



October 2, 2026

The Honorable Ron Wyden
Ranking Member
Committee on Finance
United States Senate
219 Dirksen Senate Office Building
Washington, D.C. 20510

Submitted electronically to: insurance@finance.senate.gov

Re: Request for Information: Health Coverage That Works for Everyone

The Infusion Providers Alliance (IPA) appreciates the opportunity to comment on the Request for Information, *Health Coverage That Works for Everyone*, released by Senate Finance Committee Ranking Member Ron Wyden and other Senate Democrats. IPA's comments respond to Section 3, Part II of the RFI, concerning vertical integration, as well as Section 2, Part II, concerning hurdles and delays in accessing care, and Section 3, Part IV, concerning unaccountable health insurance middlemen.

IPA is a national trade association and leading voice for non-hospital, community-based infusion providers, including physician offices and freestanding ambulatory infusion centers. Our members operate more than 1,000 sites across 45 states, providing convenient access to high-quality, lower-cost care for patients with complex and chronic conditions. These sites are located in the communities where patients live and work and provide flexible, convenient access to treatment for conditions such as Crohn's disease, ulcerative colitis, multiple sclerosis, rheumatoid arthritis, Alzheimer's disease, and many other chronic, complex, and rare conditions.

IPA works to protect timely patient access to infused and injected therapies, preserve the integrity of the provider-patient relationship, and safeguard both the traditional buy-and-bill model and access to provider-administered drugs under the medical benefit. Studies have shown that, when clinically appropriate, community-based infusion settings deliver high-quality care with outcomes comparable to or better than hospital outpatient departments (HOPDs), but at significantly lower costs. Preserving access to these settings is therefore important to patients, employers, health plans, and the broader health care system. Policies that weaken independent community-based providers risk accelerating consolidation and shifting care to higher-cost hospital settings.

Unfortunately, IPA members increasingly encounter payer policies and practices that interfere with timely access to provider-administered therapies and undermine decisions made by patients

and their treating providers. These challenges are particularly pronounced in the commercial and Medicare Advantage markets.

Most significantly, in the commercial market, IPA members increasingly encounter mandatory white-bagging policies that require provider-administered drugs to be obtained through a specialty pharmacy, often designated by or affiliated with the payer, rather than allowing treating providers to acquire and administer them through the traditional buy-and-bill model. Mandatory white bagging can generate significant drug waste, delay treatment, increase patients' out-of-pocket costs, limit providers' ability to make clinically necessary treatment adjustments at the point of care, and shift coverage from the medical benefit to the pharmacy benefit.

IPA members also encounter related policies that require certain injectable therapies to be self-administered and obtained under the pharmacy benefit, even when administration by a health care professional may be clinically appropriate or preferred by the patient and treating provider.

More broadly, IPA members encounter prior authorization and utilization-management requirements in both the commercial and Medicare Advantage markets that can delay treatment or direct care toward payer-preferred products and distribution channels. In the commercial market, IPA members and the patients they serve also encounter copay accumulator and maximizer policies, as well as third-party medical-benefit copay-assistance programs. These third-party programs can delay provider reimbursement and raise concerns regarding patient notice, consent, and continuity of care.

Many of these practices are connected to the growing vertical integration of insurance companies, pharmacy benefit managers (PBMs), specialty pharmacies, third-party administrators, and other entities. In some cases, the same corporate enterprise establishes the coverage policy, administers the prior authorization process, designates the required specialty pharmacy, and can capture revenue from the resulting transaction. Patients, providers, and employers generally lack sufficient visibility into these ownership relationships, financial incentives, and whether the arrangements produce meaningful savings or primarily shift revenue among affiliated entities.

IPA recognizes that health plans have a legitimate role in promoting safe, evidence-based, and cost-effective care. However, coverage and utilization-management policies should be clinically grounded, transparent, timely, and subject to meaningful accountability. They should not override clinical judgment, disrupt continuity of care, undermine patient and provider choice, or steer patients and health care spending toward affiliated entities at the expense of access and competition.

Accordingly, IPA's comments focus on three specific areas:

1. Mandatory white bagging of provider-administered drugs and related self-administration mandates, including medical-to-pharmacy benefit shifts and concerns arising from vertical integration;
2. Prior authorization and utilization management for provider-administered drugs; and
3. Copay accumulator and maximizer policies and third-party entities operating medical-benefit copay-assistance programs.

