September 15, 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: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems; Quality Reporting Programs; Overall Hospital Quality Star Ratings; and Hospital Price Transparency (CMS-1834-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

IPA wishes to comment on two policies within the 2026 hospital outpatient prospective payment rule:

1. IPA supports CMS's proposal to control unnecessary and inflated costs at "excepted off-campus provider-based sites," with respect to Part B drug administration; and

2. IPA supports CMS's proposal to conduct a survey of drug acquisition costs of 340B hospitals to determine more appropriate Medicare payment rate for those hospitals.

These two policies, taken together, and pursued to their logical conclusion will help level the playing field between physician office/infusion clinic setting and hospital-owned sites where hospitals enjoy tremendous payment and drug acquisition advantages for administering *identical* Part B drugs. However, we want to emphasize that over the long-term, if policymakers

– both CMS and Congress – want to pursue site-of-service payment reform, they must examine and pursue payment reforms that ensure these more efficient sites of care are adequately funded and have the incentive and capacity to take on additional patients who may be turned away from hospitals. Simply cutting reimbursement to certain hospital sites or reducing payment overages for 340B drugs is not sufficient; those reforms must be coupled with protecting and advancing patient access to independent physician practices and infusion clinics.

IPA Supports Reforming Payments to Excepted Off Campus Provider Sites

The IPA appreciates that CMS proposes finally reforming payments to "excepted off campus" Hospital outpatient department sites of care. These off-campus HOPD sites were typically acquired physician practice or other outpatient provider sites that are now owned by a hospital and bill Medicare services under the hospital provider identification number.

The Bipartisan Budget Act of 2015 included a critical reform to deter provider consolidation and protect the Medicare program from excessive billing[1]. It did so by prohibiting hospitals from acquiring physician practices and freestanding infusion facilities and subsequently billing for identical procedures at off-campus facilities by using the higher hospital outpatient rates. This provision was designed to allow for a more 'level playing field', ultimately driving care to the most appropriate, lowest cost site of service or at least continuing to pay the physician office rate when a physician practice is acquired and continues to provide care at an off-campus site. Unfortunately, research has found that most hospitals have evaded this provision because they have been billing the care in these off-campus outpatient facilities as if the care were being delivered at the main hospital campus where the higher rate is charged.[2,3] Hospitals have been able to evade the law's intent due to CMS's inability to determine whether care was provided at an off-campus site of an acquired practice. We encourage CMS to modernize and reform the claim and payment protocols to ensure the law is being complied with properly.

Pursuant to the BBA of 2015, CMS implemented a policy in 2017 to apply lower, physician fee schedule (PFS) equivalent rates to certain off-campus PBDs, aiming for site neutral payments, as sought by Congress in the Bipartisan Budget Act of 2015. However, departments that were already billing under OPPS before enactment were "excepted" or "grandfathered" under the hospital outpatient prospective payment system. In the HOPPS proposed rule, CMS suggests reducing payments for these additional off campus HOPD departments to the physician office payment rate.

In the proposed rule, CMS notes that payment differentials between OPDs and other sites encourages providers to shift care to hospital sites even if services can be safely performed at the more efficient sites. CMS concludes, "Taking into account that any payment differential

