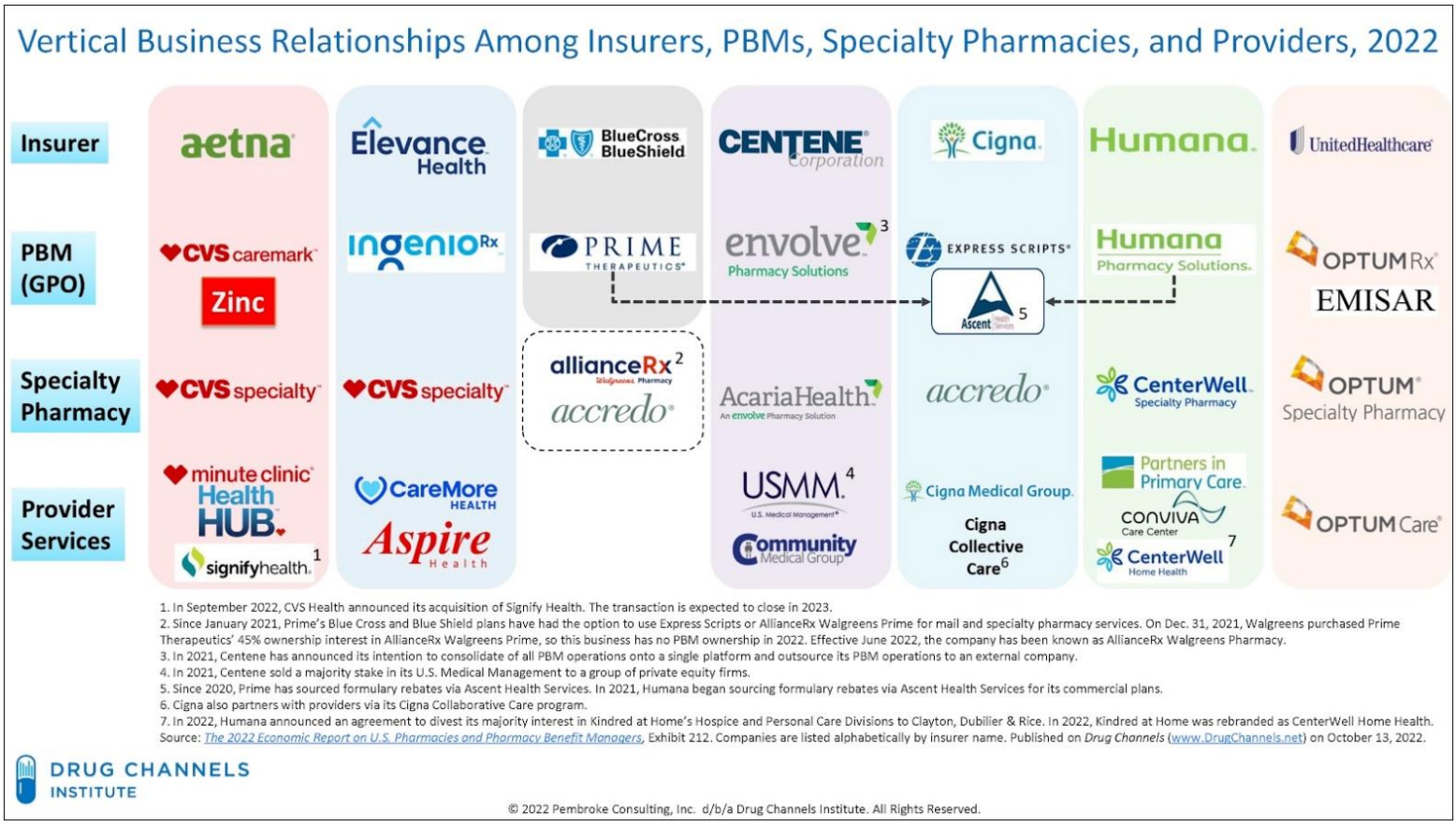
INFUSION PROVIDERS ALLIANCE

440 1st Street NW, Suite 430
Washington, DC 20001

Need for Transparency of PBM and Specialty Pharmacy Relationships Regarding "White Bagging"

"White Bagging" is a dangerous drug management tool utilized by health plans that requires infused patient-specific medication to be distributed from a preferred pharmacy to the physician's office, hospital, or clinic for administration. This practice poses many risks to the patients and has negative implications for providers, as outlined below. White bagging has become a growing challenge due to the vertical integration of health plans with pharmacy benefit managers (PBMs) and specialty pharmacies as some PBMS are now mandating that certain infused biologic drugs be procured exclusively though their own specialty pharmacy. This integration and white bagging requirement essentially allows health plans to line their own pockets by demanding drugs be procured through their own pharmacy networks with virtually no transparency to the public and stakeholders on the nature and extent of the financial relationship between the plans, PBMs, and specialty pharmacies. The below infographic illustrates how widespread the integration has become between these entities, thus exacerbating the issue of white bagging in the health care system. Many states have recognized this issue and imposed restrictions on specialty pharmacies, including CA, AR, GA, LA, NJ, ND, MA, TX (pending governor's signature) and VA.[i]



White bagging introduces several public policy and clinical concerns around patient safety, treatment delays, and economic burdens on both patients and providers:

