

# Drug Brown and White Bagging; what is it and where does it Lead Us?



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Assistant Vice President - System Oncology Pharmacy Service Line  
Baptist Health South Florida

# Learning Objectives

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- Define clear, brown and white bagging
- Describe quality, safety and chain of custody concerns associated with brown and white bagging
- Review provider and professional organization advocacy aims
- Describe emerging state regulation

# Definitions

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## **Brown Bagging**

Dispensing a patient-specific medication from health plan's preferred pharmacy directly to a patient, who then transfers the medication(s) to a medical practice for administration

# Definitions

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## White Bagging

Distribution of patient-specific medication from health plan's preferred pharmacy, to the physician's office, hospital, or clinic for administration.

# Definitions

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## Clear Bagging

Distribution of patient-specific medication from provider pharmacy under common ownership to the physician's office, hospital, or clinic for administration.

# Background

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## White Bagging Introduces the Following Concerns:

Supply chain integrity

Bypasses clinical and operational safety checks

Systematic treatment delays

Reduced ability to tailor treatment at point of care

Increased and largely unmitigated clinical and economic burdens

1. 21 CFR 208.3 Definitions. Legal Information Institute. Accessed August 22, 2021 <https://www.law.cornell.edu/cfr/text/21/208.3>

2. How Boards of Pharmacy are Addressing White and Brown Bagging. National Association of Boards of Pharmacy. August 11, 2021

# Definitions

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## Dispense

*Act of delivering a prescription drug product to a patient or an agent of the patient*

1. Can the patient's provider(s) serve in the capacity of agent?
2. Some dispensed white bagged drugs require sterile compounding or reconstitution before dispensation; is it lawful to manipulate and re-label a previously dispensed prescription?

## Distribute

*Act of delivering, other than by dispensing, a drug product to any person*

# Definitions

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**“Dispensed”** patient-specific medications are property of the patient

Administering provider never takes formal ownership of medication

1. *Receive*
2. *Handle*
3. *Return*
4. *Waste*
5. *Recalls*

# Definitions

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## Adulterated Drug

Deemed such if it consists in whole or in part of any filthy, putrid, or decomposed substance

1. Burden of responsibility for drugs that become adulterated as a result of mishandling?
  1. Drug replacement
2. Hospitals can't determine if drugs are counterfeit, diverted, stolen, adulterated, or fraudulent
  1. No transaction history
  2. No transaction statement
  3. No invoices
  - Increasing risk as “suspect” drug
  - How does provider exercise due diligence?

1. 21 CFR 208.3 Definitions. Legal Information Institute. Accessed August 22, 2021 <https://www.law.cornell.edu/cfr/text/21/208.3>

2. How Boards of Pharmacy are Addressing White and Brown Bagging. National Association of Boards of Pharmacy. August 11, 2021

# Background

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Are plan-mandated white bagging pharmacies functioning as unregistered distributors and bypassing security controls required by the Drug Supply Chain Security Act (DSCSA)?

- track and trace requirements
- secure product integrity during handoffs

*Escalated to the FDA*

# Background

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Many boards of pharmacy require pharmacies under common ownership to demonstrate policies and procedures outlining safe practices for dispensing, distribution, and transporting drugs from one pharmacy to another

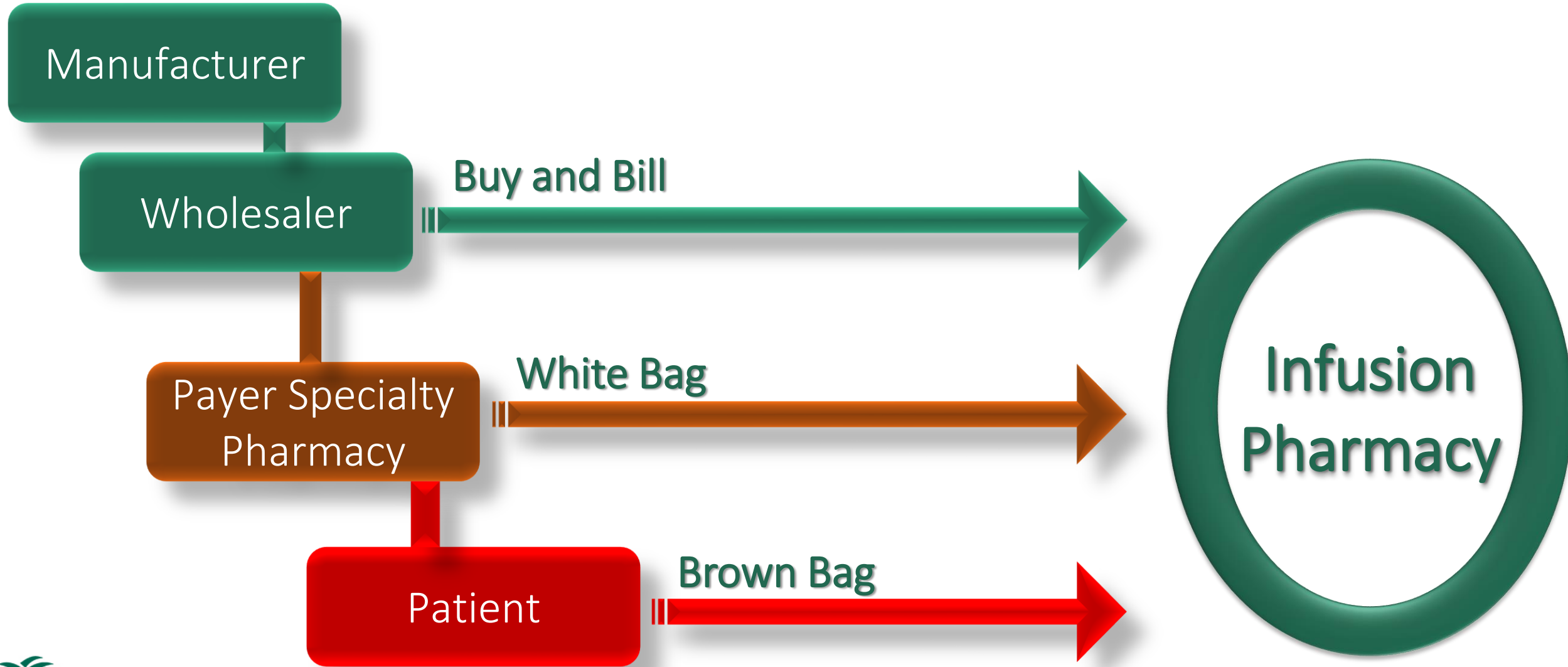
Florida Class III Institutional Pharmacy Permit

