REPORT OF THE COUNCIL ON MEDICAL SERVICE

CMS Report 10-A-16

Subject: Medication "Brown Bagging" (Resolution 827-I-15)

Presented by: Robert E. Hertzka, MD, Chair

Referred to: Reference Committee G (Steven Hattamer, MD, Chair)

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At the 2015 Interim Meeting, the House of Delegates referred Resolution 827-I-15, which was sponsored by the Organized Medical Staff Section. The Board of Trustees assigned this item to the Council on Medical Service for a report back to the House of Delegates at the 2016 Annual Meeting. Resolution 827-I-15 asked:

> That our American Medical Association (AMA) study the potential benefits and harms of medication "brown bagging," which is the practice of patients bringing their own medications into their physicians' offices or into hospitals for administration in those settings, with report back at the 2016 Interim Meeting.

This report explains the practice of "brown bagging," highlights its risks and benefits, summarizes relevant AMA policy, and presents policy recommendations.

## BACKGROUND

"Brown bagging" is a colloquial term describing the practice of patients acquiring pharmaceuticals, such as chemotherapy drugs, through their pharmacy benefit and bringing the drugs to a physician's office or hospital to have them administered. "Brown bagged" (patient-acquired, physician-administered) drugs are shipped directly from a pharmaceutical wholesaler either to a patient or to an in-network pharmacy where the patient picks up the medication and transports it to a facility to be administered.[1] This practice differs from the traditional "buy and bill" arrangement in which providers purchase and stock infused and injectable medications, administer them and then bill payers for the drugs and their administration under patients' medical benefits.

Office-administered drugs are generally covered under an insurer's medical benefit (Part B for Medicare patients), while self-administered drugs are covered under an insurer's pharmacy benefit. "Brown bagging" shifts coverage of office-administered drugs from a medical benefit to a pharmacy benefit, and it is the pharmacy that then bills payers for the drugs, presumably at lower cost.[2] Pharmacies also bill payers directly under the practice of "white bagging," whereby the drug is shipped by a specialty pharmacy directly to the facility for administration to a particular patient. Because specialty and biologic agents drive up the overall cost of prescription drugs, payers may incentivize alternative distribution methods for these drugs such as "brown" and "white bagging." While there is evidence that the use of "white bagging" is increasing, [3] the extent of "brown bagging" by patients is less well-defined.

*"Buy and Bill"*

Fee-for-service Medicare generally pays for office-administered drugs through its Part B benefit using a drug's average-sales-price (ASP) plus six percent, which is subject to the federal budget sequester. ASPs are posted quarterly by the Centers for Medicare & Medicaid Services (CMS) and based on calculations submitted to CMS by pharmaceutical companies six months prior. When the cost of a drug increases, there is a gap between what physician practices or hospitals pay to acquire the drug and what Medicare reimburses them for it. This cost differential must be borne by these facilities until CMS increases the ASP.

Payments for office-administered drugs by private insurers can be higher than the Medicare formula. However, providers who "buy and bill" are still vulnerable to increases in pharmaceutical prices, the proliferation of costly specialty drugs and the risk that some patients may be unable to pay their cost-sharing expenses. Acquisition costs for biologics and other new specialty medications may be prohibitive for small practices that are unable to pay for them up front. Large practices and hospitals are often better positioned to "buy and bill" high-priced pharmaceuticals because they have greater purchasing power.

*Benefits of "Brown Bagging"*

An advantage of "brown bagging" is that it permits physician practices to avoid financial pressures under "buy and bill" that have led to a shift in the administration of office-infused drugs from private practices to hospital settings. Under "brown bagging," practices no longer bill for the costs of the medications; rather, they bill only for the drug's administration and related services.

Patient acquisition of their physician-administered drugs may enable physician practices to administer certain costly medications that they cannot afford to "buy and bill." Practices are also relieved from storage and inventory responsibilities. In these cases, "brown bagging" may facilitate patient access to effective medications when the administering facility cannot otherwise provide them. Patients are thus able to have their medication administered at their physicians' offices, where they have an established physician-patient relationship, instead of a hospital.

"Brown bagging" also benefits patients if their physician-administered drugs are more affordable when purchased directly from the pharmacy or because of reduced cost-sharing expenses. Some insurers or pharmacy benefit managers may be able to negotiate more favorable prices for certain high cost drugs, and that savings could theoretically pass down to patients. It is the potential for decreased costs that likely makes "brown bagging" attractive to insurers and perhaps some patients, especially patients who are unable to access office-administered medications through other distribution channels.

*Risks of "Brown Bagging"*

Because the chain of custody of "brown bagged" medications is broken during distribution, providers administering these drugs cannot ensure their integrity. There may be additional liability issues associated with administering these medications if they have not been properly handled or if their potency or efficacy has been compromised. Biologic and other specialty drugs are complex to manufacture, prepare and dispose of, and include strict handling and storage instructions that patients may not be equipped to manage. Storage and handling become larger concerns when volatile drugs are delivered to patients through the mail, or if patients travel large distances to have the drugs infused. "Brown bagging" medications may also inconvenience patients; those who are neither trained nor at ease handling therapeutic medications may not be appropriate custodians.