I. Mandatory White Bagging and Related Medical-to-Pharmacy Benefit Shifts Undermine Patient Choice and Access

Mandatory white bagging is one of the clearest examples of how vertical integration can enable an insurer to use coverage policy to steer patients and health care spending toward an affiliated entity. In the commercial market, insurers and PBMs increasingly require provider-administered drugs to be dispensed by a specialty pharmacy and shipped to the treating provider for administration to a specific patient. In many cases, the payer designates the specialty pharmacy, which may be owned by or affiliated with the insurer or PBM imposing the requirement.

Mandatory white bagging displaces the traditional buy-and-bill model. Under buy-and-bill, an infusion provider purchases and maintains medication inventory, evaluates the patient on the day of treatment, administers the appropriate therapy, and then bills the patient's health plan. This allows the provider to adjust the medication or dose based on the patient's weight, laboratory results, treatment response, or other clinical circumstances. Under mandatory white bagging, the designated specialty pharmacy ships a patient-specific dose before the appointment. If the patient's treatment plan changes, the product generally cannot be returned to inventory or administered to another patient and the patient's appointment may need to be rescheduled.

IPA's concern is not with voluntary white-bagging arrangements agreed to by the patient and treating provider when appropriate. It is with insurer mandates that require specialty-pharmacy sourcing rather than allowing the treating provider to use its own inventory, including arrangements that shift coverage from the medical benefit to the pharmacy benefit. These mandates remove choice from patients and treating providers. The American Medical Association (AMA) and the Association for Clinical Oncology (ASCO) have taken a similar position. In a joint issue brief, the organizations identify treatment delays, drug waste, administrative burdens, and increased patient out-of-pocket costs among the consequences of mandatory white bagging.¹ Their brief states, "While some physicians engage in voluntary white bagging within their health system and have found satisfactory arrangements, the AMA and ASCO oppose its mandatory imposition."²

A 2024 Avalere survey examined white bagging and other specialty-pharmacy acquisition arrangements among non-hospital infusion providers.³ Its findings illustrate the role of payer requirements in driving the use of white bagging. Among surveyed practices that acquired at least some drugs through white bagging, 81 percent attributed that acquisition approach to payer contract restrictions, while 19 percent cited an operational or financial decision. Among practices acquiring white-bagged drugs through a specialty pharmacy, 76 percent reported that payers mandated the specific specialty pharmacy used.

¹ American Medical Association and Association for Clinical Oncology, *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>.

² *Id.*

³ Avalere, *Payer White-Bagging Requirements: Considerations for Access to Infusion Care* (June 2024), https://advisory.avalerehealth.com/wp-content/uploads/2024/06/Payer-White-Bagging-Requirements_Considerations-for-Access-to-Infusion-Care.pdf.

Mandatory white bagging creates drug waste, delays treatment, and increases patients' out-of-pocket costs

Drug waste is an inherent risk of white bagging because each medication is dispensed for a specific patient and generally cannot be returned or administered to another patient, even if it remains unopened. Provider-administered therapies are not always static prescriptions that can be filled days in advance without modification. Often on the day of treatment, a provider may need to evaluate laboratory results, weight, disease progression, adverse effects, or other clinical factors. Under buy-and-bill, the provider generally can make a necessary adjustment at the point of care. Under mandatory white bagging, an adjustment can make the patient-specific shipment unusable, requiring the medication to be discarded, a replacement shipment to be obtained, and the patient to reschedule treatment.

Avalere's survey found that the average estimated annual cost of vials wasted due to white bagging ranged from \$35,000 to \$662,000 per respondent, depending on practice size and type. Estimated annual practice overhead costs associated with storing, handling, and disposing of those wasted drugs ranged from approximately \$13,000 to \$67,500. The survey also identified broader, unquantified costs associated with white bagging: practices must distinguish buy-and-bill drugs from specialty-pharmacy products, adding administrative burden and infrastructure and software costs.