These requirements do not extend to dispensing of drugs between pharmacies that are not under common ownership

1. *21 CFR 208.3 Definitions*. Legal Information Institute. Accessed August 22, 2021 <https://www.law.cornell.edu/cfr/text/21/208.3>
2. *How Boards of Pharmacy are Addressing White and Brown Bagging*. National Association of Boards of Pharmacy. August 11, 2021

# Background

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# Vertical Business Relationships Among Insurers, PBMs, Specialty Pharmacies, and Providers, 2021



1. Cigna partners with providers via its Cigna Collaborative Care program. However, Cigna does not directly own healthcare providers.  
2. AllianceRx Walgreens Prime is jointly owned by Prime Therapeutics and Walgreens Boots Alliance.  
3. Since 2020, Prime sources formulary rebates via Ascent Health Services. In 2021, Humana began sourcing formulary rebates via Ascent Health Services for its commercial plans.  
Source: Drug Channels Institute research; Companies are listed alphabetically by insurer name.

This chart appears as Exhibit 210 in *The 2021 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers*. Available at <http://drugch.nl/pharmacy>

# Health Plans Recent White Bagging Mandates

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Health Plan	Mandate*
BCBS of TN	Required for all provider-administered specialty drugs
Aetna	Required for certain checkpoint inhibitors when administered in HOPD** setting
Anthem Blue Cross CA	Required for specialty medications for Medicaid HMO beneficiaries. Then expanded to all PPO plans
Cigna	Required for specialty drugs administered in HOPD
United Healthcare	Required for an additional 13 specialty drugs added to list requiring external sourcing
Many others	

\* Taking effect in 2020 or 2021 \*\* HOPD = Hospital-Based Outpatient Department

1. *Responding to White Bagging Requirements. Advisory Board. 2021*

# Health Plans Recent White Bagging Mandates

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Health Plan	Mandate
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BCBS of TN	<ul style="list-style-type: none"><li>○ Effective July 1, 2020</li><li>○ Provider administered drugs must be externally sourced (except select chemo protocols)</li><li>○ 72% market share in TN</li><li>○ 91 self-funded plans impacted</li><li>○ Patient cases receiving both buy-and-bill and clear bagged drugs</li></ul>
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# White Bagging Prevalence

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## HOPD Report White Bagging:

<b>13%</b>	almost daily
<b>29%</b>	a few times per week
<b>33%</b>	a few times per month
<b>8%</b>	once a month
<b>17%</b>	never

*Survey; 24 individuals, 20 unique health systems, 18 unique states.*

HOPD = Hospital-Based Outpatient Department

1. *How Boards of Pharmacy are Addressing White and Brown Bagging.* National Association of Boards of Pharmacy. August 11, 2021

# Polling Question

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Is your institution currently experiencing any payer-mandated drug bagging requirements?

A) Yes

B) No

# Impact Scope

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Academic medical centers

Community hospitals

Critical access / rural hospitals

Pediatric hospitals

Cancer centers

Independent infusion centers

Physician clinics

Rehabilitation centers

# Patient Cases

*Pegfilgrastim  
for oncology  
patient arrives 2  
days after  
treatment due  
date*

Baptist Health

*Health Plan sends  
peginterferon alfa 2a  
to patient's home for  
self-administration*

Baptist Health

*Health Plan and provider  
discussions regarding  
white bagging appeal  
process delay care  
resulting in patient  
seeking care at different  
health system*

Baptist Health

*Health Plan arranged  
for patient to receive  
pegfilgrastim-cbqv  
under home health  
arrangement*

Baptist Health

*Health Plan arranged  
pegfilgrastim home  
treatment but home  
health company did  
not show*

Health System

# Patient Cases

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*Health Plan arranged shipment of IVIG via UPS, shipment delayed, product deemed unusable at time of arrival. Patient treatment delayed*

Wolfson Children's

*Provider to Health Plan communication burden and barriers leading to crizanlizumab patient treatment delays*

Wolfson Children's

*Health Plan held shipment until collecting patient copay delaying crizanlizumab treatment by two weeks*

Wolfson Children's

*Multiple cases of lab and/or weight driven changes rendering payer delivered dose suboptimal/inappropriate day of treatment.*

Wolfson Children's

# Patient Cases

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*Pediatric Remicade  
delay resulting in  
hospital admission.*

Lee Health

*Pediatric  
Corticotropin Gel  
delay resulting in  
prolonged patient  
admission (by 2  
days)*

Lee Health

*Patient treatment  
discontinued while  
drug has already  
shipped*

Jackson Health

**Payer Cost Savings  
Initiative**

**Higher Utilization  
of Health Care  
Resources**

**Increased cost to  
whom?**

# Fragmentation of Care

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## Access to Patient's EMR

- ↑ care coordination
- ↑ resources
- ↑ delays
- ↓ safety

## Medication Delivery

- ↑ Drug transit time
- ↑ Potential incorrect delivery location within facility
- ↑ Potential for product integrity damage

# Fragmentation of Care

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## Patient Dose Modification or Cancellation