Physicians may be unable to determine visually whether a drug has been compromised during transit, which could render a drug less effective and potentially jeopardize a patient's safety.

There is also risk that a "brown bagged" medication will be wasted if, because of changes in laboratory values or disease progression, a patient cannot be infused at the time the drug is transported or before it expires. Medications that are acquired and stored by a practice can be given to another patient; however, "brown bagged" drugs cannot. Patients who are unable to have their "brown bagged" drugs administered in a timely manner may be responsible for returning the drugs or otherwise disposing of them. Billing may be complicated, and there is also a risk of medication misuse.

Although "brown bagging" may make certain office-administered drugs more affordable for some patients, it is also possible for patient cost-sharing to be higher when drugs are procured through a specialty pharmacy rather than the administering physician. Finally, it is important to point out that facilities whose patients "brown bag" their pharmaceuticals can only bill for administration of these drugs. These physician practices and hospitals thereby forego the margin on medications made available under the "buy and bill" system.

AMA POLICY

No current policy speaks specifically to "brown bagging," although AMA policy supports physician access to office-administered drugs and the ability to dispense them. Policy H-330.884 states that the AMA will: (1) advocate that physician access to in-office administered drugs, including drugs dispensed by pharmacies, be preserved; (2) work with involved national stakeholders to improve and support patient access to in-office administered drugs; and (3) advocate for coverage for in-office administered drugs and related delivery services for patients who are physically unable to self-administer the drug. Policy H-330.888 supports exempting physician-administered drugs from Medicare sequestration.

Policy H-120.990 supports the physician's right to dispense drugs and devices when it is in the best interest of the patient and consistent with AMA's ethical guidelines. Under Policy D-330.960, the AMA supports efforts to ensure that Medicare payments for drugs fully cover the physician's acquisition, inventory and carrying cost and that Medicare payments for drug administration and related services are adequate to ensure continued patient access to outpatient infusion services. Policy D-330.960 also calls for strong advocacy efforts working with relevant national medical specialty societies to ensure adequate physician payment for Part B drugs and patient access to biologic and pharmacologic agents.

Policy H-55.995 states that carriers should recognize and encourage the administration of chemotherapy in physicians' offices, wherever practical and medically acceptable, as being more cost-effective than administration in many other settings. The AMA supports existing policy principles in evaluating legislative language on matters relating to Medicare reimbursement for physician acquisition and administration of prescription drugs under Policy H-330.897. More broadly, AMA policy opposes interference by pharmacy benefit managers in the provision of medical care by physicians (Policies D-125.997 and H-125.986[4]).

DISCUSSION

The Council clarifies that the "brown bagging" practice as described in referred Resolution 827-I-15 refers to patients acquiring medications through their pharmacy benefit and bringing them to a physician's office or hospital to be administered. Patients who bring self-administered

medications into hospitals or clinics for use or for medication reconciliation are not addressed in this report.

Although the prevalence of "brown bagging" is not known, the Council recognizes that the proliferation of high-priced specialty drugs could potentially fuel growth in the practice. Council on Medical Service Report 2-I-15, Pharmaceutical Costs, discussed the increased financial burdens on payers, physicians and patients resulting from utilization of biologics and specialty drugs, many of which are office-administered. One way for insurers to gain control over the cost of these agents is to integrate them into their pharmacy benefits through "white bagging" or "brown bagging" programs.

The Council weighed the risks and benefits of "brown bagging" against several criteria, including patient safety, patient access, provider responsibility, and preservation of the physician-patient relationship. The Council reiterates its support for adequate payments for office-administered medications that are procured and stocked by physician practices in order to maintain the medication's chain of custody. The Council further acknowledges the value of care provided by independent and small practices that administer chemotherapy, anti-rheumatic and other medications to patients in the office setting. Accordingly, the Council recommends reaffirming Policies H-330.884 and D-330.960, which advocate for the preservation of physician and patient access to office-administered drugs and adequate payment that ensures continued patient access to outpatient infusion services.