[1] P.L. 114-74

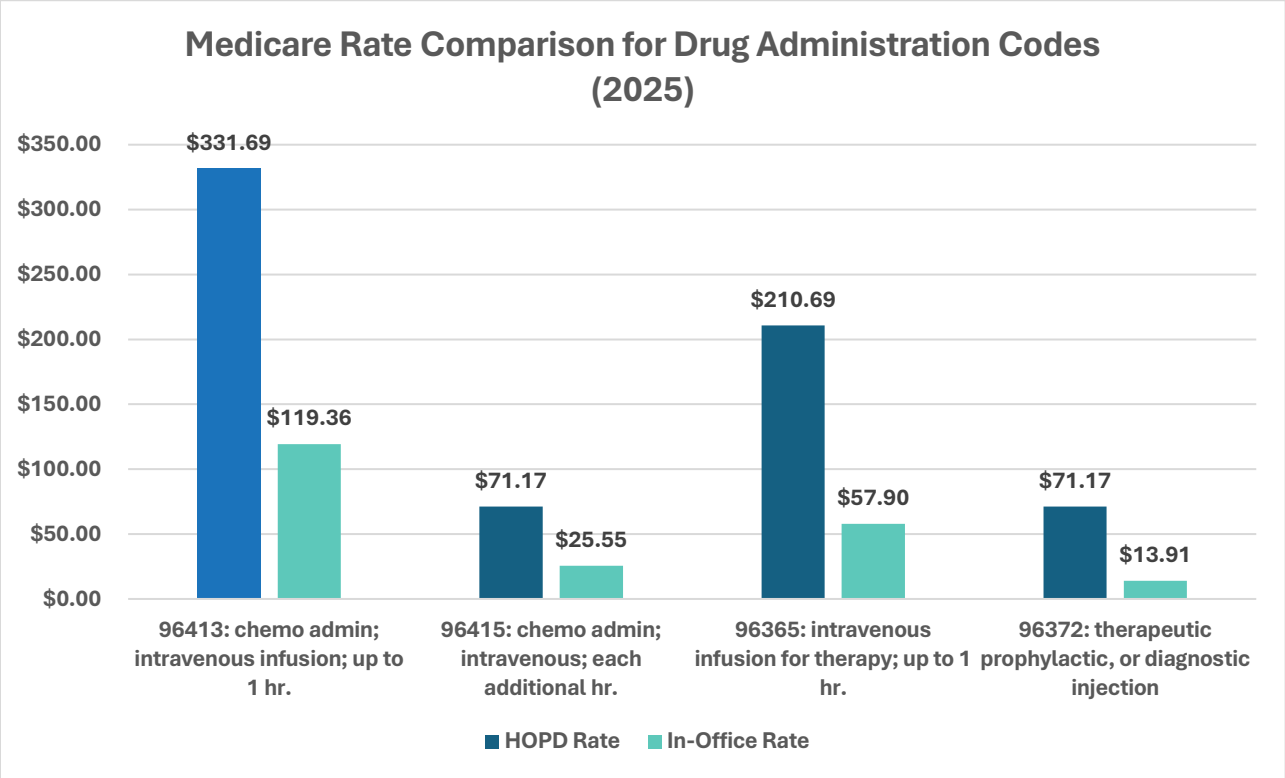
[2] HHS OIG, "CMS is Taking Steps to Improve Oversight of Provider-Based facilities, But Vulnerabilities Remain." June 2016.

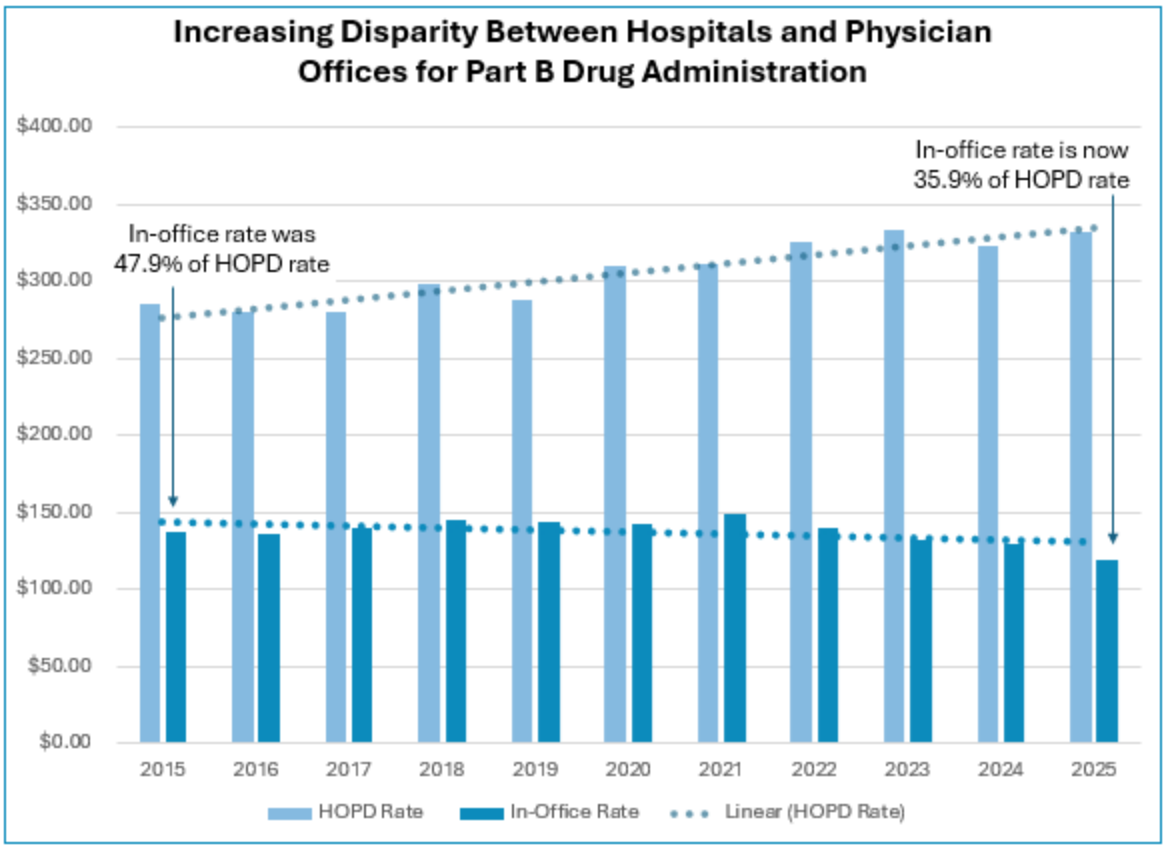
[3] HHS OIG, "Incorrect Place-of-Service Claims Resulted in Potential Medicare Overpayments Costing Millions." May 2015

