

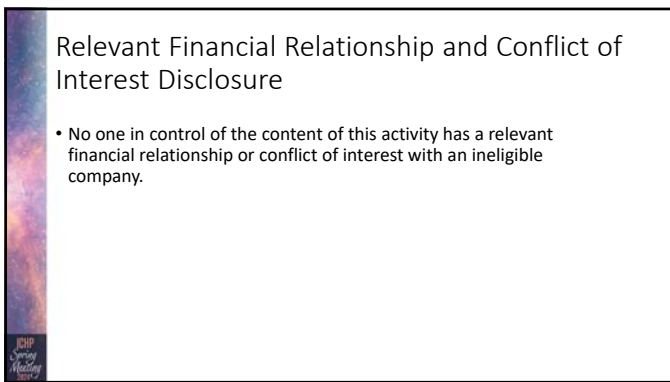
**Medication Bagging Challenges:
Where Do We Go From Here?**

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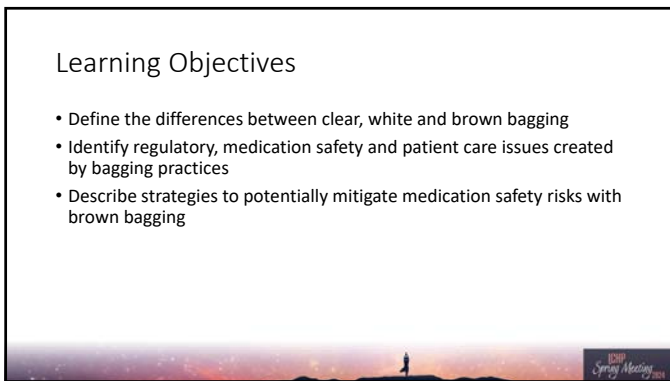
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Relevant Financial Relationship and Conflict of Interest Disclosure

- No one in control of the content of this activity has a relevant financial relationship or conflict of interest with an ineligible company.

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Learning Objectives

- Define the differences between clear, white and brown bagging
- Identify regulatory, medication safety and patient care issues created by bagging practices
- Describe strategies to potentially mitigate medication safety risks with brown bagging

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Provider-Administered Medications


- Clinics, hospital outpatient departments, infusion services
- Traditionally buy and bill plus an administration fee
- Subject to strict regulatory requirements for acquisition, storage and handling
- Frequently specialty medications



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Buy and Bill Payment Structures


Medicare	Medicaid	Commercial
<ul style="list-style-type: none">Average sales price + 6% + administration fee	<ul style="list-style-type: none">Often acquisition cost + administration fee	<ul style="list-style-type: none">Percentage of chargesNegotiated rates



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Drug Acquisition and Payment Shifts

Buy and Bill	→	Bagging
Medical Benefit	→	Pharmacy Benefit
Lower Patient Cost Sharing	→	Higher Patient Cost Sharing



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Payer Rationale for Transitioning to Bagging

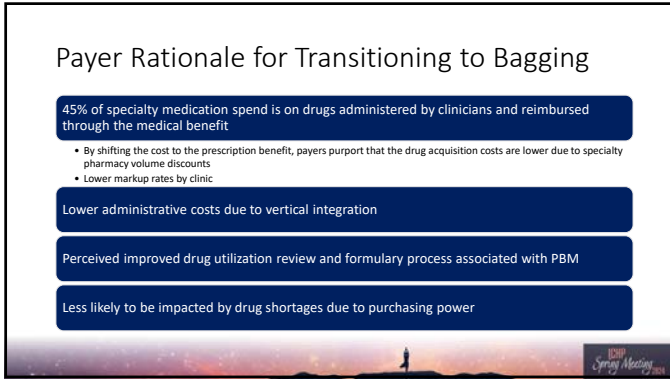
45% of specialty medication spend is on drugs administered by clinicians and reimbursed through the medical benefit

- By shifting the cost to the prescription benefit, payers purport that the drug acquisition costs are lower due to specialty pharmacy volume discounts
- Lower markup rates by clinic

