

White Bagging/Brown Bagging/Clear Bagging of Controlled Substances – What the Future Holds

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Learning Objectives

- Define key terms “white bagging” and “brown bagging” as related to distribution of clinician-administered drugs
- Discuss unique challenges to maintaining patient safety, access to care, and regulatory compliance that can arise from payer-driven white and brown bagging
- Review regulatory aspects of white and brown bagging in relation to dispensing controlled substances

Clinician-Administered Drug Defined

- An outpatient drug that cannot be reasonably self-administered by the patient to whom the drug is prescribed and is typically administered by a health care provider in a clinical setting
- Alternatively known as “physician-administered drugs” or “provider-administered drugs”

Traditional Drug Acquisition Process

- Hospital or clinic buys bulk drug from a wholesaler, then stores and prepares drugs for administration as needed
- Payer reimburses the provider for costs associated with both acquisition and administration of the drug
- Process is commonly known as “**buy-and-bill**”

What Is White Bagging?

- An external pharmacy that is not under common ownership with the administering practitioner purchases, dispenses and delivers a clinician-administered drug directly to the practitioner for administration
 - The dispensing pharmacy is reimbursed for drug cost and provider is reimbursed for administration
- White bagging is typically **payer-mandated**, meaning the health plan requires the drug to be distributed exclusively from a plan-designated pharmacy and reimbursement for drugs acquired via buy-and-bill is excluded

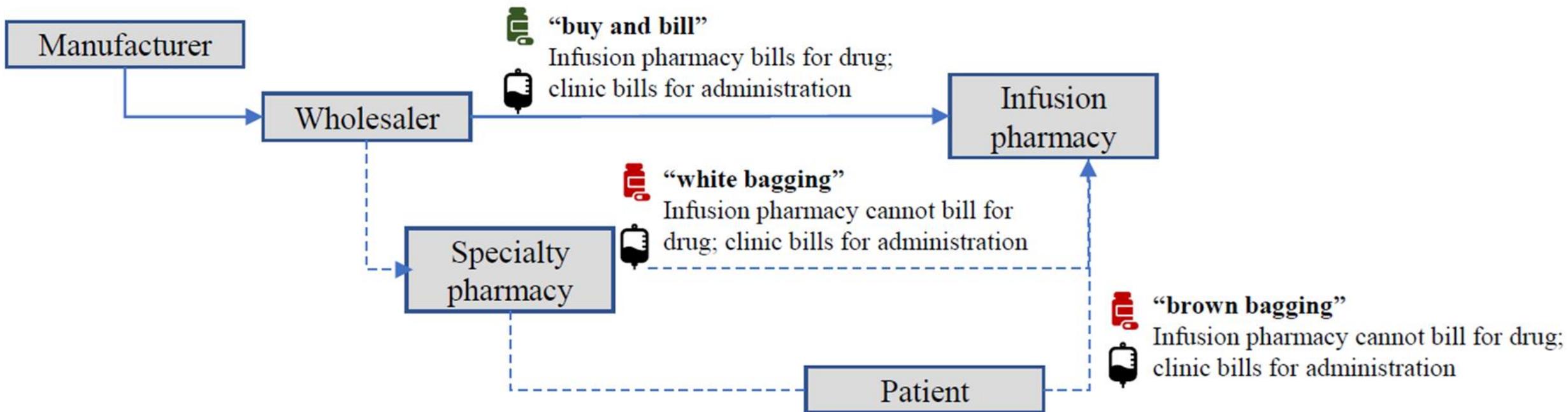
What Is Brown Bagging?

- A pharmacy dispenses a prescription for a non-self-administered drug directly into the patient's custody
- Patient is responsible for proper storage, handling, and transportation to practitioner location for administration

What Is Clear Bagging?

- A specialty pharmacy and provider under shared common ownership coordinate distribution of clinician-administered drugs
- Pharmacy is reimbursed for drug
- Provider is reimbursed for administration

Drug Distribution Models



Why Do Payers Want to White Bag?

- **Steer reimbursable services to affiliate entities**
- Shift costs onto providers
- Increase manufacturer price concessions
- Tighten controls on drug utilization

Vertical Business Relationships Among Insurers, PBMs, Specialty Pharmacies, and Providers, 2022



1. In September 2022, CVS Health announced its acquisition of Signify Health. The transaction is expected to close in 2023.
 2. Since January 2021, Prime’s Blue Cross and Blue Shield plans have had the option to use Express Scripts or AllianceRx Walgreens Prime for mail and specialty pharmacy services. On Dec. 31, 2021, Walgreens purchased Prime Therapeutics’ 45% ownership interest in AllianceRx Walgreens Prime, so this business has no PBM ownership in 2022. Effective June 2022, the company has been known as AllianceRx Walgreens Pharmacy.
 3. In 2021, Centene has announced its intention to consolidate all PBM operations onto a single platform and outsource its PBM operations to an external company.
 4. In 2021, Centene sold a majority stake in its U.S. Medical Management to a group of private equity firms.
 5. Since 2020, Prime has sourced formulary rebates via Ascent Health Services. In 2021, Humana began sourcing formulary rebates via Ascent Health Services for its commercial plans.
 6. Cigna also partners with providers via its Cigna Collaborative Care program.
 7. In 2022, Humana announced an agreement to divest its majority interest in Kindred at Home’s Hospice and Personal Care Divisions to Clayton, Dubilier & Rice. In 2022, Kindred at Home was rebranded as CenterWell Home Health.
 Source: [The 2022 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers](#), Exhibit 212. Companies are listed alphabetically by insurer name. Published on *Drug Channels* (www.DrugChannels.net) on October 13, 2022.



