Payor Benefit Design Changing Oncology Care Delivery

Jorge J. Garcia, PharmD, MS, MHA, MBA, FACHE
Assistant Vice President
Oncology, Infusion and Investigational Drug &
Research Pharmacy Services
Baptist Health

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 Neurosciences

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 Vide President,

Pharmacy Services

Board of trustee member at ACCC and FLASCO

Committee Chair or Member at ASHP, ATOPP

Faculty for ASHP PLA

Active with HOPA, ACHE

Learning Objectives

1. Discuss impact of drug bagging practices
2. Discuss impact of site-of-care mandates
3. Review trends shifting oncology care delivery

Background

- Drug spend is the largest cancer expenditure and growing
  - $535 billion U.S. pharmaceutical spend in 2020
  - 39% 5-year growth rate

- Number of new cancer cases expected to rise
  - 14% combined 10-year growth

- Number of outpatient service volumes expected to rise
  - 4% combined 5-year growth

2022 Pharmacy Market Trends. Advisory Board

Payor Tactics to Control Drug Spend

- Prior authorizations
- Clinical pathways
- Formulary exclusions
- Outcomes-based contracting
- Value-based payment models
- White bagging policies
- Site-of-care

2022 Oncology State of the Union. Today's Opportunity to Shape the Future of Cancer Care. Advisory Board.

White and Brown Bagging Policies; A Mandate, or not?

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.

*Impacting HOPDs & community providers

HOPD = Hospital Outpatient Departments

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

White and Brown Bagging Policies; Patient Case Reports

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

White and Brown Bagging Practice Impact

- Chain of custody
- Stability
- Fragmentation of care
- EHR and automation incompatibility
- Charge integrity
- Provider receives, stores, compounds, coordinates visit, "re-dispenses" administers, handles waste; all without any compensation
- Hinders point of care treatment decisions
- Waste (pt. specific label)
- Increased provider liability
  Undermines 340B program intent

EHR = electronic health record

1. American Hospital Association Letter "RE: UnitedHealthcare Coverage Policies" to Center for Medicare & Medicaid Services. February 4th, 2021.
2. 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)
3. White and Brown Bagging Emerging Practices, Emerging Regulation. The National Association of Boards of Pharmacy (NABP). April 2018

White and Brown Bagging Provider National Survey

Top Issues Reported by Respondents:

- **83%** - Product did not arrive on 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

All Vizient content and infographics shared with permission from Vizient. August, 2021. 268 Respondents

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

White and Brown Bagging Policies; Patient Out-of-Pocket Impact

50 cancer drugs w/ highest spending in 2020

Medicare Part B Spending Dashboard

- **113 076** patient-drug pairs
  - **53.1%** – immunotherapy / targeted therapy
  - **27.6%** – supportive therapy
  - **19.3%** – other anticancer drug

Shih, YT., Xu, Y., Yao, JC. *Financial Outcomes of Bagging Oncology Drugs among Private Insured Patients With Cancer*. September 7, 2023

