

Professional Practice Advisory on Brown Bagging

Pharmacists need to understand the risks and benefits of brown bagging medications in order to make informed decisions on the appropriateness of a brown bagging program. This paper provides information about the practice of brown bagging, its advantages and disadvantages, selection criteria, factors that should be taken into account when considering implementation of a brown bagging program as well as the role of pharmacists in this practice.

Background

Pharmacists bring value to the health care system by assuring safe and effective medication use for patients. In doing so, pharmacists can potentially improve health outcomes and improve patients' quality of life. With this expanded role in health care, pharmacists must balance the interests of the patient and financial reality.

Many new injectable and infusible drugs are major contributors to the rising cost of health care. These drugs account for \$40 billion per year in health care expenditure and are expected to increase to \$75 billion during 2008. Moreover, these costs can account for 25-30% of a health plan's medical costs.¹ The escalating drug costs are having an impact on the pharmacy budgets of managed care organizations (MCOs), and MCOs are continually searching for ways to improve health outcomes while managing these growing costs.

In response to these challenges, many MCOs have changed the distribution method for certain physician-administered medications. Traditionally, physicians have purchased those types of medications, administered them to patients, and billed the MCO for reimbursement. A recent development has MCO members obtaining the medications from a pharmacy within the MCO's network and carrying the medication to their physician's office or hospital for administration. This practice has been coined "brown bagging."

There are numerous medications in brown bagging programs. Some of the most common include parenteral chemotherapeutic agents and chemotherapeutic support medications, medications used to treat rheumatoid arthritis and Crohn's disease, blood factors, immune globulins, and some vaccines. The increasing number of new drugs and expanded indications make managing these drugs more challenging for MCOs.

Managed care organizations seeking ways to gain better control over drug utilization and cost may consider integrating injectable or infusible products into their pharmacy benefit and employing a

¹ D.B. Stern & D. Reissman, *Specialty pharmacy cost management strategies of private health care payers*, J Manag Care Pharm., 2006; 12:736-44

brown bagging program. Before implementing such a program, an evaluation should be conducted to determine if the practice fits the organization. In addition, the MCO should understand the benefits, risks and impacts of brown bagging programs on patients, providers and other stakeholders.

Advantages and Disadvantages of Brown Bagging

Advantages:

There are several advantages of brown bagging programs and including injectable or infusible drugs in the pharmacy benefit.

Patients who participate in brown bagging programs may see some advantages when medications are obtained through pharmacies. Dispensing pharmacists perform drug utilization reviews, checking for duplication of therapy, appropriate dose, drug-drug interactions, etc. Counseling of patients also occurs, with pharmacists providing information about the drug, what to expect when the drug is administered, and possible adverse reactions. For some patients, obtaining a medication through a pharmacy instead of through the physician's office may make the drug more affordable by reducing their out of pocket coinsurance or copayment.

Some physician's offices also view brown bagging as being beneficial. Brown bagging programs save physician offices from bearing the burden of buying and stocking expensive biological medications. Billing and waiting for reimbursement for the costs of the drugs is also eliminated; physicians need only bill for the office visit and drug administration. In addition, the Centers for Medicare & Medicaid Services (CMS) concluded that any medication dispensed at a retail pharmacy cannot be considered a physician service, and should be covered by prescription drug plans. Therefore, some physicians now require that patients obtain their drugs from the pharmacy. In doing so, the medications are covered under the patients' Medicare Part D prescription drug plans.

MCOs may also benefit from brown bagging programs. One of the primary benefits is improved patient care management. Medications provided to a patient as a pharmacy benefit are captured in real time within a sophisticated infrastructure of concurrent and prospective drug utilization reviews (DUR) designed to detect and prevent adverse drug events, drug/drug interactions, and duplication of therapy. The drug therapy reviews occur before the drug is administered, reducing adverse drug events. When physicians procure, administer and bill medications, drug utilization screening is not performed until after the patient has received the drug. In addition, the real-time pharmacy claim infrastructure allows case management clinicians to view a patient's medication and medical history and tailor counseling accordingly.

