



**The Nation's Voice for
Community-Based Infusion Care**

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September 16, 2026

John Brooks
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244

Re: Medicare Drug Price Negotiation Program: Draft Guidance, Manufacturer Effectuation of the Maximum Fair Price in 2028

Dear Mr. Brooks:

The National Infusion Center Association (NICA) is a nonprofit organization formed to support community-based infusion centers caring for patients in need of provider-administered medications. To improve access to medical benefit drugs that treat complex, rare, and chronic diseases, we work to ensure that patients can access these drugs in safe, more efficient, and cost-effective alternatives to hospital care settings. NICA supports policies that improve drug affordability for beneficiaries, increase price transparency, reduce disparities in safety across care settings, and foster patient access to the highest-quality, lowest-cost setting.

NICA's members administer medications to patients – including Medicare beneficiaries – with serious, often lifelong conditions including autoimmune diseases that can result in permanent disability if not appropriately managed. Fortunately, the treatment of autoimmune disease, including such conditions as rheumatoid arthritis, psoriasis, and lupus, has come a long way in that there are now specialty biologics that enable patients to manage their condition, in many cases with such success that these patients are able to fully engage in activities of daily living and/or remain employed in the same way they were prior to diagnosis.

We appreciate the opportunity to provide comments on the *Medicare Drug Price Negotiation Program: Draft Guidance, Manufacturer Effectuation of the Maximum Fair Price in 2028*. As providers of Part B medications, our comments focus exclusively on the provisions applicable to Part B drugs. We appreciate your consideration of how this new policy will fundamentally change Part B reimbursement and urge CMS to avoid any action that would compound existing reimbursement and access concerns for community-based infusion providers and the Medicare beneficiaries they serve.

Maintaining the Viability of Community-Based Infusion Centers

Community-based infusion centers play a key role as the most efficient setting for drug administration, compared to hospital outpatient departments and, in many cases, even compared to the home. The Employee Benefit Research Institute (EBRI) quantified the cost differences in healthcare services by site

of treatment, including for the delivery of specialty medications, and determined that employers and workers could save as much as 36 percent on their medication if administered in a physician's office compared to a hospital outpatient department.¹ Therefore, it is clearly beneficial to advance policies that support our nation's in-office drug administration capacity to further the Administration's goals to reduce the overall cost of prescription medications for both the federal government and for patients.

With that in mind, NICA encourages CMS to ensure that implementation of the Maximum Fair Price (MFP) for Part B drugs does not create new responsibilities or shift costs associated with carrying out the Medicare Drug Price Negotiation Program (MDPNP) onto community-based infusion centers. As noted in the draft guidance, section 1193(a)(3)(B) of the Social Security Act assigns Primary Manufacturers with the duty to provide access to the MFP. Thus, CMS should coordinate directly with Primary Manufacturers, Medicare Advantage (MA) organizations, and its contractors to build the infrastructure needed to effectuate the MFP, rather than layering new enrollment, reporting, reconciliation, or other administrative duties onto Part B providers.

NICA members already dedicate considerable financial resources towards helping patients access their prescribed Part B medications – services that are not reimbursable through Medicare or commercial insurance. This includes navigating an ever-growing web of hurdles imposed by insurance companies, such as prior authorization and step therapy, or by the patient's Pharmacy Benefit Manager, including shifting formularies, coverage rules, and patient cost-sharing obligations. Far too much staff time is already consumed by administrative burdens. For many infusion centers, this work is often substantial enough to require one or more staff members whose primary job is managing payer requirements so patients can get the care they medically need. Requiring practices to enroll in new systems, take on extra reporting, reconcile manufacturer payments, or fix problems stemming from MFP effectuation would pile uncompensated administrative work and financial exposure onto practices that are already stretched thin trying to help patients overcome coverage and affordability obstacles.

To compound those challenges, infusion centers operate under the "buy and bill" model for Medicare Part B drugs, which presents considerable financial risk and a delicate management of cashflow. Through buy and bill, infusion providers order medications, manage inventory, and handle all storage and processing. Medications are ordered based on the center's estimated needs over a certain time period, rather than ordered individually per patient. This system allows flexibility to adjust dosing and allocate inventory based on real-time needs.