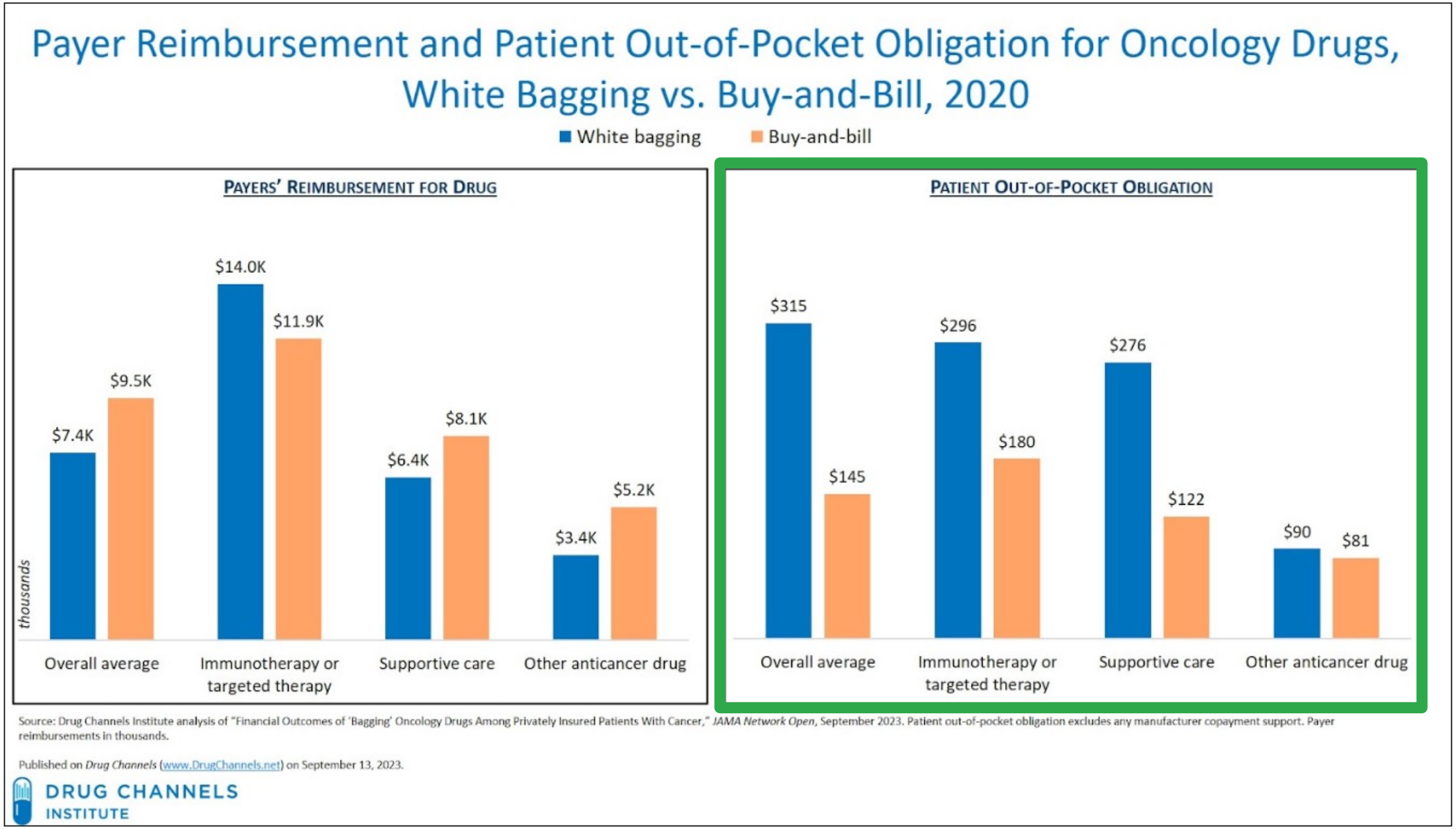
White and Brown Bagging Policies

- On average, payors paid $2,000 less for white-bagged oncology drugs
- Patient out-of-pocket was higher for white-bagged products vs. buy-and-bill

Pharmacy Benefits	Medical Benefits
○ Co-insurances ○ Deductibles for specialty drugs	○ Minimal to no patient cost sharing

1. Shih, YT., Xu, Y., Yao, JC. *Financial Outcomes of Bagging Oncology Drugs among Private Insured Patients With Cancer*. September 7, 2023
2. White Bagging Update 2023: Saving Money or Shifting Costs? Drug Channels. September 13, 2023

White and Brown Bagging Policies



Site-of-Care Policies
A mandate, or not?