Improved billing procedures for medications are a second advantage. Pharmacy claims are submitted using the product's National Drug Code (NDC) number which ties directly to a specific product, manufacturer, dose and dosage form. This provides more accurate accounting of the drug and dose administered. When physicians bill for drug products administered in their offices, claims are not submitted in real-time and a different coding system is typically used, the Healthcare Common Procedure Coding System (HCPCS). HCPCS codes, commonly referred to as 'J' Codes, provide less information than NDC numbers, identifying only the generic drug name and quantity administered. NDC numbers also facilitate the identification of specific drug products in the event of medication recalls. Using information obtained from real-time billing of drug products, communication may be

targeted to affected patients and providers only, and removal/replacement of recalled drug products is easier.

The practice of brown bagging provides improved trend management. Managing these drugs as a pharmacy benefit provides MCOs greater control of the costs and management of injectable medications. For example, physicians have commonly been reimbursed a percentage of the average wholesale price (AWP) and more recently the average sales price (ASP) for medications which can foster the selection of more expensive medications in order to realize a higher reimbursement. MCOs, however, may be able to negotiate with network pharmacies to obtain a more favorable rate than individual physicians. In addition, MCOs may also contract with the drugs' manufacturers to attain lower costs for the products.

Disadvantages:

There are also disadvantages that need to be weighed in the decision to institute a brown bagging program.

Obstacles may occur for some patients when obtaining medications through brown bagging programs. There is the inconvenience of acquiring the drug from the pharmacy before going to the facility where the medication is to be administered. If the drug is delivered through the mail, it may not be received on time or may be inadvertently damaged during shipping or compromised during patient transit and have to be replaced. The dosage of the drug may change after it has been picked up by the patient, but before it has been administered. This may lead to wasted doses of medication or the patient may be required to return the drug to the pharmacy. In some cases, patients may be required to dispose of potentially hazardous materials, such as contaminated needles and unused medication. Patient financial responsibility must also be considered. Under some benefit coverages, the patients' copayment or coinsurance for drugs may be higher when obtained through a pharmacy than when the drug is obtained through the physician. In addition, the cost of drugs may accrue towards the coverage maximums of prescription drug plans, as is the case under the Medicare Part D prescription drug program. Lastly, there may be the perception that brown bagging interferes with the physician-patient relationship.

There are financial disadvantages to brown bagging that fall on physicians and hospitals.² Hospitals typically prepare and handle these types of medications but with the patient supplying the medication, the hospital loses most of the expected revenue. Hospitals and physicians lose money because they can bill only for the administration of the product, and lose the profit margin on the medication itself.

Hospitals and physicians may have potential liability issues. After being dispensed to patients, the medications leave pharmacies, and physicians and hospitals have no knowledge of their handling and storage conditions prior to administration. The safety and integrity of the medication is not assured. The question that concerns physicians and hospitals is, "who is liable if an improperly handled

² Fred Gebhart, *Final rules may slow brown bagging*, Drug Topics, Jan. 22, 2007; The Lewin Group, Inc., *Patient Advocate Foundation Survey: Patient and Consumer Views of Brown Bagging and Mandatory Vendor Imposition*, Jan. 24, 2003, at 1.

medication leads to injury?" Hospitals also need to consider accreditation standards that may restrict or prohibit brown bagging programs.

Additional Considerations

In addition to the advantages and disadvantages to brown bagging, there are other factors that should be considered when implementing such a program.

Special handling requirements for medications considered for a brown bagging program should be reviewed. Several medications require special handling, such as refrigeration, to maintain potency; the efficacy of the drug may be compromised if it has been left in a mailbox, doorstep, or hot car. Other drug safety and efficacy concerns from brown bagging include: the safety and security of transportation, proper storage, correct mixing process, and timeliness of providing the drugs.

Another factor for consideration is the potential for misuse or abuse of certain drugs. Careful monitoring of drug therapy should be included in all brown bagging programs.

MCOs need to judge the willingness of physicians to accept drugs for administration from patients. Some physicians, concerned with patient safety, quality of care, and liability issues, have declined to treat patients in brown bagging programs. MCOs should formulate contingency plans for such instances. Exception procedures should be established for situations in which brown bagging is not feasible.

The patient's or caregiver's ability to comprehend and carry out specific instructions must be considered in a brown bagging program. If the patient or caregiver is incapable of performing the necessary tasks, he/she is not a candidate for the program. Likewise, transportation issues must also be considered. If the patient does not have the proper means of transportation, brown bagging should not be considered. Transportation issues may be overcome by delivery of the medication directly to the physician's office.