occurs across millions of claims for drug administration and other services each year, this threatens to create a significant source of unnecessary spending by Medicare beneficiaries directly in the form of unnecessarily high copayments and on behalf of Medicare." In its 2023 report, MedPAC stated that the share of chemotherapy services furnished in OPDs have grown from 35.2 percent in 2012 to 51.9 percent in 2021. CMS observes that code 96413 – which describes chemotherapy (and other complex drugs administered by IPA members) – is one of the most frequently billed drug administration codes in OPPS."

As the IPA pointed out in our comments to CMS on the proposed physician fee schedule rule, hospital outpatient departments, including "excepted off campus" sites, are paid nearly three times more than physician offices and infusion clinics for drug administration for Medicare beneficiaries ($119 vs $341 for code 96413) and that disparity has grown over the past decade from 47.9 percent of HOPD in 2015 to 35.9 percent of HOPD in 2025.

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



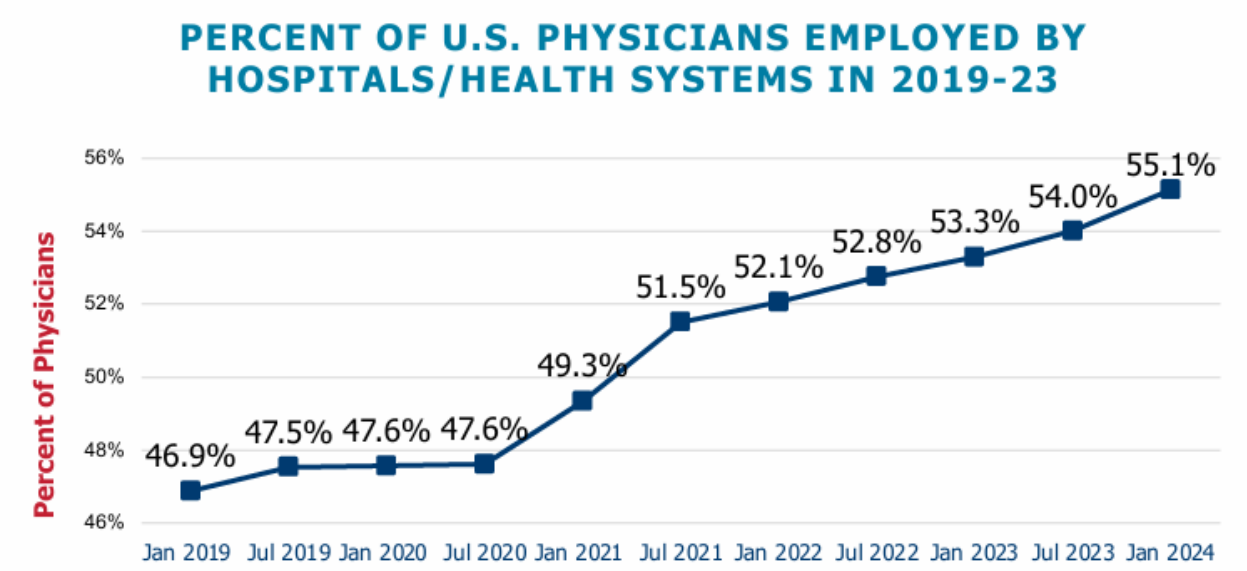


Data based on Code 96413: Chemotherapy administration intravenous infusion, up to one hour
Sources: HOPD Rate = Hospital Outpatient PPS: Addendum B / In-Office Rate = PFS Search