- Common among various patient populations
- Lack of ability to re-manipulate the compound
- Patient specific drug; cannot use on another patient
- Patients often change appointments

# Operational Barriers

## Medication Procurement | Administration

- Little-to-no notice to provider
- Tracking and keeping record of patient-specific doses
  - Procuring from multiple sources
- Care coordination
- Increase patient
- Provider can't
- Provider can't
- Provider conditioned successful to patient's responsibilities

*Imagine a restaurant where everyone with a reservation has sent bags and boxes of raw food and ingredients from numerous vendors for the restaurant's staff to prepare and cook for each specific client*

Rita Shane, PharmD, FASHP, FCSHP

# Operational Barriers

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## Drug Authorization

- Pharmacy staff rarely responsible for provider-administered drug authorization
  - 50% prior auth team
  - 29% infusion center or clinic staff
  - 8% pharmacy

1. *White and Brown Bagging Emerging Practices, Emerging Regulation*. The National Association of Boards of Pharmacy (NABP). April 2018

2. *How Boards of Pharmacy are Addressing White and Brown Bagging*. National Association of Boards of Pharmacy. August 11, 2021

# Operational Barriers

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## Charge Integrity

- “Redispensing” a drug billed by a different pharmacy
- Potential unintended double-billing to patient
- Charge-on-dispense vs. charge-on-administration
- Reverse charges
- Monthly audit for compliance
- Potential for charged co-pays for drugs not received due to shipping errors, treatment changes, cancellations, etc.

# Operational Barriers

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## Storage | Inventory

- Manage separate inventory
- Unable to return unused product to originating specialty pharmacy
  - Patient no shows
  - Patient clinical status change calling for dose adjustments
- Waste handling
- Drug disposal record keeping (e.g., chart documentation)

# Operational Barriers

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## Increased Operating Cost | Uncompensated Services

Provider must:

- Receive drug
- Store drug
- Compound drug
- Coordinate patient visit
- Prepare drug for administration
- “Redispende” drug
- Manage medication waste
- Conduct drug monitoring

. . . all without any compensation

# Operational Barriers

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## Uncompensated Service | Unmitigated Cost

- Full-time Administrative Coordinator (Mount Sinai)
  - New role developed to manage 500+ patients currently impacted by white bagging mandates
- Provide drug to patient in absence of payer authorization
- Executive, Pharmacy, Managed care, Informatics, Clinician resources.

# Quality and Safety Barriers

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## Point of Care Treatment Decisions

- Common among various patient populations
- Lab/weight-monitored regimens calling for same day treatment adjustments
- Time-sensitive treatment initiation, change or cancellation
- Treatment delays
- Impact on patient satisfaction
- Impact on patient health outcomes

# Quality and Safety Barriers

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## Quality | Safety

Increased LOS\*

- Delayed discharge planning and transitions of care

Increased Patient Admissions

- Delayed processing
- Increased mail order delivery time

Impact on

- Patient experience
- Patient adherence\*\*
- Patient clinical outcomes

\*Avoidable hospital induced risks; e.g., falls, nosocomial infections, etc. LOS = Length of Stay

\*\*Treatment non-adherence is a leading cause of hospital readmission; e.g., CHF

1. *White-Bagging of Medications Negative Consequences on Individual and Organization Patient Safety. Pharmacy Executive Leadership Alliance Section of Pharmacy Practice Leaders. American Society of Health-System Pharmacists (ASHP)*

# Quality and Safety Barriers

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## Quality | Safety

Provision of drugs that are incompatible with EHR

- Non-formulary
- Alternate concentration
- Formulation
- Vial sizes

Bypasses health system's operational and system safeguards, including those that have been put in place to mitigate previous quality and safety adverse events

→ Compromising/undermining EHR integrity

# Quality and Safety Barriers

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## Quality | Safety

Targets the most vulnerable and sickest patient populations

- Cancer care
- Rare Diseases
- Immune disorders
- Complex disorders
- Pediatrics

→ Stripping providers of their control over quality and safety

→ Introducing many additional and avoidable risk points in the medication use process

# Increased Provider Liability

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- Primary onus of patient safety remains with providers
- Providers lack ability to control product quality, handling, and turnaround time, etc.
- Retain full risk for potential error in preparation/administration for a drug not procured or billed by facility
- Providers opting out of buy-and-bill

# Increased Provider Liability

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- Lack of indemnification to protect hospital or patient for drug integrity or treatment delay from payer designated pharmacy
- Who is responsible for suboptimal or bad patient outcomes?

# Disruption of 340B Drug Pricing Program

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- White/Brown Bagging allows insurer to control the distribution of the drugs
- Eliminates the 340B benefit to the provider
  - Based on need; disproportionate indigent population
- Undermines the intent of the 340B Drug Pricing Program
  - Utilize savings from discounted drugs to improve access to care for the vulnerable communities they serve

