PCMA

March 19th, 2024

The Honorable Susan Donavan
Members, House Committee on Health and Human Services
Room 135 - State House
82 Smith St.
Providence, RI 02903

RE: H 7365 AN ACT RELATING TO INSURANCE -- ACCIDENT AND SICKNESS INSURANCE POLICIES: Opposed

Chair Donavan and Members of the Committee,

The Pharmaceutical Care Management Association (PCMA) submits the following testimony in opposition to H 7365.

PCMA is the national trade association for America's Pharmacy Benefit Managers (PBMs), which administer prescription drug benefits for more than 275 million Americans with health coverage through large and small employers, health insurers, and federal and state-sponsored health programs.

Our comments provide additional information on the following topics:

1. **Benefits of 'White Bagging' to patients, providers, and plan sponsors.**
2. **What a specialty drug is and how they differ from traditional medications.**
3. **How PBMs manage specialty drug benefits.**
4. **The value of specialty pharmacy accreditation to all stakeholders.**
5. **Limiting PBM tools specific to biosimilars.**

Benefits of 'White Bagging' to patients, providers, and plan sponsors

There is significant debate around the practice of 'white bagging'. Here, I would like to clarify what 'white bagging' is, how the dispensing of specialty drugs works under the practice, and the benefits to patients, providers, and plan sponsors.

What is white bagging?

Physician administered drugs are prescription drugs administered by a health care provider to a patient through injection or infusion. The physician administered drugs can be administered in a variety of settings, including a hospital outpatient setting or a provider's office. These drugs are often high priced and represent a growing share of all prescription drug spending.

The two dispensing and reimbursement models are as follows:

1. **Buy and Bill** - the provider (ex: physician's office, hospital) purchases and stores specialty drugs for use in the clinic. The payor reimburses the provider for the drug and an administration fee, billed under the medical benefit. The cost of buy and bill drugs are inflated above the cost of drugs provided by a specialty pharmacy. **Hospitals, on average, charged 118% more for the same drugs**, compared to specialty pharmacies. **Physician**

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325 7th Street, NW, 9th Floor
Washington, DC 20004
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offices charged 23% higher prices than specialty pharmacies for the same drugs, on average[1].

2. **White Bagging** is the process in which a specialty pharmacy safely and efficiently dispenses and sends a prescription drug that requires health care provider administration directly to the health care provider (ex: physician, hospital). The health plan sponsor reimburses the specialty pharmacy for dispensing the medication and reimburses the provider for the drug's administration.

Below you will see the comprehensive step-by-step process for 'White Bagging' dispensing that ensures patients and providers receive the right drug, in the right dosage, at the right time:

Step 1:

- The prescription is received by the specialty pharmacy from the prescriber through a secure electronic hub.
- The specialty pharmacy reviews the prescription to ensure there are no drug-drug interactions or other clinical safety concerns.

Step 2:

- The specialty pharmacy contacts the patient or caregiver to provide consultation. The consultation:
  - Answers any questions about the prescription.
  - Confirms the patient's consent to the prescription.
  - Confirms the manner of dispensing, site of administration, and appointment date; including any pre-testing and other clinical safety reminders.
  - Discusses patient cost sharing and, if needed, financial support.

Step 3:

- Once confirmed with the patient, the specialty pharmacy contacts the provider to verify:
  - The patient's information, including their personal health information, diagnosis, the prescribed medication and dosage amount, and clinical information that may affect dosage (e.g. blood test results, weight).
    - **Note:** Real time changes in dosage amounts are addressed directly with the provider to prevent a delay in treatment and to mitigate waste.
  - When the provider will be administering the prescription to the patient.
  - When the provider will be available to receive the package.
  - The delivery date.
    - **Note:** Specialty drugs are delivered in time for the members appointment or in advance per the provider's preference.
    - **Note:** The specialty pharmacy confirms the availability of the provider or hospital sign the receipt on the date of delivery.

[1] AHIP. February 16, 2022. *Hospital Price Hikes: Markups for Drugs Cost Patients Thousands of Dollars.* https://www.ahip.org/resources/hospital-price-hikes-markups-for-drugs-cost-patients

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Step 4:

- The specialty pharmacy mails the prescription to the provider or hospital using overnight shipping. The prescription is mailed using temperature controlled or sensitive packaging in line with the US Pharmacopeia guidelines.
    - These shipments often involve very specialized shipping containers that have been evaluated by third parties for the time frames required (e.g., 60-hour pack out, so the prescription is stable in any weather condition for up to 60 hours)
    - Packaging is individually tailored and sensitive to the prescription's handling needs.
- The provider receives the shipped package immediately following delivery. **To ensure immediate receipt, the specialty pharmacy requires the provider or their designee to sign at time of delivery to ensure chain of custody, pursuant to federal Drug Supply Chain Security Act (DSCSA) requirements.**

Step 5:

- The prescription is administered by the provider to the patient.

