing costs without adversely affecting access, some observers express concerns about the impact of white bagging and brown bagging on patient safety, access, clinician burden, and drug waste. In the past several years, some states have passed legislation (VT, LA, MN, TN, AR) or introduced bills (KY, MO, AZ, IL, OH, CA, NY) to limit white bagging. As one pharmacy stakeholder group put it, “As white bagging increases and payers direct where medications come from, it reduces the opportunity for patients to have a say in where they get their medications.”¹² The status of state legislation is summarized in more detail in a dedicated section on page 23 of this paper.

Patient Safety and Access to Care. Brown bagging has raised significant safety concerns from provider groups. Because specialty pharmacies are less common than retail pharmacies, if patients are required to pick up their medication themselves, they may need to travel unreasonably long distances, increasing the risk that patients will abandon their prescriptions. Brown bagging policies can pose a particular burden for vulnerable patients who face transportation challenges, difficulty getting time off from work, or have low health literacy. Even when brown bagging is done by shipping drugs directly to patients’ home, which is often an option offered by specialty pharmacies, not all individuals live in a setting where they can receive private mail deliveries or have someone responsible receive drug deliveries and store them appropriately. Providers worry that packages containing temperature-sensitive drugs could be left outside in the heat or unpacked and left at room temperature.

Even if drugs are received and initially stored properly, concerns are raised about whether patients can handle drugs appropriately on the way from home to their clinicians’ offices. Nearly all stakeholders agree that not all patients can be expected to transport drugs safely. But some payers feel the degree of risk posed by brown bagging is overstated, noting that providers frequently rely on the same specialty pharmacy for drug delivery that payers use.

White bagging is generally viewed as a safer practice than brown bagging because drugs are delivered by a specialty pharmacy to clinicians. Still, clinicians point to challenges when a change in a patient’s condition noted at the office visit means that the patient needs a different dose or an entirely different medication than the one previously delivered. According to a Vizient member survey of US health systems and hospitals, 66% of respondents said that they had received a product via white bagging that was no longer correct due to updated patient treatment course or dose being changed.⁴³ Under buy-and-bill, clinicians have a stock of medications that provide more flexibility when changes in treatment are needed, a not uncommon occurrence for oncology patients.⁴⁴ But with white bagging, clinicians can feel like their hands are tied, and that patients can suffer unnecessary and potentially dangerous delays before a new dose/medication can be approved and delivered.

Patient Out-of-Pocket Costs. While payers often reduce markup costs by implementing white bagging and brown bagging policies, critics contend they are not obligated to pass any of those savings through to patients in the form of lower out-of-pocket costs and premiums. In fact, because white bagging is often implemented with a corresponding shift of coverage from the medical benefit to the pharmacy benefit, some patients may experience higher out-of-pocket costs when payers save money through white bagging.⁴⁵ On the other hand, other patients may benefit from a shift over to the pharmacy benefit because they can take advantage of the patient support provided by specialty pharmacies, which often includes additional transparency about expected out-of-pocket costs, access to copay assistance or coupon cards, and payment plans. The ultimate impact on cost sharing and overall patient experience therefore varies widely across plan sponsor benefit designs, payers, and specific provider contracts.

Provider Revenue and Administrative Burden. Many providers, especially those eligible for 340B discounts, experience a loss of revenue shifting from buy-and-bill to contracted specialty pharmacy rates under brown bagging or white bagging policies. In particular, by losing revenue from spread pricing under buy-and-bill, providers assert that they often do not retain adequate compensation for the costs and administrative burden associated with receiving and storing drugs delivered through white bagging. As white bagging has become more common, providers suggest there is additional burden for their staff to manage a separate inventory of white-bagged drugs. Hospitals also complain that they receive limited notice when a drug is added to the white bagging list, creating an administrative rush to come into compliance (e.g., maintain separate inventory, workflow) within a short time window (30-60 days). As a result, providers maintain that white bagging adds multiple new resource-intensive requirements to their processes and disrupts safety mechanisms already in place for their current care flow.⁴³

Finally, providers express concerns that white bagging disrupts care enough to affect their patient satisfaction quality scores, such as those compiled through Consumer Assessment of Health Providers and Systems (CAHPS) surveys. For instance, if a patient needs to change their medication or dose on the day of administration, white bagging policies could force a delay in care, but physicians may be left to explain the payer's decision. Patients may not understand that a payer policy caused the delay and would be more likely to blame providers for the inconvenience or disruption in care. In turn, these patients may report low satisfaction with provider visits.

Drug Wastage. Provider advocates suggest white and brown bagging policies may also increase drug wastage for high-priced products. Because drugs obtained via white or brown bagging are specific to an individual, as opposed to the buy-and-bill process whereby physicians purchase drugs to have in-stock, any excess drug in the white or brown bagged vial must be discarded and cannot be used for another patient, leaving the payer and patient responsible for the entire vial and associated cost-share. If the drug had been purchased via buy-and-bill, physicians would have only charged for the amount of drug used. Conversely, this is a reason some small providers support

white bagging, because it limits their own drug wastage by allowing them to avoid stocking drugs, and paying for full vials, that they are not likely to use up entirely.²⁶

Health plans counter this concern by noting that plans and enrollees are not “billed by the milliliter”, as some critics suggest. They also note that most white bagged medications requiring compounding at the site of care (to adjust for patient presentation) are shipped as separate components for use by the provider to combine as needed. Plans suggest that providers are then free to use any non-compounded amounts remaining in a vial to supplement their own stocks if clinically appropriate. Even if the remaining amounts of product are discarded, plans suggest that the cost to the plan enrollee and sponsor remains significantly lower than what would be paid under a buy and bill arrangement with high markup.