However, systemic changes to this very sensitive buy and bill ecosystem, such as those proposed under this draft guidance, can quickly worsen the reimbursement crisis experienced by our members. Infusion centers face continued cuts to Medicare's payment for drug administration services, sequestration applied to payments for physician-administered drugs, and a growing number of cases where Medicare reimbursement fails to cover what the practice paid to acquire the drug. These reimbursement challenges are a real risk to the community-based infusion center model, as Medicare reimbursements have not kept up with the rising cost of running a medical practice. Practice-cost inflation has increased by 63 percent over the past twenty years, while reimbursements have dropped by 33 percent during that same period, once adjusted for inflation.² In fact, CMS's own draft guidance acknowledges that "independent physician

¹ EBRI Issue Brief No. 525. "[Location, Location, Location: Cost Differences in Health Care Services by Site of Treatment — A Closer Look at Lab, Imaging, and Specialty Medications.](#)" February 2021.

² American Medical Association. "[Medicare physician payment continues to fall further behind practice cost inflation.](#)" January 2026.

clinics" are among the Part B providers likely to face material cash-flow problems tied to MFP effectuation. When surveyed, the majority of NICA members stated they would require a minimum of 3-6 months to operationally prepare for significant changes to the buy and bill ecosystem.

Infusion centers will be unable to offer services if left underwater, either through excessive administrative burdens or inadequate reimbursement. If furnishing selected drugs becomes substantially more burdensome or financially risky, some centers may eventually be unable to keep offering medications that CMS has worked so hard to make more accessible. This could cause a reduction in infusion capacity throughout communities, placing rural and underserved communities at the greatest risk. A loss or consolidation of community-based infusion access points would have the effect of driving patients into the hospital for infusion care, which places immunocompromised patients' health in jeopardy. A lower negotiated price will not benefit Medicare beneficiaries if the Part B providers treating them cannot sustainably continue providing the selected drugs. Our members serve a valuable role in the community, providing localized care at a safe and cost-effective site, and it's critical that CMS does not adopt policies that threaten the viability of these sites of care.

40.4 Providing Access to the MFP in 2028

Within the draft guidance and corresponding statute, the obligation to provide Part B providers with access to the MFP is on Primary Manufacturers, ensuring that the provider's acquisition cost is no greater than the MFP. CMS has suggested two possible pathways for drug manufacturers to provide access to the MFP for Part B medications, including a prospective payment and a retrospective payment. Through the prospective method, manufacturers would ensure that the price paid by the dispensing entity or Part B provider is no greater than the MFP. In the retrospective method, Part B providers would purchase the drug and then the manufacturer would provide a retrospective reimbursement for the difference between the acquisition cost and the MFP. NICA previously commented on these proposals within IPAY 2028.

NICA believes both models are problematic as they put the provider and infusion center in the middle of drug negotiations between the federal government and pharmaceutical manufacturers. The prospective model could put infusion providers underwater because they would not be adequately reimbursed for the medications they administer due to the decreased add-on payment. Beginning in 2028, the transition from ASP + 6% to MFP + 6% reimbursement for selected Part B drugs could create a significant financial challenge for providers. According to a recent Avalere analysis, this new reimbursement formula could reduce Medicare Part B add-on payments by approximately 42% to 61% and decrease corresponding commercial-market reimbursement by 12% to 18%.³ The impact may be particularly hard felt by infusion centers that administer large quantities of drugs subject to the Program, as well as smaller and independent centers that have fewer resources to absorb reductions in drug-related revenue. These centers may be forced to reconsider how they purchase, stock, and administer affected medications. Without adequate mechanisms to offset both the lower reimbursement and the additional administrative and operational burdens associated with implementing the Program, some practices could determine that administering these selected drugs is no longer financially sustainable, potentially limiting patient access to important treatments.

However, as outlined in our response to 40.4.1, the retrospective method would create extreme hardship for infusion centers as they would be responsible for floating the difference between the acquisition cost and the MFP until they receive reimbursement from the Primary Manufacturer. When surveyed, only 2%

³ Avalere Health. "[Commercial Spillover Impact of Part B Negotiations on Physicians.](#)" September 2024.

of NICA members believed they would be able to operationalize a retrospective payment model successfully.

