

# White-Bagging Journey in Florida; Strategies to Protect Practices and Patients



**Baptist Health**

Cancer Care



# Baptist Health South Florida



## Overview

- Non-for-profit 12-hospital health system
- More than 100 outpatient centers, urgent care facilities and physician practices
- Four counties: Monroe, Miami-Dade, Broward & Palm Beach
- More than 24,000 employees
- More than 4,000 affiliated physicians
- Centers of excellence in Cancer, Cardiovascular, Orthopedics and Sports Medicine, and Neuroscience



## National Recognition

- 100 Best Companies to Work For – *Fortune Magazine* (21 years)
- 100 Best Companies – *Seramount* (29 years)
- World's Most Ethical Companies – *Ethisphere Institute* (11 years)
- Most Wired Hospitals and Health Systems - *Hospital & Health Networks* (19 years)
- Magnet designation – *American Nurses Credentialing Center* (5 hospitals)
- Best Hospital Rankings with 48 High-performing Honors – *U.S News & World Report* 2021-2022



**Jorge J. Garcia, PharmD,  
MS, MHA, MBA, FACHE**

Assistant Vice President,  
Pharmacy Services

Board of trustee member at ACCC  
and FLASCO

Committee Chair or Member at  
ASHP, APhA, ATOPP

Faculty for ASHP PLA

Active with HOPA, ACHE

Since the beginning, our mission has been  
**to contribute to the prevention and cure of cancer.**

### *Clinical Impact*

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### *Research Impact*

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### National Recognition



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National Comprehensive Cancer Network®

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Nurse Excellence

US News & World Report  
**Best Hospitals in the Nation**

Ranked for the Last 20+ Years

### Employer of Choice



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### **Kenneth Komorny, Pharm.D, BCPS**

- Vice President, Chief Pharmacy Officer
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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

## **White Bagging**

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

## **Clear Bagging**

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

# 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.



## Concerns:

- Supply chain custody and integrity
- Bypass of clinical and operational safety checks
- Systemic treatment delays (point of care tx changes)
- Increased and largely unmitigated clinical and economic burdens for providers
  - Impact on
    - Patient experience
    - Patient adherence
    - Patient clinical outcomes
  - Providers closing the risk gap

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





- Pegfilgrastim arriving after due date
- Authorizations delaying processing and delivery of drugs (e.g., admissions, prolonged LOS)
- Biologics stored at home
- Home health RN not showing-up
- Suboptimal dose delivered based on DOT lab / pediatric weight
- Drug shipped for discontinued orders



## Increased Operating Cost | Uncompensated Services

Provider must:

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

. . . all without any compensation

*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





## *Survey on the patient care impact and additional expense associated with white and brown bagging*

### Top Issues Respondents Reported Experiencing:

- 83% - Product did not arrive in time for patient administration
- 66% - Product received was no longer correct due to updated patient treatment course or dose being changed
- 42% - Product delivered as inappropriate / wrong dose
- 43% - Product not built in computer system
- 37% - Product delivered was damaged
- 95% of respondents experience operational and safety issues

# Disruption of 340B Drug Pricing Program



- 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

# Advocacy Letter-Florida Board of Pharmacy Dated

2/8/21



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

- Letter of 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



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

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:



## Emerging State Board of Pharmacy Rules

- Texas
- California
- Missouri
- Washington
- Others emerging

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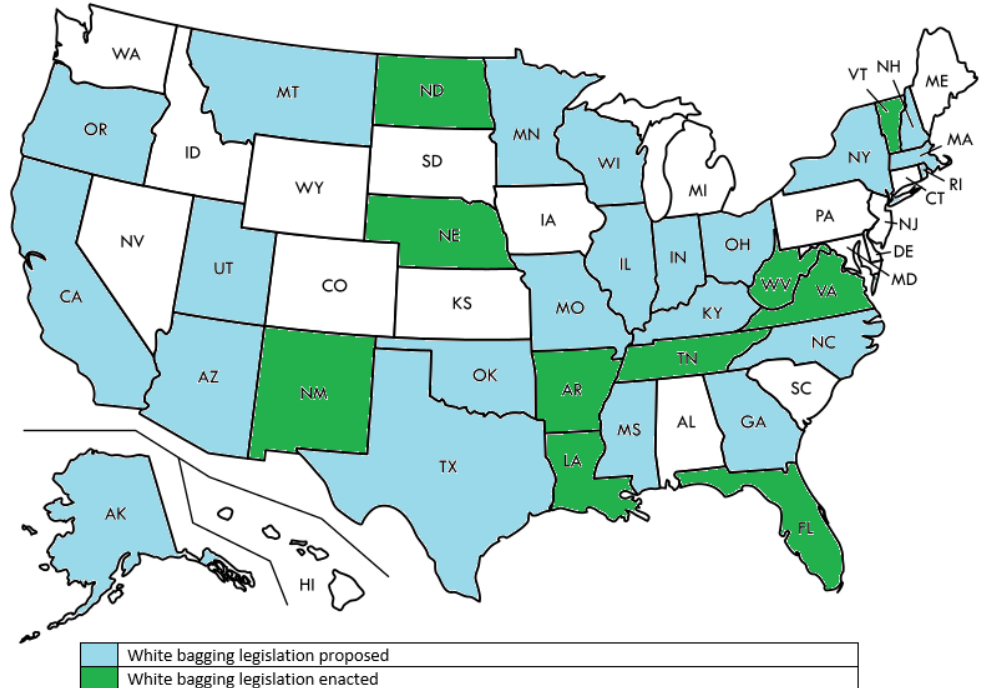


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# National perspective




# SB 1550/HB 1509

- 2. Require a pharmacy benefit manager to offer a provider contract to licensed pharmacies physically located on the physical site of providers that are:
  - Essential providers
  - Cancer Center of Excellence
  - Organ transplant hospitals
  - Specialty Children’s hospitals
  - Regional perinatal intensive care centers
- Such provider contracts must be solely for the administration or dispensing of covered prescription drugs, including biological products, that are administered through infusions, intravenously injected, inhaled during a surgical procedure, or a covered parenteral drug, as part of onsite outpatient care;
- 3. Do not require a covered person to receive a prescription drug by United States mail, common carrier, local courier, third-party company or delivery service, or pharmacy direct delivery



Moffitt Cancer  
Center  
experience with  
payer mandated  
site of care  
steerage policies

Delayed Drug Delivery Impacting Moffitt Patients

 Comments (0)

JOURNAL ARTICLE ACCEPTED MANUSCRIPT

## Payer site of care mandates with oncology medications: It's time to demand payer accountability on behalf of patients

[Get access >](#)

Kenneth M Komorny, PharmD, BCPS ✉, Jason M Burkett, MAcc, CPA, CSBI, Tracey Mensing, BSN, RN, OCN, Bridget A Whaley, MHA, Kyle Robb, PharmD, BCPS, David Chen, BPharm, MBA

*American Journal of Health-System Pharmacy*, zxad078,

<https://doi.org/10.1093/ajhp/zxad078>

# Discussion and Q&A



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