Mandatory white bagging can also delay treatment. IPA members report problems involving incorrect, damaged, or delayed shipments. Because providers do not control the medication's full chain of custody in white-bagging arrangements, these problems present real safety concerns and can lead to postponed appointments, missed doses, and additional administrative work for providers. A separate provider survey found that 92 percent of respondents experienced problems with products obtained through white or brown bagging, including incorrect or damaged products, delays, and an inability to make necessary dose adjustments at the point of care.⁴

These disruptions affect patients who may have taken time away from work, arranged transportation or child care, or traveled a significant distance for treatment.⁵ If the appropriate medication is not available, the patient may be required to reschedule the appointment and wait for the designated specialty pharmacy to dispense and ship a replacement. The resulting delay can disrupt continuity of care, treatment adherence, and quality of life for patients managing chronic diseases.

⁴ Vizient, Survey on the Patient Care Impact and Additional Expense of White/Brown Bagging (2021), https://assets.senate.mn/committees/2021-2022/3095_Committee_on_Health_and_Human_Services_Finance_and_Policy/Vizient%20white%20bagging%20report%202021.pdf.

⁵ Infusion Providers Alliance, "IPA Submits Comments to E&C and W&M Ahead of Hearings with Health Insurance CEOs" (Jan. 22, 2026), <https://www.infusionprovidersalliance.org/ipa-submits-comments-to-ec-and-wm-ahead-of-hearings-with-health-insurance-ceos/>.

Finally, white bagging can increase patients' financial exposure when coverage is shifted from the medical benefit to the pharmacy benefit. Patients may pay more because:

1. The patient's cost-sharing through the pharmacy benefit has a larger copayment amount or coinsurance percentage than cost-sharing for care received through the medical benefit;
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; or
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.

Avalere found that 46 percent of surveyed providers had encountered instances in which patients paid cost sharing for a white-bagged medication that was not ultimately administered.⁶ A separate study found that privately insured patients with cancer under bagging arrangements paid an average of \$315 per month out of pocket, compared with \$145 under the traditional buy-and-bill model.⁷

Lower-cost community care does not require mandatory white bagging

Although health plans often present mandatory white bagging as a cost-containment strategy, specialty-pharmacy acquisition is not necessarily less expensive than provider acquisition through buy-and-bill. IPA commissioned Berkeley Research Group (BRG) to analyze 2022 commercial claims and compare median payment rates for physician-administered drugs across different sites and acquisition channels: HOPD buy-and-bill, ambulatory infusion center (AIC)/physician-office buy-and-bill, and specialty-pharmacy white bagging.⁸ For 19 specialty drugs commonly administered in both AIC/office and HOPD settings, the median AIC/office rate was lower than the median HOPD rate for every drug studied. The drug-specific differentials ranged from 27 to 61 percent and averaged 41 percent. For a subset of eight drugs for which BRG also compared specialty-pharmacy white-bagging rates, the median AIC/office buy-and-bill rate was lower than the median specialty-pharmacy rate for five drugs. Although the results varied by product, BRG concluded that white bagging may lower commercial insurers' drug costs when employed in an HOPD setting but could raise costs when employed in an AIC or physician-office setting where the provider's buy-and-bill rate is lower.

Research by investigators affiliated with The Cigna Group and Elevance Health further supports the clinical and economic value of non-hospital infusion settings. A large real-world study of Cigna Healthcare commercial claims involving more than 122,000 patients and nearly one million injection and infusion instances found lower odds of medication-related adverse events,

⁶ Avalere, Payer White-Bagging Requirements: Considerations for Access to Infusion Care (June 2024).

⁷ Ya-Chen Tina Shih, Ying Xu, and James Ching Yao, "Financial Outcomes of 'Bagging' Oncology Drugs Among Privately Insured Patients With Cancer," <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2809059>.

⁸ John Barkett and Gregory Johnson, Specialty Drug Prices: An Analysis of Savings Opportunities for Physician-Administered Drugs (Berkeley Research Group, Sept. 2024), <https://media.thinkbrg.com/wp-content/uploads/2024/09/09132730/BRG-Specialty-Drug-Prices-2024-final.pdf>.

emergency department visits, and hospital admissions in non-hospital outpatient settings than in HOPDs.⁹ A separate matched-cohort study conducted by Elevance Health researchers examined more than 52,000 infusions among nearly 19,000 patients. The study found no significant differences in serious or mild adverse events between HOPDs and alternative sites of care, while outpatient costs within one day of infusion were 41.9 percent higher for HOPD infusions. The authors concluded that alternative sites of care offer similar quality outcomes at lower costs.¹⁰ Taken together with the BRG analysis, these studies support policies that preserve access to clinically appropriate non-hospital settings as a means of reducing costs without mandating that drugs be obtained through an insurer-designated specialty pharmacy.

