January 22, 2026

Chairman Jason Smith
U.S. House of Representatives
1011 Longworth House Office Building
Washington, D.C., 20515

Ranking Member Richard Neal
U.S. House of Representatives
372 Cannon House Office Building
Washington, D.C., 20515

RE: Comments & Recommendations from the Infusion Providers Alliance (IPA); House Ways & Means Committee, "Full Committee Hearing with Health Insurance CEOs"

Dear Chairman Smith and Ranking Member Neal,

Thank you for holding this hearing examining the health insurance industry and policies that lower patients' costs. The vertical integration of insurers with pharmacy benefit managers (PBMs), specialty pharmacies, and other subsidiaries is raising costs and harming patient access to therapies relied upon by individuals living with complex and chronic conditions. The Infusion Providers Alliance (IPA) has serious concerns with these trends and the business practices these vertically integrated insurance companies are adopting, including specialty pharmacy mandates, sometimes referred to as "white bagging" and self-administration mandates imposed on patients who may wish to continue to receive their medication in a healthcare setting administered by highly trained practitioners. Insurers often pursue specialty pharmacy mandates to capture a larger portion of the prescription drug spend as they own or have a contractual relationship with the dispensing pharmacy. Research suggests white bagging may lower quality and access, raise out-of-pocket costs for patients, and introduce anticompetitive concerns in healthcare markets.[1] Similarly, coerced self-administration of injectable drugs undermines patient adherence and can raise out-of-pocket costs when benefits are moved from the medical benefit to the pharmacy benefit.

About the Infusion Providers Alliance

IPA represents community-based, non-hospital affiliated independent ambulatory infusion clinics and physician practices that deliver complex biologic infused or injected therapies to patients at the lowest cost, clinically appropriate setting of care. Our members operate over 1,000 community-based, non-hospital sites across 46 states. These sites of service are strategically located in the communities where patients live and work. They provide patients with flexibility and convenience when receiving treatment for conditions such as Crohn's disease, ulcerative colitis, multiple sclerosis, rheumatoid arthritis, and many other chronic, complex, and rare conditions and do so with a level of clinical excellence that studies have shown to be superior to

[1] Barkett, J., & Johnson, G. (2024). *Specialty Drug Prices: An Analysis of Savings Opportunities for Physician-Administered Drugs.* Berkeley Research Group.

any other setting of care.[2] IPA members are committed to preserving the integrity of the provider-patient relationship in a manner that delivers exceptional care to patients and value to the health care system.

Overview:

The vertical integration of large insurance companies has led to situations where insurers, through their affiliated specialty pharmacies and PBMs, abuse their market position and disrupt clinically appropriate treatment, limit patient choice and provider autonomy, threaten provider viability, and subject patients to higher out-of-pocket costs, among other issues. This also introduces anticompetitive concerns. In a 2024 report on PBMs, the Federal Trade Commission suggested that consolidation among PBMs has created financial conflicts of interest when PBMs use practices like white bagging to steer patients toward specialty pharmacies they own.[3] These strategies result in greater profits for insurance companies but result in downstream costs to patients and providers when insurers and their affiliates interject themselves into the patient-physician relationship. The infographic from Drug Channels Institute below illustrates how widespread the integration has become between these entities, thus exacerbating specialty pharmacy mandates and the "bagging" issue in the health care system.[4]

