

PERSPECTIVES

## Getting a white-bagging exemption: A win for the patient, employer, and rheumatologist

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When we talk about advocacy in rheumatology, we think about our patients and how we can help them gain access to the best care. Whether it's filling out a prior authorization form or testifying before Congress, it is an action we perform that ultimately helps our patients achieve that care. We are familiar with many of the obstacles that block the path to the best care and interfere with our patient-doctor relationships. Much work has been done to pass legislation in the states to mitigate some of those obstacles, such as unreasonable step therapy regimens, nonmedical switching, and copay accumulators.

Unfortunately, that state legislation does not cover patients who work for companies that are self-insured. Self-insured employers, which account for about 60% of America's workers, directly pay for the health benefits offered to employees instead of buying "fully funded" insurance plans. Most of those self-funded plans fall under "ERISA" protections and are regulated by the federal Department of Labor. ERISA stands for Employee Retirement Income Security Act. The law, which was enacted in 1974, also covers employee health plans. These plans must act as a fiduciary, meaning they must look after the well-being of the employees, including their finances and those of the plan itself.

The Coalition of State Rheumatology Organizations (CSRO) has learned of a number of issues involving patients who work for self-funded companies, regulated by ERISA. One such issue is that of mandated "white bagging." White bagging [has been discussed](#) in "Rheum for Action" in the past. There is a long list of white-bagging problems, including dosing issues, lack of "chain of custody" with the medications, delays in treatment, mandatory up-front payments by the patient, and wastage of unused medication. However, there is another issue that is of concern not only to the employees (our patients) but to the employer as well.

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### Employers' fiduciary responsibility

As mentioned earlier, the employers who self insure are responsible for the financial well-being of their employee and the plan itself. Therefore, if certain practices are mandated within the health plan that harm our patients or the plan financially, the company could be in violation of their fiduciary duty. Rheumatologists have said that buying and billing the drug to the medical side of the health plan in many cases costs much less than white bagging. Conceivably, that could result in breach of an employer's fiduciary duty to their employee.

### Evidence for violating fiduciary duty

CSRO [recently received redacted receipts](#) comparing costs between the two models of drug acquisition for a patient in an ERISA plan. White bagging for the patient occurred in 2021, and in 2022 an exemption was granted for the rheumatologist to buy and bill the administered medication. Unfortunately, the exemption to buy and bill in 2023 was denied and continues to be denied (as of this writing). A comparison of the receipts revealed the company was charged over \$40,000 for the white-bagged medication in 2021, and the patient's cost share for that year was \$525. Under the traditional buy-and-bill acquisition model in 2022, the company was charged around \$12,000 for the medication and the patient's cost share was \$30. There is a clear difference in cost to the employee and plan between the two acquisition models.

Is this major company unknowingly violating its fiduciary duty by mandating white bagging as per their contract with one of the three big pharmacy benefit managers (PBMs)? If so, how does something like this happen with a large national company that has ERISA attorneys looking over the contracts with the PBMs?

### Why is white bagging mandated?

Often, white bagging is mandated because the cost of infusions in a hospital outpatient facility can be very high. Nationally, [it has been shown](#) that hospitals charge four to five times the cost they paid for the drug, and the 100 most expensive hospitals charge 10-18 times the cost of their drugs. With these up-charges, white bagging could easily be a lower cost for employee and company. But across-the-board mandating of white bagging ignores that physician office-based infusions may offer a much lower cost to employees and the employer.

Another reason large and small self-funded companies may unknowingly sign contracts that are often more profitable to the PBM than to the employer is that the [employer pharmacy benefit consultants are paid handsomely by the big PBMs](#) and have been known to “rig” the contract in favor of the PBM, according to Paul Holmes, an ERISA attorney with a focus in pharmacy health plan contracts. Clearly, the PBM profits more with white-bagged medicines billed through the pharmacy (PBM) side of insurance as opposed to buy-and-bill medications that are billed on the medical side of insurance. So mandated white bagging is often included in these contracts, ignoring the lower cost in an infusion suite at a physician’s office.

## Suggestions for employers

Employers and employees should be able to obtain the costs of mandated, white-bagged drugs from their PBMs because the Consolidated Appropriations Act of 2021 (CAA) mandates that group health plans ensure access to cost data. The employer should also have access to their consultant’s compensation from the PBM as [Section 202 in the CAA](#) states that employer benefit consultants must “disclose actual and anticipated cash and non-cash compensation they expect to earn in connection with the sale, renewal, and extension of group health insurance.”

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It would be wise for all self-insured companies to use this section to see how much their consultants are being influenced by the company that they are recommending. Additionally, the companies should consider hiring ERISA attorneys that understand not only the legalese of the contract with a PBM but also the pharmacy lingo, such as the difference between maximum allowable cost, average wholesale price, average sales price, and average manufacturer’s price.

## Suggestion for the rheumatologist

This leads to a suggestion to rheumatologists trying to get an exemption from mandated white bagging. If a patient has already had white-bagged medication, have them obtain a receipt from the PBM for their charges to the plan for the medication. If the patient has not gone through the white bagging yet, the PBM should be able to tell the plan the cost of the white-bagged medication and the cost to the patient. Compare those costs with what would be charged through buy and bill, and if it is less, present that evidence to the employer and remind them of their fiduciary responsibility to their employees.

Granted, this process may take more effort than filling out a prior authorization, but getting the white-bag exemption will help the patient, the employer, and the rheumatologist in the long run. A win-win-win!

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