

Specialty Drug Channel Management Report | July 1, 2021



Indiana
Department
of
Health



Report Requirement

IC 34-30-2-101.4 requires: (c) Before July 1, 2021, the state department of health, in consultation with the department of insurance, the office of the secretary of family and social services, and the Indiana board of pharmacy created by 25-26-13-3, shall submit to the legislative council in an electronic format under IC 5-14-6 a report setting forth the following concerning specialty drugs:

- (1) Best practice guidelines in providing specialty drugs to a patient in a manner that ensures the patient's safety during the process.
 - (2) Information concerning any adverse events affecting the safety of patients resulting from the specialty drug protocols of a health carrier or hospital.
- (d) The report required under this SECTION:
- (1) may not contain any personal identifying information; and
 - (2) must be compliant with the federal Health Insurance Portability and Accountability Act (HIPAA) (P.L.104-191).

Definitions

Specialty drug as defined by IC 25-27-2-1: A prescription drug that is typically high cost and

- (1) is prescribed for an individual who has:
 - (A) a chronic, complex, or life-threatening condition;
 - (B) a rare medical condition; or
 - (C) both conditions referred to in clauses (A) and (B);
- (2) has limited or exclusive distribution; or
- (3) requires:
 - (A) specialized product handling or administration by the dispensing pharmacy; or
 - (B) specialized clinical care, including:
 - (i) frequent dosing adjustments;
 - (ii) intensive clinical monitoring; or
 - (iii) expanded services for patients, including intensive patient counseling, education, or ongoing clinical support beyond traditional dispensing activities, such as individualized disease and therapy management to support improved health outcomes.

Buy and Bill: The provider acquires and stores drugs on site for administration to the patient. Both the drug and an administration fee are reimbursed by the payer under the patient's medical benefit.

White Bagging: The drug is procured through the pharmacy benefit and is filled and shipped or transported to the final infusion destination by a specialty pharmacy. The provider only bills for an administration fee using the patient's medical benefit.

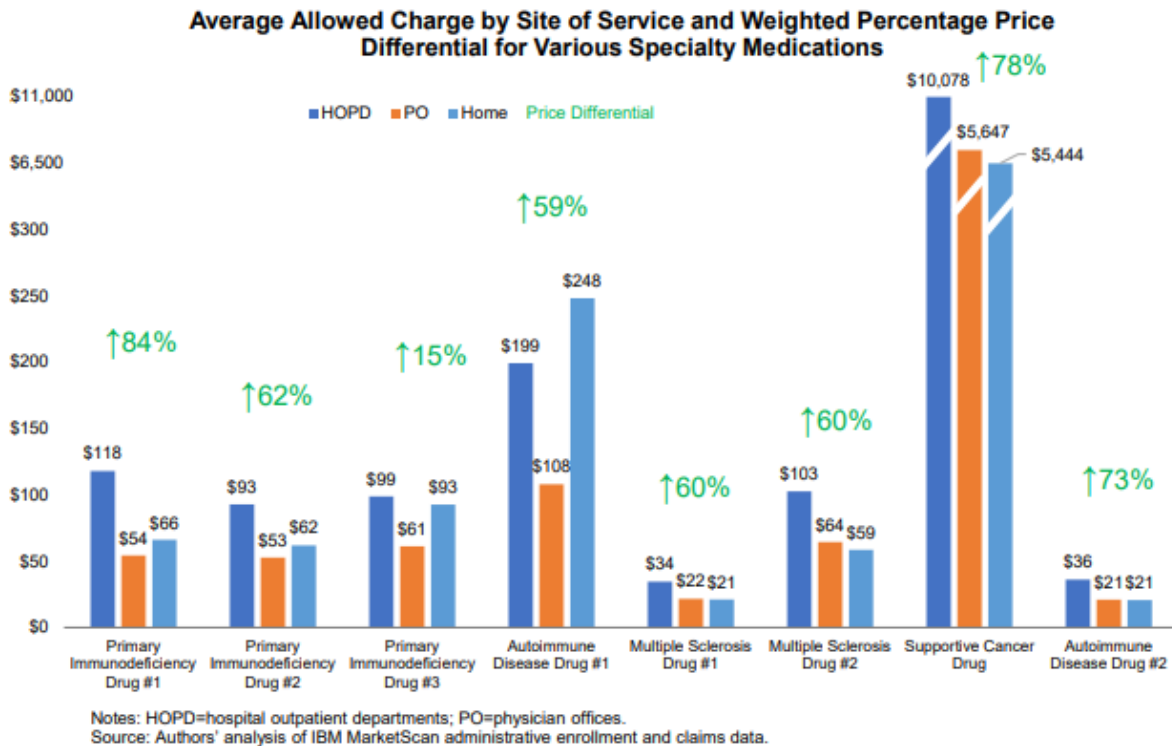
Brown Bagging: The drug is procured through the pharmacy benefit and is filled and shipped or transported to the patient’s home. The patient transports the drug to the final infusion destination. The provider bills for an administration fee using the patient’s medical benefit.