Consistent with these findings, IPA members report that health plans are actively seeking to move clinically appropriate infusion services from higher-cost HOPDs to lower-cost physician offices and ambulatory infusion centers. IPA supports that objective. However, health plans often implement these site-of-care strategies in conjunction with mandatory white bagging and medical-to-pharmacy benefit shifts that can restrict access to the same lower-cost community settings they seek to promote. When the insurer or PBM is affiliated with the designated specialty pharmacy, the integrated enterprise may still benefit from mandatory white bagging because it redirects revenue associated with supplying the drug from the treating provider to an affiliated business. This financial incentive may help explain why some health plans impose mandatory white bagging even when specialty-pharmacy acquisition is not the lowest-cost option.

Health plans can also effectively compel white bagging by combining product-specific sourcing requirements with reimbursement below providers' acquisition costs. IPA previously provided the Committee with "underwater biosimilar" examples, including our members' experience with Avsola, Inflectra, and other products, in our response to your Request for Information, "*Commonsense Policy Options to Lower Drug Prices for Patients*."¹¹ IPA members report that some plans permit buy-and-bill for Inflectra or Avsola even though reimbursement for those products falls below providers' acquisition costs, while requiring the reference product, Remicade, to be obtained through a specialty pharmacy. These policies force providers to obtain a patient's medication through white bagging or furnish the biosimilar at a loss. Although insurers may characterize these arrangements as allowing buy-and-bill, they do not preserve a financially viable alternative to specialty-pharmacy sourcing.

⁹ Journal of Clinical Pathways, "Comparison of Specialty Injection and Infusion Adverse Events Among Hospital Outpatient Settings vs Non-Hospital Outpatient Settings" (2025), <https://www.hmpgloballearningnetwork.com/site/jcp/original-research/comparison-specialty-injection-and-infusion-adverse-events-among>.

¹⁰ Journal of Managed Care & Specialty Pharmacy, "Infusion Therapy Patient Outcomes Are Similar at Reduced Costs" (Dec. 20, 2025), <https://www.jmcp.org/doi/10.18553/jmcp.2025.25264>.

¹¹ Infusion Providers Alliance, "IPA Submits Comments to Senate Finance Committee on Drug Pricing RFI" (Aug. 17, 2026), <https://www.infusionprovidersalliance.org/ipa-submits-comments-to-senate-finance-committee-on-drug-pricing-rfi/>.

Vertical integration creates incentives to favor affiliated specialty pharmacies

In a July 2024 interim staff report, the Federal Trade Commission reported that the three largest PBMs processed nearly 80 percent of the approximately 6.6 billion prescriptions dispensed by U.S. pharmacies in 2023 and that pharmacies affiliated with those PBMs accounted for nearly 70 percent of all specialty drug revenue. The report stated that vertical integration likely creates the ability and incentive for PBMs to increase utilization of certain drug products at affiliated pharmacies to generate the greatest revenue and profits for their respective conglomerates. It further stated that vertically integrated PBMs may have the ability and incentive to prefer their own affiliated businesses, which in turn can disadvantage unaffiliated pharmacies and increase prescription drug costs. The report discussed white bagging in its section on specialty prescription steering, citing the AMA's report that PBM contracts may require a patient's provider to obtain specialty drugs administered in a clinical setting from a PBM-affiliated pharmacy.¹² Mandatory white bagging provides a mechanism through which those incentives can operate in the provider-administered drug market, allowing an integrated enterprise to use coverage policy to redirect drug spending from treating providers to its affiliated specialty pharmacy. A 2026 Drug Channels Institute mapping further illustrates the breadth of vertical integration across insurers, PBMs, specialty pharmacies, healthcare services, and other companies within U.S. drug channels.¹³

The same corporate enterprise may establish the coverage policy, administer the authorization process, select the required distribution channel, and capture revenue from the resulting transaction. As a result, patients, providers, employers, and other plan sponsors generally lack sufficient information to determine whether these arrangements produce genuine savings or primarily shift revenue among affiliated entities.

