

Report on Medicare Compliance Volume 31, Number 2. January 17, 2022 White Bagging Is Used to Cut Specialty Drug Payments, Lawyers Say

By Nina Youngstrom

Health plans are using so-called white-bagging policies to reduce payments to hospitals for specialty drugs, and in the process, there may be a delay in patient care, attorneys say. Hospitals reportedly find white bagging thrust on them by Medicare Advantage plans and commercial payers in the middle of a contract year through amendments or policies, which means they won't be paid for oncology and other high-cost specialty drugs they prepare for patients on-site. Some hospitals have resigned themselves to white bagging and are making up lost revenue in other parts of their payer contracts, while others try to scrap the policies in future contracts or fight back in arbitration and court battles. They are getting some help from state lawmakers, and relief possibly could come from federal agencies that are poking around white bagging, according to attorneys.

"This is a cautionary tale in the importance of contract language," said attorney Jim Boswell, with King & Spalding. "Providers too often focus only on pricing and don't pay attention to amendments and the effect of policies and protocols and the ability to vary the contract through things that are called utilization management but are really substantial changes to the scope of the contract." Payers have set in motion white-bagging and other policies that affect reimbursement for imaging and surgery while contracts are already under way, Boswell said at a Dec. 9 webinar sponsored by his firm. "The imagination is limitless in terms of what these policies can be. I don't find that COVID has slowed down these policy rollouts."

White bagging was announced in 2020 and implemented across the country in phases, said attorney Zuzana Ikels, with King & Spalding. Some commercial payers require hospitals to buy specialty drugs from nonhospital suppliers on lists approved by the payers, Boswell said. Normally, hospitals have their own specialty pharmacies and prepare the drugs on–site. The main focus of white bagging is expensive drugs for treating some of the most serious diseases, such as cancer, multiple sclerosis and neurological illnesses, Ikels said. Hospitals are worried that shipments of drugs from outside pharmacies, which may be delayed, put patients at risk, the attorneys alleged.

'The One Thing You Don't Want to do Is Nothing'

For example, in a provider bulletin on specialty pharmacy requirements for outpatient hospitals, UnitedHealthcare states that outpatient hospitals "source the specialty and oncology supportive care drugs listed on UHCprovider.com through an indicated specialty pharmacy." [1] Cigna reiterated recently that it "will no longer reimburse facilities directly for the drugs included in the Specialty Medical Injectables with Reimbursement Restriction list, unless otherwise authorized by Cigna. Please note that facilities cannot bill patients with Cigna-administered coverage for the cost of these injectables when they are not obtained from a specialty pharmacy in the Cigna network." [2]

About six months ago, Boswell said there was a new round of white bagging around oncology support medication, such as Neulasta. "We are representing a client challenging those in particular because the drugs are administered relatively close in time to chemotherapy and having to go through another process and pay another co-pay and have it shipped to the hospital is bothering people," he explained. For example, a United bulletin

states that "Starting with dates of service on June 7, 2021, outpatient hospitals must obtain certain oncology supportive care medications from the participating specialty pharmacies we indicate, except as otherwise authorized by us." [3]

Hospitals should push back on white bagging in some way, shape or form, whether they have conversations with payers, lay the groundwork to ban white bagging in subsequent contracts or go all the way with arbitration or a lawsuit, Boswell said. "The one thing you don't want to do is nothing," he said. "You don't want to let policies roll by without any kind of response. Inaction could be construed as acquiescence."

Boswell's sense is that payers are willing to let hospitals provide the specialty drugs themselves, notwithstanding the white-bagging policies. "White bagging looks like a way to get a price reduction, and many hospitals have negotiated a way to continue to provide drugs themselves because it's in the best interest of patients and promotes the most timely delivery of drugs without prior authorization delays," he said.

Watch Your Language

Since the advent of white bagging, hospitals have responded in different ways, depending on where they're located, the volume of patients from a particular plan and whether they're in a major metropolitan area vs. a remote location, Boswell said. Some hospitals forbid white bagging for clinical reasons, he said. "It's also found to interfere with patient safety standards at the hospital," Ikels said. For example, physicians may change the drug cocktail on the day of administration, which wouldn't be a problem if the drugs were prepared at the hospital's in-house pharmacy but could delay treatment if the new cocktail has to be shipped from an outside pharmacy, Boswell said.

"You have to throw out the drug, reschedule infusion, and the process continues with a new infusion date," said attorney Daron Tooch, with King & Spalding. "We have had patients who have suffered real damages. One patient lost the use of a hand during this process of delays on infusions."

Other hospitals allow white bagging. They have found patients are receiving treatment that corresponds to what the provider orders in a timely way. The hospitals agree to lower prices and fix the reduction at the next contract negotiation, or make up lost revenue through price concessions by payers in other areas of the contract.