Criticisms of Site of Service Policies

Patient Safety and Burden. The most significant concern regarding site of service policies voiced by providers is that these policies can create a disconnect between the treating clinician and the patient, potentially resulting in substantial logistical burdens for patients and increasing the risk that their treatment will be incorrectly dosed or delivered.

Site of service policies may require patients to travel a long distance to receive an IV drug at a specialized facility connected to the payer's specialty pharmacy. Just the hassle of sorting out additional time and transportation can lead to missing or delaying of treatment. Interviewed providers suggest that patients with lower financial and social resources are at higher risk for this negative outcome, adding to the disparities of care experienced by many patients from communities of color. Conversely, home infusion may reduce the burden on patients, but not all patients live in settings conducive to home infusion, with the same patients with lower financial and social resources being less likely to be able to benefit.

We are unaware of peer-reviewed data comparing the clinical outcomes of patients receiving treatment in different sites of care, but some providers have anecdotes of patients who had to leave their office to receive a treatment at another site, only to arrive there and find that their treatment was not ready, or that the dosage was incorrect, requiring a delay to set up another appointment for a future date. Any delay increases the risk of treatment abandonment, and for patients with serious conditions any delay may increase their risk of adverse outcomes.

Providers note that many therapies are initiated in the hospital or infusion center setting because of the potential for an adverse reaction or immunological toxicity, particularly with oncology drugs. If an initial treatment goes without complication, patients may become ideal candidates for outpatient or at-home care. However, providers also maintain that addressing adverse reactions to medications while at home can be difficult, raising some concern that patients could suffer an adverse outcome that would have been easily managed if they had received treatment in a clinician's office.

In addition to the proximity to emergency services being limited when care is provided at home, providers also raise concerns about the psychological challenges associated with patients receiving chemotherapy at home, alone and isolated, away from their regular medical team. The importance of social and emotional support during cancer treatment is well documented.^{46,47} There have been evaluations of online social communities that have shown modest success in improving patient experience that can be utilized to address some of the provider concerns about the quality of patient experience with home infusion.^{48,49} Interestingly, one payer suggested patient experience for those receiving infusions at home throughout the COVID-19 pandemic tended to be better than those who received care in an infusion center. While payers suggest that some patients prefer the

convenience of care at home, with the ability to avoid transportation or other challenges, there has been low uptake of home infusion when site of service shifts are voluntary.

Patient Out-of-Pocket Costs. The extent to which payers are sharing savings with patients who receive drugs in lower cost settings of care is not clear. A recent study found that while large savings accrue to commercial payers who shift care from HOPDs to non-hospital settings, the financial burden on some patients could increase, sometimes significantly, depending on consumer cost-sharing strategies imposed by payers.⁴⁵ However, more commonly, plans implement site of service policies with a linked benefit design that reduces cost-sharing for patients when they receive care at lower-cost sites.⁴⁵

Provider Impact. Site of service policies negatively affect many large providers' revenue by reducing the total volume of drugs they administer—moving from HOPD to physician office or physician office to home. Providers also suggest that site of service policies result in considerable unpaid administrative burden for individual physician offices, since patients often call their clinicians to ask questions about medication administration. Patients may also call clinicians' offices to ask questions about the scheduling of home infusions. While most payers have case managers to assist with logistical issues, there have been reports from providers that monitoring patient treatment at home can be difficult. One provider stakeholder reported challenges associated with nurses tracking drug shipments and deliveries. Even though the home infusion provider is responsible for drug delivery, patients often turn to providers for this information. This means that patient experience with home care could affect how patients rate their prescribing clinician on their overall care experience or quality, with downstream implications for providers who have compensation tied to those ratings.

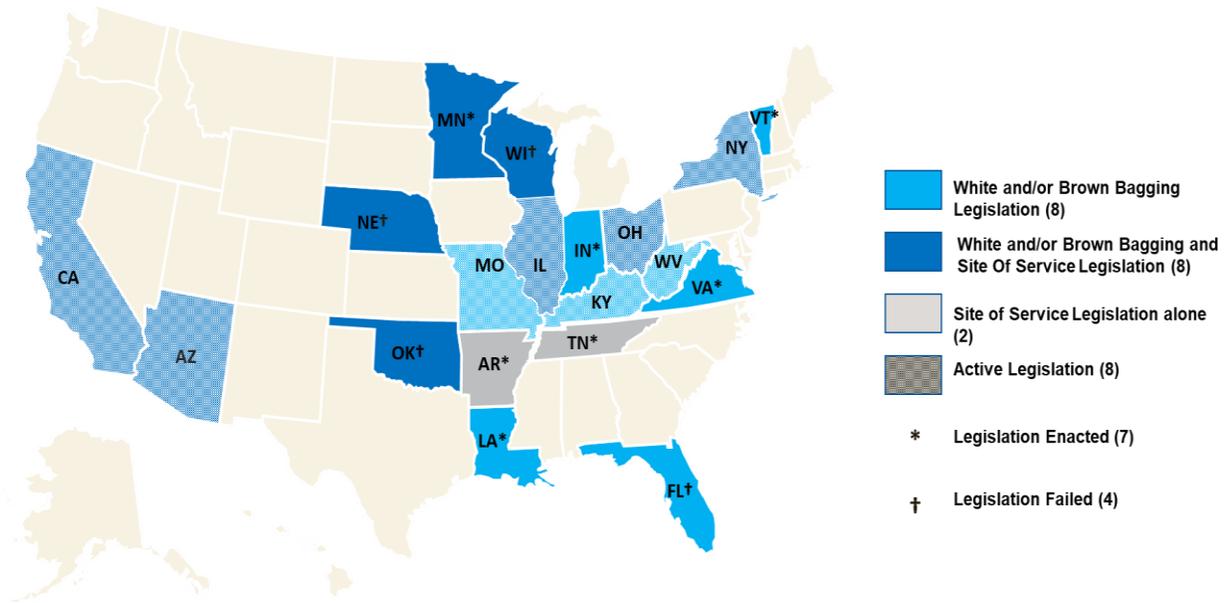
Recent Legislation

Organized opposition to white bagging, brown bagging, and site of service policies has grown in recent years. As shown in the Figure on the following page, as of November 2022, 15 states have introduced legislation to date to restrict and/or prohibit the use of white/brown bagging practices or policies affecting site of care.