Related self-administration mandates also restrict patient and provider choice

Some injectable therapies may be either self-administered by a patient or administered by a health care professional. IPA supports self-administration when it is clinically appropriate and selected by the patient and treating provider. However, IPA members increasingly encounter commercial health plan policies that require certain injectable therapies to be self-administered and obtained from a designated specialty pharmacy under the pharmacy benefit. Under these arrangements, the medication is shipped directly to the patient, and access to administration by a health care professional under the medical benefit may be restricted or eliminated.

Self-administration is not appropriate for every patient merely because a product can be self-administered. Some patients may lack the physical or cognitive ability to administer the medication properly, lack appropriate storage conditions, require laboratory testing or clinical monitoring, or be concerned about experiencing an adverse reaction without clinical supervision.

¹² Federal Trade Commission, Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies, Interim Staff Report (July 2024), https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf.

¹³ Adam J. Fein, "Mapping the Vertical Integration of Insurers, PBMs, GPOs, Specialty Pharmacies, and Healthcare Services: DCI's 2026 Update," Drug Channels (Apr. 14, 2026), <https://www.drugchannels.net/2026/04/mapping-vertical-integration-of.html>.

Mandatory self-administration also can disrupt an established course of treatment, create delays in specialty-pharmacy fulfillment, increase patients' out-of-pocket costs under the pharmacy benefit, and reduce treatment adherence. Decisions about whether an injectable therapy should be self-administered or administered in a health care setting should be based on the patient's individual clinical circumstances and preferences and incorporate the treating physician's guidance, not mandated as a one-size-fits-all policy by the health plan's preferred benefit or distribution channel.¹⁴

It is also worth noting that a shift from clinician-administered treatment under the medical benefit to pharmacy dispensing does not necessarily reduce costs for patients or payers. In a 2024 evaluation of subcutaneous Stelara, the HHS Office of Inspector General found that, in 2021, Medicare paid 80 percent more on average when the drug was obtained under Part D for self-administration than when it was administered in a physician's office under Part B. Some enrollees also faced substantially higher out-of-pocket costs under Part D.¹⁵ The findings underscore that moving a drug to specialty-pharmacy dispensing under the pharmacy benefit does not necessarily reduce costs for patients or the health care system.

Congress should preserve medical-benefit access and protect patient and provider choice

Although a growing number of states have enacted protections addressing mandatory white bagging and related patient-choice concerns, those laws vary in scope and application. Many state insurance protections apply only to fully insured commercial plans. Self-funded private-employer health plans are generally governed by the Employee Retirement Income Security Act of 1974 (ERISA) and not subject to state insurance mandates, including mandates addressing specialty-pharmacy requirements. Some states have regulated PBM conduct or pharmacy practice in ways that may apply more broadly, but those approaches remain uneven and have received differing treatment in the courts. As a result, many patients enrolled in commercial health plans lack consistent protection from these practices. IPA therefore urges Congress to establish baseline federal protections applicable to commercial health coverage that preserve access to provider-administered drugs under the medical benefit and prevent health plans and PBMs from conditioning coverage on the use of a designated specialty pharmacy or other mandated distribution channel.

Those protections should apply to group health plans, including self-funded plans governed by ERISA, as well as health insurance issuers, PBMs, and affiliates acting on their behalf. At a minimum, they should:

1. Protect coverage of provider-administered drugs under the medical benefit when furnished in community-based, non-hospital settings, including sites billed under Place of

¹⁴ Infusion Providers Alliance, "IPA Submits Comments to E&C and W&M Ahead of Hearings with Health Insurance CEOs."

¹⁵ U.S. Department of Health and Human Services, Office of Inspector General, Medicare and Some Enrollees Paid Substantially More When Stelara Was Covered Under Part D Versus Part B, <https://oig.hhs.gov/reports/all/2024/medicare-and-some-enrollees-paid-substantially-more-when-stelara-was-covered-under-part-d-versus-part-b/>.

Service 11, and preserve providers' ability to acquire and administer those drugs through the traditional buy-and-bill model.

