

## Creating a Policy on Brown Bagging

by Judy Stone

“Brown bagging” is the term for the practice of shipping drugs directly to the patient, who then brings the drug to the physician office for injection or infusion. Over the years, this term has sometimes encompassed situations where payers require that drugs be purchased through designated specialty pharmacies and then shipped to the patient’s home or to the practice on behalf of the patient.

Brown bagging inherently raises concerns about quality control, chain of custody, and patient safety issues. In a time when hospitals and healthcare providers are focused on reducing and eliminating medication errors, a policy on brown bagging can be an important component of establishing best practices.

Our institution, Carolinas Healthcare System, is the third largest public healthcare system in the country with 22 hospitals and approximately 170 practice locations with more than 1,100 physicians. Physician practices within our healthcare system have long fought against brown bagging, but recently our hospitals and outpatient clinics also began to experience patients bringing medications into our hospital clinics and acute care settings.

Because the practice of brown bagging raises concerns regarding quality control and patient safety, our healthcare system established a task force charged with developing an institution-wide policy on brown bagging to cover our entire healthcare system—practices and hospitals.

The task force was composed of a range of stakeholders including

cardiology, urology, and medical oncology practices, as well as the executive in charge of pharmacy, members of the risk management and legal departments, our outpatient cancer center, and home infusion company. Although our discussion initially focused on brown bagging, it quickly expanded to include specialty pharmacies because these share some of the same problems related to chain of custody and quality control. Of particular concern were drug pedigree issues. The exposure of counterfeit drug rings in south Florida over the past several years raised additional concerns. As a body of evidence began to grow about the potential for counterfeit oncologic and supportive care drugs, hospitals and practices alike have become more aware of the potential dangers of patients bringing drugs into the hospital for administration. Our institution needed a policy in place that would address these concerns.

To draft our policy on brown bagging and specialty pharmacies, the task force met once a month for nearly a year. The intent of our policy was to ensure patient safety and drug integrity. Our policy does not allow *any* brown bagging. We believe that we cannot be assured that a brown-bagged drug has come from a trustworthy source or that it was maintained properly while in possession of the patient. As such, we believe that brown bagging represents a risk to patients and does not represent quality care. Further, we believe that brown bagging does not meet The Joint Commission’s standards.

Our policy does not totally prohibit the use of specialty pharmacies, however, because we recognized that there are certain instances in which specialty pharmacies are effective and necessary. Our task force agreed that we had to put some fairly specific measures in place to deal with exceptions, and that our policy would include some absolute exceptions, for instance, when the specialty pharmacy is the sole resource for a drug.

We also had to consider appropriate exceptions that would cover our patients who may participate in patient assistance programs and indigent patient populations, and that there would be times when we will have to make exceptions and deal with a specialty pharmacy; however, in these instances we will require that the pharmacy ship the drug to us (either the practice or the hospital) and not the patient.

In drafting a policy on brown bagging and specialty pharmacies, we have also developed a mechanism for exceptions to be raised and a decision-making process for approval of exceptions. The task force recognizes that our policy will have to be re-visited on a regular basis.

The policy has been presented to our Physician Services Group, which represents physician interests, and is presently before our Policy Committee awaiting approval. Our hope is that our Policy on Brown Bagging and Specialty Pharmacies will create consistency in our practices and throughout our healthcare system in providing quality care and additional safety to our patients. ■

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