The importance of these reforms is underscored by CMS in the proposed rule: in previous rulemaking CMS "discussed vertical consolidation and the practice of hospitals purchasing freestanding physician practices and converting the billing from PFS to higher paying OPD visits. These conversions shift market share from freestanding physician offices to OPDs. We stated that we believed there was a correlation among the increasing volume of OPD clinic visits, vertical integration, and the higher OPPS payment rates for clinic visits. Favorable reimbursement for hospital-owned sites has been shown to encourage hospitals' acquisition of physician practices."

A study by Avalere for the Physician Advocacy Institute found that the percentage of hospital-employed physicians increased by more than 70 percent from July 2012 through January 2018. During that timeframe, hospital acquisitions of physician practices more than doubled. In 2017 and 2018 alone, an additional 8,000 physician practices were

acquired by hospitals.[4] The trend is disturbing and continuing. A separate study by Avalere for the Physicians Advocacy Institute found more than half of physicians (55.1 percent in 2024) were employed by hospitals/health systems.[5]



This harmful trend is being increasingly recognized and acknowledged. Recently, The New York Times reported, "The level of hospital consolidation today – 75 percent of markets are now considered highly consolidated – decreases patient choice, impedes innovation, and erodes quality and raises prices… When hospitals buy doctors' practices, research shows, rates for visits tend to go up. Some purchases are essentially catch-and-kill operations: Buy a nearby independent cardiac center, for example, in order to eliminate cheaper competition."[6]

Long-Term Reform Necessitates Protecting Reimbursement to Physicians and Infusion Centers, Not Just Reducing Hospital Payments for Drug Administration

In short, the IPA supports CMS proposal to reduce payments for excepted off campus hospital departments to the physician office rate. That policy will help disincentivize the acquisition of efficient, independent providers of Part B drugs. However, we want to underscore our more fundamental concern with payment reforms currently underway that will disproportionately negatively impact physician practices and freestanding infusion clinics because they have limited or no ability to cost-shift to other business lines.

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[4] Physicians Advocacy Institute. Updated Physician Practice Acquisition Study: National and Regional Changes in Physician Employment 2012-2018. February 2019

[5] Physicians Advocacy Institute. Updated Report: Hospital and Corporate acquisition of Physician Practices and Physician Employment 2019-2023. April 2024.

[6] Elisabeth Rosenthal, "Your Exorbitant Medical Bill, Brought to You by the Latest Hospital Merger." The New York Times, July 25, 2023

Most notably, the anticipated cuts to the "add-on" Part B payment for drugs (i.e. ASP+4.3% after sequester) subject to negotiation will have a devastating effect on these efficient providers' ability to provide these products. Over the long-term, it severely threatens their economic viability. CMS must take a more holistic view of drug administration payment policy and acknowledge that a very small portion of provider reimbursement is derived from the professional fee/APC that is the focus of this site neutrality payment reform. Much more important to the vitality of physician practices and infusion clinics is the add-on payment associated with the reimbursement of the drug. Cuts of 50 percent or more, as projected by the Congressional Budget Office are not sustainable.

We encourage CMS to do what it can to minimize the impact of these looming payment cuts that are sure to result in a patient access crisis for impacted products by 1) Limiting their application to Medicare payments only (i.e. do not impact the calculation or publication of ASP); and 2) Work with Congress to enact the Protecting Patient Access to Cancer and Complex Therapies Act (HR 4299), which will achieve the same or more desired savings as the Inflation Reduction Act through a rebate mechanism paid by pharmaceutical manufacturers rather than making physician practices, infusion centers and their patients collateral damage to such payment reforms.