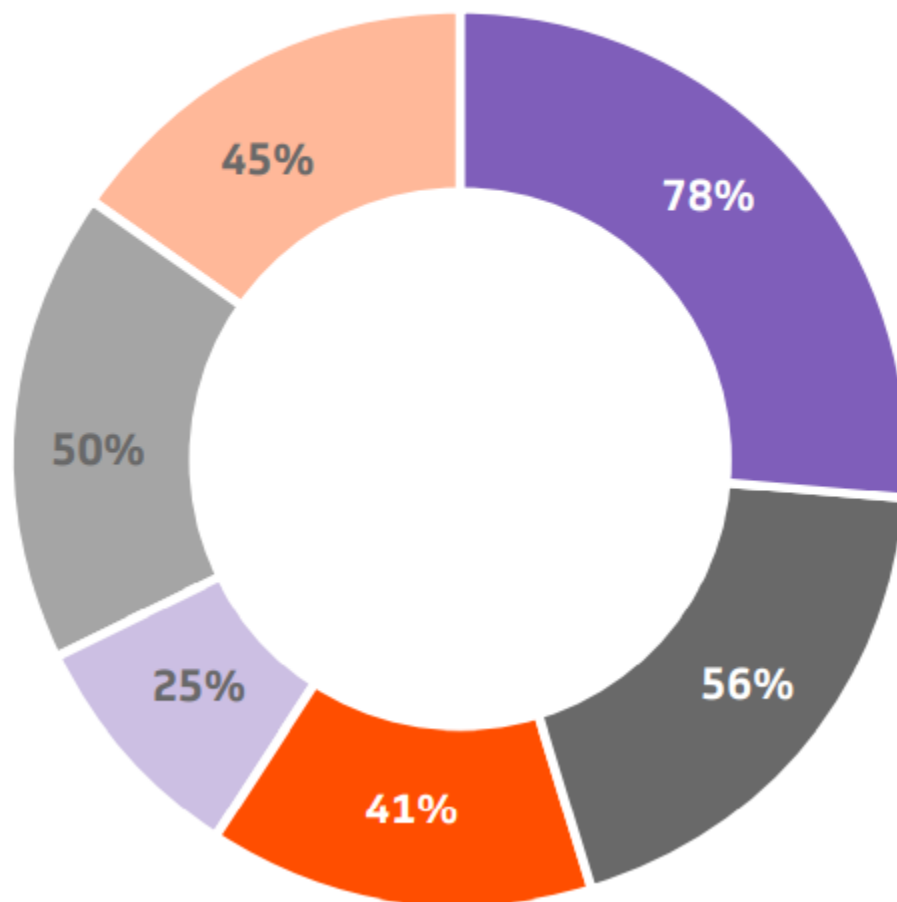
# Providers Closing the Risk Gap

- Shift
  - 
  - 
  - Ass
  - Ren
  - Pro
  - Unsustainable
- 2. Impact on patient care**
- For facilities that accept white or brown bagged medications, the majority experience issues that delay treatment due to not receiving the medication on time, not receiving the correct dosage, or receipt of the wrong product altogether. When treatment is delayed, most hospitals are using their own inventory of product to ensure a patient is treated on time.

odel

# Provider National Survey - Vizient

## Survey Respondents



### Responses by organization type

340B

AMC

Pediatrics

N=268

Critical access

Community

Physician clinics

# Provider National Survey - Vizient

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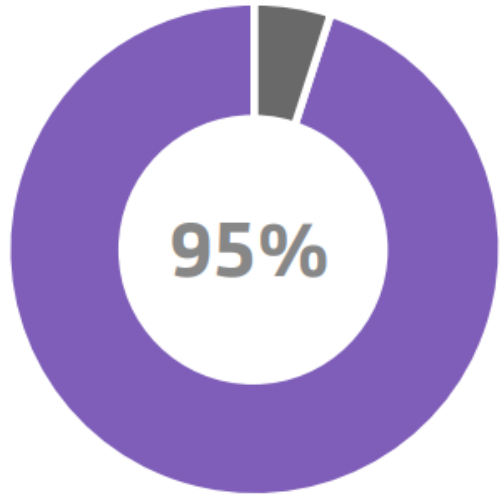


Survey on the patient care  
impact and additional expense  
of white/brown bagging

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1. Survey on the Patient Care Impact and Additional Expense of White/Brown Bagging. Vizient. April, 2021

# Provider National Survey - Vizient



Of respondents experienced operational and safety issues associated with white/brown bagging

*“When a medication is supplied from a mandated specialty pharmacy, we lose all control over the preparation, handling, storage and delivery of that product. When we can’t guarantee the integrity of the medication, we are not going to administer it to the patient. The provider and the patient trust us to provide the highest quality of product prescribed.”*

John Pastor, PharmD, FASHP, FMSHP  
System Vice President, Pharmacy & Respiratory Care  
M Health Fairview

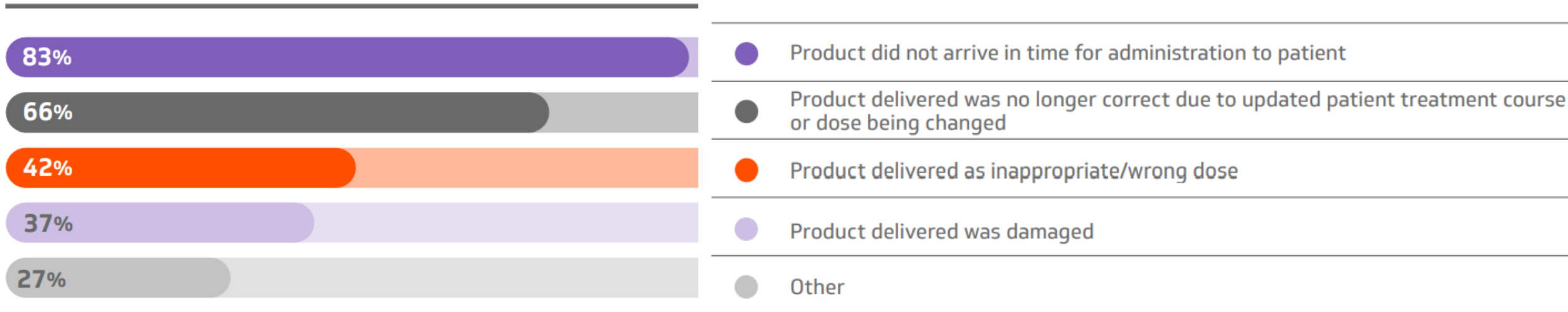
- Additional space requirements
- Management of patient-specific medications
- Incorporating 3<sup>rd</sup> party provided medications in pharmacy inventory
- Products delivered to wrong locations
- Ordering systems challenges (bar code scanning, IV pump library, IV workflow)