Equally important, it is unclear how manufacturers could operationalize these models. Because drug acquisition costs are proprietary and vary by provider, it would be operationally infeasible for manufacturers to ensure the price paid is no greater than the MFP under a prospective model. Similarly, the retrospective model would require disclosure of confidential pricing data and impose significant financial and administrative burdens on providers, making it unworkable in practice. In addition, the retrospective model forces providers to absorb the opportunity cost of tying up capital while waiting for reimbursement, further threatening the financial viability of infusion centers.

As cost-effective sites for infusion treatment, community-based infusion practices operate on thin margins and may not have sufficient capital to sustain this type of business model. The Part B drug add-on helps offset costs and risks that are integral to buy-and-bill—including financing drug purchases while awaiting reimbursement; shipping, receiving, temperature-controlled storage, and inventory management; potential spoilage, wastage, and nonpayment; and the clinical and administrative work required to furnish and bill for treatment. ¹² Instead, NICA supports policies that stabilize Part B drug reimbursement for providers, including Sen. John Barrasso's (R-Wy.) *Protecting Access to Cancer and Complex Therapies Act* and encourages CMS to work with Congress to find solutions that remove providers from the middle of government negotiations with manufacturers.

40.4.1 Retrospective Refund Amount to Effectuate the MFP and the Standardized Default Refund Amount (SDRA)

Within the draft guidance, CMS proposes that Primary Manufacturers and Part B providers can use either actual acquisition cost or a standardized pricing metric to determine the retrospective refund necessary to provide access to the MFP.

NICA supports establishing a practical and administratively feasible process for implementing the refund mechanism. However, CMS should ensure that infusion centers are not required to assume additional administrative burdens or bear undue financial exposure to obtain reimbursement to which they are entitled. Under a retrospective approach, centers may be required to advance the difference between the drug's acquisition cost and the MFP, potentially tying up significant capital until the manufacturer issues the applicable refund. For smaller and independent infusion centers in particular, extended delays in receiving these payments could create substantial financial strain.

NICA also questions whether the proposed 14-day payment period, which begins only after the MTF transmits the applicable claim-level data, is sufficient in light of the challenges experienced during implementation of the retrospective process for Part D. The experience with Part D effectuation offers an important point of comparison, particularly with respect to the difficulties faced by small and independent pharmacies. Those challenges have demonstrated how payment and administrative requirements can place disproportionate pressure on providers with limited financial and operational resources. CMS should account for these lessons when designing the Part B process to avoid imposing similar burdens on independent infusion centers that administer selected Part B medications.

40.4.1.2 Retrospective Refund Amount to Effectuate the MFP and the Standardized Default Refund Amount for Drugs Payable Under Part B

Issue 1: Identifying MFP-Eligible Claims Billed with a HCPCS Code

CMS has proposed three different models for identifying negotiated drugs when a single Healthcare Common Procedure Coding System (HCPCS) code includes National Drug Codes (NDCs) for both a selected and a non-selected drug. CMS offers models that require new claims modifiers, require reporting of the 11-digit NDC (NDC-11), or establish separate HCPCS codes.

NICA recommends that CMS determine which claims qualify for MFP reimbursement by relying, to the greatest extent possible, on claims information and other data that are already available to the Agency. Creating new reporting obligations for infusion centers and other Part B providers could add unnecessary complexity to existing billing processes. In particular, requiring centers to adopt MFP-specific modifiers or new HCPCS codes would necessitate changes to established billing systems and workflows and could impose significant operational burdens.

HCPCS-based identification also raises substantive concerns about the accuracy of the proposed approach. Because a single HCPCS code may correspond to multiple drugs or NDC-11s, HCPCS codes alone may not provide sufficient information to determine precisely which drug was administered, whether the drug qualifies for MFP reimbursement, or the amount of the manufacturer refund. This limitation could also make it difficult for CMS or the Primary Manufacturer to determine the applicable WAC when multiple NDC-11s associated with the same selected drug are billed under a common HCPCS code. CMS acknowledges in the draft that not every claim submitted under a HCPCS code associated with a selected drug necessarily represents administration of that selected drug. These issues demonstrate the limitations of relying on HCPCS codes as the primary mechanism for identifying eligible claims.

