Analyzing Policies Designed to Control Specialty Drug Costs

By Dean Celia

ICER's new white paper addresses white bagging, brown bagging, and site of service policies, and offers best practice recommendations. Our panel examines the issue and explains which suggestions are likely to work best.

The Institute for Clinical and Economic Review (ICER) recently published a white paper entitled, "White Bagging, Brown Bagging, and Site of Service Policies: Best Practices in Addressing Provider Markup in the Commercial Insurance Market."[1] In short, brown bagging requires a patient to fill a clinician administered drug through a specialty pharmacy, take possession of the drug, and bring it to the provider for administration. White bagging involves a specialty pharmacy shipping a medication directly to the provider for administration. Of note, site of service defines where the medication is administered.

These policies can produce heated debate among stakeholders who either endorse them or question their value. We asked our managed care experts to turn down the temperature, analyze the policies, and weigh in on ICER's best practice recommendations. Our panelists include:

- Larry Hsu, MD, medical director, Hawaii Medical Service Association, Honolulu
- Charles Karnack, PharmD, BCNSP, assistant professor of clinical pharmacy, Duquesne University, Pittsburgh
- David Marcus, managing director, National Railway Labor Conference, Washington, DC
- Gary Owens, MD, president of Gary Owens Associates, Ocean View, DE
- Norm Smith, principal payer market research consultant, Philadelphia
- Daniel Sontupe, associate partner and managing director, The Bloc Value Builders, New York
- F. Randy Vogenberg, PhD, RPh, principal, Institute for Integrated Healthcare, Greenville, SC

Certain stakeholders differ in their views of brown and white bagging. For example, the American Hospital Association believes such practices

bypass safety systems; lead to treatment delays; and are open to supply chain issues and error due to separate inventories, among other issues. Meanwhile, America's Health Insurance Plans maintains that these policies lead to lower costs when coupled with the negotiating power of pharmacy benefit managers (PBMs). Plus, specialty pharmacies must adhere to stringent safety requirements.

Who is right?

Dr Karnack: The major advantage is clearly cost savings for the payer, which is seldom passed onto patients. But the problem is more nuanced. In my experience with home infusion and specialty pharma, I was amazed at how many homes in this country do not have the necessary refrigeration for perishables. That is bad news for individuals taking certain medications, which become compromised when not stored properly.

It is a particular concern with certain oncology medications. Sunlight and humidity come into play, as does potential hazard when small children and pets are present.

Even many ambulatory centers lack enough refrigeration. For example, recall that some rural areas could not carry frozen COVID-19 vaccines because of inadequate freezer space.

Dr Hsu: Particularly with brown bagging, there are reasonable concerns about ensuring that the drug is delivered, received, and given to the right patient at the provider's office.

Mr Smith: White bagging benefits the health system, but patient safety should be paramount. However, the reality is that everyone is protecting their own financial turf.

Mr Marcus: The pros to brown and white bagging clearly favor the practice. Providers add cost to the overall system by marking up the price of drugs. Evidence that supports the negative patient safety effects of brown and white bagging is scant. If outcomes are the same, the lower cost treatment should be deployed.

Mr Sontupe: I think neither side is right and will not be until providers and health systems, as well as payers and PBMs, realize that the goal is determining affordable, best outcomes on these high-priced, specialty in-office administered products.

Of note, the physician or system should control administration and management. To ask the provider to manage the flow of the specialty pharmacy products is unfair and changes the dynamic.

Dr Vogenberg: Asking who is right might not be the best question. Each stakeholder thinks it is right for supposedly very good reasons. The problem is stakeholders are not aligned.

Each key stakeholder has a different perspective around brown- and white-bagging practices. Hospitals, physicians, third-party administrators, and pharmacies are all middlemen. They are not the ones who should benefit—the employer plan sponsor and the patient should.

Do you think that payers are overstating the benefits and providers overstating the potential harms?