# Provider National Survey - Vizient

*“White bagging delays care for patients who need real-time dose adjustments to ensure the best outcome. If 66% of people say they have received the incorrect dose for their patients, that's a real problem.”*

Erin Fox, PharmD, BCPS  
Senior Pharmacy Director, University of Utah Health

## Top issues respondents reported experiencing



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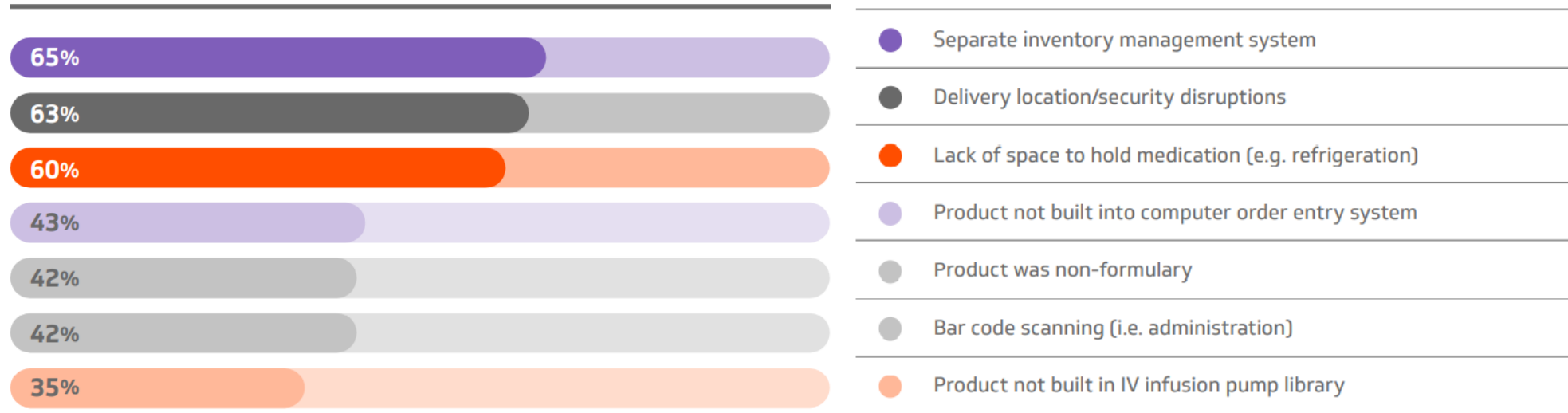
1. Survey on the Patient Care Impact and Additional Expense of White/Brown Bagging. Vizient. April, 2021

# Provider National Survey - Vizient

*“The treatment of patients who have cancer and other complex diseases is compromised when we cannot ensure the integrity of the medications they are receiving in our clinics. Patients also don’t know that when a drug is received via a “white bag,” it is not coming from the health-system.”*

Rita Shane, PharmD, FASHP, FCSHP  
Vice President and Chief Pharmacy Officer

Percentage of respondents who reported experiencing the following pharmacy operations and product management issues that could impact patient safety



All Vizient content and infographics shared with permission from Vizient. August, 2021.

1. Survey on the Patient Care Impact and Additional Expense of White/Brown Bagging. Vizient. April, 2021

# Provider National Survey - Vizient

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**\$310M/YR**

Estimated labor expense required to manage the additional clinical, operational, logistical, and patient care work associated with white/brown bagging to prevent negative patient and financial outcomes.



**\$114M**

Amount spent thus far to hire additional prior authorization/administrative FTEs to manage these logistics.

# Driver

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- Brown/White bag presented as cost-savings to keep premiums low
- Are premiums trending down?
- Bottom lines are increasing (despite federal and state laws attempting to limit how much profit health insurers can make)

# Driver

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- Brown/White bag presented to convenience the patient
- Patient's ability to assess risk/benefits?
- UnitedHealthcare Designated Diagnostic Provider Program aims to remove coverage for diagnostic tests at most freestanding and hospital labs
- Still listing facilities with white bag mandates as in-network at point of purchase
- Increase patient access

# Emerging Regulations

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Provider and Professional Organization National Movement

**White & Brown Bagging**

Legislation

Boards of Pharmacy Rules

# Advocacy – Letter to CMS Dated 2/4/2021

## American Hospital Association (AHA)

5,000 Member Hospitals | 270,000 Affiliated Physicians | 2 Million Nurses & others | 43,000 Healthcare Leader Members

- Letter to CMS
- “Deep concerns regarding a series of new restriction creating significant barriers to access to necessary specialty pharmacy services for tens of millions of health plan enrollees”



Washington, D.C. Office  
800 10th Street, N.W.  
Two CityCenter, Suite 400  
Washington, DC 20001-4966  
(202) 638-1100

February 4, 2021

Elizabeth Richter  
Acting Administrator  
Center for Medicare & Medicaid Services  
Hubert H. Humphrey Building  
200 Independence Avenue, S.W., Room 445-G  
Washington, DC 20201

**Re: UnitedHealthcare Coverage Policies**

Dear Ms. Richter:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, and our clinician partners – including more than 270,000 affiliated physicians, 2 million nurses and other caregivers – and the 43,000 health care leaders who belong to our professional membership groups, the American Hospital Association (AHA) writes to express deep concerns regarding a series of UnitedHealthcare health plan coverage policies. These new restrictions will create significant barriers to access to necessary diagnostic and specialty pharmacy services for tens of millions of health plan enrollees.