Of the three proposed models, NICA believes that NDC-11 reporting will be the most practical and least burdensome. Infusion centers currently collect NDC information for many physician-administered drugs, and that information is incorporated into certain existing payer billing processes. CMS should build upon these existing practices by using NDC-11 data where it is already collected and reported, rather than requiring providers to implement new MFP-specific modifiers or HCPCS codes.

Before establishing a new nationwide Medicare requirement for NDC-11 reporting, CMS should first assess how broadly this information is currently available and evaluate the administrative and operational burden that additional reporting would impose on Part B providers. NICA members believe that operational changes and training would be required for their infusion center to comply with any new NDC-11 reporting requirements, including, but not limited to: modifying interfaces between clinical, inventory, and billing systems; training clinical or pharmacy staff; updating billing or practice-management software; and train billing staff.

Issue 2: Calculating the SDRA for Selected Drugs Payable Under Part B When Billed with a HCPCS Code.

Within the draft guidance, CMS proposes four models for calculating the Standard Default Refund Amount (SDRA) for Part B drugs selected under the MDPNP.

The SDRA methodology should be designed to closely reflect the gap between the actual cost incurred by infusion centers to acquire a drug and the applicable MFP. A standardized proxy should not be set at a level that systematically understates providers' acquisition costs and leaves infusion centers responsible for absorbing the resulting shortfall. At the same time, the process for calculating the refund should be sufficiently streamlined so that infusion centers are not required to undertake additional data reporting, reconciliation, or other administrative activities to establish the amount owed. NICA is concerned that none of the proposed models – which are based on the Wholesale Acquisition Cost (WAC) and Average Sales Price (ASP) – will accurately capture acquisition for Part B providers.

Models based on WAC

WAC may be an unreliable proxy for the actual cost incurred by Part B providers to acquire selected drugs because it generally does not account for the discounts, rebates, and other price concessions available. Using WAC as the basis for calculating the SDRA could therefore overstate the amount needed to compensate providers, particularly where acquisition prices are materially below the published WAC. The potential for such a discrepancy is greatest for drugs subject to substantial discounts or other purchasing concessions, for which WAC may bear little resemblance to the price providers ultimately pay.

Models based on ASP

NICA also has concerns with approaches that rely on a weighted-average ASP to establish the SDRA. As MFP pricing is incorporated into ASP calculations over time, ASP could become progressively less representative of the underlying acquisition costs faced by infusion centers. CMS has indicated that the SDRA would decline as ASP declines; however, this dynamic could result in a gradual reduction in the calculated refund even if providers' acquisition costs do not decline at a comparable rate. Without corresponding adjustments to account for actual acquisition costs, the methodology could increasingly understate the difference between what practices pay for a drug and the applicable MFP.

There are additional limitations to using ASP as a benchmark for Medicare-specific acquisition costs. ASP data encompasses sales to purchasers across the broader U.S. market and multiple payer segments, rather than reflecting transactions limited to Medicare. As a result, an average per-unit sales price derived from ASP data may not provide an appropriate benchmark for the costs associated specifically with Medicare patients and could cause the SDRA to diverge further from providers' actual Medicare acquisition costs. Finally, reporting exceptions for certain drugs may result in incomplete ASP Portal data, creating another limitation on the use of ASP as a reliable proxy for acquisition cost.

Alternative Model

NICA encourages CMS to continue consulting with stakeholders as it refines the SDRA methodology and to incorporate those discussions into future rulemaking. The methodology should build on established ASP principles while excluding the effect of MFP discounts from the calculation. As discussed above, incorporating MFP pricing into ASP can undermine the methodology's ability to reflect the actual costs incurred to acquire. Excluding MFP discounts from the SDRA is therefore essential to creating a reimbursement mechanism that more accurately compensates infusion centers for the difference between their acquisition costs and the MFP.

CMS should also consider whether an additional add-on payment is necessary for MFP-selected drugs to ensure that providers are fully compensated for the costs associated with acquiring and administering these medications. Finally, continued publication of quarterly data on selected drugs would provide important transparency into the Part B drug market and allow providers and other stakeholders to better understand the ongoing effects of the MFP.