Some community pharmacists have tried to alleviate the problem of improper storage and handling by having patients pick up their drugs en route to the physician's office. Moreover, many community pharmacies do not regularly stock the medications for brown bagging, thus, in an effort to ensure the availability of the medications, some pharmacists have asked physicians to order them in advance.

The increased availability and utilization of injectable therapies has resulted in the emergence of specialty pharmacies as a means of providing these medications. While there is no standard definition of specialty pharmacy, such pharmacies specialize in the handling of injectable products. Specialty pharmacies deliver drugs directly to physicians' offices or patients' homes, typically provide education to physicians and patients, and offer additional care management and monitoring services after drug delivery. For additional information about specialty pharmacies and their role in the provision of health care, see [*AMCP's Concept Series Paper on Specialty Pharmaceuticals*](#). It is argued that specialty

pharmacies solve many of the concerns raised by opponents of brown bagging while preserving the benefit design strategy of the payer.

Roles of Pharmacists

Many factors lead to patients' receipt of brown bagged pharmaceuticals. Depending upon their placement within the health care system, pharmacists have different roles in the design, implementation and management of brown bagging programs. Pharmacists are in a unique position to interface with this patient population which may not present to the pharmacy for traditional services. Pharmacists managing patients in brown bagging programs should understand the impact those programs have on their patients, providers and pharmacies and the complex payment systems involved. They should also be able to educate patients, physicians and other healthcare providers on the variety of services offered by each provider.

Community Pharmacists

Community pharmacists typically dispense medications, counsel patients on appropriate medication handling, usage, storage, potential adverse reactions, and advise general practitioners on medication selection. The community pharmacist's prime responsibility in brown bagging programs is to assist in the coordination of patients' care by educating patients, providing ongoing monitoring for the non-traditional pharmaceuticals, developing professional relationships and working with physicians' offices to facilitate medication delivery. When faced with the challenge of managing patients' brown bagged medications, pharmacists should be able to provide education to patients and caregivers about:

- the importance of timely medication procurement and refills,
- recognizing and promptly reporting adverse events related to their treatment,
- maintaining a comprehensive medication list which includes all brown bagged pharmaceuticals,
- proper storage, compounding, transportation, and administration techniques for brown bagged pharmaceuticals,
- the most convenient and effective method for procurement and transportation, and
- the patient's medical and pharmacy benefit, especially as it relates to obtaining specialty pharmaceuticals.

Hospital Pharmacists

Hospital pharmacists write many medication protocols, prepare medications, advise physicians on appropriate medication usage, and counsel patients on adverse effects of their medication regimen. Pharmacists practicing in a hospital or ambulatory care setting should:

- develop drug specific protocols for managing patients whose benefit plans require brown bagging. This may include administrative procedures, drug compounding protocols, adverse event management, etc.
- provide follow up and continued monitoring for adverse events and treatment efficacy.

Managed Care Pharmacists

The role of the managed care pharmacist is in influencing benefit designs and in developing a contracted network of providers that can support brown bagging. These roles include:

- instituting policies and procedures for each medication in brown bagging programs to ensure seamless delivery and administration, e.g., syringes and needles shipped with the medication,
- training specialized personnel at every point of patient contact to serve the unique needs of this patient population,
- ensuring integrity of drug source and ensuring all storage conditions are optimal prior to, during, and after delivery to the patient, along with providing detailed instructions for patient storage and transportation,
- providing patient education, monitoring adherence, and gathering outcomes data for further study,
- developing relationships with medical centers/physician offices co-located with pharmacies. Because of their location, those pharmacies may have the capability to deliver medications to physicians without there being questions about the integrity of the drugs.

Conclusion

The practice of brown bagging has generated discussion about the most efficient and efficacious method of providing needed medications to patients with a myriad of disease states. Those opposed to brown bagging raise questions of patient safety, medication efficacy, and the ability of physicians, clinics and hospitals to provide services without sufficient reimbursement to cover overhead costs. Those in favor of brown bagging argue that the patient safety and medication efficacy concerns are overstated and can be mitigated through the use of a well designed brown bagging program and/or specialty pharmacies that house the necessary expertise and infrastructure to appropriately deliver medications to the site of administration. Moreover, it is argued that reimbursement and overhead concerns can be resolved through negotiation. It is advisable that both sides while at times passionate in their support of or opposition to brown bagging, maintain their focus on the single most important metric: patient well-being.