

White and Brown Bagging Emerging Practices, Emerging Regulation

Prepared By

The National Association of Boards of Pharmacy



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NABP Mission Statement

NABP is the independent, international, and impartial Association that assists its member boards and jurisdictions for the purpose of protecting the public health.

NABP Vision Statement

Innovating and collaborating today for a safer public health tomorrow.

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Overview

At the NABP 112th Annual Meeting in May 2016, the membership passed Resolution 112-1-16 requesting that NABP conduct a study to review and define the practices of “white bagging” and “brown bagging,” and recommend regulatory language, if necessary, to *The Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy (Model Act)*. The “study” design and methodology were framed in the discussions of the Resolutions Committee at the Annual Meeting, as they had not been defined in the actual resolution. The Resolutions Committee determined that a task force to examine these practices was not warranted because of the finite body of knowledge surrounding them and the limited consideration of the practices by boards of pharmacy. In lieu of a task force, the Resolutions Committee proposed that NABP staff research the issue and present the findings to the Executive Committee, and the Executive Committee decide what, if any, revisions would be made to the *Model Act*.

The Executive Committee, in approving the implementation of the resolution, directed that NABP staff perform a review of the professional literature, utilize **NABPLAW** and other sources to determine how state boards of pharmacy have defined and regulated the practices, and develop model language, if appropriate, for the Executive Committee’s consideration.

Results

NABP staff executed the study as directed by the Executive Committee with the following results:

1. Within the professional literature, “White Bagging” and “Brown Bagging” are defined as follows:
 - a. “White bagging” refers to the distribution of patient-specific medication from a pharmacy, typically a specialty pharmacy, to the physician’s office, hospital, or clinic for administration. It is often used in oncology practices to obtain costly injectable or infusible medications that are distributed by specialty pharmacies and may not be available in all non-specialty pharmacies.
 - b. “Brown bagging” refers to the dispensing of a medication from a pharmacy (typically a specialty pharmacy) directly to a patient, who then transports the medication(s) to the physician’s office for administration.
2. Prevalence of “Bagging” Practices
 - a. Magellan Rx Management’s [2015 Medical Pharmacy Trend Report](#), which includes data from 59 health plans, representing 129.7 million covered individuals, found that 28% of medical benefit drug volume was distributed to physician offices by specialty pharmacies or by patients through brown bagging.

- b. The [2016 Genentech Oncology Trend Report](#) also provides data from managed care organizations, which reported that 28% of oncology drugs were distributed to practices by retail, mail, and specialty pharmacies.
 - c. A Zitter Health Insight's survey of managed care executives reported that 31% of provider-administered infusible oncology therapies were fulfilled by either specialty pharmacies or patient brown bagging. See a 2013 write-up in [Payers Want Specialty Drug Distribution to Change](#).
3. Regulatory Roles – A review of state practice acts and regulations determined that few states define the concepts of white bagging or brown bagging. The delivery methods, although a component of some medical practices, such as oncology, may be a more significant issue in the reimbursement arenas.

Results Background

Pharmacists, patients, prescribers, and payers all have distinct incentives for adopting the white bagging or brown bagging model. Of significant benefit, these models give pharmacists a greater opportunity to utilize their expertise to improve patient outcomes. For example, pharmacists work closely with prescribers and other health care providers to determine the best possible treatment for specific diseases and ensure their patients understand how to optimize drug therapy and manage potential medication side effects. Pharmacists can also use their patient medication therapy management skills by checking for duplicate drug therapy, assessing drug-drug interactions, providing drug utilization reviews, and suggesting appropriate changes. Finally, pharmacists can ensure patient adherence by engaging with patients through educational, empowerment, and self-management programs.

From the prescriber perspective, there are clear benefits that come from these drug distribution models. Brown bagging and white bagging models reduce physicians' costs associated with purchasing and stocking expensive medications and limit the lengthy administrative process of billing payers for reimbursements, as the provider neither purchases the drug nor seeks drug reimbursement from a third-party payer. However, the provider is still paid for professional services associated with the drug's administration. From the payer perspective, benefits include cost savings through negotiated dispensing rates and increased transparency.

Despite offering some benefits for all parties involved, there are still issues within the brown bagging and white bagging models that must be considered. One concern stems from the nature of the medications provided through these models. These medications are often patient-specific and require special handling and can thus pose safety, operational, and unexpected financial burdens. Additionally, medication delivered directly to the patient through

the brown bagging model may have been incorrectly stored or handled, which can affect the drug's efficacy.

Another obvious challenge for specialty pharmacies comes from the potential lack of access to the patient's electronic medical record, which then requires additional coordination between the patients and their physicians.

Furthermore, under the white bagging model, physicians and dispensing pharmacies face the unpaid expense of safeguarding and storing patients' medication until drug administration.

In some instances, patients participating in white bagging or brown bagging programs often require therapy modification. Change of dosage or strength or transition to a different class of medications is common. When therapy modification occurs, it often leads to excessive waste because the previously dispensed medication cannot be reused for a different patient.

On occasion, these drugs are highly toxic and require special handling to discard. The disposal process can be very costly and requires compliance with additional state and federal requirements overseen by environmental protection agencies.

For patients, there may be some obstacles to obtaining the medication from a specialty pharmacy. Patients may have trouble acquiring the medication from the pharmacy before proceeding to their clinic, hospital, or physician's appointment because of delays in processing requests for insurance coverage. Medication delivered through the mail may arrive late or damaged. Additionally, patients may be inconvenienced by dosage changes made after receipt of their medication but prior to administration. It is also important to note the financial burdens that exist for patients who need specialty drugs, as many have costly out-of-pocket copayments.

As the specialty pharmacy model becomes more prevalent and is often mandated by third-party payers, it appears that the practices of white bagging and brown bagging will be utilized more often and incorporated into the care of a greater number of patients. The terms and conditions for this business model are most often set by the third-party payers, who are frequently not under the regulatory authority of the state boards of pharmacy. As previously mentioned, white bagging and brown bagging are not without shortcomings. The boards must determine who is accountable for verifying the authenticity and integrity of the drug before administration. Furthermore, regulators must decide who is responsible when a delay in therapy, due to a lack of coordination between patient, prescriber, and pharmacy, leads to adverse outcomes for patients. These issues are left to the state boards of pharmacy to grapple with in an effort to protect the public.

The control and responsibility for the integrity and timely delivery of the medications under each bagging practice are two of the issues most relevant to the role and responsibility of the boards of pharmacy. The specific questions to be considered are: Where, when, and from whom were the medications purchased? Were the medications manufactured abroad and not Food and Drug Administration-approved? A shipment of sensitive drugs sitting outside a pharmacy or patient's residence for hours may result in compromised contents and raises concerns about whether the medication was handled appropriately and safely at all times.

Recommendations

1. The practice of dispensing a specialty drug directly to the patient, who then transports the specialty drug to the physician's office or clinic, colloquially referred to as "brown bagging," is determined to be included in the definition of the practice of pharmacy. As such, there is no need to define this concept separately in the *Model Act*. Similarly, all the conditions and requirements applicable to the practice of pharmacy, including, but not limited to, the performance of a drug utilization review, responsibility for the integrity of the medication, patient counseling and education, and the provision of disposal instructions, are applicable to specialty drugs dispensed directly to the patient for subsequent administration by the physician.
2. The study determined that there is a legitimate patient protection issue when a specialty drug is distributed to an entity other than the patient. The pharmacy distributing the specialty drug is responsible for appropriate notification to the dispensing pharmacy or to patient's agent if the specialty drug is to be administered by the agent.

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