40.4.2 Medicare Transaction Facilitator Data Facilitation

CMS is utilizing a Medicare Transaction Facilitator (MTF) contractor to facilitate the exchange of claim-level data and payments to effectuate the MFP for selected Part B drugs. NICA recommends that CMS design the MTF to maximize the use of data that are already accessible to CMS, Primary Manufacturers, Medicare Administrative Contractors (MACs), and Medicare Advantage (MA) organizations. Infusion centers should not be placed in the position of collecting, transmitting, or reconciling information that is already available to other participants in the MDPNP. Minimizing these duplicative requirements will be

important to ensure that implementation of the MTF does not create unnecessary administrative burdens for providers.

NICA also supports CMS's decision to cover the costs of operating the MTF DM for 2028 rather than imposing user, transaction, or other participation fees on Part B providers. Providers should not bear the cost of participating in infrastructure created to facilitate the MDPNP. CMS should make this policy permanent and ensure that providers are not subject to participation fees in the future.

40.4.2.1.2 Claim-level Data Elements for Part B Claims

Within the draft guidance, CMS proposes leveraging claims that have already been adjudicated to generate and transmit the claim-specific data needed to implement MFP effectuation for beneficiaries enrolled in Original Medicare. For Medicare Advantage beneficiaries, the proposed approach would instead rely on encounter data reported by MA organizations.

NICA supports CMS's proposal to leverage existing claims and encounter-data processes for MFP effectuation. Once an infusion provider has submitted a claim through its standard billing process to the applicable MAC or MA organization, the center should not be required to supply any additional information to determine MFP eligibility or initiate the refund process. NICA also supports prohibiting Primary Manufacturers from imposing supplemental reporting requirements on Part B providers for purposes of verifying MFP eligibility and recommends that CMS retain this safeguard.

If CMS determines that MA encounter data must be submitted more quickly or with additional information to facilitate timely MFP effectuation, any corresponding obligations should be placed on MA organizations rather than Part B providers. Providers should not be held financially responsible for delays, missing information, or errors arising from an MA organization's submission or processing of encounter data—particularly where the provider has fulfilled its standard billing obligations.

CMS should also address situations in which MA encounter data are subject to Encounter Data System (EDS) edits that affect MFP eligibility. Under the proposed guidance, an unresolved edit could prevent claim-level information from being transmitted to the Primary Manufacturer and potentially postpone the start of the 14-day payment period by as much as 90 days. Such delays could expose infusion centers to significant financial consequences despite being outside the provider's control. CMS should therefore implement safeguards to prevent EDS edits and other MA data-processing issues from unnecessarily delaying MFP refunds owed to Part B providers.

40.4.2.1.3 MFP Payment Window

Under the draft guidance, the 14-day payment period does not begin until the MTF DM transmits the relevant claim-level information to the Primary Manufacturer. For Original Medicare, CMS recognizes that requiring claims to complete adjudication and reach final action before transmission could add a week or more to the process. Delays may be even more significant in Medicare Advantage, where CMS reports that approximately 85% of encounter data are submitted within 60 days of the claim. As a result, an infusion center could be required to purchase and administer a selected drug and finance the difference between its acquisition cost and the MFP for weeks or months before the manufacturer's 14-day payment period begins.

When surveyed, the majority of NICA members stated that they would not be able to finance the difference between a selected drug's acquisition cost and the MFP for more than 30 days without experiencing a material cash-flow problem. Twenty-one percent said they would be unable to carry the

difference for more than 14 days. When asked how delayed payment would impact their business, NICA members expressed concerns that they would be forced to stop offering one or more of the affected drugs. They also cautioned that they may be required to limit the number of Medicare patients served at the clinic or shift treatment of the patient's care to a hospital or another site of care. All of these options would significantly impact the business operations of community infusion centers and patient access to care in those communities.