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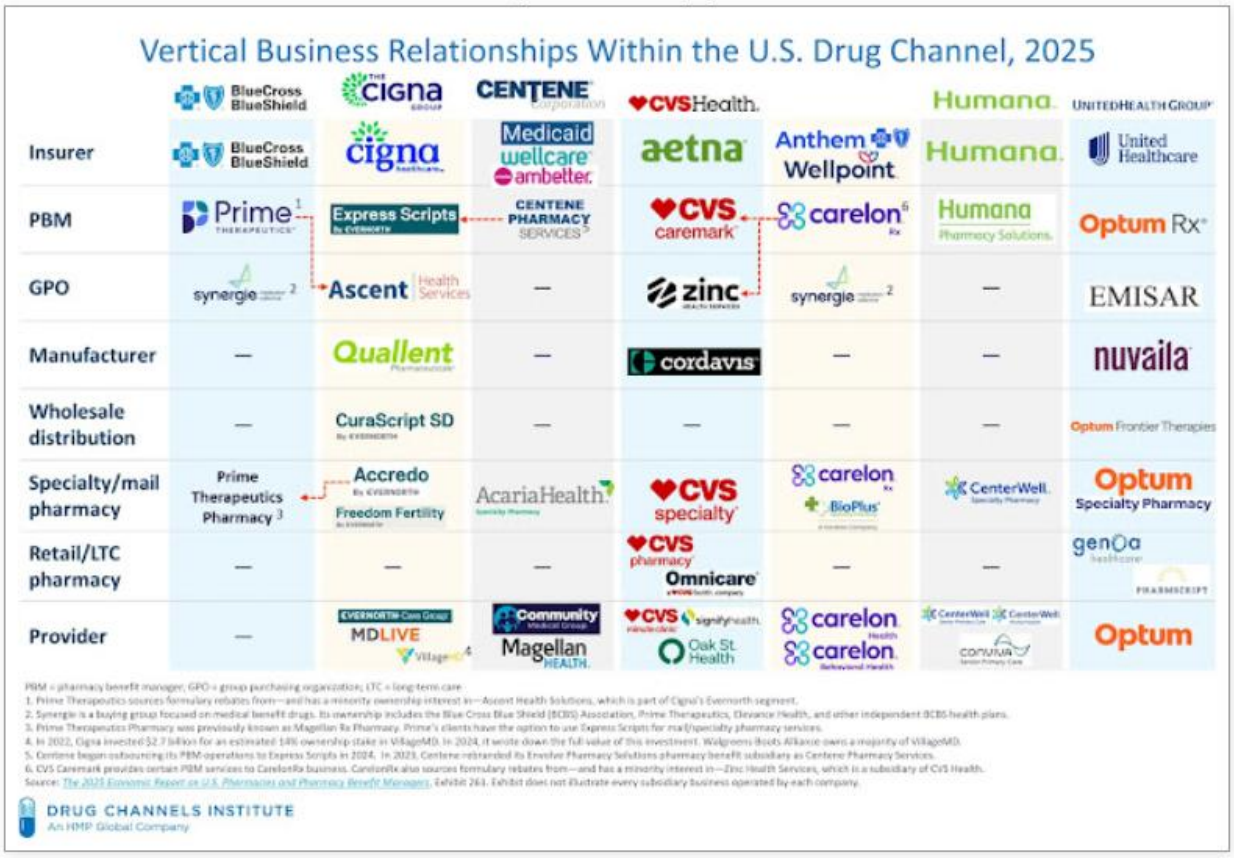
[2] Raj L, Stinson G, Langsam JW, DeMacio J. Comparison of specialty injection and infusion adverse events among hospital outpatient settings vs non-hospital outpatient settings. *J Clin Pathways*. 2025;11(1):34-38. doi:10.25270/jcp.2025.11.01

[3] US Federal Trade Commission, *Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies* (July 2024).

[4] Drug Channels, *Mapping the Vertical Integration of Insurers, PBMs, Specialty Pharmacies, and Providers: DCI's 2025 Update and Competitive Outlook* (Apr. 9, 2025), https://www.drugchannels.net/2025/04/mapping-vertical-integration-of.html



The IPA is concerned that many insurance plans are employing strategies that limit physician and patient choice and undermine the patient-doctor relationship. In some cases, these vertically integrated companies are trying to shift the reimbursement for administering drugs away from administering clinicians (through the patient's medical benefit) to their own in-house specialty pharmacies (through the patient's pharmacy benefit). This may increase out-of-pocket costs for patients for one of three reasons:

1. The patient's cost-sharing through the pharmacy benefit has a larger co-payment amount or co-insurance percentage than cost-sharing for care received through the medical benefit; or
2. The price used to determine patient cost-sharing in the pharmacy benefit may be higher than the price used to determine cost-sharing in the medical benefit.
3. In certain circumstances, patients may initiate care under the medical benefit and then be forced to move to the pharmacy benefit, thereby forcing them to expend dollars in the deductible phase for two separate benefits.

In other cases, these strategies mandate that therapies can only be self-administered by the patient when patients would prefer to receive treatment in a healthcare setting administered by a healthcare professional due to patient-specific or clinical factors. Self-administration requirements also shift coverage from the patient's medical benefit to pharmacy benefit.

To combat this reality, our members would welcome the opportunity to work with Congress on legislative solutions to:

- Protect medical benefit coverage for patients in non-hospital-based settings;
- Adopt nationwide bans or prohibitions on insurer specialty pharmacy mandates;
- Provide an exclusion from self-administration requirements for patients who wish to continue to receive treatments in a healthcare setting through their medical benefit; and
- Exclude and protect community-based, non-hospital providers, broadly defined as Place of Service 11 sites[5], from specialty pharmacy mandates.