Cigna
Alternate (non-hospital) site of care required for 24 oncology drugs

Aetna
"In certain cases" checkpoint inhibitors must be infused outside of hospital facilities

United Healthcare
Members can opt to receive monoclonal antibodies or checkpoint inhibitors at home

Anthem BCBS Virginia
Patients will be voluntarily redirected from HOPD to home infusion for certain checkpoint inhibitors

1. Brito,RA, et al., *Site of Service trend and Chemotherapy Costs of Commercial Insured Patients in 2020 compared to 2014*. Journal of Clinical Oncology.
2. Fein, A. *Buy-and-Bill Market Trends*. Drug Channels, September, 2021

Home Infusion

Driver:

- Payor tactic to mitigate cost

Barriers:

- Quality and safety
- Access
- Reimbursement
- RN Staffing
- Model Economic Viability

Home Infusion

Home Health Care News

CVS-CTCA Pilot Offers In-Home Infusion of Cancer Therapies

AISHEALTH an MMIT company

INNOVATION

CVS Health Partners with National Oncology Network to Offer In-Home Chemotherapy

NEJM Catalyst

Accelerating the Delivery of Cancer Care at Home During the Covid-19 Pandemic

Penn Medicine | CENTER FOR HEALTH CARE Transformation & Innovation

Cancer Care @ Home

Safe, efficient, life-extending care in the comfort of home

1. https://chti.upenn.edu/cancer-care-at-home Accessed January, 2024.
2. https://nhia.org/about-infusion-therapy/ Accessed January, 2024
3. https://catalyst.nejm.org/doi/full/10.1056/CAT.20.0258 Accessed January, 2024
4. https://homehealthcarenews.com/2021/01/cvs-health-partners-with-national-oncology-network-to-offer-in-home-chemotherapy/ Accessed January, 2024
5. https://www.mmitnetwork.com/aishealth/spotlight-on-market-access/cvs-ctca-pilot-offers-in-home-infusion-of-cancer-therapies-2/

Infusion Centers / Emerging Professional Organizations

IVX HEALTH

PURE® INFUSION SUITES

NICA NATIONAL INFUSION CENTER ASSOCIATION

NHIA National Home Infusion Association

1. https://infusioncenter.org/ Accessed January, 2024
2. https://ivxhealth.com/ Accessed January, 2024
3. https://pureinfusionsuites.com/ Accessed January 2024
4. https://nhia.org/ Accessed January 2024

From “Partner” to “Competitor” The Birth of “Payviders”

Legacy Healthcare Systems

UHealth
UNIVERSITY OF MIAMI HEALTH SYSTEM

Memorial Healthcare System

Cleveland Clinic Florida

HCA Florida Healthcare

Tech & Retail Disruptors

amazon | one medical

Village Medical PRIMARY CARE | Walgreens

Walmart Health

Teladoc HEALTH

Emerging Pay-viders

United Healthcare | OPTUM

CVS Health | aetna

Humana

Florida Blue

Background

Vertical Business Relationships Among Insurers, PBMs, Specialty Pharmacies, and Providers, 2023

1. Since 2021, Prime's Blue Cross and Blue Shield plans have had the option to use Express Scripts or AllianceRx Walgreens Pharmacy for mail/specialty pharmacy services. IN Dec. 2021, Walgreens purchased Prime Therapeutics' 45% ownership interest, so this business had no PBM ownership as of 2022. Effective June 2022, the company was rebranded as AllianceRx Walgreens Pharmacy.
2. Centene has announced that it would outsource its PBM operations to Express Scripts in 2024. In 2023, Centene rebranded its pharmacy benefit subsidiary as Centene Pharmacy Services.
3. In 2021, Centene sold a majority stake in its U.S. Medical Management to a group of private equity firms.
4. 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.
5. Previously known as Evernorth Care Group and Cigna Medical Group.
6. In 2021, Cigna's Evernorth business acquired MDLive.
7. In 2022, Cigna invested $2.7 billion for an estimated 14% ownership stake in VillageMD. Walgreens owns a majority of VillageMD.
8. In September 2022, CVS Health announced its acquisition of Signify Health. In February 2023, CVS announced its acquisition of Oak Street Health. Both transactions closed in 2023.
9. Previously known as IngenioRx.
10. In 2021, Partners in Primary Care and Family Physicians Group businesses were rebranded as Centerwell Senior Primary Care.
11. In 2022, Kindred at Home was rebranded as CenterWell Home Health. 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. Humana also announced plans to close a majority of its SeniorBridge home care locations.

