

# Who's Left Holding the "Bag?"

The Challenges with White and Brown Bagging from a Pediatric Perspective

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# Disclosures

- There are no disclosures or conflicts of interest to report

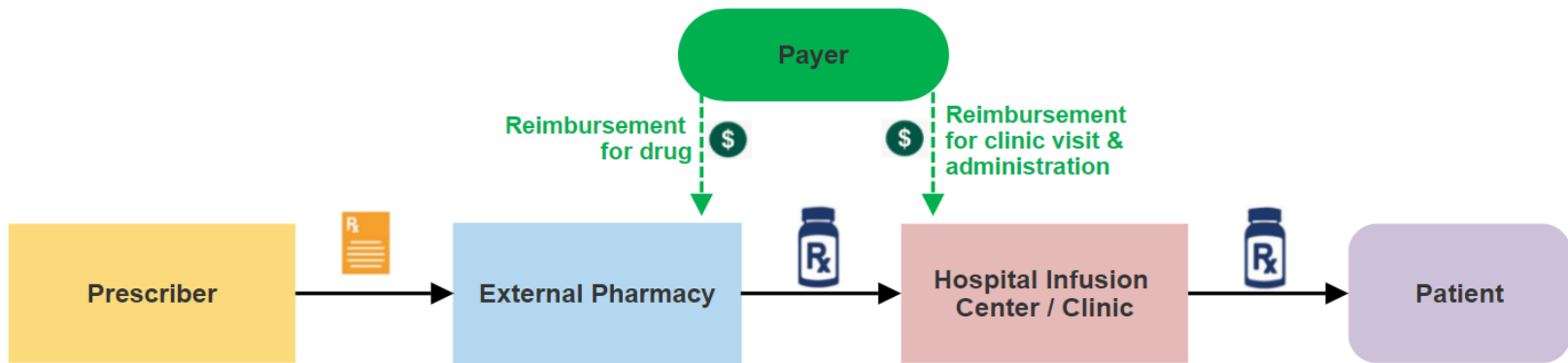
# Comparison of Distribution Models

	Buy and Bill	White Bagging	Brown Bagging	Clear Bagging
Process	<ul style="list-style-type: none"> <li>The hospital purchases a medication from a pharmaceutical wholesaler or specialty distributor</li> <li>After administering the medication, the <b>hospital provider submits a claim for reimbursement of the medication</b></li> </ul>	<ul style="list-style-type: none"> <li>The patient-specific labeled medication <b>ships directly to the hospital infusion center from an external pharmacy</b> not associated with the clinic.</li> <li>The <b>dispensed product is stored in the hospital</b> until the patient presents at the infusion center for administration.</li> <li>The external pharmacy submits a claim for drug reimbursement.</li> </ul>	<ul style="list-style-type: none"> <li>The <b>patient receives a medication from a pharmacy</b> (retail, mail order etc.) and <b>brings the medication to the clinic or infusion center</b> for administration by a healthcare provider.</li> </ul>	<ul style="list-style-type: none"> <li>The patient's insurance company requires that the drug is provided through a specialty/retail pharmacy.</li> <li>A specialty/retail pharmacy <b>associated with the same institution</b> as the hospital infusion center <b>dispenses medications to the infusion center</b> for patient-specific use</li> </ul>
Insurance Benefit Billed	<b>Medical</b>	<b>Pharmacy</b>	<b>Pharmacy</b>	<b>Pharmacy</b>

