

# Use of Externally Supplied Medications in UC Outpatient and Clinic Settings

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Scope:	This policy applies to all hospital outpatient and clinic settings throughout the University of California system.

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## I. POLICY SUMMARY

The responsibility and accountability for purchasing, mixing, and administering injectable medications resides solely with University of California Health System ("UC Health") pharmacists, and the physicians, nurses, and physician assistants who

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administer the drugs. The legitimacy of original drug source and appropriateness of subsequent storage and handling must be assured by UC Health. Accordingly, UC Health will not administer any drug to a patient that UC Health does not purchase directly from either the manufacturer or an accredited wholesaler. Exceptions include patient assistance and patient teaching, as defined below.

#### II. 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 UC Health 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 a UC Health hospital outpatient or clinic setting for compounding and patient administration.

#### III. POLICY TEXT

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, lost shipments, and dosage errors; 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); and compromised patient safety. Both practices also result in increased risk and liability to the University's clinical locations and prescribing clinicians. Accordingly:

 Sterile and non-sterile medications dispensed, compounded and administered in a UC Health outpatient or clinic setting must be procured by UC, via an approved

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- 2. Brown bagging of injected and infused medications in the hospital outpatient or clinic setting at UC Health is prohibited, except for self-administered medications for patient education and in the case of patient assistance.
- 3. White bagging of injected and infused medications in the hospital outpatient or clinic setting is prohibited. If the patient's insurance requires white bagging, UC will try to obtain insurance approval to for the UC pharmacy to procure, compound and dispense the medication to the patient.

#### IV. COMPLIANCE / RESPONSIBILITIES

The Chief Pharmacy Officer or equivalent at every UC Health clinical location shall be responsible for implementing this policy locally.

#### V. PROCEDURES

Not applicable.

### VI. RELATED INFORMATION

U.S. Food & Drug Administration (FDA), <u>Drug Supply Chain Security Act (DSCSA)</u>

American Society of Hospital Pharmacists, <u>ASHP Statement on Pharmacist's</u> <u>Responsibility for Distribution and Control of Drug Products</u>

American Society of Clinical Oncology, <u>"Brown Bagging" and "White Bagging" of Chemotherapy Drugs</u>

Children's Hospital Association, Does White Bagging Pose a Risk to Patient Safety?

Community Oncology Alliance, *White & Brown Bagging Position Statement* (September 19, 2017)

#### VII. FREQUENTLY ASKED QUESTIONS

Not applicable

#### VIII. REVISION HISTORY

TBD:

**11/30/2020**: New policy issuance date. This interim policy meets the Web Content Accessibility Guidelines (WCAG) 2.0.