



White/Brown/Clear Bagging Payer Policy Changes

2/18/2021

Outline

- Definitions
- Why is this an issue now?
- Regulatory Concerns
- Safety Concerns
- Patient Impact
- Related State Legislature
- Recommendations

Definitions

White bagging: A specialty pharmacy ships a patient's prescription directly to the provider, (Hospital or Clinic) . The provider holds the product until the patient arrives for treatment.

Brown bagging: The patient picks up a prescription at a pharmacy or has it delivered to their home which is then taken to the provider (Hospital or Clinic), for administration.

Clear bagging: A provider's internal specialty pharmacy dispenses the patient's prescription and transports the product to the location of drug administration.

Why is this an issue now?

- Payer Cost of Care initiative
 - Rolling out policy changes
- Vertical Integration
 - Payer + PBM + Specialty Pharmacy
- Transition from Medical Benefits to Pharmacy Benefits
 - Adding the additional layer of Specialty Pharmacy
 - Specialty Pharmacy buys and bills for drug
 - Hospital or Provider only bills for administration
- Increasing number of Payers making and mandating these policy changes.
 - Impacts patient care and patient safety
 - Conflicts with various regulatory requirements

Concerns – Regulatory

The hospital pharmacy is responsible for procuring, storing, compounding and dispensing medications to be administered to hospital patients

- California Business and Professions Code 650, 4024, 4059, 4119
- CCR, Title 16, 1776.1(g)(3) – Recalls
- Drug Supply Chain Security Act (Title II of Pub. L. 113-54)
- Conditions of Participation in the Medicare Program (42 CFR §482.25)
 - A hospital's pharmaceutical service functions to procure, store, compound and dispense all medications, biologicals and devices within the hospital – including its outpatient locations
- The Joint Commission, and many professional associations expect the hospital pharmacy to control the process for procuring, storing and dispensing medications as a recognized medication safety measure
 - Example: Joint Commission Standards MM.02.01.01, MM.03.01.01, and MM.05.01.07

Concerns – Regulatory

| CA BOP | Conflicts |
|--|--|
| B&P article 2 4024: Dispense | <ul style="list-style-type: none"> 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 |
| B&P article 3 4059: Furnishing of Drugs prohibited without prescriptions | |
| B&P article 19 4119.5 Transfer or Repackaging of Dangerous Drugs by pharmacy | |

| Business and Professions Code | Conflicts |
|---|--|
| <ul style="list-style-type: none"> B&P 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” | <ul style="list-style-type: none"> The definition of white bagging is in essence requiring to use a designated/contracted specialty pharmacy for medications based on financial incentives for the payer. |

Concerns – Regulatory

| CMS Conditions of Participation | Conflicts |
|--|--|
| <ul style="list-style-type: none">• 42 CFR §482.25 Condition of Participation: Pharmaceutical Services.<ul style="list-style-type: none">• " hospital must have pharmaceutical services that meet the needs of the patients. The institution must have a pharmacy directed by a medications 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" | <ul style="list-style-type: none">• In the case of White Bagging, Hospital pharmacies will not procure medications• White-bagged medications are not controlled and distributed in accordance with applicable standards as well as Federal and State laws |

Concerns – Regulatory

| Drug Supply Chain Security Act (DSCSA) | Conflicts |
|--|--|
| <ul style="list-style-type: none">Requires transaction information traced back to original distribution. | <ul style="list-style-type: none">Payer-designated pharmacies do not directly dispense white-bagged medications to the patient nor sell them to another pharmacy. No transaction information |

| CA Health & Safety Code | Conflicts |
|--|--|
| <ul style="list-style-type: none">HSC 1367 g : The (health) plan shall be able to demonstrate... that medical decisions are...unhindered by fiscal and administrative management | <ul style="list-style-type: none">White Bagging is driven by Financial Incentive for Health Plan |

Concerns – The Joint Commission

| TJC Medication Management | Conflicts |
|---|--|
| <ul style="list-style-type: none">• MM02.01.01 (Selection and procurement of medications)• MM03.01.01 (Safe storage of medications)• MM05.01.07 (Safe preparation of medications) | <ul style="list-style-type: none">• White/Brown bagging is in direct conflict with all 3 standards as it removes the control of the process for procuring, storing and dispensing medications out of hospital purview. |