- **White bagging:** Three states (LA, MN, VT) have passed legislation restricting white bagging and nine states (AZ, CA, IL, KY, MO, NY, OH, WV) have proposed legislation that would restrict payer-mandated white bagging by stipulating that a clinician be reimbursed at the contracted amount for a clinician-administered drug obtained from a pharmacy other than the one affiliated with the payer. Legislation in five of these states would explicitly prohibit additional patient cost sharing when the physician obtains the drug from a non-payer affiliated pharmacy. Additionally, Indiana has passed legislation addressing patient safety challenges associated with white bagging without using the precise term.
- **Brown bagging:** Two states (VA and VT) have implemented policies to prohibit brown bagging. Proposed legislation in three states (CA, IL, NY) would prohibit brown bagging in addition to white bagging. In its proposed legislation, California would require payers to provide a 45-day notice to clinicians and facilities before requiring an infused or injected drug be delivered through a specified pharmacy.
- **Site of Service:** Three states (AR, MN, TN) have passed legislation prohibiting payers from requiring a clinician-administered drug to be infused at home. The Tennessee legislation also prohibits varying patient cost sharing by site of service. The Arkansas legislation only applies to hematology and oncology patients. Bills put forward in California and Vermont are focused on maximizing clinician autonomy in care decision making for patients.

In addition to state legislation, providers and hospital associations are advocating for rulemaking changes through their state boards of pharmacy and nursing. In many states, these bills are being advanced by state hospital associations who stand to lose the most revenue from white or brown bagging and site of service policies.⁵⁰ These rule changes are commonly opposed by employer groups aiming to reduce health care premiums.

Figure 4. State policy efforts to restrict white and brown bagging and site of service. (See Appendix B for details)



Best Practices and Potential Policy Reforms

Specialty drugs are an essential component of treatment for many patients with serious health conditions. It is important that patients have broad access to these products in a setting and mode of delivery that is safe and convenient for them. At the same time, payers have an obligation to reduce unnecessary spending on markup for clinician-administered drugs, which adds financial strain on insurance premiums. In this section, we explore potential best practices among the different variants of these policies in the marketplace. We also analyze the potential advantages and disadvantages of broader policy options that could support the right balance between controlling unnecessary costs and maintaining adequate flexibility in coverage to ensure that patients and clinicians can make appropriate, patient-centered care decisions.

Table 3 on the following page is a high-level summary of the potential best practices and policy reforms that emerged from our research and analysis. In the sections that follow, we present the potential advantages and risks of each approach to guide future discussions and decisions.

Table 3. Summary of Best Practices and Broader Policy Options

White and Brown Bagging	
Promote patient-centered care and health equity	<ul style="list-style-type: none"> • Prohibit brown bagging outside of selected treatments suitable for home infusion • Establish criteria for clinical appropriateness • Facilitate rapid exceptions inclusive of clinical and social factors • Share cost savings with patients
Address same-day medication changes	<ul style="list-style-type: none"> • Devise emergency reimbursement mechanisms for same-day treatment changes
Increase specialty pharmacy oversight	<ul style="list-style-type: none"> • Increase transparency of the chain of custody for white-bagged drugs
Create balance with existing physician incentives under buy-and-bill	<ul style="list-style-type: none"> • Require payment parity between specialty pharmacy and buy-and-bill • Replace white bagging with a fee schedule, eliminating buy-and-bill incentives • Target white bagging to high-cost settings • Cap markup through legislation
Improve transparency for providers and patients	<ul style="list-style-type: none"> • Provide advance notice of new coverage policies
Site of Service Policies	
Promote patient-centered care and health equity	<ul style="list-style-type: none"> • Measure patient experience and clinical outcomes • Establish criteria for clinical appropriateness • Facilitate rapid exceptions inclusive of clinical and social factors • Measure rates of exceptions • Share cost savings with patients
Improve transparency for providers and patients	<ul style="list-style-type: none"> • Provide advance notice of new coverage policies • Communicate effectively with patients about site of service shifts

Best Practices and Policy Reforms Related to White Bagging and Brown Bagging

Promote patient-centered care and health equity

Prohibit brown bagging outside of selected treatments suitable for home infusion. As described above, some states have already passed legislation prohibiting insurers from requiring designated pharmacies to brown bag medications. Though many payers also report that they no longer use brown bagging practices in any region, the limited data that exists suggest that approximately 9% of patients receiving care in HOPDs are subject to brown bagging policies.³⁴ Given the complex requirements for safely storing drugs, many stakeholders suggest that brown bagging presents serious patient safety and quality assurance concerns.

The only negative consequence of eliminating brown bagging would be the loss of its potential to reduce markup costs, but it is unclear that brown bagging reduces costs more than a comparable white bagging policy. Therefore, actions by payers or legislators to eliminate existing brown bagging policies would be welcomed by patients and providers while being unlikely to jeopardize broader initiatives to reduce markup costs. It is important to note, however, that prohibitions on brown bagging should be designed to allow its use in appropriate home infusion situations, where brown bagging may be the most convenient and cost-effective approach to delivery of the medication.

Establish criteria for clinical appropriateness. As a potential best practice, payers could establish explicit and transparent clinical criteria by which to determine whether white bagging and/or brown bagging would be acceptable, allowing some patients to be exempt from either approach without having to go through an exceptions process. Payers interviewed suggested that most payers implement white bagging or brown bagging only after a first successful treatment is provided by the clinician, thereby avoiding the disruption that would follow on the need to reschedule patients for a separate appointment to receive their initial dose. This approach may already be nearly universal and should be considered a required feature of white bagging or brown bagging policies.