Payer, PBM, & Specialty Pharmacy Mandates Undermine Clinical Outcomes, Patient & Provider Choice, and Increase Costs

Increasingly, our members experience payer and PBM mandatory "white bagging" and "brown bagging" policies requiring infused patient-specific medication to be obtained from a payer's affiliated specialty pharmacy instead of allowing providers to pre-purchase medication through the traditional "buy-and-bill" method and submit a claim for reimbursement after a patient's therapy has been administered. White bagging specifically has become a growing challenge due to the vertical integration of health plans with PBMs and specialty pharmacies as some PBMs are now mandating that certain infused biologic drugs be procured exclusively through their own specialty pharmacy.

White bagging and brown bagging practices are defined below.

- **White bagging:** Patient-specific medications delivered from a specialty pharmacy, either owned by or contracted by a patient's insurance company, to the healthcare provider.
- **Brown bagging:** Patients pick up prescribed drugs at a specialty pharmacy, or have them delivered, then bring them to the provider.

As currently structured, specialty pharmacy bagging mandates, which replace the traditional buy-and-bill model our members and the patients we serve rely on, is untenable. These specialty pharmacy mandates threaten patient clinical outcomes and access, result in higher costs and medication waste, and subject providers to unnecessary financial strain as well as increased administrative burden. Additionally, these mandates also introduce significant supply chain and safety risks by removing provider control and chain of custody over drugs administered to patients. This has led to shipment errors, treatment delays, cold chain failures, contamination risk, and more. For these reasons, an overwhelming majority of our members refuse to white bag as a matter of policy.

Disruptions in Patient Care: From the patient's perspective, specialty pharmacy mandates may lead to disruptions of care. A specialty pharmacy model creates a middleman where there was not one previously. Providers have reported that this practice has resulted in the receipt of incorrect or damaged products, delivery delays, and difficulties in adjusting a patient's dosage at the point of care.[6] Delays in drug administration can lead to missed doses, lower adherence, and poorer quality, while drugs delivered with the incorrect dosage could create additional costs for the plan

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[5] Centers for Medicare & Medicaid Services, *Place of Service Code Set* (2025), https://www.cms.gov/medicare/coding-billing/place-of-service-codes/code-sets

[6] Vizient, *Survey on the Patient Care Impact and Additional Expense of White/Brown Bagging* (2021).

when paying for the replacement dose.

Higher Costs: Specialty pharmacy mandates also contribute to overall increased healthcare spending and medication wastage. A 2024 survey of nonhospital infusion providers found waste associated with white bagging to cost $35,000 to $652,000 per site per year (depending on the number of patients served and types of drugs administered), and higher administrative costs for practices due to white-bagging waste on average from $13,000 and $67,500.[7]

An important distinction between a specialty pharmacy mandate model and the traditional buy-and-bill model relates to provider flexibility and patient convenience. Specialty pharmacy mandates require medication arriving at a provider's office to be specific to an individual patient. The buy and bill model allows providers the flexibility to substitute medication from their own inventory should a patient's lab values, weight or other factors necessitate a change in therapy dosage at the time of administration. Specialty pharmacy mandates increase costs in the form of waste of expensive medications (as they cannot be repurposed for another patient), but more importantly, these mandates severely degrade patients' experience, convenience and quality of life. Consider the all-too-real example of a patient arriving for treatment and receiving specialty-pharmacy-sourced medication that, through no fault of the patient or provider, is sent to the wrong address, damaged or contaminated during shipment from the specialty pharmacy to the provider, or requires a change in dosage on the day of administration due to changes in the patient's physiological or other clinical factors. Under specialty pharmacy mandates, the patient must be rescheduled. By contrast, the buy-and-bill model allows providers to adjust for physiological changes while enabling the patient to receive treatment at their originally scheduled appointment time. Many of the therapies our members administer can take several hours to infuse. For patients juggling work and family obligations, rescheduling an appointment when they have taken time off work or arranged childcare can introduce severe disruptions to their quality of life, along with therapy adherence. The flexibility to adjust dosage at time of administration through the buy-and-bill model not only contributes to decreased cost and wastage but significantly improves patient quality of life and clinical outcomes.

The vertical integration of health plans, PBMs, and specialty pharmacies combined specialty pharmacy mandates 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.

