September 11, 2025

Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8013
Baltimore, MD 21244-8013

Re: Medicare and Medicaid Programs; CY 2026 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; and Medicare Prescription Drug Inflation Rebate Program (CMS-1832-P)

Background on the Infusion Providers Alliance

The Infusion Providers Alliance (IPA) is a leading voice for in-office and freestanding ambulatory infusion providers, with over 1,000 community-based, non-hospital sites across 43 states. Our 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, typically saving Medicare more than 64 cents on the dollar per Part B drug infusion compared to hospital administration. Our facilities are major access points of care for patients with complex and chronic health conditions in communities, large and small. The IPA's mission is to serve as a thought leader and to educate on issues critical to safeguarding, supporting, and strengthening provider-directed, patient-focused access to infused medications. More information about IPA can be found on our website: www.infusionprovidersalliance.org.

Overview of IPA Comments

The IPA's comments focus on four issues:

1. The IPA believes the "maximum fair price" (MFP) should not influence the calculation of average sales price (ASP) and strenuously objects to substituting the MFP for the ASP in the reported ASP file, as it would result in significant access problems to these products for commercially insured patients.

2. The IPA strongly supports CMS's proposal to make virtual direct supervision in non-facility settings permanent. This change will maintain increased access to quality care, allow for a nimble health care ecosystem in the face of future pandemics, and ensure patient adherence to vital therapies.

3. The IPA supports the proposed reforms to indirect practice expense payments, which will support office-based providers, and finally provide a modest payment increase to drug administration in the physician office and infusion clinic setting.

4. The IPA has concerns over the proposed revisions to the "Bona Fide Service Fee" (BFSF) definition. We urge CMS to not move forward with this proposal.

Calculation and Reporting of Average Sales Price as It Relates to Maximum Fair Price

We have grave concerns about the potential impact to our providers and their ability to continue to serve Medicare beneficiaries who need access to Part B drugs subject to Secretarial "negotiation" under the Inflation Reduction Act (IRA). Because the key part of our reimbursement for drug administration is tied to the price of the drug through the "add-on" payment to the average sale price (ASP) plus 6 percent payment methodology due to the insufficiency of the administration fee on a stand-alone basis, policies that substantially reduce that add-on payment will have enormous negative ramifications to our providers and the patients we serve.

The IPA's top legislative priority is enacting *The Protecting Patient Access to Cancer and Complex Therapies Act* (H.R. 4299*)*, which removes providers from the drug pricing negotiations between the manufacturer and Medicare, and preserves the ASP+6% reimbursement structure, while securing the same savings (to Medicare and beneficiaries) demanded by the IRA via a rebate paid by the manufacturer to CMS. That policy has been endorsed by over 60 patient and provider organizations including the Infusion Providers Alliance (IPA), American Academy of Allergy, Asthma, & Immunology (AAAAI), American Academy of Ophthalmology, American College of Rheumatology, Association of Women in Rheumatology (AWIR), Community Oncology Alliance (COA), ICAN-International Cancer Advocacy Network, Large Urology Group Practice Association (LUGPA), Lupus Foundation of America, among others.[1]

In the proposed rule, CMS would substantially extend this looming patient access crisis for Medicare beneficiaries to commercially insured patients by immediately substituting the reported average sales price with the maximum fair price in its pricing file. CMS may be unaware that commercial insurers base contracts with infusion providers and physician practices on the ASP pricing file. ASP is the predominant benchmark used by commercial

[1] Part B Access Coalition Letter on Protecting Patient Access to Cancer and Complex Therapies Act of 2025

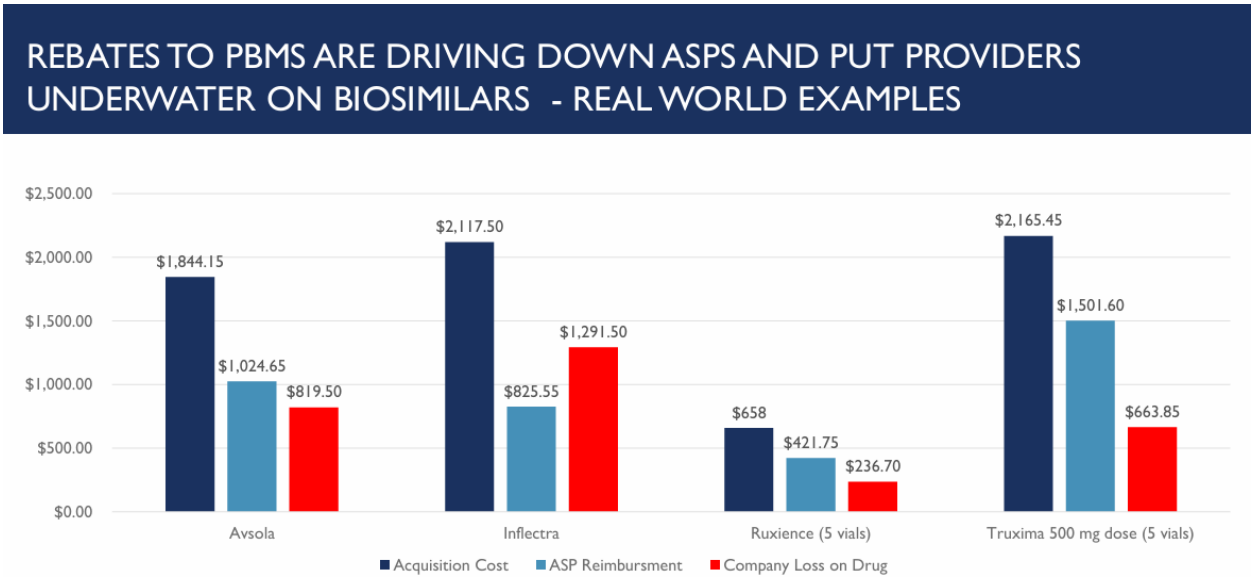
payors in their provider contracts for provider-administered medications, and our members have literally thousands of contracts based on ASP. Replacing ASP with the substantially lower MFP price will have a devastating impact on providers ability to deliver care to commercially insured patients for drugs subject to negotiation. Over time, as more drugs – and, by definition, the most economically important drugs – come into "negotiation," the long-term viability of non-hospital, community-based infusion providers will be severely threatened. Patient access to these important therapies for chronic and complex diseases will be compromised and Medicare costs will rise as patients will be forced into more expensive hospital settings (where capacity allows).