While NICA supports establishing a clear and enforceable deadline for Primary Manufacturers to issue MFP refunds, CMS should distinguish between a 14-day manufacturer payment requirement and a physician practice actually receiving the refund within 14 days of administering a selected drug. The experience with Part D demonstrates that a 14-day standard may not reflect the actual timeframe for providers to receive retrospective refunds. A March 2026 National Community Pharmacists Association survey found that 67% of respondents reported waiting at least 22 days to receive manufacturer refunds, while 22% reported turnaround times exceeding 28 days.⁴ CMS should consider these implementation challenges when developing the Part B framework and establish requirements that address the entire period between administration of a selected drug and receipt of the corresponding MFP refund. This should include measures to promote timely submission of MA encounter data and prevent delays attributable to claims adjudication, encounter-data processing, the MTF, or manufacturer payment processes from shifting financial risk to infusion centers.

40.4.2.2 Dispensing Entity and/or Part B Provider Enrollment in the MTF DM

Within the draft guidance, CMS encourages Part B providers to enroll in the MTF DM and contemplates future rulemaking that require MA organizations to include MTF DM enrollment provisions in their provider contracts.

NICA strongly opposes any requirement that Part B providers enroll in the MTF DM as a condition of administering or furnishing selected Part B drugs. Mandatory enrollment would impose an additional administrative burden on infusion centers that already participate in established Medicare enrollment and payment systems. Since CMS recognizes that enrollment in a separate payment platform could be duplicative and burdensome, we question why the Agency would encourage enrollment. While using information from the Provider Enrollment, Chain, and Ownership System (PECOS) to prepopulate MTF enrollment profiles may alleviate some of the administrative burden, it does not address the underlying concern that infusion providers should not have to affirmatively enroll in a new system for Primary Manufacturers to meet their statutory obligation to provide access to the MFP.

CMS should instead rely on information it already possesses—including PECOS records, Medicare claims, MA encounter data, and other existing CMS systems—to identify eligible providers and facilitate MFP effectuation. This approach would allow CMS to support manufacturer payments without making physician enrollment in the MTF DM a prerequisite for receiving MFP-related refunds.

40.4.3 MTF Payment Facilitation

CMS has proposed the use of the MTF Payment Module (MTF PM) to facilitate electronic or paper payments and track adjustments to those payments.

⁴ National Community Pharmacists Association. "[NCPA Advocates for Medicare Drug Price Negotiation Program Overhaul Due to Pharmacy Cash Flow](#)." March 2026.

NICA recommends that CMS structure the retrospective MFP payment process to require as little involvement as possible from Part B providers and their staff. Manufacturer refunds should be delivered and documented using standardized processes that enable infusion centers to receive, identify, and record payments within their existing financial and accounting systems, without requiring providers to create separate MFP-specific reconciliation processes. CMS should also prohibit user, transaction, and other participation fees for Part B providers using the MTF PM. Infusion centers should not be required to incur additional fees to receive MFP refunds that Primary Manufacturers are statutorily required to provide.

40.4.3.2.2 Primary Manufacturer and MFP Refund Payment Adjustments due to Part B Claim Amendments Through the MTF PM

CMS proposes to use an MTF credit/debit ledger to account for MFP refund adjustments resulting from Part B claim reversals, adjustments, or subsequent determinations that a claim is not MFP-eligible.

NICA recommends that CMS incorporate MFP refund adjustments into existing Medicare claims-correction processes rather than creating a separate process for Part B providers. Providers should continue to use the standard corrected-claim procedures applicable to Original Medicare or Medicare Advantage, without additional MFP-specific steps. Once a corrected claim is submitted, any resulting changes to the MFP refund should be handled among CMS, the applicable MAC or MA organization, the MTF, and the Primary Manufacturer. Infusion centers should not be responsible for separately notifying manufacturers, recalculating refund amounts, initiating payment adjustments, or reconciling individual manufacturer transactions.

40.4.3.4 Pass Through Payment to Part B Providers When a Primary Manufacturer Participates in the MTF PM for drugs payable under Part B

In the draft guidance, CMS proposes to leverage existing PECOS enrollment and payment information to pre-populate MTF DM profiles for Part B providers and generally issue MFP refund payments through electronic funds transfer (EFT). CMS also solicits comments on additional ways to reduce burden for Part B providers and how practices may use claim reconciliation vendors to receive and reconcile MFP refund payments.