The reason that hospitals may get stuck with white-bagging policies is that health plans present them in provider manuals, utilization management procedures or protocols—some version of that language—and that the white bagging is therefore a routine part of the contract that hospitals agreed to, Boswell said.

"To solve these problems, you have to think creatively about what this animal called white-bagging policy is. Ditto on imaging or ambulatory surgery center policies," he said. "It requires getting into the definitions and the words." Boswell argues there's a difference between a routine adjustment in a contract and a unilateral decision to only pay for a specialty drug when it's purchased from an external vendor. "That doesn't look like a utilization management policy," he said. It's a significant amendment. Hospitals should question whether their contracts allow a one-sided amendment like this. "What does your amendment provision say about how a plan can be amended? Does it say amendments must be through bilateral signed writing? Does it specify what's a good provision to include? Does it say new protocols and policies will become part of the contract unless objected to? Does it require notification that a new policy will be applied on a certain day, and you have to be notified?" Hospitals also have to look ahead. "It is not only a present business issue, but a future business issue," Boswell said.

For example, hospitals should consider writing into their next contract a requirement that health plans will notify them of changes by certified letter or overnight courier "as opposed to publishing in a 50-page provider

bulletin or some online reference that can be changed anytime."

Hospitals aren't on their own. The Federal Trade Commission in the summer of 2020 began investigating the relationship between health plans and pharmacy benefit management companies "and associated cost savings for patients and the coordinated nature of how white-bagging policies are implemented," Ikels said. CMS has been looking at the issue in the context of Medicare Advantage plans. And there's been action at the state level, she said. For example, Louisiana banned white bagging in July 2021 legislation. Other state laws in states like New Jersey and Georgia took an indirect route that essentially had the same effect, Ikels said. Similar legislation is pending in California and elsewhere.

Arbitration May Help Stop White Bagging

Hospitals also may challenge white bagging in arbitration with health plans, Tooch said. If hospitals take that route, they have to decide whether to challenge white bagging in isolation or bring in other health plan behavior. The upside of including all underpayments is it shows arbitrators that white bagging is just one way that health plans reduce payments under the contract, Tooch said. The downside is white bagging may get lost in the shuffle. "Also, many arbitrators want to get repeat business from hospitals and insurers, and there may be a tendency to split the baby."

Tooch added that a preliminary injunction is an effective strategy before arbitration. It prevents white bagging from taking effect. "You say to the arbitrator that you need to stop the program immediately vs. going through an arbitration hearing and asking for damages and declaratory relief, which says health plans cannot use the policy to change the terms of the contract and seek an injunction at the end of arbitration to say they won't do it in the future." But there's a high bar for a preliminary injunction, Tooch noted. "You must show irreparable harm," he explained. "It's not just contractual damages or money. The most obvious harm here is patient harm."

AHIP Cites Benefits of Specialty Pharmacies

In a statement, Kristine Grow, senior vice president of communications for AHIP, which represents insurers, said "everyone should be able to get the medications they need at a cost they can afford. But drug prices are out of control, and hardworking families feel the consequences every day. The problem is the price, and health insurance providers are working every day to lower drug prices for all Americans. To fight back against these out-of-control drug prices, health insurance providers have developed many innovative solutions to make prescription drugs more affordable, including leveraging lower-cost pharmacies – called specialty pharmacies – to safely distribute certain drugs."

Grow noted that lower-cost specialty pharmacies save money and help make insurance premiums more affordable. "Specialty pharmacies can deliver drugs directly to a physician's office or to a patient's home right before a patient's appointment. This means that patients can avoid inflated fees and other costs that hospitals and physicians charge to buy and store specialty medications themselves," her statement said. "For example, specialty pharmacies can protect patients from a hospital's markup for prescribed drugs, which on average run between 200-400% of the hospital's acquisition cost."

Grow's statement asserted that "specialty pharmacies also protect patient safety." They're required to satisfy "extra safety requirements for specialty drugs imposed by the Food and Drug Administration (FDA), and by drug manufacturers. They also must satisfy stringent state and federal requirements for the safe storage, handling, and dispensing of the drugs."

Contact Boswell at jboswell@kslaw.com, Ikels at zikels@kslaw.com and Tooch at dtooch@kslaw.com.

- <u>1</u> UnitedHealthcare, "Specialty pharmacy requirements for outpatient hospitals," accessed January 13, 2022, https://bit.ly/3fkOyMt.
- <u>2</u> Cigna, "Medical coverage policy update Nutritional Support effective February 15, 2021," accessed January 13, 2022.
- **3** UnitedHealthcare, "Oncology supportive care medication sourcing requirement," news release, March 2021, https://bit.ly/3nigRQb.
- 4 S.B. 191, 2021 Leg., Reg. Sess. (La. 2021), https://bit.ly/3GpJ1jP.

This publication is only available to subscribers. To view all documents, please log in or purchase access.

Purchase Login