Effective January 1, 2026 CMS proposes substituting ASP with MFP as "no ASP information (will be) displayed." CMS argues that the underlying ASP statute, Section 1847A of the Social Security Act compels the inclusion of MFP in the ASP calculation. **But nothing in that statute nor in the amendments made by the Inflation Reduction Act require CMS to *replace* the ASP drug pricing file with MFP.** CMS argues that the ASP pricing file is actually a payment limits file. That characterization is entirely subjective and ignores the reality that commercial insurers utilize the ASP file as the basis for their contracts with providers. Even if CMS believes it must include MFP in the ASP calculation, it should not prevent commercial insurers from continuing to contract with providers based on market prices by refusing to publish the ASP. We object to MFP being included in the ASP calculation, as explained below; and we strenuously oppose eliminating any semblance of market pricing for commercially insured patients for whom the IRA was never intended to impact. CMS should not under any circumstances replace the ASP file entirely with MFP.

We do not have to speculate about the result of such a policy because we have already witnessed the real-world experience and continued challenges facing "underwater biosimilar" products. As detailed in our testimony to the Ways & Means Committee[2] and illustrated below, when reimbursement schemes drive prices below provider acquisition costs for biosimilar products, providers are put substantially underwater and cannot administer the products without taking a substantial loss. As a condition of formulary placement for competing biosimilar products, PBMs are demanding and receiving substantial rebates from manufacturers. This rebating dynamic, in turn, drives down the ASP that determines provider reimbursement for Medicare and most commercial plans. But as providers do not have access to those price concessions, they find themselves substantially "underwater" on the price they acquire the product compared to the price they are reimbursed. As a result, our members must decide between becoming financially

[2] Infusion-Providers-Alliance-WM-Biosimilar-Hearing-Comments-FINAL-Submitted.pdf

insolvent by providing these products at a substantial loss or not provide the underwater biosimilar products and attempt to send the patient to the higher cost hospital setting (if capacity and proximity allow). Neither situation is advisable or tenable.



Similarly, we note that nothing in the statute compels manufacturers to provide drugs, subject to MFP, to providers at those substantially discounted prices for Medicare Advantage and commercially insured patients. We fear a patient access crisis will result from this misguided policy of eliminating the publication of the ASP file and only reporting MFP prices. We urge CMS not to pursue this path.

Replacing ASP with MFP Undermines the Trump Administration Policy of Incentivizing Care in the Most Efficient Site of Service

A key Trump Administration priority in health care policy – as articulated in its April 15 Executive Order – is encouraging Part B drugs to be provided in the physician/clinic setting,[3] which is paid about one-third of the amount as hospitals for administering the identical drugs. Replacing ASP with MFP would act contrary to this important Executive Order.

Non-hospital-based infusion providers cannot absorb a 50 percent cut to their primary form of reimbursement – the add-on payment – and still provide these drugs to patients.

[3] Indeed, in an April 15, 2025 Executive Order, President Trump called on the Secretary to propose regulations "to ensure payment within the Medicare program is not encouraging a shift in drug administration and volume away from less costly physician offices to more expensive hospital outpatient departments." Exec. Order No. 14,273, Lowering Drug Prices by Once Again Putting Americans First, Section 11, available at https://www.whitehouse.gov/presidential-actions/2025/04/lowering-drug-prices-by-once-again-putting-americans-first/

Hospitals have many other revenue streams to cost-shift from (including inpatient procedures, diagnostics, surgery, endowments, and other lines of business). Our members do not. The Trump Administration can protect this vital access channel for patients by simply applying a straightforward interpretation of the statute, which limits these payment cuts to Medicare beneficiaries and preserves access to low-cost and convenient providers for all other patients. It should do so without equivocation, recognizing that these providers not only deliver excellent care but also provide necessary competition to huge hospital systems attempting to consolidate the provider market further.

Background on the High Quality and Efficient Care IPA Members Provide in their Infusion Clinics and Physician Offices

The IPA membership is comprised of organizations that either operate the infusion portion of a specialist physician's practice or companies that administer biologic medications in freestanding facilities conveniently located in communities where many Medicare beneficiaries reside. These care sites are an important and convenient access point for care, saving Medicare $0.65 on the dollar for drug administration compared to infusions provided at hospital outpatient departments.

Physicians, nurses and highly trained medical personnel are better able to monitor a patient and ensure adherence if the infusions are done in an in-office setting. Office-based infusion services have been shown to produce improved patient adherence, a key metric for the treatment of chronic and complex diseases that require infusions. 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.[4] In addition, patients enjoy the more relaxed atmosphere of the non-hospital setting, which prevents them from being unnecessarily exposed to severely ill and often contagious patients who require hospital care. A recent, first of its kind study published in the *Journal of Clinical Pathways* found that shifting injected and infused specialty medications from high-cost hospital outpatient settings to more affordable, clinically appropriate alternative settings is associated with favorable clinical outcomes and quality in the non-hospital outpatient settings compared with hospital outpatient settings.[5] Authors conclude widespread adoption of site-of-care management strategies that offer alternatives to the

[4]Giese-Kim, May Wu, et al. "Home Infliximab Infusions are Associated with Suboptimal Outcomes Without Cost Savings in Inflammatory Bowel Disease." The American Journal of Gastroenterology. July 22, 2020. https://journals.lww.com/ajg/Abstract/9000/Home_Infliximab_Infusions_Are_Associated_With.99217.aspx

