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Payer Policy Change AKA “White Bagging”

- Move from the “buy and bill” method, where providers buy and store these drugs for general use and bill payers for the dose used when they administer the drug to the patient

- Payers reimburse the third-party pharmacies, which then distribute the medications to outpatient medical providers

AKA “White Bagging”

Payer Policy Change AKA "White Bagging"

- This upsets the current traditional system, potentially sacrificing patient safety and quality care to benefit profit margins

- These changes disregard many "guardrails" in the medication administration and handling process necessitating thorough scrutiny by the pharmacy community

- April 1, 2020 – **Anthem** notified physicians (not hospitals) that providers are required to obtain certain medical specialty pharmacy medications administered in the office or outpatient hospital setting through CVS Specialty for commercial HMO beginning July 1, 2020.
- July 1,2020 – **Aetna** site of care management program for select oncology drugs
- September 2020 – **Anthem** announced (to hospitals and physicians) as of Dec 2 it will **expand** to commercial PPO/EPO plans
- September 2020 – **Cigna** applies to providers who bill using a hospital fee schedule rather than a physician fee schedule
- October 2020 – **United HealthCare** announced that it was requiring commercial plans to source drugs through specialty pharmacy in most states beginning Dec 2, 2020.

CHA Concerns

- **No notification to hospitals and non-specialty physicians (payer advance notice requirements)**
- **Patient safety and treatment delays**
  - Medication Integrity
  - Medication Adjustments and timely delivery of medications
  - Preparation and labeling
- **Impact on hospital operations**
  - Strain on hospital systems
  - Increased administrative burden
  - Threats to 340B Drug Pricing Program for hospitals

CHA Advocacy

- **June 2020** – CHA was notified by members of Anthem change on July 1
- **June 2020** – met with DMHC (Mary Watanabe) in partnership with APG and members; argued the neglect of advance notification requirement to hospitals and the patient safety and operational issues inherent in white bagging. Response: DMHC would not ask Anthem to delay or stop the role out of policy. Asked for us to report any enrollee patient care issues
- **July/Sept** – CHA has internal member discussion as well as external discussions with CMA, CCHA, APG, ANOC, American Cancer Society/ California
- **Sept/Dec 2020** – CHA Agenda topics at CHA Managed Care and Medication Safety Committee
- **January 2021 -** CHA sent letter of concern to DMHC

State Board of Pharmacy

Regulation	Conflict
4024. Dispense ➢ "'Dispense' also means and refers to the **furnishing of drugs or devices directly to a patient** by a physician…" **4059. Furnishing Dangerous Drugs or Devices Prohibited Without Prescription** ➢ 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**" **4119.5. Transfer or Repackaging Dangerous Drugs by Pharmacy** ➢ (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 • White-bagged medications are not sold between the designated payer specialty pharmacy and receiving health-system pharmacy • White-bagged medications are patient-specific medications and not considered "reasonable supply" being transferred between pharmacies

Centers for Medicare & Medicaid Services Conditions of Participation

Regulation	Conflicts
➢ **42 CFR §482.25 Condition of Participation: Pharmaceutical Services.** ❖ "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**" ❖ **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**." ➢ **42 CFR: §482.25 (b) Standard: Delivery of Services.** ❖ "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 • White-bagged medications are not controlled and distributed in accordance with applicable standards as well as Federal and State laws

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**" ➢ "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" ➢ "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 • 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 • 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"	

Other Advocacy Efforts

- **Mass Health Policy Commission 2017**
  9% of drugs WB/1% BB, in hospital, MD office, 26%WB, 2%BB, detailed study with recommendations – now evolving to 2021 legislation

- **2018 NABP Survey/Study**
  28-31% of drugs nationally through white bagging/brown bagging and few states define the concept of white bagging – terms and conditions are under payer not regulator, therefore regulatory boards must consider accountability and efforts to protect the public, the control and responsibility for the integrity and timely delivery of the medications under these practices are two issues most relevant to boards of pharmacy. “There is legitimate patient protection issues when a specialty drug is distributed to an entity other than the patient.”

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"

Recent Advocacy

- 2/4/21 – AHA Letter to CMS
- The practice should only be permissible in instances where the provider and health plan agree through their standard negotiations that such arrangements are in the best interest of the patient…providers must be joint partners, and safety cannot be compromised… providers should not be required to accept these arrangements when they are unilaterally forced upon them by payers. Providers should be permitted to decline any such arrangements based on quality-of-care concerns”

Options for White Bagging Policy

- Is this a public safety, consumer protection issue?
- Is white bagging in conflict with our present state pharmacy regulations? If so why; if not, why not?
- Can the Board of Pharmacy review present state regulations against white bagging policies?
- Can the Board of Pharmacy suggest next steps based on the information provided?