Currently, however, most payers specify white bagging requirements on a product-by-product basis without any additional qualifying clinical criteria through which the appropriateness of either approach could be determined for an individual patient. It is likely that clinical considerations guide which drugs are selected for white bagging or brown bagging, but these criteria are not transparent. For white bagging, there is one single clinical criterion that could be presented to clinicians for confirmation at the outset of treatment in order to determine whether white bagging would be appropriate:

- The treatment selection and dosing is not subject to same-day variation during the course of treatment.

For brown bagging, additional clinical criterion could be added to assure clinical appropriateness:

- The patient has adequate social supports to ensure safe receipt and timely transport of the treatment to the clinician’s office, and
- The patient has appropriate equipment at home to store the medication safely

The potential downside of establishing clinical criteria is that it may leave so much discretion in the hands of clinicians that the financial incentives embedded in buy-and-bill could lead them to exempt many patients from white bagging, undermining the goals of reducing markup. However, this risk should be balanced against the possible advantages of adding a more nuanced approach to patient selection that would reduce the burden of an exceptions process and enable care to be tailored more effectively for individual patient needs.

Policymakers seeking to improve the application of white bagging or brown bagging are more likely to consider a blunt approach of banning either approach for drugs used to treat specific conditions, such as oncology, where there may be a higher risk of treatment changes and adverse clinical outcomes should care be disrupted. The advantage of blanket prohibitions is that they are easier to implement in a consistent manner across payers, but a total prohibition eliminates the opportunities for restraining growth in health care insurance premiums that is ultimately in the best interests of patients as well as payers.

Facilitate rapid exceptions inclusive of clinical and social factors. While payers have existing channels for clinicians to seek an exemption to white bagging and brown bagging for individual patients, these procedures can be opaque and cumbersome to navigate. If payers do not create clinical criteria by which clinicians would confirm the appropriateness for each patient at the initiation of treatment, payers could improve the process on the back end by creating a real-time electronic portal to support an efficient exemptions process. Exemptions could be based on explicit criteria or could be left broadly to the clinician’s judgment that clinical or social factors (e.g., transportation challenges, housing instability, and or difficulty storing medications safely) make white bagging or brown bagging inappropriate.

A rapid exceptions process would improve clinician buy-in to white bagging and brown bagging policies and would reduce the risk that the burden of seeking exceptions would inhibit clinicians from taking the time and effort necessary to affirm the approach that would be in patients’ best interest. These benefits are likely to accrue particularly to patients with lower financial and social resources, thereby improving health equity and perhaps reducing disparities in outcomes across diverse communities. However, as with upfront clinical appropriateness criteria, there is some risk that the most efficient exceptions process would make it “too easy” for clinicians to blunt the cost-saving potential of white bagging and brown bagging. There is also risk that the exceptions process

is not as rapid or efficient in practice, resulting in what could seem like another round of prior authorization.

Share cost savings with patients. Payers have seen savings as a result of white bagging and brown bagging policies. A potential best practice would be for payers to structure benefit designs so that the cost savings associated with white bagging or brown bagging are shared in a meaningful way with patients, or that, at the very least, these approaches do not lead to increased out-of-pocket requirements for patients. Aligning the cost-sharing of patients with the savings from white bagging and brown bagging can be done independently by payers or could be mandated by policymakers.

The key reason to consider this reform is that patients can end up paying more out of pocket when their treatment is subject to white bagging or brown bagging due to the shift in coverage from the medical benefit to the pharmacy benefit. Patient cost-sharing within their pharmacy benefit frequently exceeds that of services covered under the medical benefit. Some payers have moved to address this by structuring their benefit designs to ensure that patient cost-sharing is lower in the pharmacy benefit. However, such broad benefit design changes may create unintended consequences and may impair the cost-saving potential of white bagging and brown bagging policies. One way to link lower cost-sharing only to those drugs provided under white bagging or brown bagging is to place these drugs on the pharmacy benefit at the lowest tier in the formulary, a tier that frequently requires relatively small cost-sharing.

Given that white bagging and brown bagging harbor the risk of at least some inconvenience for patients, it would be ideal if payers can adjust their benefits so that patients spend even less out of pocket for drugs under these policies than they would otherwise under buy-and-bill in the medical benefit. But at the very least payers would seem accountable for ensuring that patients do not spend more and benefit indirectly by the impact of overall cost savings on moderating their insurance premiums.

Address same-day medication changes

Devise emergency reimbursement mechanisms for same-day treatment changes. Physicians who obtain medication via brown or white bagging face challenges if the drug delivered for a patient is not correct or no longer the appropriate treatment or the right dose based on changes in the patient's condition. Such scenarios are particularly common for seriously ill patients with cancer, who may have disease progression or side effects at any time that necessitate an immediate, even same-day shift in treatment.

When this occurs in the setting of white bagging or brown bagging, clinicians' hands may be tied, requiring the patient to return for another visit to receive the newly updated drug or dosage. However, in some instances, the needed drug or dosage may be in stock within the clinician's office. To reduce the risk of imposing a disruption in care, payers could adopt as a best practice an emergency buy-and-bill reimbursement mechanism for such situations. Providing this option would be favored by providers not only because it reduces patient burden, but because disruptions in patient care can negatively influence patient satisfaction and provider quality metrics.