[5] 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

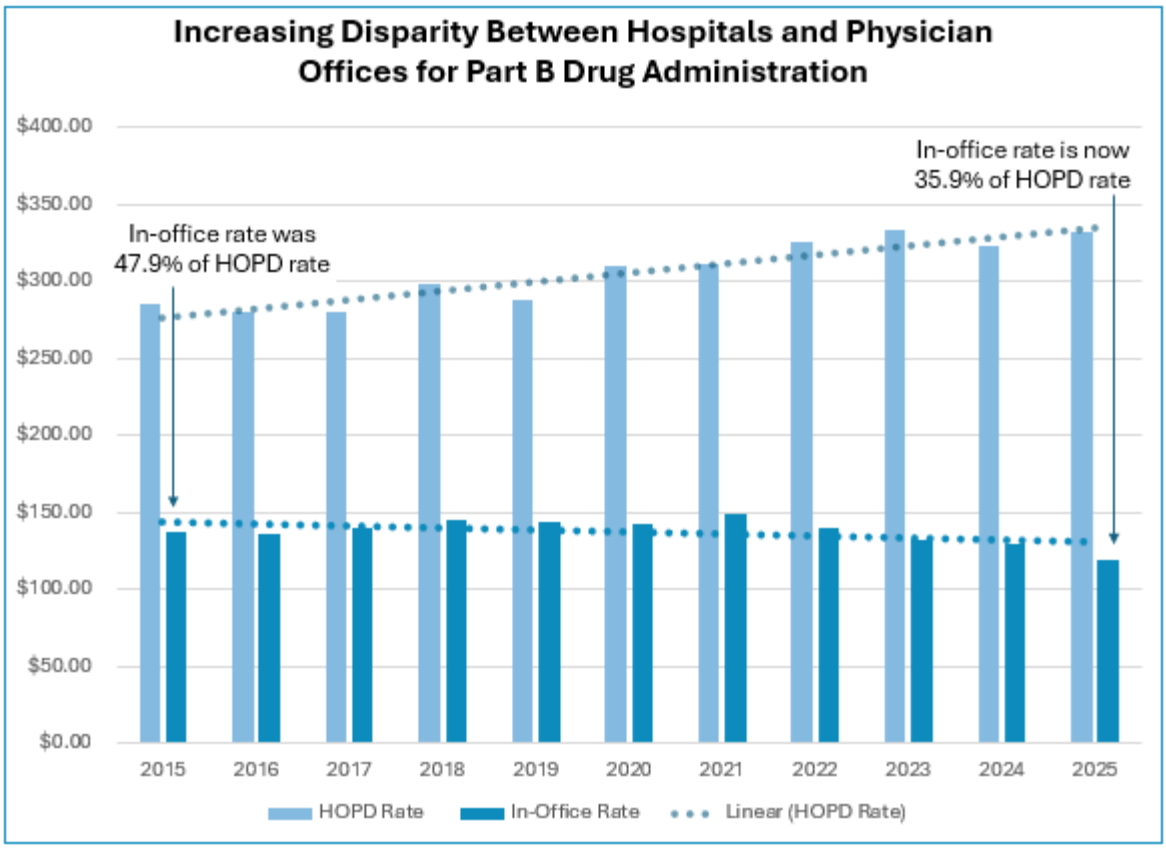
hospital outpatient setting might reduce the burden of rising health care costs, increase affordability, enhance patient convenience, and improve patient choice.

Physician practices and infusion facilities that directly administer drugs to patients in outpatient facilities typically engage in a practice known as "buy and bill." They 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 this 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 of Part B drugs have two sources of reimbursement from Medicare and other payers: their professional fee, which covers a small fraction of their costs,[6] and the "add-on" payment, related to the cost of the drug. The professional fee for a complex drug is less than $120 and has been declining over the years in both real and nominal terms (as noted in the chart below). More troubling, physician practices and infusion clinics have seen these reimbursement cuts while hospital outpatient departments are simultaneously experiencing substantial payment *increases*. Indeed, relative payments compared to hospitals have steadily declined from 47.9% of HOPD payments in 2015 to 35.9% in 2025.

These disturbing reimbursement trends favoring hospitals are exacerbated by the dramatic expansion of the 340B drug discount program, which has made Part B drug administration extremely profitable for 340B hospitals (where margins are 60 percent or more per drug) but has threatened independent practices and infusion facilities with further provider consolidation, which only drives up costs to Medicare, all payers, and most importantly, patients. (Please see our comments on the Hospital Outpatient Prospective Payment rule, which describe this issue in more detail.)

[6] "Medical Benefit Drug Economics: The Price of Furnishing Part B Drugs." National Infusion Center Association



Data based on Code 96413: Chemotherapy administration intravenous infusion, up to one hour
Sources: HOPD Rate = Hospital Outpatient PPS: Addendum B / In-Office Rate = PFS Search