Clear Bagging: The provider’s own internal specialty pharmacy procures the drug and delivers it to the site of administration.

Channel Management: The implementation of policies that dictate a required procurement route for a specialty drug, either requiring the pharmacy benefit or the medical benefit be utilized.

Background and Introduction

Specialty drugs are one of the fastest growing areas of healthcare spending. These medications are used for relatively small number of patients but have much higher costs than traditional medications: specialty drugs account for 2% of all prescriptions but almost half of all medicine costs (IQVIA Institute for Human Data Science, 2019). Infusion therapies are an increasing portion of that cost and will be the focus of this report. The site the patient receives specialty infusion therapy as well as who supplies the medication dictates the cost of therapy, and this cost varies widely. This chart shows the difference in allowed charge (the amount the payer will pay to the provider), not cost, depending on site of administration for eight common deidentified specialty drugs (Fronstin et al., 2021):



Reimbursement formulas are different for physician offices, hospital outpatient departments, home care, and specialty pharmacies. Hospitals typically negotiate drug reimbursement at a higher rate than physician offices or home health care agencies. Specialty drugs are usually priced using average wholesale price (AWP) minus a discount for brands and maximum allowable cost (MAC) rates for generics (Milliman, 2019).

Other States' Action

Few states have taken legislative action to regulate or prohibit white or brown bagging. The most thorough investigation and reporting of the topic to date was completed in 2019 by The Massachusetts Health Policy Commission (HPC) in response to Section 130 of Chapter 47 of the Acts of 2017. As a result of their analysis, the HPC recommended that brown bagging should never be required. Regarding white bagging, the HPC recommended that payers requiring this channel should use best practices in policies and ensure that specialty pharmacies can meet suggested safety standards. The report also recommends adopting a site neutral payment policy whereby the drug is reimbursed at the specialty pharmacy rate when the provider purchases and administers it. Finally, the report recommends that lawmakers take action to increase public transparency and oversight for drug distribution (Commonwealth of Massachusetts, 2019).

A limited number of states have enacted legislation that prohibits or can be interpreted to prohibit the practice of white and brown bagging. Massachusetts Code 247 CMR 9.01(4) states that "unless otherwise permitted by law, a pharmacist shall not redispense any medication which has been previously dispensed. New Jersey and Georgia laws prohibit steering or sending a prescription to a specific pharmacy thereby circumventing the patient's choice (NJAC 13:39-3.0 and A. Code Ann. § 26-4-119). Ohio law prohibits the dispensing of any intravenous or subcutaneous cancer drug that is not to be self-administered to the patient, the patient's representative, or at the patient's residence, effectively eliminating the practice of brown bagging for these drugs (OAC 4729.43). On June 1, 2021, Louisiana became the first state to enact legislation banning white bagging by mandating that insurers pay for physician-administered drugs provided from an out-of-network pharmacy. In addition, the law requires that insurers pay the rate specified in the contact agreement, or, if none is specified, the wholesale acquisition cost (LA. REV. STAT. ANN. 22:1020.51).

New York Medicaid published guidelines for proper dispensing and delivery of drugs that are physician administered but provided through the pharmacy benefit. These guidelines do not mandate a specific channel but provide best practices for drugs provided through white bagging. These best practices prohibit brown bagging and automatic refills and dictate who is responsible for the drug during each part of the delivery process (New York Medicaid, 2019).

Federal Considerations

Title II of the Drug Quality and Security Act, the Drug Supply Chain Security Act (DSCSA), provides steps required to improve the quality and safety of drugs dispensed in the United States (21 U.S.C. § 360eee). Manufacturers, wholesalers, repackagers and pharmacies must keep detailed information about a drug and who handled it as well as verify that the drug is legitimate. Electronic pedigree information must be kept on file for all drug purchases and dispensers must only buy products that are encoded with specific identifiers. Inventory that a hospital is holding for a patient dispensed by an outside party is not owned by the hospital and will not have pedigree information readily available. Since specialty pharmacies do not sell the drug to the administering provider, the exemption for provision of tracking information for sale from one dispenser to another for a specific patient may not apply. Specialty Pharmacies do require signature by the provider or designee upon receipt. Delivery procedures should protect patient information from exposure and require delivery directly to infusion center or pharmacy staff with required signature to avoid loss and storage issues. Pedigree information and chain of custody history should be provided to staff with the drug as best practice although this may not be required by DSCSA.

