



ARROWHEAD REGIONAL MEDICAL CENTER
Department of Pharmacy Services Policies and Procedures

POLICY NO 9.11 Issue 1
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SECTION: PHARMACEUTICAL PURCHASING

SUBJECT: EXTERNAL SUPPLIED MEDICATIONS

APPROVED BY: _____
Director of Pharmacy Services

PURPOSE

The responsibility and accountability for acquiring and purchasing medications resides solely with the Arrowhead Regional Medical Center (ARMC) department of pharmacy services to ensure the legitimacy of original drug source and the appropriateness of subsequent storage and handling.

ARMC will not administer any drug to a patient that ARMC does not purchase directly from either the manufacturer or an accredited wholesaler. Exceptions include patient assistance and patient teaching, as defined below.

PERSONNEL

- Clinical Staff

BACKGROUND

Brown bagging can negatively impact the safety and effectiveness of a medication due to loss of control over drug provenance and purity, as well as conditions of storage. White bagging has been associated with errors including delivery delays, dosage errors, and waste (because when white bagged medication cannot be used by the intended recipient, for any reason, the provider is prohibited from using the medicine for another patient). Both practices increase risk and liability to the patient and to the hospital

POLICY

- Sterile and non-sterile medications dispensed, compounded and administered in an ARMC outpatient or clinic setting must be procured by ARMC pharmacy, via an approved manufacturer or a DDA (formerly VAWD) accredited wholesaler in order to ensure quality, safety, and chain of custody of the medication, consistent with the DSCSA.
- Brown bagging of injected and infused medications in the hospital outpatient or clinic setting at ARMC is prohibited, except for self-administered medications for patient education and in the case of patient assistance.
- White bagging of injected and infused medications in the hospital outpatient or clinic setting is prohibited. If the patient’s insurance requires white bagging, ARMC pharmacy will try to obtain insurance approval for ARMC pharmacy to procure, compound, and dispense the medication to the patient.

PROCEDURE

N/A

REFERENCE AND RELATED DOCUMENTATION:

- U.S. Food & Drug Administration (FDA), Drug Supply Chain Security Act (DSCSA)
 - <https://www.fda.gov/drugs/drug-supply-chain-integrity/drug-supply-chain-security-act-dscsa>
- American Society of Hospital Pharmacists, ASHP Statement on Pharmacist's Responsibility for Distribution and Control of Drug Products
 - <https://www.ashp.org/-/media/assets/policy-guidelines/docs/statements/pharmacists-responsibility-distribution-control-drug-products.pdf>
- American Society of Clinical Oncology, "Brown Bagging" and "White Bagging" of Chemotherapy Drugs
 - <https://society.asco.org/sites/new-www.asco.org/files/content-files/advocacy-and-policy/documents/2021-White-Brown-Bagging-Update.pdf>
- Children's Hospital Association, Does White Bagging Pose a Risk to Patient Safety?
 - <https://www.childrenshospitals.org/news/childrens-hospitals-today/2020/03/does-white-bagging-pose-a-risk-to-patient-safety>
- Community Oncology Alliance, White & Brown Bagging Position Statement (September 19, 2017)
 - <https://communityoncology.org/wp-content/uploads/2019/09/COA-White-Brown-Bagging-PosStmnt-Final.pdf>

DEFINITIONS:

- **Brown Bagging** – A practice where medication procured from an external pharmacy is dispensed directly to a patient and brought by the patient to a hospital outpatient or clinic setting for administration.
- **DDA (Drug Distributor Accreditation)** – Accreditation of facilities engaged in the act of wholesale drug distribution that demonstrate they meet specified standards for operation, licensure, and compliance to the satisfaction of the National Association of Boards of Pharmacy.
- **DSCSA (Drug Supply Chain Security Act)** – A federal law enacted in 2013 to enhance the U.S. Food & Drug Administration's (FDA) ability to protect consumers by improving detection and removal of potentially dangerous products from the pharmaceutical supply chain. The law requires hospital pharmacy chain of custody and end-to-end product traceability ("track and trace") for medications from manufacturer to patient.
- **Patient Assistance** – A program to help people with no health insurance and those who are underinsured to afford their medications.
- **Patient Medication Teaching** – The practice of training a patient how to use a medication the most appropriately. This generally encompasses injection training, and/or other complex therapies. This would be a one-time exception.
- **White Bagging** – A practice where a patient-specific medication is procured from an external pharmacy (e.g., a national specialty pharmacy owned by or contracted with a patient's health insurance plan) and delivered to the hospital outpatient or clinic setting for compounding and patient administration.

ATTACHMENTS: N/A

APPROVAL DATE:

<u>9/19/24</u>	Theo Moy, Director of Pharmacy Department/Service Director, Manager or Supervisor
<u>9/19/24</u>	Pharmacy and Therapeutics Committee Applicable Administrator, Hospital or Medical Committee
<u>10/16/24</u>	Quality Management Committee Applicable Administrator, Hospital or Medical Committee
<u>10/24/24</u>	Medical Executive Committee Applicable Administrator, Hospital or Medical Committee
	Board of Supervisors Approved by the Governing Body

REPLACES: N/A

EFFECTIVE: 10/24/24

REVISED: N/A

REVIEWED: N/A