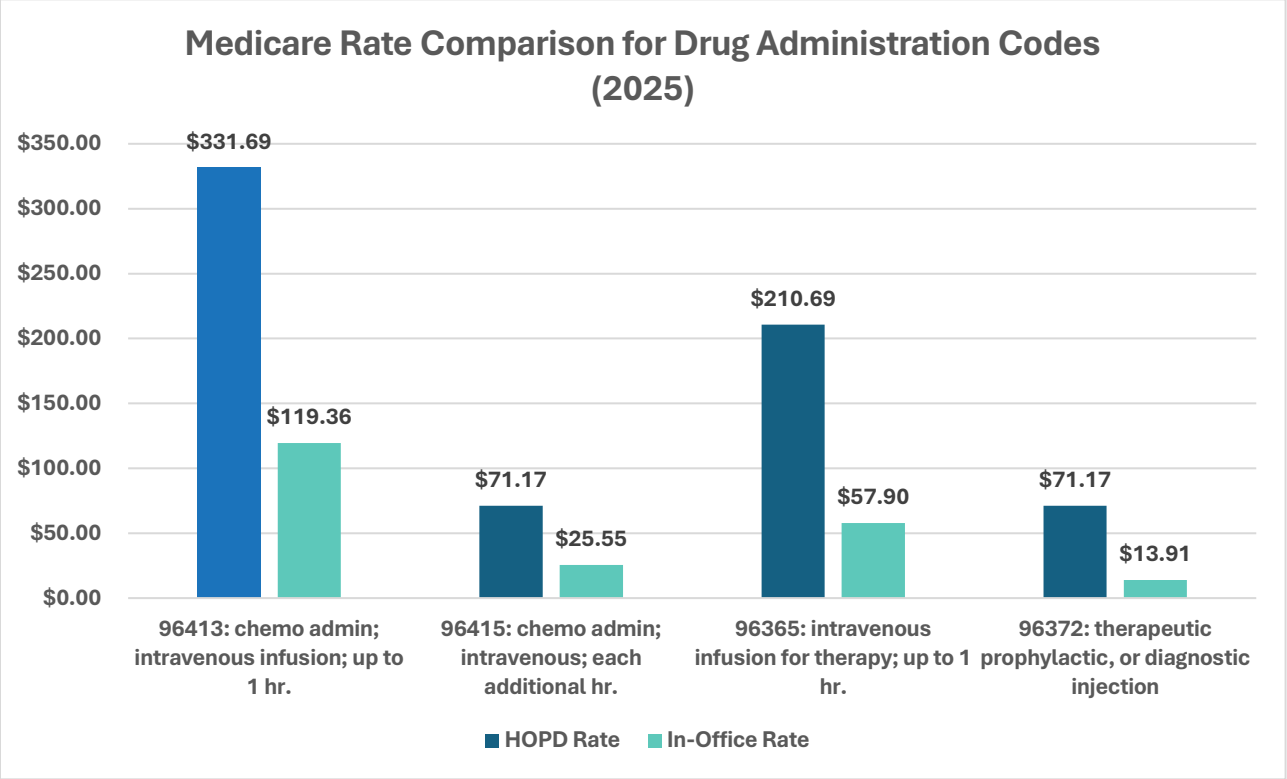


Figure 1: Citations: HOPD Rate = Hospital Outpatient PPS: Addendum B / In-Office Rate = PFS Search

Untoward Implementation of the Inflation Reduction Act Could Threaten Patient Access to Part B Drugs

Under the IRA, reimbursement for Part B drugs subject to Secretary negotiation will be slashed from Average Sales Price plus six percent to the Maximum Fair Price (MFP) plus 6 percent.[7] According to the Congressional Budget Office, reimbursement for Part B drugs (and the associated add-on payment) will be cut by 50 percent or more for those drugs that are subject to negotiation.[8] For example, the add-on payment would be reduced from $430 to $215 for a Part B drug whose reimbursement was cut from $10,000 to $5,000 (after sequestration). Cuts of this magnitude will cause patients to lose access to these drugs as, over time, non-hospital-based providers will be unable to sustain the tremendous losses to their reimbursement.

[7] MFP-designated products of manufacturers that refuse to agree to the "negotiated" price would be subject to a 1,900% excise tax or other products of the manufacturer could be excluded from coverage by Medicare and Medicaid.

[8] Congressional Budget Office: How CBO Estimated the Budgetary Impact of Key Prescription Drug Provisions in the 2022 Reconciliation Act. https://www.cbo.gov/publication/58850

Once these Part B reimbursement cuts commence in 2028, many more essential drugs to these practices and infusion centers will receive similar cuts, with as many as 20 added annually. The paltry professional fee simply cannot sustain these practices and infusion clinics. Over the long-term, this policy will jeopardize the viability of medical practices and infusion centers, especially those in rural or underserved areas. If infusion centers and physician practices can no longer afford to administer these drugs, patients will be forced to obtain their medications in the more expensive hospital setting, assuming those facilities have the capacity to handle the extra patients.

The economic impact of these cuts would be substantially magnified if these statutory payment cuts to Medicare flow through to commercially insured enrollees. Depending on the drug, the payment cuts to our infusion centers and physician practices would be magnified two to three-fold, as commercially insured patients often have a much larger market share than Medicare-covered beneficiaries. That scenario is economically untenable and will certainly threaten the long-term viability of these providers who are at the front lines of caring for some of the most vulnerable and sick Medicare beneficiaries. Congress would not have silently permitted CMS to decide whether to trigger such a massive, across-the-board and long-lasting deterioration of the marketplace that is crucial to patients' health.

Legal Analysis of Excluding MFP from ASP Payment Methodology

The IRA requires the manufacturer to provide Part B drug providers with the maximum fair price (MFP) but is silent on whether those prices would be used to calculate the ASP. Specifically, for Medicare fee-for-service, the payment rate is MFP+6%, not ASP+6%. However, the IRA law does not speak to whether payments by Medicare Advantage and commercial plans, which are typically based on ASP, would be impacted by the new MFP requirement. While the IRA does specify that Medicare Advantage beneficiaries are entitled to coinsurance based on the lower MFP+6% rate, it is silent on how providers would be reimbursed.

Historically, many private payors and Medicare Advantage plans have used ASP as the basis of the payment formula for physician-administered drugs.[9] They could continue to follow this long-standing practice after the MFP is available by ignoring that artificially deflated price, assuming CMS keeps publishing ASPs. We strongly urge CMS to continue

[9] Milena Sullivan, et al., *Commercial Spillover Impact of Part B Negotiations on Physicians*, Avalere (Sept. 16, 2024), https://avalere.com/insights/commercial-spillover-impact-of-part-b-negotiations-on-physicians.

publishing market-based ASPs, which may or may not exclude MFPs from this payment methodology.

IPA believes MFPs should not influence the calculation of ASP and should be excluded from the payment methodology. The legislative history of IRA enactment shows that the Senate considered and subsequently rejected regulating commercial drug prices due to the Byrd Rule. The IRA was considered under budget reconciliation rules, which require provisions to be primarily budgetary in nature. Provisions that have only an "incidental" impact on the budget are considered non-germane and subject to a point of order. Pricing policies that impact Medicare reimbursement of prescription drugs are clearly germane; however, policies that affect commercial prices (e.g., price caps on commercial drug prices) are not germane, even if they have an incidental fiscal impact. This is the primary reason the IRA lacks any legislative language requiring MFPs to be used to calculate ASPs, which commercial payers utilize. It would be entirely inappropriate for CMS to use this legislative exclusion as the basis for now subjecting commercial prices to the MFP price controls specified in the IRA for Medicare only.

Under the "major questions doctrine", federal agencies are not authorized to make decisions with "vast economic and political significance" absent explicit statutory language that provides clear congressional authorization to do so.[10] The IRA is silent, and as such, does not require inclusion of MFPs in the calculation of ASP. Certainly, the Part B drug spend meets the significance criteria, and it would be a disallowed, improper use of executive authority to seize this power from the Congress who wrote the statutes and deliberately did not authorize the MFPs to be included in the ASP methodology.