Lower administrative costs due to vertical integration

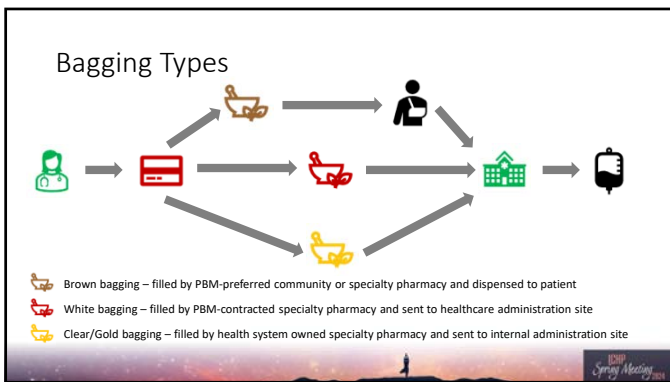
Perceived improved drug utilization review and formulary process associated with PBM

Less likely to be impacted by drug shortages due to purchasing power



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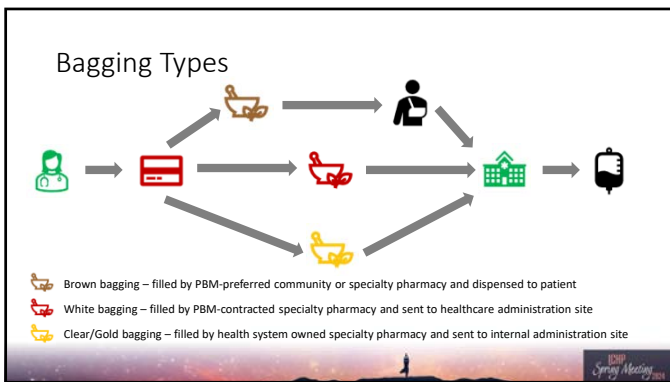
Bagging Types



Brown bagging – filled by PBM-preferred community or specialty pharmacy and dispensed to patient

White bagging – filled by PBM-contracted specialty pharmacy and sent to healthcare administration site

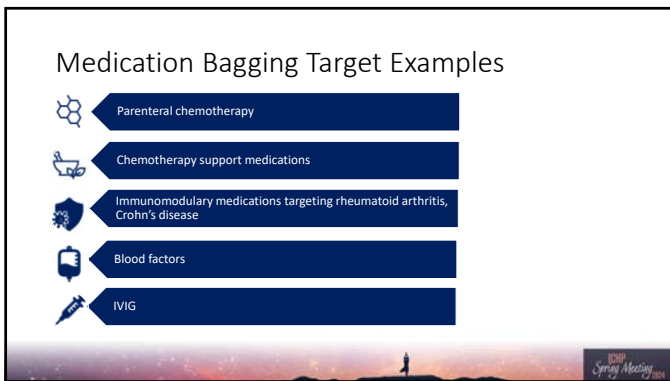
Clear/Gold bagging – filled by health system owned specialty pharmacy and sent to internal administration site



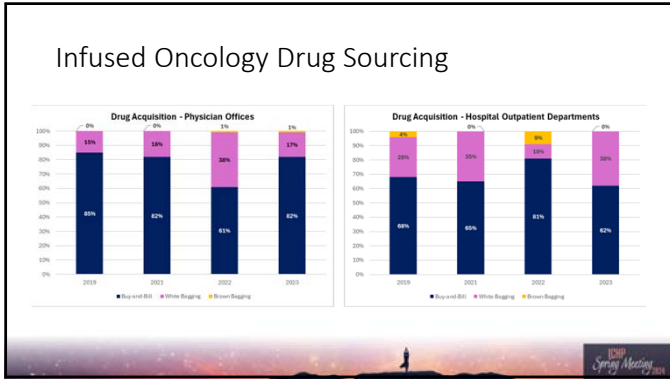
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Medication Bagging Target Examples

- Parenteral chemotherapy
- Chemotherapy support medications
- Immunomodulatory medications targeting rheumatoid arthritis, Crohn's disease
- Blood factors
- IVIG