Growing Stakeholder and Public Opposition: There is broad opposition to these mandates within the provider community. The American Medical Association and the Association for Clinical Oncology (ASCO) recently issued a brief encouraging state medical associations to support legislation that prohibits the mandatory use of white and brown bagging policies.[8] The brief, "*Mandatory White Bagging and Brown Bagging Policies Threaten Patient Access to Care*," highlights how payer and PBM mandatory bagging policies disrupt the patient experience

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[7] Avalere, *Payer White-Bagging Requirements: Considerations for Access to Infusion Care* (June 2024).
[8] American Medical Association, Aug. 1, 2025: State Advocacy Update (2025) (https://www.ama-assn.org/health-care-advocacy/advocacy-update/aug-1-2025-state-advocacy-update)

and hinder physicians' ability to deliver timely and consistent high-quality, patient-centered care.[9]

The brief notes, "As of July 2025, 12 states have banned mandatory white bagging and brown bagging policies."[10] While we endorse these prohibitions, it unfortunately leaves patients and providers in 38 other states without protection and subject to payer bagging schemes. IPA supports expanding prohibitions to other states and would welcome the opportunity to work with Congress on legislative solutions to protect all patients and providers nationally from specialty pharmacy mandates. See links to existing statutes in certain states pertaining to specialty pharmacy mandate bans or significant prohibitions.[11] These states have enacted such measures to protect patients and reduce costs. We believe these policies are well founded and warrant nationwide expansion for the reasons detailed throughout this testimony.

Self-Administration Requirements Restrict Patient and Provider Choice

In addition to specialty pharmacy mandates, our members are also increasingly experiencing policies implemented by commercial payers which mandate certain injectable medications must be self-administered by a patient. IPA providers agree that certain products can and should be self-administered by appropriate patients, as detailed in the product's Food and Drug Administration (FDA) labeling. However, for safety reasons, many doctors and patients want to continue to receive their injected medication in office administered by a healthcare provider. For example, some patients do not have the physical or cognitive dexterity to properly self-administer an injectable drug, do not have proper medication storage infrastructure in their home, or are afraid of adverse reactions that may occur without clinical supervision, among other issues. The desire to continue therapy administration in a healthcare setting by a patient could be based on several patient-specific factors or due to clinical considerations. Self-administration mandates limit both patient autonomy and clinical discretion. They remove physicians from decisions that should be made by the patient and provider together and amount to an insurance company effectively "practicing medicine" without training or important patient history.

Oftentimes, these policies are coupled with requirements that the medication must be sourced through an exclusive specialty pharmacy and covered under the patient's pharmacy benefit. As previously detailed, due to the vertical integration of many large commercial insurers, the removal of choice and competition in pharmacy services raises legitimate questions about conflicts of interest, anticompetitive concerns and whether financial considerations, not clinical evidence, are driving benefit design.

Significant concerns from IPA providers around operational and patient access implications include:

- **Lack of flexibility** in administration options, which may not suit all patient scenarios

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[9] American Medical Association, *Mandatory White Bagging and Brown Bagging Policies Threaten Patient Access to Care* (2025), https://www.ama-assn.org/system/files/issue-brief-asco-patient-access-to-medication-safety.pdf

[10] *Id*.

[11] Alaska, Arkansas, Georgia, Louisiana, Minnesota, Mississippi, North Dakota, Oklahoma, Rhode Island, Tennessee, Texas, Vermont, Virginia

- **High out-of-pocket costs or deductibles** under pharmacy benefits, which could create financial barriers for patients
- **Delays in approval and fulfillment** through specialty pharmacies, potentially disrupting continuity of care

Ultimately, this could result in harm to patients due to treatment delays or non-adherence. Treatment decisions, particularly for complex biologics, should be individualized and made collaboratively by patients and providers, not insurance companies.

Additionally, like specialty pharmacy mandates, these self-administration requirements introduce unnecessary friction, compliance concerns, and other factors that degrade the patient experience.

- Mishandling or improper storage outside a healthcare setting may compromise drug efficacy
- Missed or delayed doses can reduce treatment effectiveness
- Some patients are fearful of self-injection or unable to consistently self-administer
- Adverse reactions at home occur without clinical supervision
- Risks associated with incomplete lab verification and documentation outside a healthcare setting

Such risks are minimized when treatment occurs in a controlled setting with qualified and trained professional healthcare staff administering medication when requested by the patient or their physician.

Background on the Traditional "Buy-and-Bill" Model & Medical Benefit Coverage

To understand why specialty pharmacy and self-administration mandates are detrimental to patient care, one must understand the economics of provider administered drug infusion and injection services. Physician practices and infusion facilities that directly administer infused and injectable biologic drugs to patients in IPA member facilities typically engage in a practice known as "buy-and-bill" with insurance coverage through the patient's medical benefit. Providers pre-purchase drugs and bill the payer for reimbursement once the medication is administered to the patient. To maintain the viability of administering drugs in the non-hospital setting, reimbursement must account for not only the drug acquisition cost, but also overhead costs such as intake and storage, equipment and preparation, nursing staff, facilities, spoilage insurance, and more.