As health care premiums continue to grow, the health insurance industry has launched a multipronged strategy to drive more consumer dollars to their bottom lines despite federal and state laws that attempt to limit how much profit health insurers can make at the expense of their subscribers. UnitedHealthcare has been particularly aggressive in developing and employing these tactics. UnitedHealth Group, UnitedHealthcare's parent organization, is the seventh largest company in America with more than \$250 billion in annual revenue. While it dominates in many health care coverage markets (and, indeed, is the largest commercial health insurer in the country), its fastest growing lines of business fall under the "Optum" portfolio of companies, which offer a diverse group of services from direct patient care through its network of 50,000+ employed or affiliated physicians and other owned/managed providers, essential services such as health care analytics, the management of pharmacy services, and the direct provision of specialty therapeutics.

Two of UnitedHealthcare's recent policy restrictions raise significant concerns about the impact on its enrollees and the stewardship of scarce health care resources, including taxpayer dollars. Much of the company's overall revenue is from government payers,

# Advocacy – Letter to CMS Dated 2/4/2021

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- Prohibit brown bagging
- Prohibit white bagging when the dosage or compounding of a pharmaceutical product is dependent upon the results of a patient's lab test
- Permissible in instances where the provider and health plan agree through their standard negotiations that such arrangements are in the clinical best interests of the patient
- Providers should not be required to accept these arrangements when they are unilaterally forced by payers
- Provider should be permitted to decline any such arrangements based on quality of care concerns

# Advocacy – Letter to FDA Dated 3/22/21

## American Society of Health-System Pharmacists (ASHP) & American Hospital Association (AHA)

- Letter to FDA
- “Strongly urging FDA to consider the patient safety and supply chain security risks of white bagging, and take appropriate enforcement action to protect patients ”

March 22, 2021

Dr. Janet Woodcock  
Acting FDA Commissioner  
Food and Drug Administration  
10903 New Hampshire Ave  
Silver Spring, MD 20903

Re: Request for Meeting – White Bagging and DSCSA

Dear Commissioner Woodcock,

The undersigned healthcare organizations are writing to express concern that the payer-mandated drug distribution model, known as “white bagging” is jeopardizing patient safety and exacerbating supply chain security challenges that the Drug Supply Chain Security Act (DSCSA) sought to address.

Payers are using white bagging to circumvent hospital supply chain controls by requiring patient medications be distributed through a narrow network of specialty pharmacies that are often directly affiliated with the payer, thereby disregarding DSCSA’s requirements for wholesale distribution of drugs. Hospitals and providers are then forced to further manipulate and dispense these medications before they can be safely administered to patients.

White bagging has surged in frequency over the past decade, creating what amounts to a shadow inventory that hospitals and health systems do not legally own and which exists largely outside of the DSCSA’s track and trace requirements. A Drug Channels report found that in 2019, nearly a third of infusion drugs (both oncologic and non-oncologic) provided in hospital outpatient departments were distributed via white bagging.<sup>1</sup> Given the growing ubiquity of payer-mandated white bagging, we are concerned that this practice threatens DSCSA’s underlying goals. Further, because hospitals do not have legal title to white bagged medications and the drugs are delivered outside of hospital-established supply chains, white bagging can raise additional patient safety risks by enabling diversion and heightening the possibility of drug spoilage/wastage. In addition, as white bagged drugs bypass established supply chain channels it also disrupts and significantly complicates the ability to respond to FDA drug recalls.

We strongly encourage FDA to consider the patient safety and supply chain security risks of white bagging, and take appropriate enforcement action to protect patients. We would welcome the opportunity to meet with your team to discuss our hospital and health system compliance concerns in greater detail. We are deeply appreciative of the work FDA staff has put into implementing DSCSA to date, and we recognize the challenge white bagging presents to the overall goals of DSCSA. We hope to work collaboratively with the Agency to protect against the creation of payer-mandated distribution models that could undermine patient safety. Please contact Tom Kraus at [tkraus@ashp.org](mailto:tkraus@ashp.org) if you have any questions or if we can provide any additional assistance.

# Advocacy – Letter to FDA Dated 3/22/21

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ASHP (American Society of Health-System Pharmacists)  
Allina Health  
Ascension  
Atrium Health  
Baptist Health - Jacksonville  
Baptist Health - South Florida  
Bay Care Health System  
Baystate Health  
Bon Secours Mercy Health  
Bryan Health  
Cincinnati Children's Hospital Medical Center  
Citizens Memorial Hospital  
City of Hope National Medical Center  
Cleveland Clinic  
Common Spirit Health  
Dana-Farber Cancer Institute  
Dartmouth-Hitchcock Health  
Deaconess Health System  
Ephraim McDowell Regional Medical Center  
Eskenazi Health  
Essentia Health  
Freeman Health System

Froedtert & the Medical College of Wisconsin  
Glens Falls Hospital  
Harris Health System  
Indiana University Health  
Inova Health System  
Lee Health  
Lifespan  
Mass General Brigham  
Memorial Healthcare System  
Memorial Care-Long Beach Medical Center  
Mercy Health  
Methodist Health System  
Moffitt Cancer Center  
Murray-Calloway County Hospital  
Nebraska Medicine/the Nebraska Medical Center  
North Oaks Health System  
Novant Health New Hanover Regional Medical Center  
OSF Healthcare  
Premier Healthcare Alliance  
Providence  
Renown Health

Saint Luke's Health System  
Sanford Health  
Sutter Health  
The University of Illinois Hospital and Clinics  
Truman Medical Centers / University Health  
Tufts Medical Center  
UC Health  
UNC Health  
Union Hospital  
Unity Point Health  
University Hospitals Health System  
University of California San Francisco Health  
University of Chicago  
University of Illinois at Chicago, College of Pharmacy  
University of Missouri Health Care  
University of Tennessee Medical Center  
Virginia Mason Franciscan health  
Vizient, Inc.  
Yale New Haven Health

# Advocacy – ASHP And AHA Meet with FDA

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## ASHP and AHA Meet with FDA Officials on Payer-Mandated White Bagging

Yesterday, government relations teams representing ASHP and the American Hospital Association (AHA) met with senior Food and Drug Administration (FDA) officials to discuss patient safety and supply chain security concerns stemming from the payer-mandated drug distribution model known as “white bagging.” The meeting follows joint letters from ASHP, along [with AHA](#) and [61 health-system partners](#), to the FDA commissioner requesting discussions on this rapidly growing trend, which jeopardizes optimal, safe, and effective medication use.

