# White Bagging Challenges:

Patient Safety and Drug Integrity

February 18, 2021

# The Bag Problem

**White bag:** Payers purchase the drugs through designated pharmacies, which then ship them to the provider (hospital or clinic) for compounding and administration

**Brown bag:** Patients pick up a prescription provided through designated pharmacies and then take the drugs to the provider for administration

# Specialty Pharmacy Payer Policies

September 1, 2020

**Cigna**: Applies only to providers who bill Cigna using a hospital fee schedule, rather than a physician fee schedule.

**Anthem/BCBS**: Roll-out varies by state

October 1, 2020

**UnitedHealthcare**: Applies only to commercial plans. Applies in all states *except* AK, HI, KY, MD, RI, UT, Puerto Rico, and USVI.

July 1, 2020

**Aetna**: Site of care management program for select oncology drugs.

King & Spalding, personal communication, Jan 26, 2021.

# State Board of Pharmacy

| Regulation | Conflict |
|---|---|
| **4024. Dispense**<br>➢ "'Dispense' also means and refers to the **furnishing of drugs or devices directly to a patient** by a physician…"<br><br>**4059. Furnishing Dangerous Drugs or Devices Prohibited Without Prescription**<br>➢ Exception: "furnishing of any dangerous drug or dangerous device by a manufacturer, wholesaler, or **pharmacy to each other** or to a physician… pursuant to Section 3640.7, or to a laboratory **under sales and purchase records**"<br><br>**4119.5. Transfer or Repackaging Dangerous Drugs by Pharmacy**<br>➢ (a) A pharmacy can transfer a reasonable supply of dangerous drugs to another pharmacy. | • White-bagged medications are marked as "dispensed" by the payer-designated pharmacy but not furnished directly to the patient<br>• White-bagged medications are not sold between the designated payer specialty pharmacy and receiving health-system pharmacy<br>• White-bagged medications are patient-specific medications and not considered "reasonable supply" being transferred between pharmacies |

https://www.pharmacy.ca.gov/laws_regs/lawbook.pdf (Accessed 10/28/2020)

# Centers for Medicare & Medicaid Services Conditions of Participation

| Regulation | Conflicts |
|---|---|
| ➢ **42 CFR §482.25 Condition of Participation: Pharmaceutical Services.**<br>❖ "hospital must have **pharmaceutical services** that **meet the needs of the patients**. The institution must have a pharmacy directed by a registered pharmacist or a drug storage area under **competent supervision**"<br>❖ **Interpretive Guidelines 482.25**: "Pharmaceutical services encompass the functions of **procuring**, storing, compounding, repackaging, and dispensing all medications, biologicals, chemicals and medication-related devices within the hospital. They also include providing medication-related information to care professionals within the hospital, as well as **direct provision of medication-related care**."<br><br>➢ **42 CFR: §482.25 (b) Standard: Delivery of Services.**<br>❖ "In order to provide patient safety, **drugs and biologicals must be controlled and distributed** in accordance with applicable standards of practice, consistent with **Federal and State law**" | • Hospital pharmaceutical services do not procure the medications<br><br>• White-bagged medications are not controlled and distributed in accordance with applicable standards as well as Federal and State laws |

https://www.law.cornell.edu/cfr/text/42/482.25 (Accessed 10/28/2020)
https://www.cms.gov/Regulations-and-guidance/Guidance/Transmittals/Downloads/R151SOMA.pdf (Accessed 10/28/2020)

# Additional Regulatory Conflicts

| | Regulations | Conflicts |
|---|---|---|
| **Drug Supply Chain Security Act** | ➢ "each transaction in which dispenser **transfers ownership of a product** shall provide subsequent owner with **Transaction Information**"<br>➢ "Dispensers are not required to provide…tracing information…if **dispensed to a patient or if it is a sale by a dispenser** to another dispenser to fulfill "a specific patient need"<br>➢ "Wholesale distribution…means **the distribution of a drug to a person other than a consumer or patient**, or **receipt of a drug by a person other than the consumer or patient**…" | • Payer-designated pharmacies do not directly dispense white-bagged medications to the patient nor sell them to another pharmacy<br>• Payer-designated pharmacies engage in wholesale distribution by providing white-bagged medications to health-system pharmacies instead of patients bypassing DSCSA requirements |
| **CA Health & Safety Code** | ➢ HSC §1367(g)"The (health) plan shall be able to demonstrate… that medical decisions are…**unhindered by fiscal and administrative management**" | • Health plan is making medical decisions based on financial incentives<br>• Payers are requiring patients to use designated specialty pharmacies for medications based on financial arrangements that serve as an inducement for patient referral |
| **CA Business & Profession Code (BPC)** | ➢ BPC 650. "any **rebate, refund, commission, preference, patronage dividend, discount**, or other consideration… as **compensation or inducement for referring patients**… irrespective of any membership, proprietary interest, or coownership in or with any person to whom these patients…are referred is unlawful" | |

https://www.fda.gov/drugs/drug-supply-chain-integrity/drug-supply-chain-security-act-dscsa (Accessed 10/28/2020)
https://codes.findlaw.com/ca/health-and-safety-code/hsc-sect-1367-2.html (Accessed 10/28/2020)

# State Progress

**MA**

- *247 CMR 9.01 (4)* "…a pharmacist shall not **redispense** any medication which has been previously dispensed"

**NJ**

- *State Board of Pharmacy 13:39-3.10* "[i]t shall be unlawful for a pharmacist to enter into an arrangement with a health care practitioner, or any institution, facility or entity that provides health care services, for the purposes of directing or **diverting patients** to or from a specified pharmacy or restraining in any way a **patient's freedom** of choice to select a pharmacy