- Because infusion providers and physician practices do not have "same-day" control over the sourcing, storage, preparation, and handling of highly expensive and complex biologics, patients may be exposed to treatment delays due to changes in dosage related to weight, lab values or other variables that influence treatment.
    - Example: Wolfson Children's Hospital in Jacksonville Florida has noted multiple cases of lab and/or weight driven changes that rendered the payer delivered dose suboptimal/inappropriate day of treatment.[ii]

- In some cases, specialty pharmacies ship the drug to the wrong address, or the drug does not arrive in time for the patient's appointment.[iii] When this happens, delay in care is inevitable as the clinic is unable to use its own inventory for a replacement but must obtain a new patient-specific supply from the designated pharmacy.
    - Example: A brain cancer patient had a one-week gap in treatment while waiting for medication and the provider was forced to change treatment from infusion to oral therapy to avoid further therapy delay.[iv]

- Specialty pharmacy control of inventory results in substantially more waste than physician control of inventory,[v] as the product is specific to an individual patient and cannot be used in the event the intended patient needs a change in dosage, changes therapy at the doctor's direction or opts not to proceed with therapy.
    - Example: Thomas Lausten, Director of Pharmacy Services at Children's Wisconsin noted in a 2021 Managed Healthcare Executive article that his hospital had to throw away two doses of Sprinraza, an infused treatment for spinal muscular atrophy priced at $125,000 per dose, which was already bought and paid for by the patient.[vi]

- There are also logistical challenges and cost-burdens for providers, as hospital and infusion sites may be forced to cover the cost of special handling disposal for drug waste and must provide storage separate from buy-and-bill drugs as they are patient-specific.
    - Other examples of incurred costs and uncompensated services include compounding the drug, coordinating the patient visits preparing the drug for administration, and conducting drug monitoring.

A national survey conducted by Vizient of 6,000 hospitals and physician offices found[vii]:

- 92% experienced patient care issues due to problems with medication received through white bagging.
- 95% of respondents experienced operational and safety issues associated with white bagging.
- $310M in labor expense to manage the additional clinical, operational, logistical, and patient care work associated with white bagging to prevent negative patient outcomes and medication waste.
- $114M spent on additional resources to manage coordination of patient and provider needs due to white bagging.

Suggested Transparency Language

For plan years beginning on or after January 1, 2025, each group health plan or health insurance issuer offering group health insurance coverage or an entity providing pharmacy benefit management services on behalf of a plan or issuer shall no less than annually publicly report:

1. Whether the plan or entity has entered into any exclusive contracts with affiliated specialty pharmacy (as defined in paragraph (A)) for the provision of biological drugs;
2. A list of drugs those affiliated specialty pharmacies are providing during the reporting period;
3. The aggregate dollars and percentage of volume in dollars paid to affiliated specialty pharmacies by the plan;
4. The number of enrollees for whom drugs were billed by affiliated specialty pharmacies;
5. The dollar amount of unadministered drugs to patients during the reporting period by affiliated specialty pharmacies and the number of times a patient was delayed a drug administration because the drug delivered by the affiliated pharmacy was no longer clinically appropriate for the patient due to changes in lab values, patient weight, etc. or the specific product was not delivered in time for the patient's appointment.

   (A) "Affiliated pharmacy" means, with respect to a Medicare Advantage plan or group health plan or an entity that provides pharmacy benefits management services under a contract with such organization, a pharmacy that, either directly or indirectly through one or more intermediaries:
   1. Has an investment or ownership interest in such organization or entity;
   2. Shares common ownership with such organization or entity;
   3. Has an investor or a holder of an ownership interest which is a Medicare Advantage organization or an entity that provides pharmacy benefit management services under contract with such organization; or
   4. Other arrangements that CMS indicates through rulemaking

---

[i] CA Health & Safety Code §1637.02 (2019), GA Code Ann. § 26-4-119, MA 247 CMR 09.01(4), N.J.A.C. 13:39-3.10, ND chapter 19-02.1, Texas HB 1647, White-Bagging in State Legislatures | Avalere Health

[ii] Garcia, Jorge. "Drug Brown and White Bagging; What is it and Where Does it Lead Us?" Florida Society of Clinical Oncology. https://flasco.org/wp-content/uploads/Pharmacy-02-Garcia-Drug-brown-and-white-bagging.pdf

[iii] Traynor, Kate. "White Bagging a Growing Concern for Health Systems," American Society of Health-System Pharmacists. March 23, 2021

[iv] Shane, Rita. Testimony provided to the California State Board of Pharmacy at a meeting entitled, "White Bagging Payer Policy Changes: Impact on Drug Integrity and Patient Safety." February 19, 2021. https://www.pharmacy.ca.gov/meetings/agendas/2022/22_jun_bd_mat_iv.pdf

[v] For example, Darling et al found three times as much waste in medically integrated specialty pharmacies: "Financial Impact of Medically Integrated Pharmacy Interventions on Oral Oncolytic Prescriptions." JCO Oncology Practice, An American Society of Clinical Oncology Journal. https://ascopubs.org/doi/full/10.1200/OP.22.00022

[vi] Kaplan, Deborah. "How 'White Bagging Affects Patients, Physicians, and 340B Funding," Managed Healthcare Executive. February, 18, 2021. https://www.managedhealthcareexecutive.com/view/how-white-bagging-affects-patients-physicians-and-340b-funding

[vii] "Survey on the patient care impact and additional expense of white/brown bagging," Vizient, Inc. 2021. https://www.senate.mn/committees/2021-2022/3095_Committee_on_Health_and_Human_Services_Finance_and_Policy/Vizient%20white%20bagging%20report%202021.pdf