2. Prohibit health plans, issuers, PBMs, and their affiliates from conditioning coverage of a provider-administered drug on its being dispensed by a designated specialty pharmacy and shipped to the treating provider, or on the use of any other mandated specialty-pharmacy acquisition or distribution channel. These entities should also be prohibited from using higher patient cost sharing, additional fees, reduced provider reimbursement, coverage limitations, retaliation, or other financial penalties to compel use of a designated acquisition or distribution channel.
3. Protect patients from self-administration mandates when the patient and treating provider determine that administration by a health care professional is clinically appropriate, and preserve medical-benefit coverage in those circumstances.
4. Establish timely-access and continuity-of-care safeguards, including a prompt process for addressing late, damaged, incorrect, or clinically unusable shipments and clinically necessary changes in medication or dosage. When a health plan or PBM requires or directs specialty-pharmacy distribution, require the applicable health plan or PBM to provide reasonable reimbursement for provider costs associated with receiving, segregating, tracking, storing, and disposing of white-bagged products.
5. Require disclosure of ownership, control, and financial relationships among insurers, PBMs, and designated specialty pharmacies, together with meaningful reporting on medication waste, treatment delays, patient cost sharing, and whether asserted savings are passed through to patients and plan sponsors.

These protections would preserve voluntary specialty-pharmacy and self-administration arrangements when clinically appropriate and selected by the patient and treating provider and would not prevent health plans from applying evidence-based clinical coverage criteria. They would ensure that decisions about how a provider-administered therapy is obtained and administered reflect clinical appropriateness and patient choice, rather than an insurer's financial interest in directing treatment through an affiliated entity.

II. Prior Authorization and Utilization Management Should Facilitate Timely, Clinically Appropriate Care

Prior authorization and other utilization-management requirements have become significant sources of treatment delays and administrative burden for community-based physician practices and ambulatory infusion centers. For patients with chronic and complex conditions, delays in receiving prescribed therapies can result in postponed treatment, disease progression, flare-ups, and avoidable hospitalizations.

Prior authorization should focus on evaluating medical necessity and clinical appropriateness. More broadly, prior authorization, step therapy, and other utilization-management policies should be clinically grounded and should not be used to force nonmedical switching, steer patients toward payer-preferred products or specialty-pharmacy arrangements based primarily on financial considerations, mandate a particular distribution channel, or otherwise interfere with provider-directed care.

IPA supports requiring electronic prior authorization for drugs covered under the medical benefit, standardized data exchange, specific explanations for denials, enforceable decision timeframes, and timely appeal and exception processes. Consistent with these principles, IPA supports the bipartisan Improving Seniors' Timely Access to Care Act of 2025 (S. 1816 and H.R. 3514), which would establish an electronic prior authorization process for Medicare Advantage plans, including standardized transactions and clinical attachments; increase transparency around Medicare Advantage prior authorization requirements and their use; clarify HHS's authority to establish timeframes for electronic prior authorization requests, including expedited determinations, real-time decisions for routinely approved items and services, and other requests; expand beneficiary protections to improve enrollee experiences and outcomes; and require HHS and other agencies to report to Congress on program integrity efforts and opportunities to further improve the electronic prior authorization process.¹⁶

Providers also should be able to rely on a valid prior authorization when they administer treatment and submit a claim consistent with the authorization. In 2024, one IPA member experienced approximately 8,000 denials requesting medical records for treatments that had already received prior authorization.¹⁷ Absent fraud, a material billing error, or treatment inconsistent with the authorization, payers should not use subsequent claims review to revisit a medical-necessity determination that was made during the prior authorization process.

Step therapy can similarly delay access to medically necessary treatment by requiring patients to try one or more insurer-preferred therapies before the plan will cover the treatment prescribed by their providers. IPA supports the bipartisan Safe Step Act (S. 2903 and H.R. 5509), which would establish a clear and timely exceptions process for step therapy protocols in employer-sponsored health plans.¹⁸

III. Copay Accumulators, Maximizers, and Medical-Benefit Copay-Assistance Programs Can Shift Costs and Threaten Patient Access

Some plan sponsors, health plan administrators, and third-party vendors use copay accumulator and maximizer policies and medical-benefit copay-assistance programs to reduce spending on specialty drugs. Although these arrangements operate through different mechanisms and present distinct concerns, each uses financial assistance intended for patients as part of a strategy to reduce plan spending. Accumulators and maximizers prevent manufacturer copay assistance provided on a patient's behalf from counting toward the patient's deductible or annual out-of-pocket limit. Medical-benefit copay-assistance programs can delay reimbursement for drugs that providers have already purchased and administered, create substantial cash-flow and administrative burdens, and interfere with established patient-provider relationships.