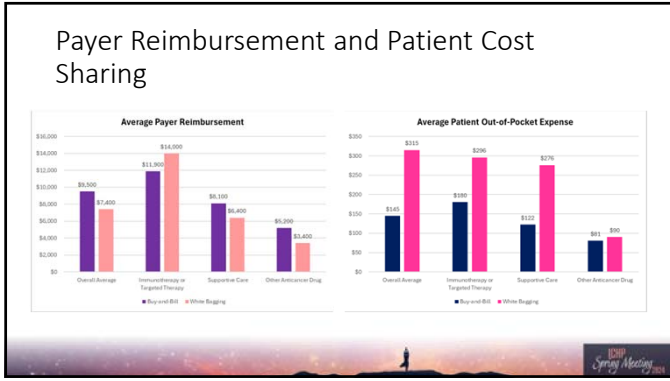
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Bagging and Regulatory Considerations

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Medication Management Standards and Bagging

MM.02.01.01: The hospital selects and procures medications

- 6. The hospital standardizes and limits the number of drug concentrations available to meet patient care needs.
- 7. The hospital follows a process to select, approve, and procure medications that are not on its formulary

MM.03.01.05: The hospital safely controls medications brought into the hospital by patients, their families, or licensed practitioners.

- 2. Before use or administration of a medication brought into the hospital by a patient, their family or a licensed practitioner, the hospital identifies the medication and visually evaluates the medication's integrity.

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Medication Management Standards and Bagging

MM.05.01.17: The hospital follows a process to retrieve recalled or discontinued medications.

- 4. When required by law and regulation or hospital policy, the hospital informs patients that their medication has been recalled or discontinued for safety reasons by the manufacturer or the US Food and Drug Administration (FDA).

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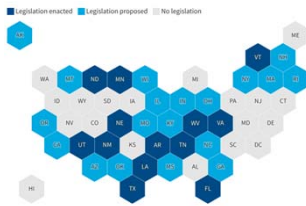
DSCSA Considerations

Drug Supply Chain Security Act (DSCSA)

- Requirements aimed to deter, detect, and remove potentially dangerous drugs from the supply chain
- Track and trace
- Patient-specific medication

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Bagging Legislation



Source: American Society of Health-System Pharmacists; legislative sessions 2021-23 Map data: Telegrams/NPR

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Illinois Proposed Legislation – SB3225

- Introduced February 3, 2023 by Cristina Castro
 - Health benefit plans (HBP) or pharmacy benefit managers (PBM) shall not:
 - Require a patient to obtain a clinician-administered drug from a pharmacy selected by the HBP or PBM
 - Require a patient to obtain a clinician-administered drug from a pharmacy selected by the HBP or PBM with the intent to have it transported to another site of service for administration
 - Offer financial incentives for patients to do one of the above
 - Deny or restrict coverage for a drug provided by a pharmacy, for provider administration, not specified by the HBP or PBM
 - Deny or limit reimbursement for the above
 - Assess higher fees to the patient for the above
 - Require an enrollee to use home infusion or use a site of service identified by the HBP or PBM
- Reassigned to the insurance committee on 1/10/24

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
Providers and Bagging Options

- Accept all bagged medications
- Deny all bagged medications and refer those patients to another location for administration
- Deny certain types of bagging and refer those patients to another location for administration
- Negotiate with insurers for buy and bill or clear bagging only



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Strategy for Addressing Brown Bagging Concerns



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- 445 bed hospital
- 30+ Outpatient clinics
- 7 onsite Ambulatory Pharmacies



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Compliance

MM.03.01.05 The hospital safely controls medications brought into the hospital by patients, their families, or licensed practitioners
Before use or administration of a medication brought into the hospital by a patient, their family or a licensed practitioner, the hospital identifies the medication and visually evaluates the medication's integrity.


UI Health Hospital Policy TX 3.11

II. Outpatient Use of Patient's Own Medications

1. As a rule, medications that are to be administered to patients in the clinics should be obtained from the Hospital pharmacy.
2. The use of the patient's own medications will be allowed if the medication cannot be obtained by the Hospital pharmacy, such as due to health plans restrictions. In these cases, medications should be sent directly to the Hospital pharmacy by the outside specialty pharmacy. They should not be brought to the clinic by the patient or mailed to the clinic from an outside source unless required.
3. Prior to administering the medication(s) to the patient, the Hospital pharmacist will, to the best of his/her ability, ensure its integrity and that it is the medication ordered for the patient.
4. The person administering the medication should document in the patient's medical record that the medication was obtained from an external source and given to the patient.