Source: *The 2023 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers*, Exhibit 234. Companies are listed alphabetically by corporate name.

DRUG CHANNELS INSTITUTE

May 2023

The Birth of "Payviders"

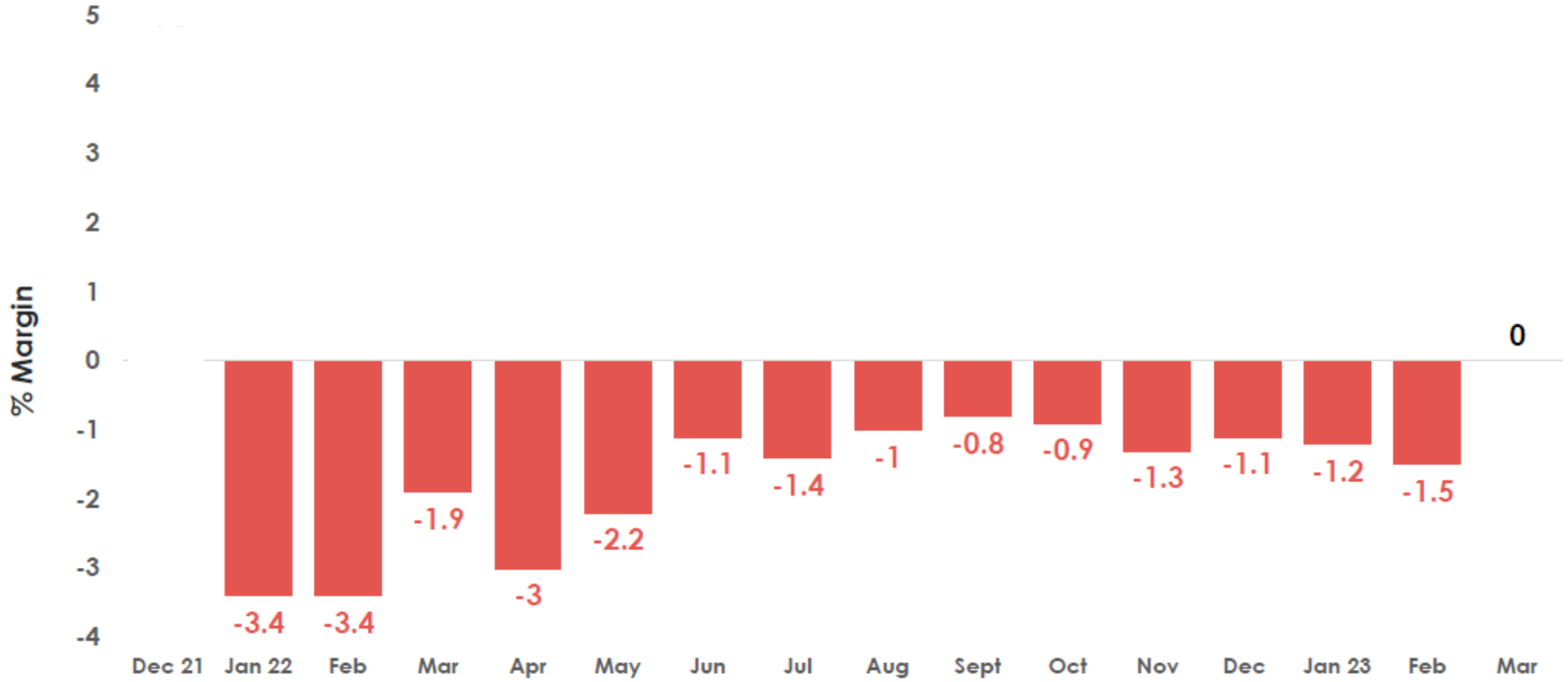
- Insurers expand provider services
  - e.g., OptumCare, Minute Clinic, Cigna Collective Care
  - e.g., Optum Infusion Pharmacy, Coram

