



August 5, 2024

University of California Health
1111 Franklin Street
Oakland, CA 94607

health.universityofcalifornia.edu

ACADEMIC HEALTH CENTERS

UC Davis Health
UC Riverside Health
UC San Diego Health
UCI Health
UCLA Health
UCSF Health

HEALTH PROFESSIONAL SCHOOLS

Schools of Dentistry
Schools of Medicine
Schools of Nursing
Schools of Optometry
Schools of Pharmacy
Schools of Public Health
School of Veterinary Medicine

INSTITUTES

Global Health Institute

CHANCELLORS
ACADEMIC COUNCIL CHAIR STEINTRAGER
LABORATORY DIRECTOR WITHERELL
ANR VICE PRESIDENT HUMISTON

Re: Systemwide Review of Proposed Presidential Policy: Externally Supplied Medications in UC Outpatient and Clinic Settings

Dear Colleagues:

Enclosed for systemwide review are proposed revisions to Presidential Policy Externally Supplied Medications in UC Outpatient and Clinic Settings.

DSCSA, a federal law enacted in 2013, requires hospital pharmacies to keep track of the chain of custody and end-to-end product traceability (“track and trace”) for medications from the point of creation at the manufacturer to administration/dispensing to a patient. Since the law was implemented, UC pharmacy has worked to improve policies to ensure that medications can be tracked throughout their entire life cycle. One way that drugs have entered our system, outside of the usual purchasing procedure, is through a process called White Bagging, which is when a medication is sent over from an outside pharmacy contracted with the patient’s insurance plan. This process doesn’t allow UC to track the medication, and it can also lead to delays in patient care and wastage if the patient no longer needs the therapy. In 2020, UC created an interim policy to decrease this process, and other types of externally supplied medications, and after assessing our system status, UC pharmacy is ready to move to a full review of this policy. Having a policy in place allows UC to use our system leverage with insurers to find alternative mechanisms for procuring these medications for our patients that both follow the regulations and provide for patient care in the safest and most cost-effective way. Exceptions to the policy were included for medications received for patient first time education and in the case of patient assistance programs. This updated policy has been approved by all our Chief Pharmacy Officers.

Systemwide Review

Systemwide review is a public review distributed to the Chancellors, the Chair of the Academic Council, the Director of the Lawrence Berkeley National Laboratory, and the Vice President of Agriculture and Natural Resources requesting that they inform the general University community, especially affected employees, about policy proposals. Systemwide review also includes a mandatory, 90-day full Senate review.

Employees should be afforded the opportunity to review and comment on the draft policy. Attached is a Model Communication which may be used to inform non-exclusively represented employees about these proposals. The Labor Relations Office at the Office of the President is responsible for informing the bargaining units representing union membership about policy proposals.

We would appreciate receiving your comments no later than **November 4, 2024**. Please submit your comments to julianna.burton@ucop.edu. If you have any questions, please contact Julianna Burton at julianna.burton@ucop.edu.

Sincerely,

DocuSigned by:
David M Rubin
D880668F622246E...

David Rubin
Executive Vice President

Enclosures:

- 1) Draft Presidential Policy Externally Supplied Medications in UC Outpatient and Clinic Settings (clean copy)
- 2) Draft Presidential Policy Externally Supplied Medications in UC Outpatient and Clinic Settings (tracked-changes copy)
- 3) Model Communication

cc: President Drake
Provost and Executive Vice President Newman
Executive Vice Chancellors/Provosts
Executive Vice President and Chief Operating Officer Nava
Senior Vice President Bustamante
Vice President and Vice Provost Gullatt
Vice President and Chief of Staff Kao
Vice President Lloyd
Vice President Maldonado
Vice President Nelson
Vice Provosts/Vice Chancellors of Academic Affairs/Personnel
Deputy Provost Lee
Associate Vice President Matella
Deputy General Counsel Woodall
Assistant Vice Provosts/Vice Chancellors for Academic Personnel