Prior to administering the medication(s) to the patient, the pharmacist will ensure its integrity and the medication is ordered for the patient

For safety purposes, a pharmacist must conduct the Outside Medication Verification process



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Descriptions We Use at UI Health (UIH)

- Patient supplied medications
- Outside medications
- Brown, white, clear & gold bagged medications



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Scenarios

For Future appointments:


- Medication is delivered (via mail) to clinic directly
- Medication is delivered to the Medication Assistance Program Clinic (MAP) embedded inside the Specialty Care Building pharmacy

For Same Day appointments:

- Medication is brought in by patient
- Medication is dispensed from in-house pharmacy

All scenarios:


- Nurse or patient must bring patient specific medication to pharmacist for verification prior to administration in clinic
- Must be prescribed by UI Health Provider only



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Partnership: Ambulatory Nursing and Pharmacy

- Rx/RN Operations Committee
 - Identified potential risks and compliance gaps
- Workflow process design was a collaboration between Ambulatory Nursing and Pharmacy
- Developed audit model and implemented



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Timeline




2019/2020
• Surveys and gap analysis

3/2021
Outside medication verification required

2021
Nurse, Provider & Pharmacy education continued

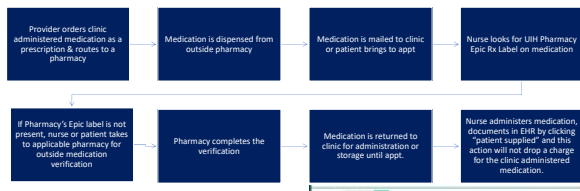
2/2022
First Audit

2024
Monthly Audits shared with Rx/RN Operations Committee & Ambulatory Services





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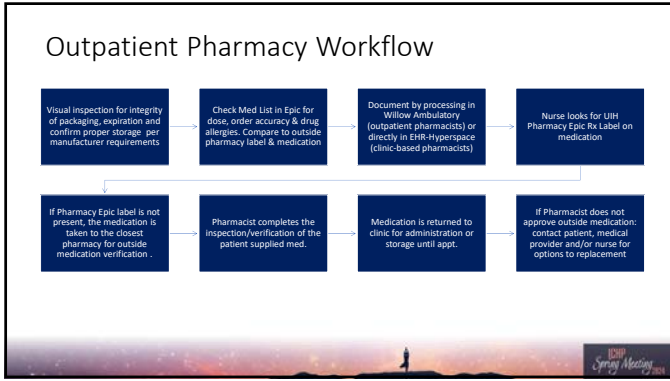
Clinic Nursing Workflow



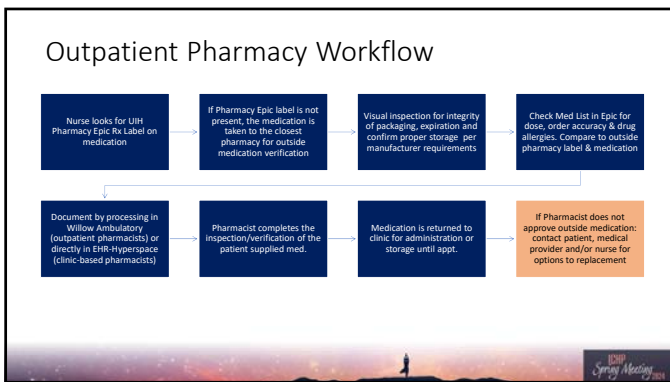
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graph TD; A[Provider orders clinic administered medication as a prescription & routes to a pharmacy] --> B[Medication is dispensed from outside pharmacy]; B --> C[Medication is mailed to clinic or patient brings to appt]; C --> D[Nurse looks for UIH Pharmacy Epic Rx Label on medication]; D --> E[Nurse administers medication, documents in EHR by clicking "patient supplied" and this action will not drop a charge for the clinic administered medication.]; E --> F[Medication is returned to clinic for administration or storage until appt.]; F --> G[Pharmacy completes the verification]; G --> H[If Pharmacy's Epic label is not present, nurse or patient takes to applicable pharmacy for outside medication verification]; H --> A;
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Outside Medication Verification Label