Clinician-Administered Drugs & The Controlled Substances Act

Key CSA Definitions

- **"distribute"** means to deliver (other than by administering or dispensing) a controlled substance or a listed chemical. ¹
- **"administer"** refers to the direct application of a controlled substance to the body of a patient or research subject by-
 - (A) a practitioner (or, in his presence, by his authorized agent), or
 - (B) the patient or research subject at the direction and in the presence of the practitioner²

1. [21 U.S.C. § 802 \(11\)](#)

2. [Id. § 802 \(2\)](#)

Key CSA Definitions

- **“dispense”** means to deliver a controlled substance to an ultimate user or research subject by, or pursuant to the lawful order of, a practitioner, including the prescribing and administering of a controlled substance and the packaging, labeling or compounding necessary to prepare the substance for such delivery.¹
- **“ultimate user”** means a person who has lawfully obtained, and who possesses, a controlled substance for his own use or for the use of a member of his household or for an animal owned by him or by a member of his household.²

1. [21 U.S.C. § 802 \(10\)](#)

2. [Id. § 802 \(27\)](#)

SUPPORT Act Amendment

- Original CSA statute prohibits pharmacies from dispensing a controlled substance prescription to anyone other than an ultimate user
 - This means a pharmacy cannot dispense a patient-specific prescribed controlled substance directly to another pharmacy or practitioner
- The SUPPORT Act of 2018 amended the CSA by establishing a limited exception to allow a pharmacy to dispense a prescribed clinician-administered controlled substance to a practitioner's office for the purpose of medication assisted treatment (MAT) for opioid use disorder (OUD)

SUPPORT Act Exemption

- A pharmacy is allowed to dispense prescribed narcotic drugs in schedule III, IV or V to a qualifying practitioner under the following conditions:
 - The medication is utilized as MAT
 - The practitioner must administer the drug to the patient named on the prescription **by implantation or injection** within 14 days of receipt
 - Dispensing and administration of the drug is done in accordance with state law
 - The prescribing practitioner and administering practitioner maintain complete and accurate records of all controlled substances delivered, received, administered, and disposed including the persons to whom controlled substances were delivered

CSA Restrictions Summary

- Pharmacies may not white bag prescriptions for controlled substances
 - Except for injected or implanted CIII-CV drugs utilized for treatment of opioid use disorder or;
 - Other limited distribution CIII-CV medications that have obtained a DEA waiver
- CSA does not prohibit brown bagging of controlled substances
 - Brown bagged drugs are dispensed to the “ultimate user”

CSA Restrictions Summary

Permitted

- Registered wholesaler or manufacturer distributes FDA-approved controlled substance to a registrant in original packaging for general use (buy-and-bill)
- In-house pharmacy provides a controlled substance for administration pursuant to a valid prescription order (clear bagging)
- An external pharmacy dispenses a clinician-administered controlled substance prescription directly to the patient (brown bagging)

Not Permitted

- An external pharmacy dispenses a non-MAT controlled substance prescription directly to the administering practitioner (white bagging)
- An external pharmacy dispenses a prescription for methadone (CII) or self-administered MAT directly to the administering practitioner

REMS Exemptions

- Risk Evaluation and Mitigation Strategies (REMS) are designed and implemented during the development and marketing of a pharmaceutical product to ensure an acceptable risk-to-marketing benefit ratio for products that are known to pose risks of harm including addiction and diversion
- REMS programs for non-self-administered drugs may prohibit dispensing the drug directly into the patient's custody
 - If the drug is a controlled substance, a DEA waiver will be required to permit delivery from a REMS-certified pharmacy to a practitioner

REMS Example: Spravato

- Spravato (esketamine) is a CIII nasal spray indicated for treatment-resistant depression in adults
- FDA guidance requires Spravato to be administered in a clinic setting under direct medical supervision
- Spravato is distributed through REMS-certified pharmacies
- The manufacturer (Janssen) obtained a waiver from DEA permitting practitioners to receive Spravato prescriptions from certified pharmacies

Policy Considerations

- Discourage utilization of brown bagging as an alternative to buy-and-bill
- Ensure payer white bagging policies are compliant with DEA regulation for white bagging of controlled substances
- Confirm state law allows pharmacy-to-practitioner distribution for REMS drugs and medication assisted treatment as permitted by Federal law