A primary challenge in implementing such a policy would lie in determining the appropriate reimbursement rate for these emergency fills. If the payer uses widespread white bagging or brown bagging policies in their commercial business, they may not have a negotiated buy-and-bill rate with the provider. In this instance, providers would likely default to billing the payer based on their chargemaster (assuming the payer and provider are not contracted), which is typically much higher than the negotiated rate for payers. Such a scenario could result in surprise bills to patients if providers balance bill them for the difference between the chargemaster and the paid amount. Recent federal policies prohibiting surprise billing to patients have revealed the complexity of finding an appropriate reimbursement rate for non-contracted services, but these policies may also provide a roadmap for how the amount of such an emergency payment could be established. Alternatively, the policy could stipulate that commercial payer payments for an emergency buy-and-bill drug would be set at the Medicare reimbursement rate of ASP+6%.

The major potential pitfall of creating this payment mechanism would be that it creates a backdoor through which clinicians could face financial incentives to find minor dosing changes or other reasons to shift from the dosage sent via white bagging or brown bagging over to their buy-and-bill stock. This risk could be minimized by devising a specific contracted rate for drugs within an emergency reimbursement system that does not pay clinicians a much higher amount than they receive under their normal negotiated rate for drugs delivered through white bagging or brown bagging.

Increase specialty pharmacy oversight

Increase transparency of the chain of custody for white bagged drugs. With little insight into how drugs are handled and stored, clinicians harbor important concerns about the safety of the drugs delivered for their use via outside specialty pharmacies. One way to address this concern would be to require specialty pharmacies to include scannable barcodes on white bagged products, as they do on drugs delivered to hospital pharmacies.⁵¹ Such bar codes enable clinicians to better track the chain of custody for a given product.

While such a change would be relatively easy to implement when shipping to hospital outpatient departments, individual physician offices and infusion centers may not have the technology and interoperable systems required to access the information. And, although addressing the concerns of clinicians and improving their acceptance of white bagging and brown bagging is an important goal, payers believe that requiring measures to augment specialty pharmacy oversight would add significant administrative burden and costs with limited tangible benefits to patient safety.

Create balance with existing physician incentives under buy-and-bill

Require payment parity between specialty pharmacy and buy-and-bill. Under this approach, for drugs that would otherwise be subject to mandatory white bagging, payers would be required to offer payment parity for products paid through buy-and-bill or filled by an in-house specialty pharmacy (i.e., clear bagging). Such a payment policy would allow clinicians to continue using the buy-and-bill purchasing and administration channels while requiring payers to reimburse providers at levels set at the specialty pharmacy rate (and only for drugs that the payer specifically subjects to white bagging policies).

Payment parity would address the concerns held by clinicians about revenue loss that results from shifting payment from buy-and-bill practices to specialty pharmacies. An example of a payer that has implemented this policy is Blue Cross and Blue Shield of Massachusetts (BCBSMA). This health plan allows any specialty pharmacy that meets its qualifications (e.g., a hospital's specialty pharmacy) to join its specialty pharmacy network for any drugs subject to white bagging. If a clinician does not have access to a pharmacy that meets those qualifications, they are eligible for an exception that allows them to buy-and-bill for the drugs that require white-bagging while being reimbursed at the third-party specialty pharmacy rate.

Such a payment policy would help mitigate safety and access concerns for patients, as many of those concerns stem from the practice of using a third-party specialty pharmacy that is not overseen by the prescribing provider. Payers would also benefit from having lower costs compared to traditional buy-and-bill reimbursement. Payers that own specialty pharmacies or other specialty pharmacies may have their own concerns that this approach diminishes their involvement in the supply chain, thus reducing their revenue. This policy could also pose challenges for contract

arrangements in place between specialty pharmacies and payers, particularly if exclusivity is a required element of the contract.²⁶

Payment parity would dramatically reduce hospital revenue by eliminating drug markups. However, relative to mandatory white bagging, this policy would effectively require payers to let hospitals clear bag and fulfill drugs through their own specialty pharmacies. This would enable 340B covered entities to maintain access to 340B discounts. Independent physicians and non-340B providers would be hurt most by this policy. Those providers may not be able to acquire clinician-administered drugs for less than the site-neutral payment, so they would likely be willing to accept white bagging arrangements rather than take a loss on buy-and-bill.

Another approach entirely could be to develop broad value-based payment approaches for specialty drugs, which could be framed to eliminate a separate mark up charge while addressing concerns about provider revenue loss and mitigating safety concerns. Experience with this approach is currently quite limited, but as the costs of specialty drugs continue to increase, more payers and providers may find innovative approaches to reimbursement may offer advantages over trying to adapt buy and bill or white bagging arrangements.

Replace white bagging with a fee schedule, eliminating buy-and-bill incentives. Rather than paying negotiated rates for clinician-administered drugs, payers could establish a fee schedule for some or all of these products. The fee schedule would specify provider reimbursement rates on a per product basis to reduce or eliminate markup. Providers who want to buy-and-bill a product would need to accept the fee schedule reimbursement rate. The fee schedule could set payment rates at any level, meaning reimbursement could remain higher than it would be through specialty pharmacy but lower than the markup charged by the highest-paid providers.

Such a policy could be challenging for payers to implement in markets with high levels of provider consolidation and negotiating strength. Any attempt to reduce reimbursement for specialty drugs through a fee schedule could be countered with outright refusal to participate in the network or demands for compensatory higher payment rates for other services.

Cap markup through legislation. Another option would be for state or federal policymakers to cap maximum provider markup at a certain percentage and/or absolute dollar amount (e.g., 200% markup or not more than \$10,000). While this would limit markup by providers, it also risks setting a new psychological ceiling for payer-provider negotiations that could result in higher markup for some drugs than would be negotiated otherwise.

Target white bagging to the highest-cost settings. In many cases, payer white bagging policies are set by product and do not vary by setting, meaning that they apply equally to products whether they are administered in more expensive HOPD settings or in independent physician offices. White bagging policies could be designed to target only the highest-cost settings while allowing physician

offices to continue to buy-and-bill. This more nuanced approach could mitigate some of the physician concerns about the impact of white bagging policies on smaller physician offices, which generally are more reliant on the revenue from drug markups and are most challenged by the operational burden associated with white bagging.