¹⁶ Improving Seniors' Timely Access to Care Act of 2025, S. 1816, 119th Cong. (2025), <https://www.govtrack.us/congress/bills/119/s1816>.

¹⁷ Infusion Providers Alliance, comment on Interoperability Standards and Prior Authorization for Drugs, Docket No. CMS-2026-1255, Comment ID CMS-2026-1255-0575 (2026), <https://www.regulations.gov/comment/CMS-2026-1255-0575>.

¹⁸ Safe Step Act, S. 2903, 119th Cong. (2025), <https://www.govtrack.us/congress/bills/119/s2903>.

Medical-benefit copay-assistance programs can delay payment for provider-administered drugs

IPA members have reported arrangements in which a health plan uses a third-party copay-assistance program to reduce its spending on provider-administered drugs that remain covered under the medical benefit. Under these arrangements, the provider purchases and administers the drug, but members report that collecting the full reimbursement for the drug can depend on obtaining and documenting manufacturer copay assistance. The plan may initially pay only a nominal amount and assign a substantial portion of the allowed amount to patient responsibility. The provider is then directed to pursue available manufacturer copay assistance. This can leave providers carrying unreimbursed drug acquisition costs while the assistance and payment process is completed. To date, IPA members operating in Alabama, Illinois, and Michigan report encountering variations of this practice. One IPA member reports receiving a payment of one cent on at least one claim.

An IPA provider has reported experiencing reimbursement challenges with Blue Care Network's HelpScript program. Blue Cross describes HelpScript as an enrollment service that coordinates commercially insured members' enrollment in manufacturer copay assistance programs for certain high-cost drugs administered under the medical benefit. Blue Cross states that the program's goals include facilitating full provider reimbursement and ensuring that enrolled members have no out-of-pocket cost. Under its published billing process, the provider must submit the claim to Blue Cross or BCN for primary payment and submit the resulting remittance advice to the manufacturer's copay assistance program for the amount designated as "member owed." If any "member responsible" amount remains after those steps have been completed, HelpScript sends that amount directly to the provider. Blue Cross states that HelpScript typically sends this payment within 14 to 21 business days after Blue Cross or BCN finalizes its payment.¹⁹ The IPA member reports that, in practice, the overall reimbursement process can take substantially longer and can impose an additional layer of uncompensated administrative work.

Another IPA member reports encountering a similar payment practice through PrudentMed, a medical-benefit copay-assistance program offered by PrudentRx in connection with an Aetna-administered plan. Aetna's 2026 disclosures provide additional detail on the program's operation and financial structure. They state that the PrudentMed program assists members in securing available third-party copayment assistance for certain specialty drugs through the various programs funded by pharmaceutical companies. The disclosures state that the plan realizes savings by increasing member cost sharing, with that increase offset by manufacturer assistance, and that a percentage of the resulting savings is charged as compensation for services provided under the PrudentMed program. The disclosures provide an illustrative calculation in which \$10,000 in manufacturer assistance, after application of a 1 percent discount factor, generates a \$2,475 administrative fee calculated at 25 percent. They also state that PrudentRx may share a

¹⁹ Blue Cross Blue Shield of Michigan and Blue Care Network, "HelpScript Enrollment Service for Manufacturer Copay Assistance Will Start July 1 for Select Medical Benefit Drugs for Additional Blue Cross and BCN Commercial Members," provider alert (May 21, 2026), <https://providerinfo.bcbsm.com/documents/alerts/2026/202605/alert-20260521-helpscript-svc-copay-assistance-jul-1.pdf>.

portion of that fee with third parties, including Aetna and/or its affiliates, for services rendered in connection with the PrudentMed program.²⁰

Although the employer may elect to participate in these programs, IPA members have raised concerns about whether affected patients receive clear notice of the arrangement and provide informed, affirmative consent before enrollment. In these arrangements, the provider may be required to carry the unreimbursed acquisition cost of an expensive specialty drug for months after it has been administered while awaiting completion of the reimbursement process involving the health plan and manufacturer assistance. This can create substantial cash-flow pressures, particularly for community-based infusion providers that purchase expensive specialty drugs in advance of treatment. Providers also incur additional administrative costs identifying available assistance, coordinating enrollment, documenting payments, and repeatedly following up with the health plan or program administrator.