The IPA Supports Undertaking a Survey of 340B Hospital Drug Acquisition Costs to Better Determine HOPPS Medicare Reimbursement

The 340B program is a government-mandated program that requires manufacturers to provide drugs to eligible providers at steeply discounted prices equal to the size of the Medicaid rebate. However, that program does not require 340B hospitals to pass on those discounts to patients, whether they be enrolled in Medicare, commercially insured or even destitute and uninsured. As a result, Medicare payments which are based on the market-driven average sales price methodology (ASP+6%) have resulted in a windfall for 340B providers but Medicare beneficiaries and other patients are not benefitting in reduced cost for those drugs provided by 340B hospitals.

In 2018, CMS issued regulations designed to reform 340B drug reimbursement for Medicare beneficiaries by establishing a payment formula of ASP minus 22.5 percent for 340B hospitals. The change stemmed from conclusive evidence that 340B hospitals acquire drugs at discounts far in excess of ASP minus 22.5 percent. Indeed, research by the Medicare Payment Advisory Commission found that hospitals were acquiring drugs at discounts more than 58 percent, providing eligible 340B hospitals with a substantial spread even at the ASP-22.5 percent payment level[7].

[7] Medicare Payment Advisory Commission. "Report to the Congress: Medicare Payment Policy," March 2020. Available at https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/mar20_entirereport_sec.pdf

Nonetheless, the American Hospital Association prevailed in the Supreme Court ruling *(American Hospital Association v. Becerra*) that the policy reform was illegal. This decision was based purely on procedural objections to the method by which the change was made and promulgated. Thus, the ruling did not express an objection to the proposed reimbursement formula of ASP minus 22 percent as too low or inappropriate but rather reversed the regulation because the Court determined that the Agency had violated its statutory obligation to conduct a survey of acquisition costs before developing the separate payment classification for 340B hospitals. We are heartened by and support CMS's proposal to now undertake that statutorily required survey.

Leveling the Playing Field for Community-Based Care

IPA members are not eligible to participate in the 340B program, meaning they do not benefit from the steeply discounted drug acquisition costs that hospitals can access. When hospitals are reimbursed at standard OPPS rates while acquiring drugs at substantially reduced 340B prices, they generate large margins unavailable to community-based providers. This dynamic creates a structural imbalance that places infusion centers outside of 340B at a competitive disadvantage. Studies have shown that hospitals participating in 340B generate substantial revenue from the "spread" between discounted acquisition costs and Medicare reimbursement,[8] which they can use to expand market share. These dynamics contribute to the well-documented trend of hospital acquisition of physician practices, including infusion centers, that raises overall costs of care.[9]

A hospital survey on 340B acquisition costs will provide CMS with the objective data needed to ensure accurate reimbursement and responsible program administration. This is a commonsense step to bring accountability to a program that has expanded well beyond its original intent. By requiring hospitals to submit acquisition cost data, CMS will move toward payment policies that more accurately reflect reality, reducing incentives that drive care away from lower-cost, community settings and ensuring that non-340B providers are not further disadvantaged.

For too long, the 340B program has operated without meaningful transparency into how hospitals acquire and utilize discounted drugs. Multiple government watchdogs have found that program growth has outpaced oversight, leading to concerns that the benefits are not consistently reaching vulnerable patients. MedPAC has repeatedly raised concerns about the distortions created when 340B hospitals are reimbursed at full OPPS rates despite paying significantly less for drugs.[10]

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[8] New England Journal of Medicine. "The 340B Drug Discount Program — Origins, Implementation, and Post-Reform Future." NEJM 2014; 371:1463-1468.
[9] Berenson, R. et al. "The Growing Power of Some Providers to Win Steep Payment Increases from Insurers Suggests Policy Remedies May Be Needed." *Health Affairs*. May 2012.
[10] MedPAC. *Report to the Congress: Medicare and the Health Care Delivery System*. June 2015, Chapter 5.

By law, independent physician practices and infusion clinics are not generally eligible for the 340B program because the 340B program is limited to certain Federal grantees and certain hospital types. Notwithstanding, our members must compete with these same large institutional providers without the benefit of mandated and steep discounted drug prices.