Dr Vogenberg: Third-party payers mostly overstate the potential harms but also do not offer any solutions as it would harm their incomes. All the distribution battles over control of product need to consider optimal patient outcomes, which aligns with what employer plans and patients are seeking.

Mr Sontupe: There is no doubt that payers are overstating the benefits. Especially because we are talking only about the commercial side. Frankly, I am looking for the evidence, but I would venture a guess that Medicare is paying for a lot more of these specialty products than commercial. An aggressive push to white bagging is more an opportunity to shift cost, than it is to truly save costs. It also could lead to worsening outcomes, as the payer will have more control when some of the products are used.

Dr Hsu: Both sides are overstating to make their case. While there is potential for cost savings, but it has not been well documented. Likewise, there are no well-designed, published studies to show that brown- and white-bagging are harmful.

Dr Owens: Of course, both are overstating their case to make a point. Payers are required to be prudent purchasers of services including drugs for their members and have a duty to self-funded clients to manage cost, quality, and access. Providers need to maintain revenue and margins to stay in business. Drug margins are an important revenue stream to providers. There are several studies that help make the case for payers.

Research That Makes the Case for Payers

A few studies help make the case that there is a need to lower specialty medication costs, paving the way for brown and white bagging policies.

According to **IQVIA data presented at the National Association of Chain Drug Stores Regional Meeting** in Orlando earlier this year, specialty medication has grown to about 55% of net pharmacy spending, which is up by 28% since 2011. Specifically, drugs in the immunology and oncology classes have grown in spending nationally by $16.7 billion and $9.4 billion, respectively, from September 2021 to September 2022.

A **2021 study by the Employee Benefits Research Institute** noted that, "on average, plan payments to HOPDs were triple what plan payments were to [physician offices] for the same unit of medication. The median unit price differential was 98%." Researchers concluded that "employers could cut spending by $14.1 billion by shifting patients away from more costly HOPD settings or by negotiating site-neutral pricing for specialty medications."

A **2022 report from the Community Oncology Alliance** points out that "340B [disproportionate share hospitals] price drugs at a median of 4.9 times their 340B acquisition costs, and the price markup differs materially by drug." The report found that commercial insurers are charged, on average, 4.9 times the acquisition price of oncology drugs by top 340B hospitals, presenting the opportunity for major profits from outpatient drugs, even if commercial insurers are deeply discounting these outpatient charges by contract with the hospitals.

The white paper notes that success is usually dependent on who has the upper hand in a specific region: payers or providers and clinics. How does such unevenness impact the health system?

Dr Karnack: Unevenness becomes a factor with access. Brown bags sometimes cannot be delivered to a patient's home or are misplaced by the delivery service. White bags can also get misplaced in large hospital networks. Established providers and clinics or payers in a rural area often have a monopoly, with newer groups regarded as outsiders who do not have the community's best interests in mind. Adding brown and white bagging into the mix reinforces these suspicions.

Mr Marcus: It's all about leverage. If providers have the high ground, costs end up being higher for all.

According to the report, little data exists to show how patients are negatively impacted. How do you think covered members are affected?

Dr Karnack: Poor patient and institutional compliance is often difficult to measure. However, seeing patients not respond to therapy, according to data, suggests comorbidity and compliance issues. Variations in access, education, and diligence—especially at home—makes it difficult to isolate the exact cause. It is easy for payers and providers to blame the patient and not the process.

Mr Marcus: Patients likely experience an increased hassle factor. Hospital and clinics can pressure patients not to brown or white bag medications. And patients probably do not realize the time, not by who controls the cost and shipment of the product.

"Large national players probably have the resources to implement ICER's recommendations, but regional and local systems may not."
~Charles Karnack, PharmD, BCNSP

Mr Smith: Each market has its own idiosyncrasies. The idea of basing provider reimbursement on the list price of the drug seems dated. Averaging actual delivery costs of a specific drug in a market is more reasonable and realistic.