USP Chapter 800 is a new set of standards published by the United States Pharmacopeia that dictate receiving, handling, storage, administration, and disposal of hazardous medications in healthcare facilities. Many specialty infusion drugs are considered hazardous to healthcare workers and must have policies dictating safe receipt and storage. Personal protective equipment (PPE) is required when unpacking hazardous drugs, and damaged items require a spill kit cleanup. Hazardous drugs must also be stored separately from other drugs in special negative pressure rooms. Hazardous drugs that are shipped to infusion centers may not be properly identified as hazardous and may inadvertently be unpacked or stored incorrectly, thereby exposing healthcare personnel or violating policy (United States Pharmacopeial Convention, 2021).

Patient Experiences

The practice of white bagging has resulted in many different experiences and outcomes for patients and their families, both positive and negative. Drug shipments can be delayed, sometimes by several days, thereby impacting chemotherapy schedules for oncology patients. Prior authorization and network issues not only place significant time and labor burden on healthcare personnel but also result in delayed treatment. Some infusion centers may refuse to accept outside shipments from specialty pharmacies, leaving the patient without any means of treatment. The following Indiana patient-specific stories have been provided by stakeholders on both sides of the debate and have not been independently verified by out of respect for and a legislative requirement of patient privacy.

A patient with an aggressive form of cancer needed to receive a drug that requires administration at a setting that could provide advanced life support if needed due to a high rate of infusion reactions. The prescription issued required white bagging by the payer. Multiple

prior authorizations were denied and appealed, finally resulting in a one-time override. Once the drug was ready to be shipped, only certain facilities accepted drugs from outside pharmacies, and none of them met the required advanced life support accommodation criteria. The delay in treatment for this patient was approximately three weeks.

A patient with metastatic lung cancer was prescribed a drug for palliative care. The patient needed to be enrolled for specialty pharmacy services and a prior authorization was needed. The oncology office reached out to the pharmacy for a status update and was told that another prior authorization was needed from a different payer entity. The turnaround time for this entity was 3 to 5 days for urgent requests. This prior authorization department then reached out to the oncology office to advise yet another process needed to be completed for prior authorization. This payer rejected the request, and the office was advised to call the number on the back of the insurance card. The office was advised to seek prior approval through the initial process attempted. The total elapsed time for approval of this claim was 2 weeks, and the patient passed away prior to the final authorization approval.

Some health plans have implemented networks with hospital providers to negotiate reimbursement for drugs provided through the medical benefit. Some hospitals have switched members who were stable on a medication on a health plan's list of required specialty pharmacy fulfillment list to one not on the list to avoid this requirement. Some hospitals have refused to negotiate prices to become in-network or have transferred members to other providers.

Purdue University has found a way to utilize white bagging and still provide quality care for its employees at a fair price. In January 2020, Purdue carved out specialty drugs for employees to a single pharmacy benefit manager. The carve out started with a single drug and resulted in a savings of more than \$179,000 over the past year. Per Purdue's report, patient safety was not sacrificed. The second round of prescriptions carved out resulted in savings of over \$100,000 within the first four months of transition. As with many transitions, disruptions did occur. Purdue reports that communication to providers and members was not as initially robust as it should have been. This was remedied, and a new communication process was implemented. This improved communication process resolved most concerns for members and providers. As of January 1, 2021, Purdue has gained approval from the Indiana State Budget Director to move all specialty drugs to their PBM. Purdue reports this strategy saved them \$2.5 million on specialty medications in the first quarter of 2021.

Best Practice Guidelines

The requirement by a plan to utilize the pharmacy benefit over the medical benefit for specialty drugs should be well planned, thoroughly communicated, and should have multiple concessions for exceptions to the process in the interest of patient safety. The following points should be considered prior to implementing processes, policies or regulations requiring white or brown bagging.

Reimbursement

The implementation of white bagging is done primarily as a cost saving measure by payers due to the higher rates of reimbursement to some sites of care. A reimbursement model that is more closely aligned among the sites of care may alleviate the incentive to utilize the practice. Some payers have implemented this payment strategy and have allowed hospital-based infusion clinics to continue to buy and bill while reimbursing them at a lower rate. Time and labor added to hospital and pharmacy staff for preparing drug and maintaining separate inventories, which may be substantial, should be factored into reimbursement.

Patient copays and cost sharing may be higher through the pharmacy benefit than the medical benefit. Patient assistance programs can help with this cost, and specialty pharmacies should work with multiple programs to assure that copay is not a barrier to treatment.