The Council recognizes that patients are administered therapeutic medications by a variety of specialists–including oncologists, hematologists, dermatologists, rheumatologists and gastroenterologists–and that best practices and safety protocols fall under the purview of the outpatient facilities administering pharmaceuticals and their respective specialty societies. Most hospitals, infusion centers and physician practices have protocols in place around the management of office-administered drugs to ensure the safety of patients and staff.[4]

The Council recognizes that physicians who administer infused and injectable agents as part of their clinical practice may hold a variety of views about "brown bagging," depending on their specialty, practice size, individual patients, payer contracts and the volatility of medications they administer. A physician may opt to accept a "brown bagged" drug of a non-toxic nature as long as the physician confirms that the patient is equipped to handle, store and transport the drug. Another physician may be willing to take extra precautions to ensure that a patient can safely "brown bag" a medication if the patient cannot access the medication by other means. Other physicians may refuse to accept any "brown bagged" products because the practice does not meet the administering facility's safety and quality control protocols, and would require responsibilities above and beyond what is required to administer medications that are procured and stocked in-house. Given concerns about patients' ability to safely handle and store "brown bagged" drugs, coupled with liability issues, it is understandable why many physicians prefer not to administer "brown bagged" medications. Accordingly, the Council recommends that the AMA affirm that decisions to accept or refuse "brown bagged" (patient-acquired, physician administered) pharmaceuticals be made only by physicians responsible for administering these medications.

The Council further believes that physicians should decide whether a given patient has the proper knowledge and training to "brown bag" therapeutic drugs without posing safety or other concerns. Accordingly, the Council recommends that the AMA affirm that "brown bagged" pharmaceuticals be accepted for in-office administration only after the physician responsible for administering these medications determines that the individual patient, or his or her agent, is fully capable of safely handling and transporting the medication.

An increase in insurer mandates or incentives to "brown bag" office administered drugs would be disconcerting, given the multitude of risks associated with the practice. In 2014, Ohio enacted the first state law to ban "brown bagging" of non-self-injectable cancer drugs. The Ohio law prohibits pharmacists from dispensing chemotherapy drugs directly to patients, their representatives or their private residences.[5] Rather than banning "brown bagging" unilaterally, the Council recommends working with interested national medical specialty societies and state medical associations to oppose third party payer policies and legislative and regulatory actions that require patients to utilize "brown bagging" to ensure coverage of office-administered medications. The Council further recommends working with interested national medical specialty societies and state medical associations to oppose payer policies that reimburse office-administered drug costs at less than the provider's cost of acquiring the drug if the provider does not accept "brown bagging."

RECOMMENDATIONS

The Council on Medical Service recommends that the following be adopted in lieu of Resolution 827-I-15, and the remainder of the report be filed:

1. That our American Medical Association (AMA) reaffirm Policy H-330.884, which advocates for the preservation of physician and patient access to office-administered drugs. (Reaffirm HOD Policy)

2. That our AMA reaffirm Policy D-330.960, which supports Medicare payments that fully cover the costs of physician acquisition, inventory and administration of office-administered drugs, and also calls for working with relevant national medical specialty societies to ensure adequate physician payment for Medicare Part B drugs and patient access to biologic and pharmacologic agents. (Reaffirm HOD Policy)

3. That our AMA affirm that decisions to accept or refuse "brown bagged" (patient-acquired, physician-administered) pharmaceuticals be made only by physicians responsible for administering these medications. (New HOD Policy)

4. That our AMA affirm that "brown bagged" pharmaceuticals be accepted for in-office or hospital administration only after the physician responsible for administering these medications determines that the individual patient, or his or her agent, is fully capable of safely handling and transporting the medication. (New HOD Policy)

5. That our AMA work with interested national medical specialty societies and state medical associations to oppose third party payer policies and legislative and regulatory actions that require patients to utilize "brown bagging" to ensure coverage of office-administered medications. (New HOD Policy)

6. That our AMA work with interested national medical specialty societies and state medical associations to oppose third party payer policies that reimburse office-administered drug costs at less than the provider's cost of acquiring the drug if the provider does not accept "brown bagging." (New HOD Policy)

Fiscal Note: Less than $500.

REFERENCES

[1] American Academy of Dermatology and AAD Association. Position Statement on Patient Access to Affordable Treatments. 2015. Available online at: https://www.aad.org/forms/policies/Uploads/PS/PS%20-%20Patient%20Access%20to%20Affordable%20Treatments.pdf.
[2] Robinson, JC and Howell, S. Specialty Pharmaceuticals: Policy Initiatives to Improve Assessment, Pricing, Prescription, and Use. *Health Affairs*, 33, no. 10 (2014):1745-1750. Available online at: http://content.healthaffairs.org/content/33/10/1745.full.pdf.
[3] Polite, BN, Ward, JC, Cox, JV et al. Payment for Oncolytics in the United States: A History of Buy and Bill and Proposals for Reform. *Journal of Oncology Practice*. Volume 10, Issue 6, November 2014.
[4] 2013 Updated American Society of Clinical Oncology/Oncology Nursing Society Chemotherapy Administration Safety St andards Including Standards for the Safe Administration and Management of Oral Chemotherapy. *Journal of Oncology Practice*. Volume 9, Issue 2, Supplement to March 2013.
[5] Ohio State Medical Association. Government Relations Statehouse Update: Lawmakers Take a Summer Break. Ohio Medicine. 2014 – Issue 2, Page 6. Available online at: https://www.osma.org/Documents/Public-Affairs/Publications/Ohio-Medicine/Ohio-Medicine-2014-Issue-2.pdf