Dr Hsu: If providers in an area organize and uniformly do not accept brown and white bagging, then this route of accessing drug will not be implemented enough to see any noticeable cost savings. The best scenario would be for payers and providers to work together and come to some agreement on what is best for the patient.

Dr Owens: The side with the upper hand in negotiations usually has the power to dictate. This is another example of our fragmented system that produces inequalities at all levels.

Dr Vogenberg: It is an increasingly problematic issue in the total cost of care borne by the plan sponsor and patient. The drug manufacturers are becoming financial and political losers, too.

The middlemen benefit.

Mr Sontupe: Success should be measured in getting the right patient the right drug at the right financial impact that inefficient markup has on premiums.

Dr Hsu: Providers and payers should be asking patients if brown and white bagging is acceptable to them and what barriers they see when the practice is implemented.

Mr Smith: For most diseases and conditions treated with specialty drugs, motivating patient behavior with financial rewards is unlikely. They have much more serious, immediate concerns than sharing in any payment plans.

Mr Sontupe: I don't think brown and white bagging or buy-and-bill are less expensive for patients. Either way, the manufacturer will offer programs to help reduced the impact of commercial copays. Then the payer will end up using that against the patient as part of the accumulator type program. The best result is for the providers and caregivers to manage the process for the patient.

Dr Vogenberg: We do not know what about the process, if anything, is harming patients.

Dr Owens: There may be some positives for patients, such as lower out-of-pocket costs if the patients have coinsurances and the payer pays less for the drug. They may experience the convenience of using an infusion center or clinician's office instead of travelling to the hospital-based outpatient department (HOPD). Potential downsides include loss of flexibility if dosing changes are needed, waste if the patient is unable to receive the medication on time, and quick medication expiration dates.

ICER suggests best practices to use when implementing brown and white bagging. Which ones do you think would be most impactful?

Dr Owens: First, establish criteria for clinical appropriateness. If everyone knows the rules, then the expectations for how the patient gets the drug are set. Next, share cost savings with patients. Certainly, patients should benefit if money is saved.

Additionally, devise emergency reimbursement mechanisms for same-day treatment changes. There needs to be away to manage dosing adjustments and delays that do not create waste or additional problems for the patients. And finally, require payment parity between specialty pharmacy and buy-and-bill.

Paying everyone the same might fix the problem. However, that will require renegotiating many, if not most, hospital contracts. This will probably work only in areas where payers have leverage.

Dr Karnack: I agree that cost savings should be shared with patients. Establishing criteria could be helpful but is cumbersome. There may end up being too many exceptions as high-tech drugs proliferate. Same day treatment changes can be difficult to track depending on the hospital information system processes and changes. Reimbursement sometimes gets so far in arrears that the tracking mechanism becomes too labor intensive to be worth the effort. The patient ends up losing. Increasing transparency is a noble endeavor, but it, too, can be cumbersome. So are efforts to achieve price parity and set fee schedules through legislation.

Large national players probably have the resources to implement ICER's recommendations, but regional and local systems may not.

Mr Marcus: I generally favor solutions that are implemented within provider reimbursement systems. By doing so, both payers and patients benefit financially. Payers benefit from lower reimbursement rates and patients benefit because cost sharing is based on lower allowances. This is not to say that safe, patient-centered care and health

equity are to be ignored—such issues should be carefully considered.

Dr Hsu: Requiring payment parity between specialty pharmacy and buy-and-bill, and replacing white bagging with a fee schedule are both worth pursuing. This would remove the potential incentive to buy-and-bill expensive agents. Resulting cost savings would be passed on in the form of lower premiums.

Mr Sontupe: ICER's recommendations put physicians in control, and process becomes patient-centric, which is the way it works under buy-and-bill. Missed appointments and other challenges are not nearly as damaging. Patient needs can be addressed at the time of the appointment. Oversight is not necessary for chain of custody, because buy-and-bill physicians manage their inventory and the process very closely.