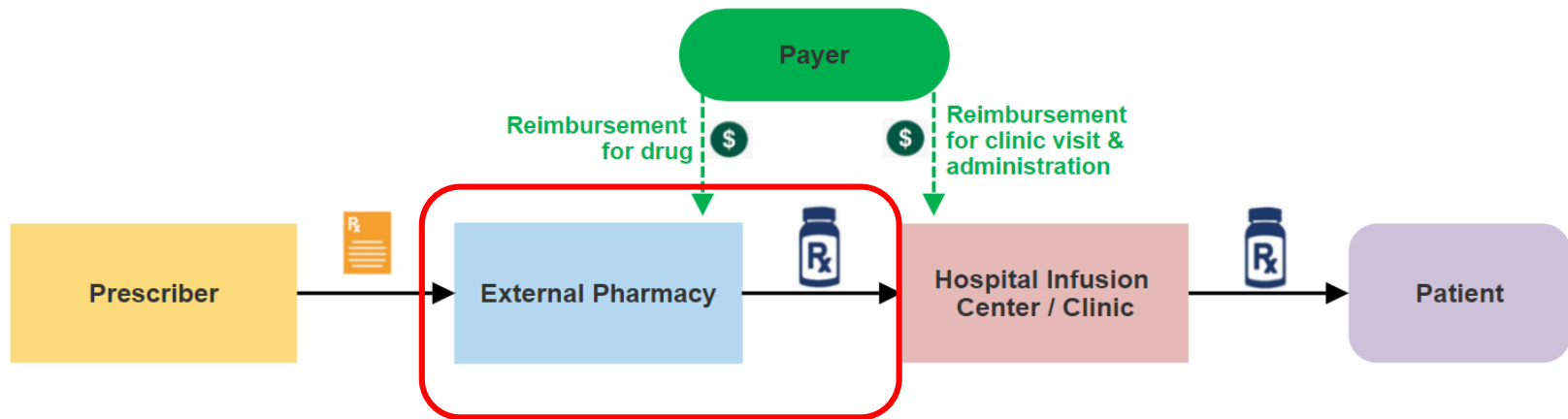
# Historical Perspective

- In April 2018, the National Association of Boards of Pharmacy (NABP) published a report on “White and Brown Bagging- Emerging Practices, Emerging Regulation,” defining both white- and brown-bagging and studying their prevalence in practice
- The report highlighted potential benefits and risks to various stakeholders impacted- the patient, provider and pharmacy/facility
- They also found that roughly 1/3 of medical benefit drug volume was being fulfilled by either white- or brown-bagging mechanisms
- The study determined that there is a legitimate patient protection issue when a specialty drug is distributed to an entity other than the patient, for administration at the entity.

# White Bagging Process



# White Bagging Process



Introduction of an extra layer that leads to greater risk than necessary & no additional benefit

# What is the Problem with White Bagging?

Medication Management Element	Risk or Failure Point
Prescribing	<ol style="list-style-type: none"><li>1. Pediatric patients experience weight changes during the growth process, which requires doses to be changed frequently in order to provide the right dose. This demands flexibility in the fulfillment process to provide the appropriate dose.</li><li>2. Dose or therapy changes will occur &amp; can result in financial burden to patient, excessive waste or potential for error if not reconciled.</li></ol>
Distribution	<ol style="list-style-type: none"><li>3. Lack of supply chain/ transport oversight, especially with drugs that require special handling and temperature monitoring → unable to verify authenticity or integrity of drug (or eliminate counterfeit &amp; contamination risk).</li><li>4. Recall management responsibility lies on the entity, who doesn't have information on what was purchased (manual process).</li><li>5. Upcoming DSCSA compliance may pose challenges to tracking at the patient level.</li><li>6. Chain of custody must be maintained for any life-saving or curative therapies (gene therapies, metabolic enzyme therapies, compounded medications administered to the CNS, etc), especially because some of these therapies are once-in-a-lifetime opportunities or extremely costly.</li></ol>