What are the benefits of white bagging?

The use of 'White Bagging' benefits multiple stakeholder groups by providing value, improving access, and lowering costs.

Patient Value: The traditional 'buy and bill' method bills the physician administered drug through the patients' medical benefit, making patients susceptible to high out of pocket costs. Costs per single treatment for drugs administered in hospitals (2019-2021) were an average of $8,200 more than those purchased through specialty pharmacies[2].

Through 'white bagging' dispensing, the physician administered prescription can be covered under the pharmacy benefit, which often has lower patient cost sharing depending on the plan benefit established by their health plan sponsor.

Provider Value: Storage of prescription medication can be costly, requiring providers to pay to maintain an inventory of specialty medications. Utilizing specialty pharmacies removes the requirement for physician offices and hospitals to buy and store expensive medications.

Plan Sponsor Value: 'White bagging' provides a significant cost controlling tool for employers and other health plan sponsors. Specialty pharmacies can dispense medications at a cost up to 118% lower than 'buy and bill' supplied drugs[3]. This results in meaningful savings for employers, other health plan sponsors, and government health care payors when these drugs are dispensed through a specialty pharmacy instead of a hospital or providers office via the buy-and-bill method. Spending on physician-administered drugs is growing faster than retail drug spending, which "are administered primarily in hospital settings, which drives additional costs on top of the drug costs"[3] The Massachusetts Health Policy Commission's report reviewing the practice of using third-party

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[2] AHIP. February 16, 2022. *Hospital Price Hikes: Markups for Drugs Cost Patients Thousands of Dollars.* https://www.ahip.org/resources/hospital-price-hikes-markups-for-drugs-cost-patients

[3]Deloitte Center for Health Solutions, Deloitte, LLP, "Drug and inpatient spending lines are crossing," a Deloitte Insights Report (2020), Page 7. https://www2.deloitte.com/content/dam/insights/us/articles/6401_Drug-and-inpatient-spending/DI_Drug-and-inpatient-spending.pdf

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specialty pharmacies for physician administered drugs observed that in 2013, the per unit price on a number of drugs, including Botox, Xgeva, and Remicade, when dispensed via 'white bagging', was 15-38% lower than when dispensed under the buy-and-bill method.[4]

What is a specialty drug and how do they differ from traditional medications?

Specialty drugs have received increased attention from patients, providers, payers, and policymakers due to the high prices set by manufacturers and their impact on total health care costs. Historically, manufacturers efforts have been focused on small-molecule drugs that treat common conditions like high blood pressure, acid reflux, and pain. However, development in science, manufacturing, and biotechnology have allowed drug companies to focus on creating specialty drugs that treat several disease states including multiple sclerosis, rheumatoid arthritis, hepatitis C, and certain forms of cancer.

While the definition of a specialty drug continues to evolve there are several common characteristics, aside from their high cost[5]:

- Prescribed for a person with a complex or chronic medical condition, defined as a physical, behavioral, or developmental condition that may have no known cure, is progressive, and/or is debilitating or fatal if left untreated or under-treated.
- Treats a rare or orphan disease.
- Requires additional patient education, adherence, and support beyond traditional dispensing activities.
- Is an oral, injectable, inhalable, or infusible drug product.
- Has a high monthly cost.
- Has unique storage or shipment requirements, such as refrigeration.
- Is not stocked at most retail pharmacies.

In the table below you see that millions of patients are taking, or likely will end up taking these high-cost, complex medications. Recent research has shown that specialty drugs account for less than 1% of prescriptions, but account for nearly 40% of net drug expenditures[6]. In order to provide affordable, safe access to these medications, PBMs use a wide range of tools to manage drug benefits effectively, one of which is the use of specialty pharmacies. These pharmacies were established in response to the industry's need to better procure, store, and dispense specialty drugs as well as better manage therapy for patients on specialty drugs.[7]

Condition	Patient Population	Estimate Treatment Cost
Hepatitis C	3.2 million patients	$100,000 per course of therapy
Alzheimer's disease	5.4 million patients	$35,000 annually
Oncology	14 million patients	>$100,000 annually
Inflammatory Disorders	24-50 million patients	>$50,000 annually
High Cholesterol	71 million patients	$10,000 annually[1]

[4] *Op. cit.*, Massachusetts Health Policy Commission (July 2019), Page 3. https://www.apcdcouncil.org/sites/default/files/media/2023-07/pharmacy-third-party-review.pdf
[5] "The Management of Specialty Drugs" SPCMA (2016). https://www.pcmanet.org/wp-content/uploads/2017/04/sPCMA_The_Management_of_Specialty_Drugs.pdf
[6] Pembroke Consulting, "2019 economic report on pharmacies and pharmacy benefit managers." March 2019.
[7] Pharmacy Benefit Managers (PBMs): Generating Savings for Plan Sponsors and Consumers. Visante, (2020)

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How Pharmacy Benefit Managers (PBMs) manage specialty drug benefits.