Allowing Permanent Use of Virtual Direct Supervision Allows for Undisrupted and High-Quality Patient Care

The IPA applauds CMS for its proposal to make virtual direct supervision in non-facility settings permanent in the CY 2026 physician fee schedule proposed rule. In previous comment submissions, the IPA has presented data demonstrating that the use of two-way audio/visual communication to fulfill the "immediate availability" requirement is safe and effective. We have consistently asserted that this policy change would maintain patient safety and access, improve patient therapy adherence, and help to mitigate workforce shortage ramifications.

[10] *West Virginia v. Env't Prot. Agency*, 597 U.S. 697, 732, 734 (2022); *Util. Air Regul. Group v. EPA*, 573 U.S. 302, 324 (2014).

Many of the infusion patients our members treat suffer from conditions such as Crohn's Disease, Multiple Sclerosis, Rheumatoid Arthritis, and other autoimmune disorders. These patients' weakened immune systems make them highly susceptible to infections. Studies have demonstrated that immunocompromised patients are at increased risk of acquiring a hospital-acquired infection (HAI) when treated in hospital settings,[11,12] therefore, these vulnerable patients are better served by safely receiving their infusions in non-hospital-based settings. Maintaining flexibilities that promote easy accessibility to care at less risky sites, such as virtual direct supervision, is key to ensuring that our most vulnerable patients are not put at unnecessary risk when receiving their treatment.

Virtual direct supervision allows highly trained Registered Nurses (RNs) to safely provide services to patients while Nurse Practitioners (NP) offer virtual oversight for these encounters. This is beneficial for both patients and practitioners because when an NP becomes ill or has a family member become ill, virtual direct supervision can be conducted to ensure that the vulnerable patient is not exposed to the illness. The infusion can still be delivered at the appropriate time according to the patient's administration schedule and does not have to be rescheduled. Patient adherence to their medication schedule is critical to treatment efficacy. Missed doses or delays due to practitioners being out sick can result in flare-ups, increased disease progression, and even hospitalization.

Additionally, there is an ongoing healthcare workforce shortage, including nurse practitioners. A study conducted by the global consulting firm Mercer projected that the United States would face a shortage of 29,400 nurse practitioners by 2025.[13] Physician offices and freestanding infusion centers compete with better-resourced hospitals for the same health care workforce. As large hospital systems can often offer bigger bonuses and more flexible hours, physician offices and infusion centers' sites of care are disproportionately impacted by these shortages. Therefore, allowing these sites of care to use virtual direct supervision will help mitigate the impact of the NP shortage by providing flexibility and permitting providers to deliver care to patients even when not physically present. Notwithstanding this important flexibility, it is important to note that freestanding infusion centers utilize this flexibility only as needed. Their business models are not built around virtual supervision, and the vast majority of cases continue to be monitored in person by nurse practitioners.

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[11] .Siegel JD, Rhinehart E, Jackson M, Chiarello L, Health Care Infection Control Practices Advisory Committee. 2007. 2007 Guideline for isolation precautions: preventing transmission of infectious agents in health care settings. Am J Infect Control 35(10 Suppl 2):S65–S164.

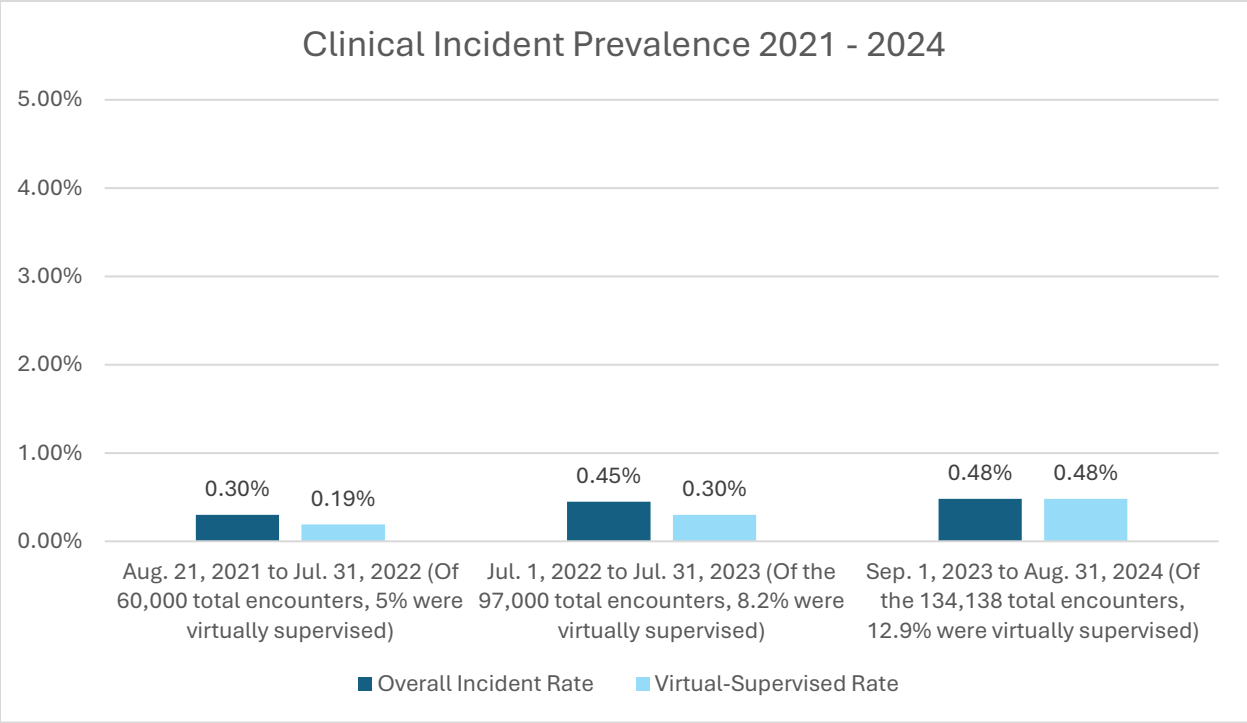
[12] Horan TC, Andrus M, Dudeck MA. 2008. CDC/NHSN surveillance definition of health care-associated infection and criteria for specific types of infections in the acute care setting. Am J Infect Control 36:309–332.