# What is the Problem with White Bagging?

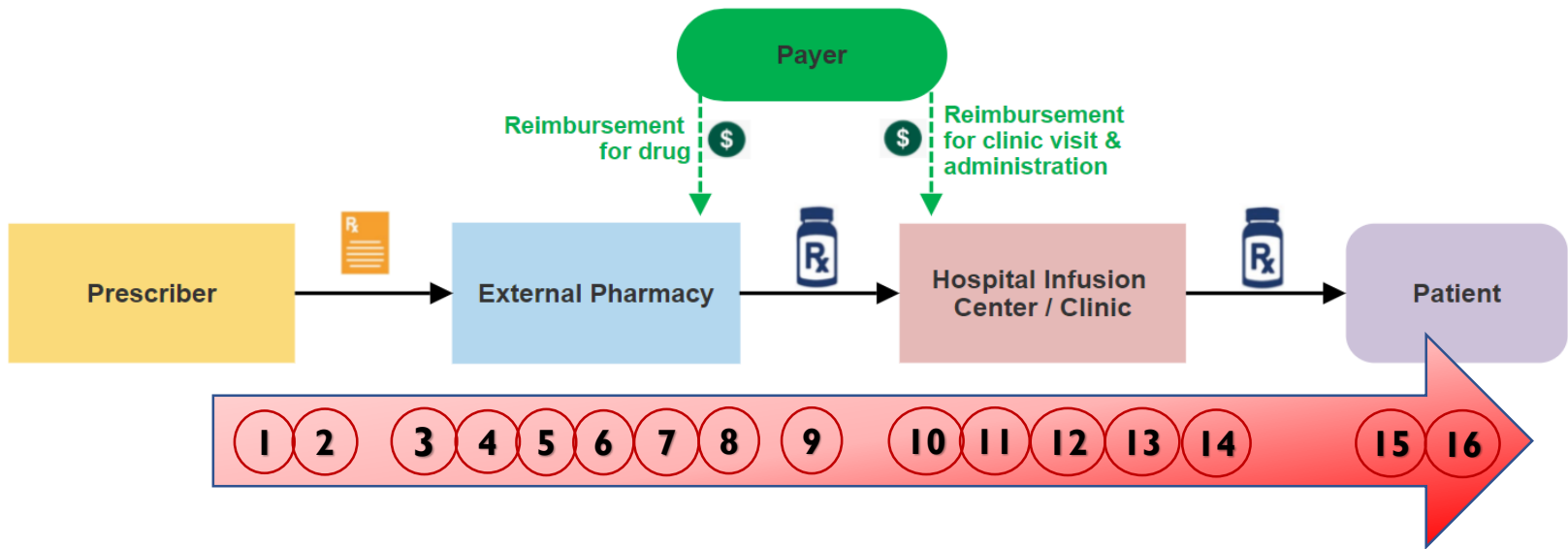
Medication Management Element	Risk or Failure Point
Dispensing	<p>7. External pharmacies do not have access to the patient's medical record, and hence have a limited ability to <b>comprehensively</b> evaluate &amp; monitor therapy appropriateness during prescription verification &amp; review.</p> <p>8. Lack of pediatric expertise, especially in specialty conditions, can lead to errors.</p> <p>9. Therapy can be delayed due to delayed deliveries, lost shipments, or lack of coordination in receipt of drug and dose administration schedule, adversely impacting patient outcomes.</p>
Compounding	<p>10. Assume liability for compounding a product where authenticity and integrity cannot be verified (CCRI 735.2(g) &amp; (h) compliance challenge)</p> <p>11. For hazardous agents, there may be incompatibilities with safety protections such as closed system transfer devices, which necessitates compounding by the entity to maintain protection of patient and staff.</p>



# What is the Problem with White Bagging?

Medication Management Element	Risk or Failure Point
Administration	<p>12. For administration related reactions, there is no way to determine if the quality of the drug was not a contributing factor.</p> <p>13. Pediatric patients require a special skill set in delivering care, which is best within a facility that is accustomed to providing pediatric care (IV line placement, monitoring, emergency response).</p>
Patient Education	<p>14. The provider takes on the full responsibility related to education and information related to administration of drug, not necessarily the dispensing specialty pharmacy.</p>
Monitoring	<p>15. External pharmacies cannot monitor as comprehensively as health system pharmacies for adverse effects, adherence and patient outcomes, while communicating effectively with the provider.</p> <p>16. External pharmacies would not be able to perform any required safety monitoring prior to dose administration of certain specialty medications.</p>

# Potential Failure Points



# And What About that Brown Bag?

- Share similar failure points as white bagging, but with more risk from lack of supply chain oversight
- Medication storage conditions observed with brown-bagging



# Recommendations

- Support buy and bill process for patients under the care of a pediatric hospital or health system, by regulating white-bagging, especially from out-of-state dispensing pharmacies.
  - Texas BoP has adopted regulations that essentially prohibits return and redispensing of prescription drugs. §291.8 Return of Prescription Drugs  
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- Support clear bagging by prohibiting exclusion from payer networks that have resulted from oligopolistic practices of vertical integration (payers, pharmacy benefit managers, and their owned specialty pharmacies).
  - These exclusions do not allow pediatric hospital/health-system owned specialty pharmacies to care for the patients that they are responsible for and accountable to

**THANK YOU!**