The risk of losing a dose is extremely cost prohibitive so they are very smart about how they carry, inventory, and access medications.

ICER also suggested best practices related to site of service policies. Which of these do you think would be most impactful?

Dr Owens: First, measure patient experience and clinical outcomes. This will help determine the best path forward. Currently, both sides are entrenched in their position and have potentially skewed data to support their respective positions. Perhaps ICER could do these studies in an unbiased manner. Next, establish criteria for clinical appropriateness. Furthermore, share cost savings with patients, and finally, communicate effectively with patients about site of service shifts. Patients must know the rules and why those rules benefit them.

Dr Hsu: I agree that measuring patient experience and clinical outcomes is critical. This will promote increased use of site of services that have the best patient experience and result.

Mr Marcus: Site of service policies are most impactful when implemented in reimbursement systems—to neutralize the differences between hospital and nonhospital providers—and with plan design—creating clear incentives for members to select nonhospital providers. Health plans and employer sponsors and members both pay less for the same treatment. Policies certainly need to be sensitive to patient-centered care and health equity.

Dr Vogenberg: The difficulty is the ability to operationalize the policy. It is difficult to implement at scale. Many of the suggestions have been discussed for years. Until we have an improved, standardized, and scalable information infrastructure, the recommendations remain impractical.

Mr Sontupe: Here's the reality, 340B systems earn extra revenue, simply to offset other risk. Additionally, payers are consistently pushing cost risk down to the system but want to overly manage the few areas where they may be making a profit. It feels like a double standard.

The site of service should be determined from a patient-centric perspective. Some patients are treated at Centers of Excellence and must travel hundreds of miles. So, a local infusion center at an HOPD is very relevant for them. Other patients are lucky enough to have a provider nearby and are treated by that provider, so in-office administration makes sense.

The Bottom Line

We all should be incentivized to drive quality adjusted life years. ■

A Pharmacist's Primer and Perspective on Brown and White Bagging Policies

By Catherine Cooke, PharmD

Large deviations from expected charges for specialty medications have spurred payer interest in policies to lower outlying costs from buy-and-bill practices. Proposed changes may include where the drug is purchased (eg, wholesaler, specialty pharmacy) and by whom (provider, specialty pharmacy) and where the drug is delivered (eg, patient, health care provider).

These policies are met with differing reactions from different stakeholder types. Proponents share information that these changes can work effectively without patient harm. Opponents note additional administrative burden, a need to ensure proper storage and handling, and decreased flexibility to adjust medication doses. Brown bagging adds additional burden to patients and another step in the process.

While there are anticipated concerns with white bagging, brown bagging, and site of administration policies, the extent of these concerns, and evidence to mitigate them are lacking. But most notably missing from these policy discussions are the patient, caregiver, and family perspectives, and even more so, the voices of our most vulnerable patients. Engaging these individuals in discussions is needed. Also, ensuring diverse representation to address social, racial/ethnic, and other considerations that affect care outcomes should help us better understand how to reform policy and implement safeguards.

The bottom line for me:

- I am not supportive of brown bagging because of patient burden and adding another step. There are also challenges with patients storing and handling the medications and lack of flexibility for clinicians to adjust doses
- Economic arguments are focused on only one aspect: the cost of the medication to the payer
- The people we are affecting are not involved in the discussions to inform policy

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REFERENCE:

1. Institute for Clinical and Economic Review. White Bagging, Brown Bagging, and Site of Service Policies: Best Practices in Addressing Provider Markup in the Commercial Insurance Market [White Paper]. Published online April 19, 2023. Accessed May 2023. chrome-extension://efaidnbmnnnibpcajpcglclefindmkaj/https://icer.org/wp-content/uploads/2023/04/ICER-White-Paper-_-White-Bagging-Brown-Bagging-and-Site-of-Service-Policies.pdf