340B Program Has Grown Out of Control and Helps Drive Hospital acquisitions of Physician Practices

IPA is alarmed by how rapidly the 340B program has expanded over the last several years. 340B participants, or covered entities, receive a 340B ceiling price discount that is equal to the Medicaid rebate for that product, which averages out to about a 59 percent discount on the list price for a drug. Data released in August 2022 by the Health Resources and Services Administration (HRSA) suggest discounted purchases under the 340B program reached $44 billion in 2021, a 16 percent increase since 2020 and nearly quadruple the amount seen in 2015, at $12.2 billion.[11] Despite the program's growth, a report by the Kaiser Family Foundation has found that the value of charity care provided by hospitals varies substantially across facilities ranging from 0.1% of operating costs to 7% or more.[12]

The just released CBO report, "Growth in the 340B Pricing Program" (September 9, 2025) underscores the rapid growth of the program and its distortionary impact on the health care system. CBO found that the 340B grew from $6.6 billion in 2010 to $43.9 billion in 2021. The report states, "In CBO's assessment, the 340B program encourages behaviors – including the prescription of more and higher priced drugs, the expansion of services, and **the integration of hospitals and off-site clinics** – that tend to increase federal spending."[13] (emphasis added). When independent infusion clinics or physician practices are acquired by a 340B hospital in order to maximize drug profit, Medicare pays substantially more for the administration of those drugs, as our comments document.

340B Eligibility Should Be Prohibited for Future Hospital-acquired Off-Campus Physician Practices

Many 340B hospitals have purchased physician practices, retained their pre-existing off-site locations (often even the name of the practice), and commenced providing drug administrations at these "child sites," which are then eligible for 340B discounts from manufacturers. This generates revenue for the hospital but does not necessarily benefit patients. Recent investigations by several newspapers found that many of these acquired child sites are not providing enhanced patient access or resources within their communities. These are often established in suburban, economically affluent areas that do not serve the lower-income areas that the 340B provisions were intended to reach.

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[11] Health Resources and Services Administration (HRSA). 2021 340B Covered Entity Purchases. August 12, 2022

[12] Levinson, Zachery, Hulver, Scott and Neuman, Tricia "Hospital Charity Care: How It Works and Why It Matters." Kaiser Family Foundation. November 3, 2022.

[13] https://www.cbo.gov/system/files/2025-09/60661-340B-program.pdf

Importantly, just as CMS is closing the loophole for "excepted off campus departments" with respect to Medicare reimbursement, it should also close the loophole that allows these off-campus outpatient facilities to benefit from 340B pricing, a major driver of hospital acquisition of physician practices and infusion clinics. Specifically, we recommend that any future acquisitions of physician practices by a 340B eligible hospital be ineligible for the 340B program if they continue to treat patients in an off-campus facility (typically the same location the practice provided care prior to the acquisition).

Protecting Patients and the Medicare Program

Accurate data on 340B acquisition costs will help protect patients from unnecessary cost-shifting and ensure that the program operates in a way that supports—not undermines—affordable access to care. Moreover, improved transparency will safeguard the Medicare Trust Fund and taxpayers from overpayments that arise when reimbursement is not aligned with actual drug acquisition costs.

IPA strongly urges CMS not only to finalize the hospital survey requirement, but also to:

- Ensure the survey is mandatory and comprehensive so that the resulting dataset reflects the full scope of hospital acquisition costs;
- Make the survey findings public to provide transparency for policymakers, taxpayers, and providers across care settings; and
- Use the results to align OPPS reimbursement more closely with actual acquisition costs, thereby reducing payment distortions that disadvantage non-340B providers and drive up Medicare spending.

Finalizing and implementing this survey in a transparent, meaningful way will bring long-overdue accountability to the 340B program, help protect patient access to community-based infusion care and preserve the sustainability of the Medicare program.

CONCLUSION

In conclusion, we support two initiatives in the proposed HOPPS rule to address site-of-service payment disparities: reforming payments to excepted off-campus departments and conducting a survey of 340B hospitals to determine the appropriate Medicare payment amount for drugs provided by those entities.

We want to underscore the point that these reforms are not sufficient to address site-of-service payment differences. CMS and Congress must do more to protect community providers, including physician practices and freestanding infusion facilities; in particular, these efficient providers of Part B drugs should be protected from becoming collateral damage from the negotiation provision in the IRA statute that would lead to substantial and devasting cuts to their most important reimbursement stream, the add-on payment to ASP.

Thank you for your consideration of our comments and we look forward to working with CMS.

Sincerely,

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