One IPA member further reports that representatives of a program administrator advised longstanding patients to seek care from a different infusion provider because of concerns regarding the provider's billing process. This conduct is particularly concerning and inappropriate. Such communications by a third party that neither prescribes nor administers the patient's treatment may disrupt continuity of care, interfere with established patient-provider relationships, and steer patients away from a provider because of a payment dispute unrelated to the clinical appropriateness or quality of the care delivered. Such communications warrant federal scrutiny and appropriate safeguards.

Manufacturer copay assistance is intended to help patients afford their cost-sharing obligations. It should not be used as a mechanism for delaying payment to providers or shifting costs that would otherwise be borne by health plans to manufacturer assistance programs. These arrangements also raise concerns regarding patient notice and consent, the use of patients' personal information, transparency concerning the third party's compensation, and whether providers ultimately receive all amounts owed under applicable contracts.

Copay accumulators and maximizers prevent financial assistance from fully benefiting patients

Manufacturer copay assistance can help commercially insured patients afford the substantial deductibles, copayments, and coinsurance associated with specialty drugs. Under a copay accumulator program, however, assistance used on the patient's behalf does not count toward the patient's deductible or annual out-of-pocket limit. Once the available assistance is exhausted, the patient may remain responsible for the full deductible and other cost-sharing obligations. Copay maximizer programs similarly seek to capture the maximum available assistance, often by setting the patient's cost-sharing obligation for a specialty drug based on the manufacturer assistance available, sometimes spreading that assistance across the plan year. Although these programs

²⁰ Aetna, Large Group and Public & Labor Self-Funded Medical Underwriting (UW) Disclosures as of 01-01-2026 (Jan. 1, 2026), 5, <https://www.aetna.com/content/dam/aetna/pdfs/aetnacom/legal-notices/documents/large-group-and-public-labor-self-funded-medical-underwriting-disclosures-as-of-01-01-2026.pdf>.

may minimize the amount the patient pays directly for the drug, the manufacturer assistance does not count toward the patient's deductible or annual out-of-pocket limit.

Both practices allow health plans to reduce their spending without crediting the full value of manufacturer assistance toward patients' deductibles or annual out-of-pocket limits. These risks are particularly serious for patients with chronic and complex conditions who depend on regularly scheduled infused or injected therapies.

IPA supports the bipartisan Help Ensure Lower Patient Copays Act, or HELP Copays Act (S. 864 and H.R. 6423), which would require financial assistance provided by prescription drug manufacturers and nonprofit organizations to count toward patients' deductibles, copayments, coinsurance, and annual out-of-pocket limits.²¹ The legislation would also clarify that the Affordable Care Act's annual out-of-pocket limit applies to all prescription drugs covered by a health plan, addressing the non-essential-health-benefit structure used by some copay maximizer programs. These protections should apply uniformly across the commercial market, including self-funded employer plans, so that patients receive the benefit of assistance provided on their behalf.

Passage of the HELP Copays Act would address the direct effects of accumulator and maximizer programs on patients but would not, by itself, resolve the payment and administrative concerns associated with medical-benefit copay-assistance programs. Congress should separately prohibit health plans and entities acting on their behalf from requiring providers to obtain or document manufacturer assistance, or await its exhaustion, as a condition of timely payment of amounts owed under applicable provider contracts for a covered provider-administered drug. Federal safeguards should require clear advance notice to patients and providers, informed, affirmative patient consent before enrollment by or through a health plan or its vendor in a manufacturer copay-assistance program, transparency regarding vendor compensation and savings calculations, and protections against steering or retaliating against providers because of disputes concerning program billing requirements.

Conclusion

IPA appreciates the opportunity to respond to your request for information and your consideration of our comments. We urge Congress to protect timely access to high-quality, lower-cost community-based infusion care and preserve patient and provider choice.

Sincerely,



Elliott Warren
Executive Director
Infusion Providers Alliance

²¹ Help Ensure Lower Patient Copays Act, S. 864, 119th Cong. (2025), <https://www.govtrack.us/congress/bills/119/s864>.