

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

Responsible Officer:	Executive Vice President for UC Health
Responsible Office:	UC Health
Issuance Date:	12/10/2024
Effective Date:	01/01/2025
Scope:	This policy applies to all hospital outpatient, inpatient 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 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<sup>1</sup> 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, Patient Medication Teaching, and Catastrophic Events, as defined below.

<sup>&</sup>lt;sup>1</sup> Does not include UC Affiliates

## II. DEFINITIONS

Administer: To dispense or apply a medication or therapy.

**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.

**Catastrophic Event**: A natural or man-made incident that causes widespread damage, loss or disruption to the drug supply chain.

**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:

- 1. Sterile and non-sterile medications dispensed, compounded and Administered in a UC Health outpatient or clinic setting<sup>2</sup> must be procured by UC, 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.
- 2. Brown Bagging of medications in the hospital, outpatient or clinic setting at UC Health is prohibited, except for self-administered medications for patient education

<sup>&</sup>lt;sup>2</sup> Dental and Veterinary Clinics are excluded from this Policy

and in the case of patient assistance.

- 3. White Bagging of 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 for the UC pharmacy to procure, compound, and dispense the medication to the patient.
- 4. If UC is unable to obtain the medication and patient care is at risk, these cases will be reviewed by the Chief of Pharmacy, or designee, at the site on a case-by-case basis.
- 5. Patients taking their own medications during a clinic or outpatient encounter do not fall under this policy. For example, if a patient is seeing their physician and it is time for their medication dose or time to provide themselves insulin for their meal, this policy does not apply. Only medications procured and Administered to the patient during the course of their care are applicable.

## 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), Drug Supply Chain Security Act (DSCSA)

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

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

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

<u>Community Oncology Alliance, White & Brown Bagging Position Statement (September 19, 2017)</u>

## VII. FREQUENTLY ASKED QUESTIONS

Not applicable

#### VIII. REVISION HISTORY

**12/10/2024**: Revisions include the addition of valid exceptions and exclusions to the Policy, additional defined terms, and clarification of language for consistency. The policy is also no longer interim.

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