Improve transparency for providers and patients

Provide advance notice of new coverage policies. White bagging and brown bagging create administrative burdens on providers, consuming staff resources and increasing administrative expenses. Payers are able to change the required administration channel of a drug at any time, even in the middle of a course of treatment, which can create confusion for providers (and patients) and requires provider staff to change processes and come quickly into compliance with payer policies. A potential best practice would be for payers to provide notification of any coverage policy changes that impose white bagging or brown bagging to providers and patients at least 60 days in advance of any changes being implemented.

Payers already do provide notice to payers and patients, but this timeframe would ensure that clinicians and their staff have sufficient time to come into compliance with the policy without significant administrative burden or impact to patients. Clinicians also may need this much time to develop new processes, ensure proper storage capabilities (as they are often stored separated from buy-and-bill drugs), and develop proper communication practices for patients in order to ensure patient education.

Best Practices and Policy Reforms Related to Site of Service Policies

Promote patient-centered care and health equity

Measure Patient Experience and Clinical Outcomes. To ensure that patients are not negatively affected by site of service policies, payers should capture data measuring the patient experience and clinical outcomes of patients who had their site of care shifted. Capturing information such as the number of skipped doses, time between treatments, and clinical outcomes would provide data that payers could use in determining future site of care policies.

In assessing patient experience with site of service policies, both payers and providers should examine CAHPS scores.⁵² Patients may not understand that it is the payer's policy, not the provider, that is responsible for a change in care setting. As such, providers are concerned that patients will report low satisfaction with the care from the provider.

Establish criteria for clinical appropriateness. As suggested for white bagging and brown bagging policies, payers could consider as a best practice the establishment of explicit and transparent

clinical criteria by which patients would be assessed by the clinician prior to implementing a site of service requirement.

Most payers specify site of service requirements on a product-by-product basis without any additional qualifying clinical criteria through which the appropriateness is determined for an individual patient. It is likely that clinical considerations guide which drugs are selected for site of service restrictions, but these criteria are not transparent.

Payers could consider establishing specific criteria regarding the maximum distance or time of travel for a patient to be considered eligible for a site of service policy. In addition, payers could consider adding criteria that must receive clinician attestation before implementing a site of service policy, such as:

- The patient's clinical condition is sufficiently stable to allow a change in site of service for this treatment without undue risk
- The patient has had no immediate side effects from this treatment that necessitate close monitoring by the current treating clinician and staff
- The patient has adequate social supports to ensure safe travel to the intended new site of service

Any set of appropriateness criteria might have the potential of adding administrative burden without there being any true benefit for patients or clinicians. In addition, opt-in clinical criteria might lead clinicians to block site of service policies more than necessary, undermining the goal of reducing costs. The potential benefit, however, would be a reduction in the risk that individual patients would face unusual risks or burdens in a shift in the site of care, while it could also lead to enhanced clinician (and patient) trust.

Policymakers seeking to address the concerns raised about site of service policies are more likely to consider a blunt approach of banning them entirely. The advantage of a total ban is that it establishes an instant safeguard across all payers, but doing so eliminates the benefit of the significant cost reductions made possible by shifts in the site of care that may present only a minimal burden for patients.

Facilitate rapid exceptions inclusive of clinical and social factors. Providers contend that existing procedures to seeking exceptions to site of service shifts are insufficient. Many policies allow the first dose of the drug to be delivered in any location, after which the site must change. But providers suggest that patients may still experience adverse events on subsequent administrations and should be able to revert to their preferred site of service in these instances. Providers also advocate for exceptions that can be requested during the course of treatment if patients report that they are struggling with site of service policies, such as home infusion, and feel they need to return to a physician’s office, infusion center, or HOPD.

If a list of clinical and social factors is not introduced as opt-in criteria for site of service policies, a robust exceptions process could also address concerns regarding the impact of these policies on health equity and timeliness of care. Payers should consider as a best practice the delineation of specific exceptions related to housing, health literacy, and availability/access to a caregiver. Patients with lower income or those with low health literacy may have difficulty accessing alternative sites of service. For example, if home infusion is required, some patients may not have a safe and comfortable location at home to receive treatment.

Measuring Rates of Exceptions. No matter how good the intentions are behind a site of service policy, it may result in high rates of exceptions that call into question whether the policy is clinically appropriate. Measuring rates – and reasons – for exceptions would therefore provide payers and other stakeholders critical insight about where policies may not be working as intended, and may help drive change in the content or application of policies so that they are a better fit for different clinical or practice situations. Suggested data for plans to capture includes:

- Total number of site of service exceptions requested for each drug, and number granted
 - What are the most common reasons for exceptions requested?
 - What are the characteristics of patients and providers seeking exceptions and of those for whom exceptions are granted?

Share cost savings with patients. Patients should benefit from their successful participation in shifting the site of care to a lower-cost setting. One approach would be to design their cost sharing so that it is lower in the site of care required by their insurance policy than it would have been otherwise. This may be difficult to administer for practical reasons, however, and so it may be reasonable only to ensure that patients do not have to pay more out of pocket than previously. Patients “held harmless” in this way still benefit indirectly through reduced cost pressures on their overall health care premiums, but patients whose site of care is being switched and may face new logistical or other burdens should be considered for lower cost sharing if possible. As with white bagging and brown bagging, one potential approach to accomplish this goal is to place a drug on the lowest relevant tier of the pharmacy benefit so that patients pay less than they would under the medical benefit.

Interestingly, several of the bills introduced at the state level to address site of service policies aim to prohibit plans from reducing patient cost-sharing when they receive care at a lower site of service. The rationale for banning lower patient cost-sharing is that this might coerce patients, particularly patients with fewer financial resources, into accepting (or even seeking) lower-cost sites of service when their clinicians believe it is better for them to receive care in a higher-cost site. It is our view that reasonable sharing of the savings of site of service policies would not be coercive and that health equity would be better served by helping reduce the out of pocket requirements for all patients.