ASHP members Rita Shane, vice president and chief pharmacy officer at Cedars-Sinai Medical Center, and Ken Komorny, chief pharmacy officer at Moffitt Cancer Center, described the negative impacts of payer-mandated white bagging policies during the meeting.

ASHP and our partners urged FDA to consider whether plan-mandated white bagging pharmacies are functioning as unregistered distributors and bypassing security controls required by the Drug Supply Chain Security Act. ASHP also urged FDA to provide guidance to providers on whether to accept white bagged drugs and how health systems can support recall efforts and supply chain integrity for white bagged drugs.

More information about white bagging can be found at [ASHP's White Bagging Resource Center](#).

# ASHP Position Statement

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*ASHP strongly opposes white bagging because*

*. . . It bypasses health system formularies, safety checks, and care planning processes. . . . It threatens practices that healthcare organizations have established to keep patient safe and hinders the ability of pharmacists to ensure medication and supply chain integrity*

# Advocacy – Letter to Florida Board of Pharmacy Dated 2/8/21

## Florida Society of Health-System Pharmacy (FSHP)



Florida Society of Health System Pharmacists, Inc.  
2910 Kerry Forest Parkway D4, Suite 376  
Tallahassee, FL 32309  
(850) 906-9333  
[www.fsHP.org](http://www.fsHP.org)

February 8, 2021

- Letter to Florida Board of Pharmacy
- Request creation of a Board of Pharmacy subcommittee to evaluate and provide recommendations regarding the quality, safety, and regulatory concerns surrounding the practice of brown and white bagging

Ms. Jessica Sapp, Executive Director  
Florida Board of Pharmacy  
Florida Department of Health  
4052 Bald Cypress Way, Bin C-04  
Tallahassee, FL 32399-3258

RE: White and Brown Bagging Practices

Dear Ms. Sapp:

I am writing on behalf of the Florida Society of Health System Pharmacists (FSHP) to request the Board of Pharmacy ("the Board") review and evaluate the safety of medications subjected to "white" and "brown" bagging, as defined in *"White and Brown Bagging Emerging Practices, Emerging Regulation"*, published by the National Association of Boards of Pharmacy (NABP) in April 2018, and which is herein enclosed. Additionally, we request the Board consider the need to adopt rules that would specify how the practice of white and brown bagging should be managed for licensed pharmacies.

The NABP report refers to "white bagging" as the dispensing of patient-specific medication from an outside pharmacy (typically a specialty pharmacy) to a physician's office, hospital, or clinic for purposes of administration. White bagging is often used in oncology practices to obtain costly injectable or infusible medications that are distributed by outside specialty pharmacies and may not be available in all non-specialty pharmacies.

"Brown bagging" on the other hand refers to the dispensing of a medication from a pharmacy (typically a specialty pharmacy) directly to a patient, who then transports the medication(s) to a physician's office for purposes of administration.

The NABP report estimates that white bagging occurs in 28 percent of medical benefit-provided drug therapy, and accounts for up to 31 percent of oncology-provided infusions.

The practice of white bagging is riddled with safety concerns and seems to conflict or operate outside of state law and regulations. The process has no controls over the sourcing, storage, preparation, and handling of many specialty, high cost, and often extremely important medications for severely ill patients. As well, white bagging often results in an interruption and delay in therapy; added costs to medication management; increased risks of medication errors and adverse events; and risks of adherence with federal REMS requirements.

In these regards, there are several aspects of the practice the FSHP requests the Board evaluate in relation to Florida law and regulatory rules:

# Advocacy – Louisiana Ban on White Bagging

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## Louisiana bans insurers from controversial 'white bagging' practice

Morgan Haefner - Wednesday, June 9th, 2021 [Print](#) | [Email](#)

[Share](#) [Tweet](#) [Share 6](#) [Listen](#) ▶

A new law in Louisiana will bar health insurers from implementing a pharmacy policy known as "white bagging."

White bagging is when health insurers don't let providers procure and manage a drug for their patients, but rather require a third-party specialty pharmacy to dispense the drug to the provider.

Health insurers have argued that healthcare costs can be lowered if members get prescription drugs from in-network specialty pharmacies. However, hospitals have called on lawmakers to limit the practice, which they [argue](#) can threaten care quality.

Under the new law, effective June 1, Louisiana health insurers can't deny payment to participating providers because they received physician-administered drugs from a pharmacy that isn't in a health insurer's network.

Additionally, health insurers in the state will have to pay providers at the rate outlined in their contract agreement. If a rate isn't included for a particular drug, then reimbursement will be at wholesale acquisition cost, according to the law.

Louisiana lawmakers said this will "ensure that health insurance issuers do not interfere with patients' freedom of choice with respect to providers furnishing physician-administered drugs and ensure that patients receive safe and effective drug therapies."