1. Brito,RA, et al., *Site of Service trend and Chemotherapy Costs of Commercial Insured Patients in 2020 compared to 2014*. Journal of Clinical Oncology.
2. Fein, A. *Buy-and-Bill Market Trends*. Drug Channels, September, 2021

Health System Operating Margins

National Operating Margins

Not-for-profit Hospital & Health System National Trend: Dec 2021 – Mar 2023



Kaufman Hall, National Hospital Flash Report April 2023

White and Brown Bagging Advocacy

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

American Hospital Association
Advancing Health in America

Washington, D.C. Office
800 10th Street, N.W.
Two CityCenter, Suite 400
Washington, DC 20001-4
(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

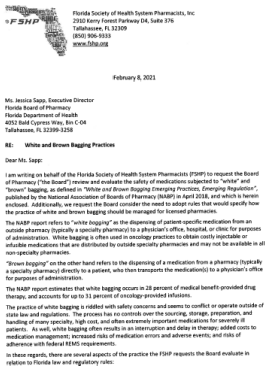
Re: UnitedHealthcare Coverage Policies

Dear Ms. Richter:

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


FSHP
Florida Society of Health-System Pharmacists, Inc.
2910 Kerry Forest Parkway D4, Suite 376
Tallahassee, FL 32309
(850) 906-9333
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:

arch 22, 2021

. Janet Woodcock
ting FDA Commissioner
od and Drug Administration
903 New Hampshire Ave
ver Spring, MD 20903

: Request for Meeting – White Bagging and DSCSA

ar Commissioner Woodcock,

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

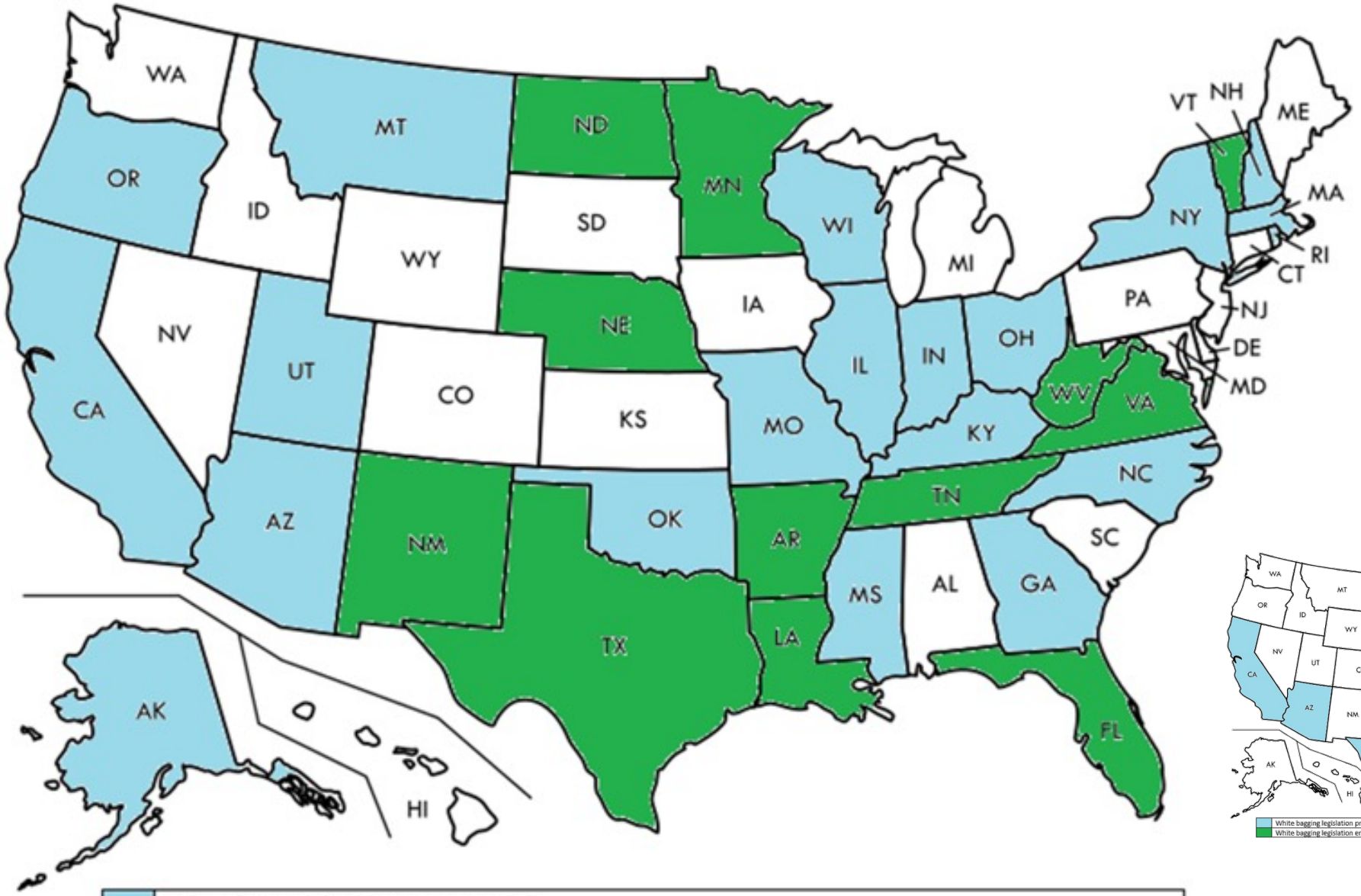
yers are using white bagging to circumvent hospital supply chain controls by requiring patient edications be distributed through a narrow network of specialty pharmacies that are often directly iliated with the payer, thereby disregarding DSCSA's requirements for wholesale distribution of drugs. spitals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