Improve transparency for providers and patients

Provide advance notice of new coverage policies. As with white bagging and brown bagging, implementing a new site of service policy creates administrative burdens on providers, consuming staff resources and increasing administrative expenses. Payers can change the site of service requirements for a drug at any time, even in the middle of a course of treatment, which can create confusion for providers (and patients). A potential best practice would be for payers to provide notification of any coverage policy changes that impose a site of service requirement to providers and patients at least 60 days in advance of any changes being implemented.

Communicate effectively with patients about site of service shifts. While payers do provide a notice of policy change to providers and patients, a best practice would be to develop a standardized form explaining to patients why the change is occurring. Providing this information to patients may reduce patient hesitation to receiving care at a different location as well as allow them to understand who is making the decision. The form should communicate any impact on accessing providers, any change in costs, and the rationale for the policy. However, there are administrative challenges to this approach. It may be time intensive for payers to develop a standard form and then distribute unique notices to every patient each time they trigger a site of service policy. The forms themselves would be difficult to develop in a way easily understandable to all patients given that in addition to ensuring accurate patient information on each letter, forms would need to distill complex policy decisions into a clear and easy to understand reading level. Rather than each payer developing its own standardized form, one option is for an industry or stakeholder organization (e.g., AHIP, PCMA, or National Patient Council) to take the lead in this effort.

Conclusion

The high cost of specialty pharmaceuticals can now be seen driving change across the health care system, including consequences for life science research and development investments, employer benefit designs, payer approaches to prior authorization and step therapy, and provider priorities for consolidation and expansion. Provider markup is just one link in the complex chain of drug delivery and payment. But payers have both a business interest and a stewardship responsibility to try to wring out unnecessary costs in the health care system, and it is therefore no surprise that they have been increasing their efforts to reduce provider markup embedded in the “buy-and-bill” system that has been the bedrock of reimbursement for many specialty drugs.

White bagging and brown bagging policies, along with site of service policies, are neither inherently good or bad. This paper has explored the complicated reasons that have given rise to these policies and has presented what little data exist regarding their impact. The contrasting views of different stakeholders have also been discussed. One theme that has emerged is how different the application of these policies is across different markets, where the relative power of payers and providers determines who “wins” a battle over markup. Another theme is how little data actually exist by which to judge the impact of these policies on patient experience and outcomes, on overall health care costs, and on provider administrative and financial challenges.

But perhaps the dominant theme is that there are approaches to the design and implementation of these policies that are more likely to reduce markup by addressing the distortions that have grown out of the buy-and-bill model while being mindful of the risk for patient harm. Among these potential best practices are elimination of brown bagging except for select home infusion situations; more precise targeting of white bagging and site-of-service policies, with more robust clinical appropriateness criteria and more expeditious exceptions policies upfront; new ways to blend payment models for white bagging and buy-and-bill; cost sharing provisions that hold patients harmless or allow them to share in cost savings; and new efforts to measure impact and adapt accordingly. All these are steps that payers and providers could take now to create a better paradigm for reducing markup through white bagging, brown bagging, and site of service policies.

Drawing from these ideas, sound business practice and policymaking should aim to balance possible savings from reducing markup while implementing thoughtful consumer protections and transparency that recognize the challenges that these policies create for seriously ill patients. Policies must also be structured to promote health equity by keeping front and center the risks to patients with less income and social support who may have the greatest challenges navigating these policies. We hope that the information and perspectives in this paper will help all stakeholders reach this important common goal.

Appendix A: 2022 ICER Policy Summit Attendees

Representatives from the following companies and organizations attended ICER's 2022 Policy Summit, which was held from November 29, 2022 to December 1, 2022 in Phoenix, Arizona:

- Abbott
- AHIP
- Alnylam Pharmaceuticals
- American Hospital Association
- AstraZeneca
- Blue Shield of California
- Boehringer Ingelheim
- Centene Pharmacy Services
- City of Hope
- CVS Health
- Elevance Health
- EQRx
- Express Scripts
- Genentech
- GlaxoSmithKline
- Gunderson Health System
- Health Care Service Corporation (HCSC)
- Humana
- Kaiser Permanente
- Karuna Therapeutics
- LEO Pharma
- Mallinckrodt Pharmaceuticals
- Merck & Co.
- National Pharmaceutical Council (NPC)
- Novartis
- Otsuka Pharmaceutical
- Point32Health
- Premera Blue Cross
- Prime Therapeutics
- Regeneron Pharmaceuticals
- Sanofi
- Sun Life
- UnitedHealthcare

Appendix B: Legislation Tracking (As of November 2022)