Safety and Waste

Payer-mandated use of external pharmacies lacks any assurances against shipment loss or delays

- Increased risk of avoidable errors:
 - delivery delays
 - lost shipments
 - dosage errors
- There is no assurance that a needed drug will be available to the patient at the time of the visit resulting in delays in care.
 - interrupt or postpone life-saving therapies received by patients, and negatively impact patient care outcomes
- Lack of leverage with specialty pharmacies to correct safety issues
- Increased waste if the shipped medication cannot be used by the intended recipient, for any reason, (dose change), then the provider is prohibited from using this patient specific medicine for another patient

Safety

- **External payer-mandated pharmacies do not provide the same level of pharmaceutical surveillance and safeguards as the on-site hospital pharmacy**
 - Lack access to up-to-date clinical information (laboratory test results, medication lists)
 - Unable to perform drug interaction checks, screen for contraindications, and medication reconciliation
 - Unable to prevent inadvertent or improper ordering and administration of a medication
 - Many of the specialty medications are high-risk chemotherapy agents, errors with which may be detrimental to patients' health and could result in harm or death
- **Forced use of external pharmacies hinders the ability of the hospital pharmacy to provide proper oversight and stewardship of medications**
 - Impairs ability to rapidly identify and quarantine recalled products
 - The provenance (pedigree, storage and handling) of the products cannot be determined.

How are patients impacted?

| Patient | Impact |
|---|---|
| 64 y/o Female with Brain Cancer and Melanoma | One week gap in treatment caused by sudden payer mandated switch to White Bagging |
| 59 y/o Male with Colon and Liver Cancer | Physician switched treatment from an infusion therapy to oral therapy to avoid gaps and delivery complications related to white bagging. Only one infusion drug of the regimen was required to be white bagged. |
| 60 y/o Male with Neuroendocrine Tumor | Two month gap in treatment caused by patient's inability to afford their share of cost as a result of conversion from medical benefit to pharmacy benefit due to payer mandated switch to white bagging |
| 54 y/o Female with Liposarcoma | Patient pending hospital discharge after chemotherapy treatment was unable to receive medication from mandated specialty pharmacy. Patient was referred to |

Keck Medicine of USC Process

- Strict policy that prohibits white and brown bagging. Exceptions under extenuating circumstances
- Patient letter
 - Option to file complaint with DMHC
- Provider communication/Townhalls
- Continue to attempt to resolve with Payer through business solutions.
- Stand united with our colleagues in asking Our Board to Advocate for our patients.

What are other states doing?

- Massachusetts – 247 CMR 09.01(4)
 - Identifies white bagging as “re-dispensing” which is prohibited
- New Jersey – N.J.A.C. 13:39-3.10 and
Georgia – GA. Code Ann. § 26-4-119
 - Prohibit diverting or redirecting patients to a specified pharmacy
- Ohio – OAC 4729.43 prohibits non-self-injectable cancer medications from being distributed directly to a patient

Summary and Ask

- Asking the Board to evaluate the public safety risk and take swift action.
 - Review and revise current regulations to prohibit unilateral payer mandated white bagging policies
 - Review and revise current regulations to prohibit unilateral exclusion of Health-System owned specialty pharmacies from payer network.
 - If oversight of these policies is outside of BOP jurisdiction, to advocate and collaborate with stakeholders to adopt appropriate regulations to prohibit payer mandated white bagging strategies
 - Provide guidance on next steps with regards to white bagging.

References

American Hospital Association

California Hospital Association

California Business and Professions and Health and Safety Codes

CMS Conditions of Participation

Health Policy Commission. (2019). Review of Third-Party Specialty Pharmacy Use For Clinician-Administered Drugs. Commonwealth of Massachusetts.

The Joint Commission

Ohio Society of Health-System Pharmacists. (2020, October 22). OhioSHP.org. Retrieved from The Ohio Society of Health-System Pharmacists Position Statement on White Bagging: <https://www.ohioshp.org/resources/Documents/20Statement%20--White%20Bagging.pdf>

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