Process for Exceptions

Due to the complicated and severe nature of the diseases specialty drugs are used to treat, payers could require specialty pharmacies to have a robust exception policy to allow for buy and bill in the event of a service disruption, whether that be a weather-related emergency, dose change, or administrative issue. A service disruption needing an exception should be defined. Purdue University's pharmacy benefit manager is affiliated with a pharmacy that has a wholesaler license, so the provider is simply sent a replacement for their product administered in an emergency under the exception process.

Drug Selection Process

Third party payers who choose to implement specialty pharmacy fulfillment of medications may want to review medications for appropriateness through their Pharmacy and Therapeutics Committees and pharmacist input. Medications with strict cold storage requirements or medications with expected dose changes may not be appropriate for shipping. Board of Pharmacy regulations and United States Pharmacopeia standards should be consulted for guidance on proper storage and handling requirements. The Massachusetts report to the legislature concluded that drugs requiring sterile compounding by a pharmacist are not appropriate for white bagging as determined by Board of Pharmacy regulation 247 CMR 9.01 (4).

Specialty Pharmacy Quality Monitoring

Third party payers who utilized specialty pharmacies for specialty drug fulfillment to the site of infusion could implement metrics to oversee performance and to monitor for adverse outcomes or treatment interruption. Examples of metrics to monitor include member and provider complaints, turnaround times, and number of expedited exceptions. Specialty pharmacies should have 24/7 shipping capabilities and call center hours. Specialty pharmacies could/can also become accredited by various quality groups. Specialty pharmacies should provide

appropriate pedigree information to the infusing provider to comply with DSCSA and to facilitate drug recalls.

Communication

Communication to members should be frequent and thorough, especially when policy or process changes are to occur. Some members lack the health literacy and skills to schedule specialty drug delivery. Concierge services when needed that provide hands-on assistance to members may help prevent lapses in treatment due to misunderstandings or frustrations related to delivery or prior authorization processes. Changes in procedures, covered drugs, or other updates to policies should be communicated to providers early and often.

Conclusion

Specialty medication development and approval continues to grow exponentially with many new agents in the pipeline. These agents contribute substantially to overall healthcare spending. The impact on patient safety, health outcomes and overall cost to the system must be considered as policies are developed. Payers, legislators, Board of Pharmacy, and providers have several avenues to explore and utilize to ensure that Hoosiers receive the best care at the best price. Regulations, policies, and contracts can all be implemented to help address safety concerns and control healthcare costs.

The issues identified in this report are but a symptom of a much larger problem: skyrocketing costs of healthcare. Indiana must find a way to bring payers and providers together to address the root of this issue to prevent Hoosiers from bearing the negative effects of the negotiation. Patients who are already dealing with catastrophic and life-altering illness should not be asked to suffer the additional distress and harm of delayed or missed treatment. Indiana has more work to do to protect and provide the best outcomes for our citizens.

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Correspondence to IDOH and FSSA, available upon request:

White Bagging Issue Brief, Coalition

Recommendations from Hoosiers for Safe Meds Coalition

"White Bagging" Patient Stories, Indiana Hospital Association

Purdue University/Archimedes Partnership Overview, Purdue University

Letter to Dr. Sullivan from the Pharmaceutical Care Management Association and Insurance Institute of Indiana

Letter to Commissioner Beard from the Pharmaceutical Care Management Association and the Insurance Institute of Indiana.

Letter to Commissioner Box from the Pharmaceutical Care Management Association and the Insurance Institute of Indiana.

Letter to Dr. Sullivan from UnitedHealthcare

Letter to Commissioner Beard from UnitedHealthcare

Letter to Commissioner Beard, Commissioner Box, Secretary Sullivan, and Ms. Turner, Anthem Blue Cross and Blue Shield

Letter to Commissioner Box from Margaret Mary Health

Letter to Commissioner Box from Good Samaritan Hospital.

Letter to Commissioner Beard, Commissioner Box, Secretary Sullivan, and Ms. Turner, Lisa Harris, MD, CEO, Eskenazi Health

Safety Strategies for Medication Management and White Bagging Workflow, Indiana Coalition for Patient Safety

Patient accounts

GRD Joint Letter Request for Meeting on White Bagging and DSCSA

Letter to the President of the Indiana Board of Pharmacy from the Hoosiers for Safe Meds Coalition

Copy of LA. REV. STAT. ANN. 22:1020.51

White Bagging Infographic, ASHP

S695 MA, Review of Third-Party Specialty Pharmacy Use for Clinician-Administered Drugs Report to MA Legislature, Indiana Pharmacists Association