**GA**

- *HB 233 Pharmacy Anti-Steering and Transparency Act § 26-4-119* prohibits pharmacies from presenting (or PBM from paying) claims for reimbursement that were received pursuant to a **referral from an affiliated pharmacy benefit manager (PBM)**

**OH**

- *OAC 4729-9-04* "No drugs that has been **dispensed** … and has left the physical premises of the **terminal distributor** … shall be dispensed or personally furnished"

https://www.mass.gov/doc/247-cmr-9-code-for-professional-conduct-professional-standards-for-registered-pharmacists/download (Accessed 10/20/20)
https://codes.ohio.gov/oac/4729-9-04 (Accessed 10/20/20)
http://www.legis.ga.gov/Legislation/en-US/display/20192020/HB/233 (Accessed 10/20/20)
https://www.njconsumeraffairs.gov/regulations/Chapter-39-State-Board-of-Pharmacy.pdf (Accessed 10/20/20)

# Safety Conflicts

| American Society of Clinical Oncology (ASCO) | National Comprehensive Cancer Network (NCCN) Specialty Pharmacy Task Force | National Coordinating Council for Medication Error Reporting and Prevention (NCCMERP) |
|---|---|---|
| Recommends against "brown bagging" and "white bagging" medications prepared by an outside entity | Recommends to standardize methods of communication with the health care team | Recommends to standardize processes to prevent error-prone aspects of the medication use process |

**Whitebagging Compromises Safety**

**Fragmentation of Care**

**Introduction of Risk Points to Medication Use Process**

ASCO: https://www.asco.org/sites/new-www.asco.org/files/content-files/advocacy-and-policy/documents/2016-ASCO-Brown-Bagging-White-Bagging-Brief.pdf (Accessed 10/20/2020)
JNCCN: https://jnccn.org/view/journals/jnccn/8/Suppl_4/article-pS-1.xml?utm_source=TrendMD&utm_medium=cpc&utm_campaign=JNCCN_TrendMD_1&print&print (Accessed 10/20/2020)
NCCMERP: https://www.nccmerp.org/recommendations-statements (Accessed 10/20/2020)

# White Bagging Patient Safety Challenges

- **Delays in care:**
  - Diseases and conditions that require drug infusions (e.g., cancer, solid organ transplant patients) require same day treatment decisions due to the critical condition of patients
  - Health-systems and doctors' offices have medications readily available to support timely, safe treatment
    - Delays can be life threatening (e.g. transplant organ rejection, chemotherapy progression or hospitalization)
    - Drugs and doses may be modified due to changes in patient-specific conditions (e.g., weight gain, renal function, bone marrow function, other labs or imaging studies)
    - Unavailable drugs and doses result in treatment delays
  - Risks at discharge and readmission risk
    - Patients remain in hospital due to delays in arranging for post-discharge dose, which increases the risk of hospital-acquired infection
    - Patient readmissions due to delay in mail order delivery resulting in exacerbation/ life threatening symptoms requiring hospital admission (esp. epoprostenol)

# White Bagging Patient Safety and Operational Challenges

- **Disrupts ordering process introducing risk of errors:**
  - Complete evidence-based drug therapy plans are built in electronic health records (EHRs) to support patient safety by having all the necessary medications, supportive treatment, labs, etc.
  - Drug therapy plans are not available for e-prescribing of infusion therapy; duplicate ordering in 2 different systems creates potential for errors
- **Patient disruption:**
  - Patients often change their scheduled appointments; patients arrive and drugs may not be available
- **Safety and Operational Concerns:**
  - Requires patient-specific inventory tracking; note most chemo regimens are 2-3 medications
  - Medications may not work with existing safety technology such as bar code scanning
  - A written master formula must be prepared prior to compounding a medication
  - Drug integrity safeguards bypassed
    - Unable to verify source of medications
    - Unable to ensure proper temperature storage

# Louisiana White Bagging Experience

**Legislative Action Letter – Louisiana Board of Pharmacy 8/27/2020**

- In many cases, patients who have been previously approved to receive their medication under the medical benefit are now being denied and forced to receive the medication under the prescription benefit outside of their healthcare organization.
- Patients have been midway through their chemotherapy regimens when these payer policies have been enacted
- Payer is unable to assist the patient in where they may go to have the medication administered resulting in severely delayed and oftentimes abandoned pursuit of treatment.

# Patient Examples

| Situation/Background | Assessment | Impact |
|---|---|---|
| Patient with prior malignancies and marked progression of **multiple sclerosis** since 2015, reported ongoing numbness/weakness in legs. Patient tolerated induction; however, PA request was denied for continued maintenance | **Insurance: UHC**<br>---<br>PA status: denied – required to be filled at **Specialty Phamacy**<br>➢ Maintenance dose due: 12/2020<br>➢ Order placed: 11/19/2020<br>➢ PA denied: 11/30/2020 | Delay in therapy<br><br>Patient needed to receive future infusions at another facility |
| Patient with **hepatocellular cancer** PA requests for new therapy were denied and **patient admitted for disease progression** | **Insurance: Blue Cross HMO**<br>---<br>PA status: denied – medication required to be filled at **Specialty Pharmacy** & administration required to be at a network facility<br>➢ Order placed: 10/6/2020<br>➢ PA denied: 11/6/2020<br>➢ Reconsideration request sent: 11/13/20<br>➢ Denial received: 11/16/2020 | Delay in therapy (~1.5 months)<br><br>Disease progression |