Providers receive two primary sources of reimbursement from payers: 1) their professional fee for administering a drug to a patient, which covers a small fraction of their costs, and 2) an "add-on" payment, related to the cost of the drug. The *2025 Artemetrx State of Specialty Spend and Trend Report* detailed that the average per-claim reimbursement to providers in the physician office for only drug administration was $125 in 2024, compared to $472 in the hospital outpatient department, almost four times the physician office rate. The report further indicated

that the average cost per specialty claim was lower under the medical benefit than under the pharmacy benefit.[12]

Superior Quality & Clinical Outcomes, Decreased Cost Associated with Non-Hospital, Community-based Infusion & Injection Sites of Service

A first of its kind study published in the *Journal of Clinical Pathways* found that shifting injected and infused specialty medications from the high-cost hospital outpatient settings is associated with favorable clinical outcomes and quality in the non-hospital outpatient settings compared with hospital outpatient settings. Authors conclude widespread adoption of site-of-care management strategies that offer alternatives to the hospital outpatient setting might reduce the burden of rising health care costs, increase affordability, enhance patient convenience, and improve patient choice.[13] Office-based infusion and injection services have been shown to produce improved patient adherence, a key metric for the treatment of chronic and complex diseases that require these therapies. A Stanford University study found that patients receiving infusions in an office-based setting had a 79 percent adherence rate, compared to 74 percent at the hospital and 64 percent at home.[14] Finally, a very recent study published in the *Journal of Managed Care & Specialty Pharmacy* analyzing infusion therapy patient outcomes, quality, and costs in hospital outpatient departments (HOPDs) versus alternative sites of care (SOC), like IPA member settings, found "patients receiving infusions in HOPDs have higher outpatient costs without a reduction in adverse events, inpatient admissions, or ED visits or an increase in infusion therapy adherence compared with SOCs, indicating that SOCs offer similar quality outcomes at lower costs."[15]

Although evidence overwhelmingly favors IPA members' community-based sites of care across cost, quality, convenience, patient adherence, satisfaction, and other metrics, payer-imposed mandates that restrict patient access undermines community-based sites of care as viable options for many patients while increasing costs. IPA welcomes the opportunity to work with payers, and policy makers, to move care into the more efficient, convenient, and less costly non-hospital affiliated site of service. Unfortunately, while many payers publicly embrace these site-of-care management strategies, their implementation utilizes specialty pharmacy mandates requiring benefit coverage to transition from the patient's medical benefit to pharmacy benefit and self-administration requirements which remove patient choice and clinical autonomy. These restrictions threaten patient access, provider viability and clinical outcomes, while contributing to increased costs.

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[12] Pharmaceutical Strategies Group. (2025, August 5). *2025 Artemetrx State of Specialty Spend and Trend Report*.

[13] Raj L, Stinson G, Langsam JW, DeMacio J. Comparison of specialty injection and infusion adverse events among hospital outpatient settings vs non-hospital outpatient settings. *J Clin Pathways*. 2025;11(1):34-38. doi:10.25270/jcp.2025.11.01

[14] Giese-Kim, N., Wu, M., Dehghan, M., Sceats, L. A., & Park, K. T. (2020). Home infliximab infusions are associated with suboptimal outcomes without cost savings in inflammatory bowel diseases. *The American Journal of Gastroenterology, 115(10), 1698-1706*.

[15] JMCP, *Infusion Therapy Patient Outcomes Are Similar at Reduced Costs* (Dec. 20, 2025), https://www.jmcp.org/doi/10.18553/jmcp.2025.25264

Solution: Preserve Medical Benefit Coverage, Protect Patient Choice & Clinical Autonomy

To ensure broad patient access to clinically appropriate treatments, dominant vertically integrated insurers and their affiliates must be prevented from abusing their market power, which is currently stifling patient choice and clinical autonomy across the country through specialty pharmacy and self-administration mandates.

Our members welcome the opportunity to work with Congress and your committee on legislative solutions that protect patient and provider choice, preserve the patient-physician relationship, and lower costs for patients and the healthcare system. As you consider holding future hearings and developing legislation on this topic, we encourage you to explore policies that:

- Protect medical benefit coverage for patients in non-hospital-based settings;
- Adopt nationwide bans or prohibitions on insurer specialty pharmacy mandates;
- Provide an exclusion from self-administration requirements for patients who wish to continue to receive treatments in a healthcare setting through their medical benefit; and
- Exclude and protect community-based, non-hospital providers, broadly defined as Place of Service 11 sites, from specialty pharmacy mandates.

Thank you for your consideration of our concerns. Our members would be happy to provide additional information on this topic that may be helpful to you in your work.

Sincerely,

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