Louisiana Bans Insurers from Controversial White Bagging Practice. Backer's Healthcare Payer Issues. Published June 9, 2021. <https://www.beckershospitalreview.com/payer-issues/louisiana-bans-insurers-from-controversial-white-bagging-practice.html#:~:text=A%20new%20law%20in%20Louisiana,the%20drug%20to%20the%20provider.>

# Advocacy – Louisiana Ban on White Bagging

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## New Louisiana Law Bans Insurer Practice Known as White Bagging

- Passed both chambers unanimously with bipartisan support
- Effective June 1<sup>st</sup> 2021

*LA health insurers are prohibited from conditioning, denying, restricting and refusing to authorize or approve the drug because the provider obtained it from an out-of-network pharmacy*

- UnitedHealthcare, Aetna, & Cigna did not respond to America's NewsHub request to comment

# Advocacy – Louisiana Ban on White Bagging

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## **New Louisiana Law Bans Insurer Practice Known as White Bagging**

- Health insurers in the state will have to pay providers at the rate outlined in their contract agreement
- Ensures that health insurance issuers do not interfere with patients' freedom of choice with respect to providers furnishing physician administered drugs
- Violations considered an unfair method of competition and unfair practice or act

# Advocacy – Louisiana Ban on White Bagging

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## Emerging State Legislation

- Texas House Bill 1585 (proposed)
- New York
- Massachusetts
- Other states have stalled

# Advocacy – Virginia Board of Pharmacy Rules

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## 18 VAC 110-20-274 Delivery of Dispensed Prescriptions

A prescription may be delivered by pharmacy to the office of such practitioner . . . provided there is written contract or agreement between the two parties describing the procedures for such delivery system and the responsibilities of each party:

- Tracking
- Product security\*
- Integrity\*
- Delivery accuracy
- Accountability

\*Stored in a lockable room or lockable cabinet, cart, or other device which cannot be easily moved and which shall be locked at all time shown not in use. Access shall be restricted to the licensed practitioner or designee

\*From the time it leaves the pharmacy until it is handed to the patient or agent of the patient

# Advocacy – Virginia Board of Pharmacy Rules

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## **18 VAC 110-20-274 Delivery of Dispensed Prescriptions**

- Procedure for providing counseling
- Procedure for recordkeeping for return of any prescription medications not delivered to patient
- Procedure for assuring confidentiality of patient information
- Procedure for informing patient and obtaining consent for using such a delivery process

# Advocacy – Virginia Board of Pharmacy Rules

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## **18 VAC 110-20-274 Delivery of Dispensed Prescriptions**

- Exemptions
  - I. The alternate delivery site does not routinely receive deliveries from the pharmacy
  - II. Compliance would create a delay in delivery that may result in potential patient harm

Routine deliveries NOT exempt

# Advocacy – Virginia Board of Pharmacy Rules

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## **18 VAC 110-20-274 Delivery of Dispensed Prescriptions**

- Exemption Conditions
  1. Pharmacy shall notify alternate delivery site of anticipated arrival, exact address of shipment, name of patient and special storage requirements
  2. Pharmacy shall provide counseling or ensure there is a process in place for the patient to receive counseling
  3. Delivered prescriptions shall be stored in a lockable room or device with access restricted to the licensed prescriber, pharmacist or either person's designee

# Advocacy – Virginia Board of Pharmacy Rules

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## **18 VAC 110-20-274 Delivery of Dispensed Prescriptions**

- A pharmacy shall not deliver dispensed drugs to a patient's residence that are intended to be subsequently transported by the patient or patient's agent to a hospital, medical clinic, prescriber's office, or pharmacy for administration and that require special storage, reconstitution or compounding prior to administration.
- An exception to this requirement may be made for patients with inherited bleeding disorders who may required therapy to prevent or treat bleeding episodes

# Advocacy – Board of Pharmacy Rules

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## Emerging State Board of Pharmacy Rules

- Texas
- California
- Florida
- Missouri
- Washington
- Others emerging

# Advocacy – Take Action

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How can you protect your patients?

Consider an institutional policy disallowing Brown and White Bagging

Why is clear bagging often excluded?

Join advocacy efforts

Consider escalating concerns to regulatory bodies like The Joint Commission and your state Board of Pharmacy during inspection visits

# Polling Question

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Has your institution created a drug bagging policy limiting the practice of drug bagging?

- A) Yes, completely restricting
- B) Yes, limiting but allowing exceptions
- C) No

Does your institutional drug bagging policy allow for clear bagging?

- A) Yes
- B) No

# Provider Mitigation Strategies

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## Clear and White Bagging Policy

### White Bagging

25% prohibit with no exceptions\*

46% prohibit with exceptions

### Clear Bagging

50% dispense

\* A Penn Medicine's Health System case study showed <1% of patients left the system as a result of white bagging requirements

1. *Responding to White Bagging Requirements. Survey. Advisory Board. 2021*

# Provider Mitigation Strategies

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## Leverage Organization Footprint

- Geographic coverage
- Brand recognition and demand
- Market share
- Investigational protocols

*Is payer mandated brown and white bagging stipulated in current contract?  
Is it enforceable?*

*Can this payer sell health insurance in your geography without your health system network?*

# Provider Mitigation Strategies

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## Leverage Provider-Payer Relationships

- Review/describe member experience and access challenges
- Value-based care journey
- Showcase cost effectiveness stewardship (e.g., biosimilar implementation)

# Provider Mitigation Strategies

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## Provider Site-of-Care Diversification

- Acute services
- Ambulatory infusion (HOPD and none)
- Specialty pharmacy
- Home health
- Physician-based infusion (non-HOPD)

**Will this be enough?**

# Provider Mitigation Strategies

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## Other

- Seek guidance from regulatory bodies with oversight of medication management
- Identify alternate treatment option
- Notify manufacture you were unable to prescribe their drug
- Patient engagement

# Summary

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- There is increasing prevalence of payer-mandated brown and white bagging practices
- Practice poses quality, safety and drug chain of custody concerns
- Practice introduces further care fragmentation and delays
- Practice negatively impacts patient care and patient satisfaction
- Suspected negative impact on treatment outcomes

# Summary

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- Providers and professional organizations come together to advocate on behalf of patients and providers
- Institutional policy and strategy needed to mitigate suboptimal care and patient risks
- State legislation and Board of Pharmacy rules are just emerging throughout the U.S.
- Provider engagement is needed to shape future practice

# Drug Brown and White Bagging; what is it and where does it Lead Us?



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