[13] Mercer. "Mercer projects a deficit of over 100,000 healthcare workers in the US by 2028, worsening health disparities and impacting patient care," August, 29, 2024. https://www.mercer.com/en-us/about/newsroom/future-of-the-us-healthcare-industry-labor-market-projections-by-2028/

Allowing infusion providers to use virtual direct supervision on a permanent basis will maintain patient therapy adherence, reduce overall medical costs due to potential therapy administration delays, and allow providers to utilize their well-trained staff effectively.

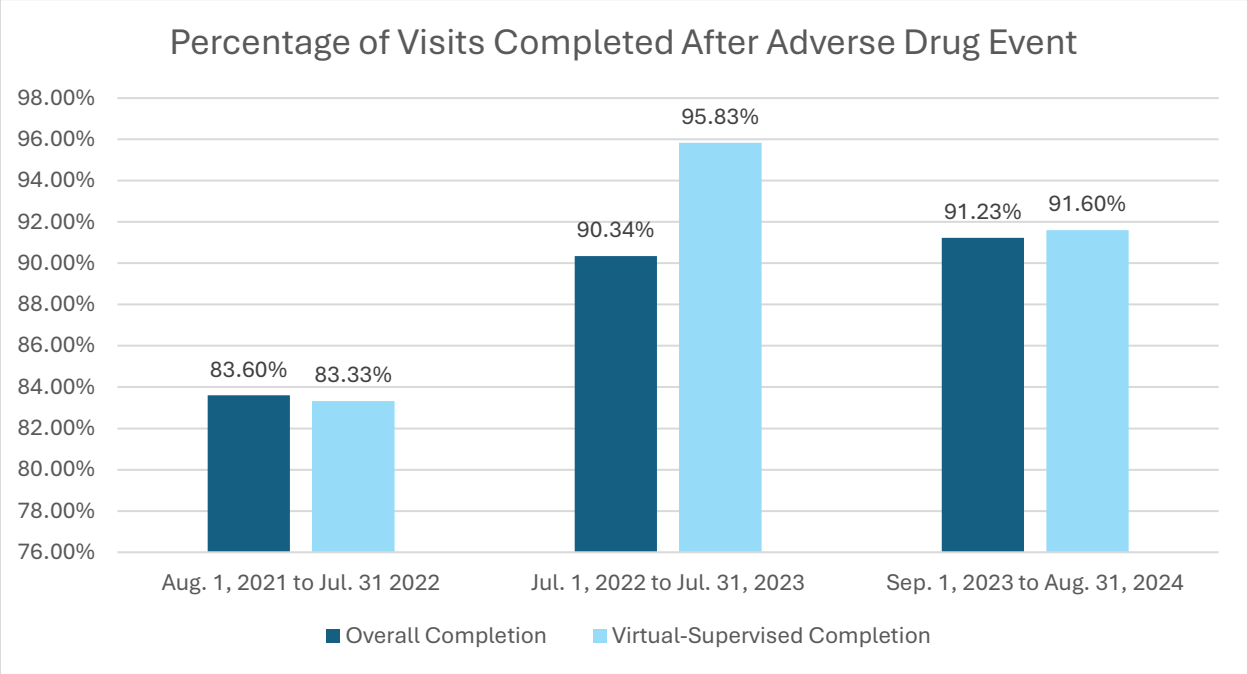
The graphs below include data collected from the IPA membership shared in previous comments. The data highlights the prevalence of incidents during virtual direct supervision and the percentage of visits completed following an adverse drug event.

The data below demonstrates that clinical incidence prevalence has remained low over the last few years, below 0.48% overall, despite an increase in the number of patient treatments. The prevalence of clinical incidents during encounters that are virtually supervised has been on par with the overall incidence rate of clinical incidents, thus suggesting that infusions administered using virtual supervision are no riskier than infusions administered using direct supervision.



Another point we wish to underscore is the percentage of visits completed after an adverse drug event (ADE) during a virtually supervised encounter has remained comparable over the years, if not slightly better than the overall encounter rate. This means that more patients were able to complete infusions after an ADE for virtually supervised encounters than directly supervised encounters. This data demonstrates that the highly trained nurses and NPs who conduct virtual direct supervision can handle these ADEs, and therefore, there is no degradation of clinical outcomes when it is utilized. The over 90% completion rate after an ADE for both directly and virtually supervised patients goes directly to

adherence and patient satisfaction, and strongly supports virtual supervision being a safe adjunct to ambulatory infusion care.



The data provided by IPA, combined with the experience of our members and their patients over the last several years, confirms that patient safety is not threatened by the incorporation of virtual direct supervision into clinical practice. While direct supervision remains the primary form of infusion administration, virtual direct supervision can be just as effective in settings with properly and extensively trained clinicians who have the requisite knowledge and experience.

Making this sensible reform permanent will provide important certainty and predictability after a succession of one year extensions. We appreciate and thank CMS for taking this important action.

