



ASHP Hospital and Health System Self-Assessment

Impact of Payer Mandated White Bagging Policies

Considerations for Hospitals and Health Systems: Patient and Prescriber Safety and Satisfaction

- Assess and document patient care issues such as delays in treatment changes, impact on transitions of care, delays in new start therapies.
- Assess patient, prescriber, and employee satisfaction as well as the financial impact resulting from white bagging.
- Evaluate the impact on patient safety by the potential by-passing of electronic health record systems designed to improve outcomes (i.e. do white bagged medications integrate with medication interaction and adverse drug reaction safe guards, disrupt patient protocols developed by P&T committee, or negatively impact P&T formulary processes)

Considerations for Hospitals and Health Systems: Drug Supply Chain Integrity

- Determine if the payer and PBM mandated white bagging policies are counter to the FDA DSCSA requirements.
- Assess the impact of drug recall management challenges that may be created due to white bagged medications and risk/liability that may be introduced to medication use system.
- Determine if there is additional indemnification required to accept a medication dispensed to a patient but mailed to the organization. This should include (a) ability to accept the medication and (b) protections from anything that is wrong with the medication dispensed from the payer directed pharmacy (i.e. dispensing error, dispensing of a FDA recalled drug, or any other issue with dispensed drug prior to receipt by hospital)

Considerations for Hospitals and Health Systems: Medication Use Processes

- Assess labor, overhead, regulatory requirements, and risk management expense not accounted for in historical rates for drug administration fees and demand new rates or separate rates to account for the lost value of buy-and-bill drug models resulting from white bagging of drugs.
- Assess whether the ROUTINE dispensing of patient specific medications delivered to a site of care bypassing the patient taking possession of their own medication is compliant with laws and regulations and determine if the practice should be allowed in organization. (I.e. What is hospitals and health systems' legal and regulatory risk for taking possession of a patient's prescription dispensed another pharmacy?)
- Assess whether accepting a patient specific medication dispensed by an external pharmacy with the intent the drug be opened by someone other than the patient and then manipulated and/or



compounded and subsequently “re-dispensed” for administration is legal according to state law and determine if the practice be allowed. This would also include an assessment of compliance requirements, if any, to Federal and State track and trace rules for each white bag.

- Determine whether dispensing a patient specific medication from hospital or health systems own pharmacies, when on a common electronic health care record, ensures patient continuity of care and regulatory compliance.

Considerations for Hospitals and Health Systems: Patient Billing and Compliance

- Assess impact on billing compliance processes to ensure patients are not double-billed for medications.
- Evaluate billing compliance laws in the cases where a white bagged medication mailed to the hospital is not used for a patient (i.e. which party has the responsibility for providing a ‘credit’ or reverse billing for the drug)

Considerations for Hospitals and Health Systems: Contract Management

- Evaluate all opportunities to mitigate the impact of white bagging, including opportunities to become an in-network provider.
- Evaluate the impact of continued willingness to provide uncompensated patient care due to payers and PBM’s requirements to use white-bagged medications (i.e. care coordination, white bagged medication storage and handling, hazardous waste management, ensuring electronic health record integrity, and patient monitoring)
- Determine if the payer and/or PBM changes to mandate white bagged medications are in accordance to the existing contract terms (i.e. has the payer implemented a practice that is a change in existing contract(s) that is prohibited without both parties agreeing)
- Assess the financial impact of not being able to buy and bill for the white bagged drugs, including impact on the saving from 340B program to meet the intent of the 340B program.