PBMs employ many strategies and tools to support the needs of patients who are prescribed specialty drugs while controlling costs for health plans, employers, or state-sponsored programs including but not limited to:

- Offering more affordable pharmacy channels, such as PBM managed mail-service and specialty pharmacies:
    - PBMs collaborate with specialty pharmacies to provide patients, healthcare providers, and payers with complex clinical care that is guided by value-based principles. When specialty pharmacies meet clear service, performance, and cost-saving goals, they are eligible for inclusion in a PBM/payer preferred network. These 'preferred' specialty pharmacies provide patients with cost-efficient delivery options, care coordination programs and insurance benefit navigation. Payers rely on PBMs to develop criteria for identifying the highest quality and most cost-efficient specialty pharmacies in the industry.
- Optimizing site of care:
    - PBMs work closely with specialty pharmacies to manage the site of care where drugs are delivered, since more specialty products can be administered by the patient at home instead of at costly sites, such as hospital outpatient facilities. Recently, more health plans in conjunction with PBMs have begun implementing these site-of-care strategies. Research has shown that implementing site-of-care management can save between 12-34%.[8] These savings are achieved by:
        - Redirecting specialty medication and administration from hospital outpatient settings to doctor offices, ambulatory clinics, or patient homes where clinically appropriate.
        - Re-contracting with outpatient networks to establish drug pricing benchmarks.
        - Recommending that clients move specialty medications from the medical benefit to the pharmacy benefit when clinically appropriate.

Since retail and manufacturer affiliated pharmacies are not typically equipped to manage the full range of products and services that PBMs and payers require for the distribution and management of specialty drugs, they rely on the technology and expertise of specialty pharmacy to properly dispense these drugs. Specialty pharmacies must offer a full range of clinical and operational services to enhance the safety, quality, and affordability of care for patients receiving specialty medications such as:

- Health care provider access via specially trained pharmacists, nurses, and clinicians that are accessible 24/7 to provide guidance and insight on disease states, in addition to the use and management of specialty drugs.
- Physician consultations to address patient side effects, adverse drug reactions and other patient concerns.
- Disease and drug-specific patient care management services that meet the unique needs of each patient and incorporate multiple safeguards.

[8] Dorholt M. (2014, Jun). Advancing drug trend management in the medical benefit. Managed Care.

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- Supply chain management that adheres to rigorous storage, shipping, and handling standards such as temperature control and timely delivery of products in optimal conditions.
- Plan optimization that aligns economic incentives across the medical and pharmacy benefit while helping patients navigate the complexity of siloed benefit structures.
- Care coordination with other health care providers, including those providing skilled nursing services and direct-to-physician distribution.

The Value of Specialty Pharmacy Accreditation to Stakeholders

PBMs consider specialty pharmacy accreditation a baseline key indicator in assessing a pharmacy's commitment to quality and safety. The three most prominent accreditation bodies in the United States are URAC, The Accreditation Commission for Health Care (ACHC), and The Center for Pharmacy Practice Accreditation (CPPA). Currently, 48 states, the District of Columbia, and several federal agencies, including the Centers for Medicare & Medicaid Services (CMS) reference URAC accreditation in state and federal statutes, regulations, and requests for proposal.

An accreditation from a national body like those listed above demonstrates high standards of best practices, including those for patient care, proper handling and distribution, and home delivery of medications. During the accreditation process best practices for use of evidence-based practices and clinical decision support programs, patient counseling and benefits coordination, patient outcome and quality of care are just few items considered. Properly accredited specialty pharmacies are expected to perform above and beyond and according to URAC's 2020 Specialty Pharmacy Aggregate Report, they do. **In 2020, 99.98% of prescriptions were dispensed with zero errors and 99.96% of prescriptions were distributed without error.**[9]

Moreover, accreditation criteria does not include requirements for how the benefit is managed or how to encourage the lowest-cost drug option. Because of this, in addition to those criteria required for accreditation by organizations like URAC, PBMs maintain their own criteria for specialty pharmacies to be included in their preferred networks as it relates to fulfilling payer and plan sponsor specialty benefit plan design.

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PCMA appreciates your consideration of our comments on H 7365 as it relates to white bagging to ensure that Rhode Islanders maintain affordable, reliable, and safe access to life saving medications. Should you have any questions or would like additional information please do not hesitate to contact us.

Sincerely,

Sam Hallemeier
Senior Director, State Affairs
PCMA

[9] 2020 Specialty Pharmacy Aggregate Report. URAC.

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