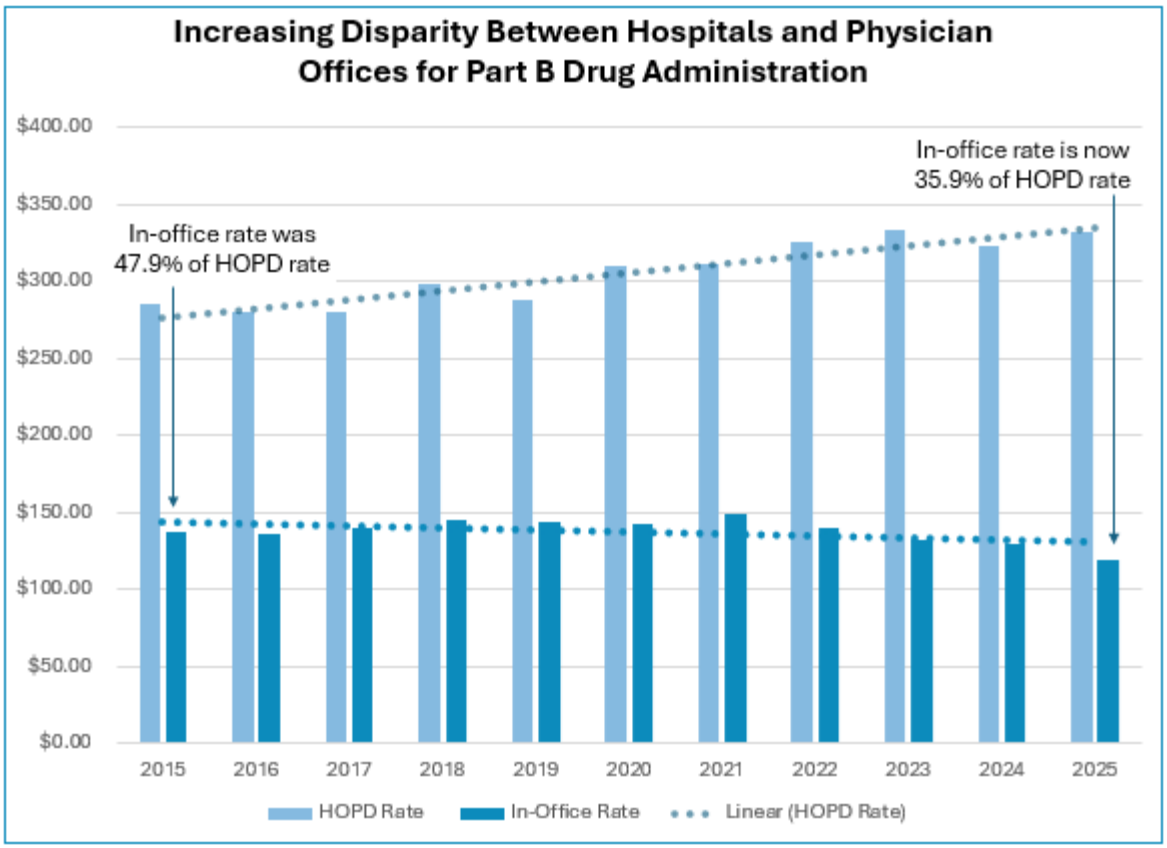
Indirect Practice Expense Methodology Reform Addressing Site of Service Payment Differential

CMS is proposing a significant overhaul of the practice expense methodology to better reflect trends in physician practice settings. CMS notes the significant site-of-service payment disparities between providers paid on the physician fee schedule (e.g. physician practices and outpatient clinics) and hospital outpatient departments, which have helped fuel hospital acquisition of these competing providers. The proposed rule states, "Specifically, in 1988 approximately 72 percent of physicians were full or part owners of their practice. This percentage has dropped to 35.4 percent, representing a 52 percent decrease, with a corresponding rise in physicians employed directly by the hospital."

CMS argues that "allocating the same amount of indirect practice expense based on work relative value units (RVUs) in both settings [hospital and physician office] may overstate the range of indirect costs incurred by facility-based physicians if it is now less likely that they would maintain an office-based practice separate from their facility practice." As MedPAC notes in its June 2025 report, "In cases when clinicians practice exclusively in a facility or where a facility is financing indirect practice expense (PE) for clinicians, payment to both entities for indirect PE costs may be duplicative and unnecessary." CMS concludes that "Within the PFS relative value system, any overstatement of practice expense in the facility setting would affect the allocation of indirect costs in the nonfacility setting. This dynamic, in which relative resources involved in furnishing PFS services may not be adequately reflected in facility and nonfacility settings, has the potential to contribute to broader undesirable financial incentives toward higher-priced settings of care, like hospitals, and away from more efficient settings, like physician offices."

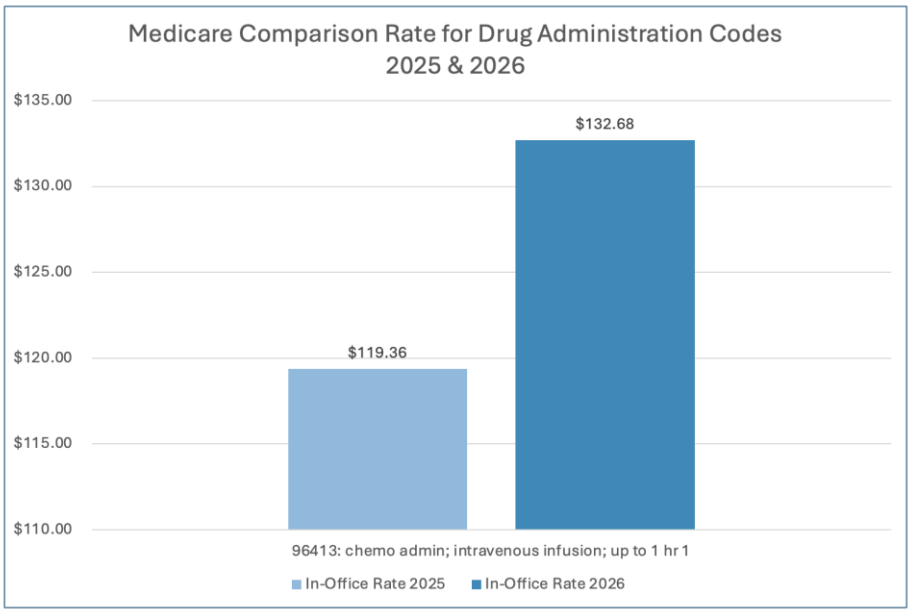
CMS is proposing to reduce the portion of the facility PE RVUs allocated based on work RVUS to half the amount allocated to non-facility PE RVUs. This will result in a corresponding increase to non-facility-based clinicians.

The IPA is pleased CMS has finally recognized that increasing payment disparities is contributing to hospital acquisitions of independent practices and other outpatient providers, such as drug infusion facilities. Over the last decade, we have seen these payment disparities grow substantially for Part B drug administration, where hospitals continue to get market basket payment increases and independent providers of the same drugs have experienced payment cuts. As a result, payments for drug administration in the physician office/clinic setting have dropped from 47.9% of HOPD in 2015 to 35.9% in 2025.