Rx filled at UIH Pharmacy

UIC WOOD ST FCC OF PHARM...
312-999-6887
840 S Wood St, Rm 183, CHICAGO, IL 60612
Rx #: 200317535-02
Filed On: 12/18/2020

Test, Maptestpt
Synagis 100 MG/ML injection

Generic: palivizumab
Inject 150mg/kg intramuscularly once monthly

Shannon Murphy MD
No refills remaining
Initial Review: SO

Qty: 1 vial
RPh: SO

Outside medication verified by UIH Pharmacy

UIC WOOD ST FCC OF PHARM...
312-999-6887
840 S Wood St, Rm 183, CHICAGO, IL 60612
Rx #: 200317547-02
Filed On: 12/18/2020

Test, Maptestpt
OUTSIDE MEDICATION VERIFICATION

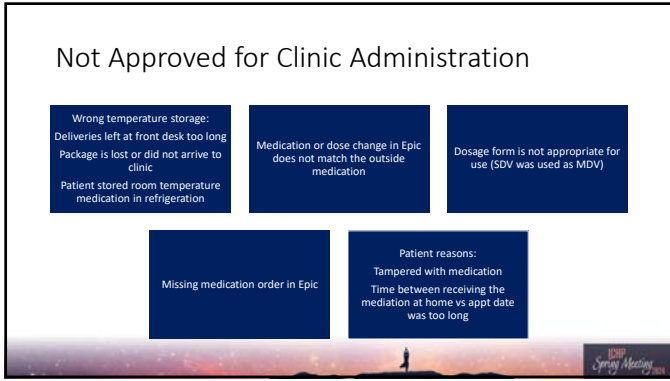
Medication: Synagis 100 mg/mL, Indication: Inject 150mg/kg intramuscularly once monthly, NDC: 60578-4113-01, Lot: LPH122, Exp: 04/2022

Shannon Murphy MD
No refills remaining
Initial Review: SO

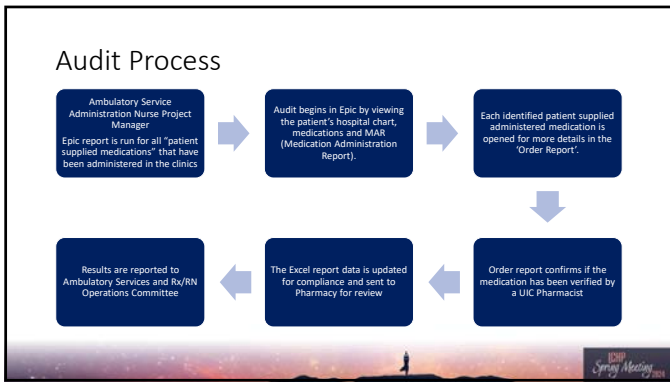
Qty: 1 vial
RPh: SO

The outside medication is processed in the same manner as a prescription. Turn around time will depend on same day (Waiter) or future appt (24 hours).

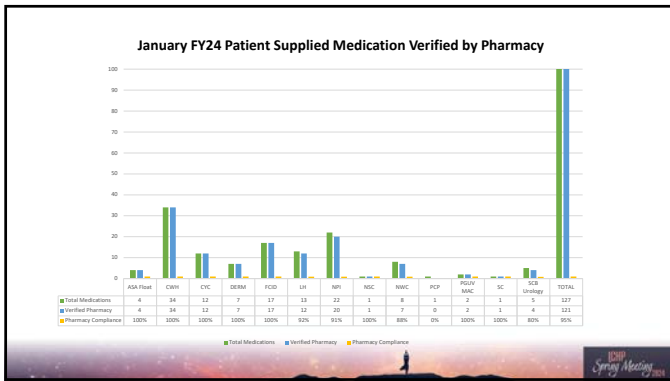
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