hite bagging has surged in frequency over the past decade, creating what amounts to a shadow ventory that hospitals and health systems do not legally own and which exists largely outside of the CSA's track and trace requirements. A Drug Channels report found that in 2019, nearly a third of usion drugs (both oncologic and non-oncologic) provided in hospital outpatient departments were tributed via white bagging.[1] 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 if you have any questions or if we can provide any additional assistance.

ASHP and AHA Meet with FDA Officials on Payer-Mandated White Bagging. ASHP News and Press Releases. Published June 14, 2021. Infographics shared with permission from ASHP.

White Bagging Legislation



Infographics shared with permission from ASHP, 2024.

Other Market Dynamics Changing Oncology Care Delivery

- Oncology Hospital-at-Home Models
  - e.g., Huntsman at Home (2012-present; > 1,100 pts. treated)

- Cancer Surgeries Moving to ASC
  - e.g., Memorial Sloan Kettering (2015)
    Ephraim McDowell Health (2022)

- Telehealth*
  - Before 2.2/2.4%; After 6.5/9.1%

*Before and after COVID. Hematology/Oncology & Radiation Oncology Respectively
1. Telehealth Adoption Tracker. The Chartis Group and Kyhera Labs. September 2021

Other Market Dynamics Changing Oncology Care Delivery

- Payor Demands for Hefty Rebates in Exchange for Formulary Access
  - ASP Erosion
  - Kills provider reimbursement
  - Risking product viability

- Enhancing Oncology Model
  - Only for those participating today; experiment; potentially impacting all later

*Before and after COVID. Hematology/Oncology & Radiation Oncology Respectively
1. Telehealth Adoption Tracker. The Chartis Group and Kyhera Labs. September 2021

Summary

- Payor benefit design impacts:
  - Drug access
  - Care delivery
  - Site-of-care
  - Quality of care and patient outcomes
  - Practice operations
  - Practice economics
  - Patients out-of-pockets
  - Practice market-share

- Advocacy and legislative action needed to protect access to oncology care

Thank You

STAY CONNECTED

Payor Benefit Design Changing Oncology Care Delivery

Jorge J. Garcia, PharmD, MS, MHA, MBA, FACHE
Assistant Vice President
Oncology, Infusion and Investigational Drug & Research Pharmacy Services
Baptist Health

Baptist Health