Data based on Code 96413: Chemotherapy administration intravenous infusion, up to one hour
Sources: HOPD Rate = Hospital Outpatient PPS: Addendum B / In-Office Rate = PFS Search

The IPA supports CMS proposed reforms to indirect PE, which will result in an increase in PE for non-facility-based clinicians. That reform would result in a much larger payment increase for PFS-based drug administration than could be expected from the 3.63 percent increase of the conversion factor to the physician fee schedule. As a result, payment for drug administration for physician practices and drug infusion clinics will rise 11 percent, or about $13 for Code 96413, which is commonly used by our members.



While the IPA supports this payment reform, we want to underscore that it in no way compensates or even more than negligibly mitigates the enormous projected cuts to our members' reimbursement that will result from MFP replacing ASP for drugs negotiated by the Secretary.

Concerns Regarding Proposed Revisions to the "Bona Fide Service Fee" (BFSF) Definition

CMS proposes to revise the definition of "bona fide service fees" (BFSFs). Currently, manufacturers may exclude BFSFs from the calculation of ASP where such fees meet a four-part test established in 42 C.F.R. § 414.802. In the Calendar Year (CY) 2007 Physician Fee Schedule (PFS) final rule (71 FR 69665 through 69678) Medicare finalized a definition of BFSF for the purposes of calculating the manufacturer's ASP at § 414.802, which states that the term "BFSFs" means fees paid by a manufacturer to an entity, that:

1. represent fair market value
2. for a bona fide, itemized service actually performed on behalf of the manufacturer
3. that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement, and
4. that are not passed on in whole or in part to a client or customer of an entity, whether or not the entity takes title to the drug.

In the proposed rule, CMS would significantly narrow the applicability of this exclusion with the following changes to BFSFs for the purpose of calculating ASP:

1. Fair Market Value (FMV): Specifying the methodology that should be used to determine FMV and the period after which manufacturers should reassess the FMV.

2. Pass-Through Certification: Requiring manufacturers to obtain a "certification or warranty" from any entities receiving BFSFs stating that such fees will not be passed on to an affiliate, client, or customer of such entity.
3. New Submission Requirements: Requiring manufacturers submit additional documentation to CMS on a quarterly basis.
4. Non-BFSF Examples: CMS also provided a "non-exhaustive" list of fees that it states are not, or may not be, BFSFs including:
    a. Payments by drug manufacturers to drug distributors, which lower the price that distributors and purchasing physicians pay, and specifically payments to cover credit card processing fees;
    b. Any payment by the manufacturer of certain cell and gene therapies to an entity for tissue procurement;
    c. Certain data sharing fees where the data is required for legal compliance and audit purposes under the applicable services agreement, as such fees may exceed FMV and not be bona fide; and
    d. Certain fees paid for distribution services that appear to exceed the FMV.

We urge CMS to not implement the proposed revisions to the BFSF definition in the final rule, which will only lower the reimbursement to our facilities but not the acquisition costs for these drugs.

The non-exhaustive list of non-BFSF examples introduces extreme uncertainty (as other unforeseen instances could arise for exclusion) and surely artificially deflate provider reimbursement for administering these products. CMS's suggestion that fees "lower the price that… purchasing physicians pay" is misleading. An isolated example of credit card processing fees is not sufficient justification for such a broad and open-ended change, subject to shifting interpretation, that would ultimately harm a key access point for patients.

Implementing such a significant change on an accelerated timeline could disrupt the pharmaceutical distribution supply chain our members depend on. As proposed, manufacturers and their distributor partners would face new contracting, reporting, and compliance requirements, and the January 1, 2026 effective date does not allow sufficient time to restructure agreements or establish appropriate compliance standards. Manufacturers and distributors already engage 3rd party entities to determine fair-market value and have established processes to ensure appropriate BFSF determinations. Additional pass-through certification and submission requirements introduce unnecessary compliance burden. Faced with this compliance risk, manufacturers will likely adopt reporting practices that will depress ASP reimbursement for providers but not the acquisition of those drugs. If finalized, this proposal could jeopardize a key access point for provider-administered drugs critical to patients with complex and chronic conditions.

This proposal also conflicts with the Administration's stated objective of incentivizing care in the most efficient site of service. Our members strongly support the Administration's

goal to incentivize administration of Part B drugs in more efficient, non-hospital-based settings. To further that policy priority, CMS should take a more circumspect view of the downstream impacts of policies that undermine community-based providers – and patient access – by making reimbursement inadequate and driving care into the higher-cost, less convenient hospital setting.

A downstream impact that CMS may not fully appreciate is the decrease in reimbursement to non-hospital-based providers. The experience of "underwater biosimilars" provides a real-world example on the risks of allowing price concessions to distort ASP. As detailed in our comments, rebates and other concessions provided to PBMs are reflected in ASP and have driven reimbursement well below many providers' acquisition costs. This has left our members unable to deliver these critical therapies, which undermines both patient access and physician choice. By broadening what is considered a "price concession" in the proposed BFSF definition, CMS risks depressing ASP in ways that could further destabilize provider reimbursement and patient access to critical therapies.

Our members would welcome the opportunity to work with CMS on refining ASP calculations in a way that safeguards provider sustainability and patient access. However, the proposed changes to the BFSF definition threaten to disrupt the drug supply chain and undermine community-based providers' ability to deliver care in convenient, non-hospital settings. Given these downstream impacts, we urge CMS to not finalize this proposal.

Conclusion

The IPA appreciates the opportunity to comment on the proposed physician fee schedule rule.

- The IPA opposes inclusion of MFP in the calculation of ASP and strenuously objects to replacing the ASP file entirely with MFP.

- The IPA supports CMS's proposal to make virtual direct supervision permanent in non-facility settings. This practice has proven to be a safe and effective way to treat patients while supporting our health care workforce.

- The IPA supports CMS's proposed reforms to indirect practice expense, which will finally result in a modest increase of professional fees for Part B drug administration.

- Due to the negative downstream impacts to patients and providers, IPA urges CMS to not implement significant changes to the definition of "Bona Fide Service Fees".

We thank you for your time and consideration.

Sincerely,

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