Deputy Chief HR Officer and Chief of Staff Henderson
Executive Director Lin
Chief of Staff Beechem
Chief of Staff Levintov
Chief Policy Advisor McAuliffe
Director Anders
Director Chin
Director Weston-Dawkes
Associate Director Dicaprio
Associate Director Garcia
Associate Director Soria
Associate Director Teaford
Associate Director Woolston
Assistant Director LaBriola
Manager Crosson
Policy Analyst Durrin
Administrative Officer Babbitt
Vice President Zoanne Nelson
Policy Advisory Committee
Julianna Burton, Policy Owner



Use of Externally Supplied Medications in UC Outpatient and Clinic Settings

Responsible Officer:	Executive Vice President for UC Health
Responsible Office:	UC Health
Issuance Date:	07/01/24
Effective Date:	01/01/2025
Last Review Date:	11/30/2020
Scope:	This policy applies to all hospital outpatient and clinic settings throughout the University of California system.

Contact:	Julianna Burton
Title:	Dir, Amcare Pharmacy
Email:	julianna.burton@ucop.edu
Phone:	(510)987-0618

TABLE OF CONTENTS

I. POLICY SUMMARY	1
II. DEFINITIONS	2
III. POLICY TEXT	2
IV. COMPLIANCE / RESPONSIBILITIES.....	3
V. PROCEDURES	3
VI. RELATED INFORMATION.....	3
VII. FREQUENTLY ASKED QUESTIONS	3
VIII. REVISION HISTORY	3

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 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:

1. 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

University of California – Policy on White Bagging and Brown Bagging

Use of Externally Supplied Medications in UC Outpatient and Clinic Settings

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 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), [Drug Supply Chain Security Act \(DSCSA\)](#)

American Society of Hospital Pharmacists, [ASHP Statement on Pharmacist’s Responsibility for Distribution and Control of Drug Products](#)

American Society of Clinical Oncology, [“Brown Bagging” and “White Bagging” of Chemotherapy Drugs](#)

[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.



Use of Externally Supplied Medications in UC Outpatient and Clinic Settings

Responsible Officer:	Executive Vice President for UC Health
Responsible Office:	UC Health
Issuance Date:	07/01/24
Effective Date:	01/01/2025
Last Review Date:	11/30/2020
Scope:	This policy applies to all hospital outpatient and clinic settings throughout the University of California system.

Contact:	Julianna Burton
Title:	Dir, Amcare Pharmacy
Email:	julianna.burton@ucop.edu
Phone:	(510)987-0618

TABLE OF CONTENTS

I. POLICY SUMMARY.....	1
II. DEFINITIONS.....	2
III. POLICY TEXT	2
IV. COMPLIANCE / RESPONSIBILITIES.....	3
V. PROCEDURES	3
VI. RELATED INFORMATION.....	3
VII. FREQUENTLY ASKED QUESTIONS	3
VIII. REVISION HISTORY	3

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

University of California – Policy on White Bagging and Brown Bagging
Use of Externally Supplied Medications in UC Outpatient and Clinic Settings

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:

1. 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

University of California – Policy on White Bagging and Brown Bagging

Use of Externally Supplied Medications in UC Outpatient and Clinic Settings

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 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), [Drug Supply Chain Security Act \(DSCSA\)](#)

American Society of Hospital Pharmacists, [ASHP Statement on Pharmacist's Responsibility for Distribution and Control of Drug Products](#)

American Society of Clinical Oncology, ["Brown Bagging" and "White Bagging" of Chemotherapy Drugs](#)

[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.

MODEL COMMUNICATION

The University of California Office of the President invites comments on a proposed Presidential Policy Use of Externally Supplied Medications in UC Outpatient and Clinic Settings. The policy is proposed to be revised and includes the following key issues:

- DSCSA is a federal law that requires UC to be able to track and trace all medications given to patients. Currently, there are medications coming into our UC system that we can't track and trace because they are externally supplied by outside pharmacies. This policy would ban the use of medications that were externally supplied outside of our contracted distributors.
- UC has identified that externally supplied medications not only go against the DSCSA, but also lead to gaps in patient care and wastage of medication.
- Rare exceptions to this policy exist in cases of first time patient education and in patient assistance programs.

If you have any questions or if you wish to comment, please contact _____ at _____, no later than _____, 2024.