State	Date Introduced	Legislation Status	White/Brown Bagging Provision	Site of Service Provision
Arkansas ⁵³	April 1, 2021	Passed	N/A	For hematology and oncology patients, a payer cannot require a member to self-administer a drug at home when it is determined by the provider that the drug should be administered by the provider. The payer also has to reimburse the provider for the cost of the drug and the administration.
Arizona ⁵⁴	January 13, 2022	Active	Prohibits PBM or payer from limiting or excluding coverage of a clinician-administered drug that is not dispensed by an affiliated pharmacy (white bagging).	Prohibits coverage of the drug under different benefit with additional cost sharing if the drug is administered at the prescriber's office, hospital outpatient infusion center, or any other outpatient clinical setting
California ⁵⁵	February 9, 2022	Active	Bans brown bagging and A payer cannot require or incentivize using a specified pharmacy to obtain infused or injected medication. Also requires the payer to give 45 day notice to the provider and facility before requiring that an injected or infused drug be provided via a specified pharmacy.	A health plan cannot refuse coverage for an infused or injected medication administered by a participating provider based on the site of service whether the site is a physician's office, infusion center or hospital outpatient department. However, it also stipulates that a health plan can authorize an injectable to be administered at home if the provider and patient determine that it is in the patient's best interest.
Florida ⁵⁶	November 2, 2021	Failed	A payer cannot require the use of its chosen pharmacy to obtain clinician-administered drugs or reimburse the provider at a lower rate or charge additional cost sharing from the enrollee, if the provider obtains the clinician-administered drug from a pharmacy not chosen by the insurer.	N/A
Illinois ⁵⁷	January 21, 2022	Active	Requires that a clinician-administered drug supplied from a pharmacy meet the supply chain security controls. The health plan cannot require a patient to obtain a drug from the pharmacy to transport it to the site of administration- brown bagging. Health plan cannot limit benefits or coverage if a patient receives a clinician-administered drug that is not from an affiliated or chosen pharmacy.	A health plan or PBM cannot require an enrollee to use a home infusion pharmacy to receive drugs in their home or to specify the use a certain site of service or use site of service in prior approval or medical necessity criteria.
Indiana ⁵⁸	January 6, 2022	Active	The bill requires the Indiana Board of Pharmacy to write rules regarding the preparation, dispensing and administration of clinician-	N/A

			administered drugs as it relates to patient care and safety	
Kentucky ⁵⁹	February 7, 2022	Active	Payer cannot require the use of a mail-order pharmacy to furnish a provider with a clinician-administered drug. The payer cannot impose increased cost sharing on an enrollee for receiving a drug that was not obtained from such a mail-order pharmacy.	N/A
Louisiana ⁶⁰	April 12, 2021	Passed	A payer or a PBM cannot refuse or reduce reimbursement to a participating provider for obtaining clinician-administered drug from a pharmacy that is not in the payer's network. Also prohibits varying patient cost sharing when a drug is obtained by a participating physician.	N/A
Minnesota ⁶¹	March 3, 2022	Passed	A health plan or PBM cannot require that a clinician-administered drug or the administration of such a drug be covered under the pharmacy benefit. Health plan cannot require that a clinician-administered drug be obtained from a pharmacy of its choice	A health plan or PBM may offer but not require the use of home infusion pharmacy to dispense a clinician-administered drug or the use of an infusion site external to the enrollee's provider clinic or office.
Missouri ⁶²	January 6, 2022	Active	An insurer or PBM cannot deny or impose any penalty, higher coinsurance if a patient receives a clinician-administered drug that was not obtained from an in network pharmacy. The payer cannot refuse to reimburse the provider at the contracted amount regardless of where the provider obtains the drug from.	N/A
Nebraska ⁶³	January 10, 2022	Indefinitely postponed as of April 20, 2022	A payer cannot impose a higher cost sharing on a beneficiary or lower reimbursement for a provider if they choose to obtain a clinician-administered drug from a pharmacy not affiliated with the payer. A payer cannot require a specialty pharmacy to dispense a drug directly to the patient who then has to transport it to the site of administration.	The payer can also not require the use of a home infusion pharmacy or the use of a site external to the provider's clinic for the administration of such a drug.
New York ⁶⁴	June 10, 2021	Active	Prohibits insurers from requiring a designated pharmacy to brown bag medications to clinics; places requirements around white bagging; Establishes patient safety and quality assurance measures regarding the distribution of patient-specific	An insurer may provide coverage for but cannot require the use of an infusion site external to a patient's provider's office or clinic

			medication from an insurer-designated pharmacy.	
Ohio ⁶⁵	October 13, 2021	Active	Prohibits a health benefit plan from requiring that clinician-administered drugs be dispensed by a pharmacy or affiliated pharmacy, limiting coverage when such drugs are not dispensed by a pharmacy or affiliated pharmacy, or covering such drugs with higher cost-sharing if dispensed in a setting other than a pharmacy.	Prohibits the health plan from covering the drug at different benefits tier if the medication is administered at a physician's office, hospital outpatient infusion center or other outpatient clinical setting.
Oklahoma ⁶⁶	February 7, 2022	Failed	Health plans cannot refuse reimbursement of a provider for providing covered clinician-administered drugs to a beneficiary. The bill also protects providers and health care facility from being held liable to any harm done to a patient as a result of insurer required white bagging practices.	A plan cannot require a patient to self-administer a drug against the recommendation of the provider
Tennessee ⁶⁷	February 22, 2022	Passed	N/A	A PBM or payer cannot require additional cost sharing from an enrollee regardless of where the patient chooses to obtain their specialty drug- a provider's office or an infusion center.
Virginia ^{68§}	Finalized June 9, 2021	Passed	Prohibits pharmacies from delivering drugs to patients' residences- "brown bagging"	N/A
Vermont ⁶⁹	February 25, 2021	Passed	Insurer or PBM cannot require that a pharmacy dispense drug directly to the patient for it to be transported to the site of administration (brown bagging). Also prohibits requiring an affiliated pharmacy to directly dispense a drug to a health care setting for the provider to administer (white bagging). These provisions are not applicable to Medicaid. Also discusses 340B payment requirements.	N/A
Wisconsin ⁷⁰	November 17, 2021	Failed	Prohibits health plan and PBM from reducing payment to provider for obtaining the drug from a pharmacy not selected by the plan. Bans brown bagging- cannot require a pharmacy to dispense drug directly to patient for	Health plan cannot require that a clinician-administered drug be administered in the enrollee's home or any other site external to the provider's clinic or office.

[§] Virginia's brown bagging provision was promulgated by the state's Board of Pharmacy rather than being established through a legislation.

			them to transport it to the site of transportation.	
West Virginia ⁷¹	January 19, 2021	Active	Health plan cannot deny reimbursement if a physician obtains a clinician-administered drug from a pharmacy that is not in the insurer's network	N/A

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