NICA supports CMS's efforts to use existing Medicare data to streamline enrollment and avoid requiring infusion centers to repeatedly submit information already available to the Agency. However, reducing enrollment requirements does not resolve the significant cashflow and administrative challenges associated with retrospective MFP payments, as outlined previously. CMS should therefore establish safeguards to limit the length of time practices must finance the difference between acquisition costs and MFP and to protect providers from financial losses resulting from delays in the effectuation process. These protections should be implemented and funded by Primary Manufacturers and should not require infusion centers to assume additional administrative responsibilities, incur new costs, or accept lower reimbursement. CMS should likewise avoid relying on third-party reconciliation vendors as a solution to challenges created by the retrospective payment model. Practices should not have to purchase additional services simply to receive and reconcile payments that manufacturers are legally required to provide. Instead, the MTF and manufacturer payment processes should be sufficiently standardized and automated to allow practices to receive, identify, and record MFP refunds using their existing payment and accounting workflows.

40.4.4 MFP Refund Payments When a Primary Manufacturer Makes a Payment Outside of the MTF PM

CMS proposes to permit Primary Manufacturers to make MFP refund payments outside of the MTF Payment Module (MTF PM).

NICA recommends that CMS establish consistent payment standards for any MFP refunds issued outside the MTF PM. A Primary Manufacturer's decision to use an alternative payment method should not impose additional administrative requirements on infusion centers or create meaningful differences in how providers receive, identify, and process their refunds. The payment mechanism should be standardized from the provider's perspective regardless of the method selected by the manufacturer.

40.4.4.1 Primary Manufacturer Payment Outside of the MTF PM

When a Primary Manufacturer makes MFP refund payments outside of the MTF PM, CMS would require the manufacturer to establish its own payment process, including a process mutually agreed upon with the Part B provider. CMS would require electronic payments to be accompanied by an X12 835 electronic remittance advice (ERA) and payments by paper check to include corresponding remittance information.

NICA is concerned that requiring infusion centers to establish separate payment relationships with individual Primary Manufacturers could create substantial administrative burdens, particularly as the number of Part B drugs subject to the Negotiation Program grows annually. CMS should require manufacturer payment mechanisms to integrate with providers' existing financial and billing systems and should expressly prohibit any requirement that Part B providers register with manufacturer-specific portals, enter into separate agreements, establish individualized payment arrangements, or resubmit information already available through Medicare systems. Manufacturers should likewise not require providers to alter their standard billing workflows to accommodate MFP refunds.

NICA also supports CMS's proposal to prohibit Primary Manufacturers and their third-party vendors from imposing transaction, processing, or similar fees on Part B providers for issuing MFP refunds. The administrative and financial costs associated with a manufacturer's choice to use a payment mechanism outside the MTF PM should remain the responsibility of the manufacturer and should not be shifted to the provider.

40.4.4.3 Dispensing Entity and/or Part B Provider Receipt of Payment Outside of the MTF PM

The draft guidance suggests that when a Primary Manufacturer makes an MFP refund payment outside of the MTF PM, the Part B provider would receive the payment directly from the manufacturer or its third-party vendor through the payment process established by the manufacturer.

NICA recommends that CMS require Primary Manufacturers to design MFP refund processes that can be accommodated within existing payment and billing workflows. Providers should not be required to register with manufacturer-specific platforms, complete duplicative administrative steps, or furnish information that is already available through CMS and Medicare payment systems. Refunds should also include standardized remittance information that enables infusion centers to readily identify the applicable claim and accurately record the payment. Regardless of whether a manufacturer uses the MTF PM or an alternative payment mechanism, the process should provide a consistent provider experience and should not introduce additional administrative burdens, uncertainty, or delays in receiving MFP refunds.

40.4.4.4 Primary Manufacturer and MTF PM MFP Refund Payment Adjustments due to Claim Amendments When a Primary Manufacturer Makes a Payment Outside of the MTF PM

As outlined in the draft guidance, the MTF credit/debit ledger would not be used to effectuate subsequent payment adjustments resulting from claim reversals or amendments when a Primary Manufacturer makes MFP refund payments outside of the MTF PM. Instead, the Primary Manufacturer would be responsible for effectuating any necessary adjustments through its alternative payment process.

NICA recommends that CMS establish a uniform adjustment and recoupment framework that does not require infusion centers to manage separate processes for individual manufacturers. When a Part B claim is corrected, the provider's obligation should end with submission of the revised Original Medicare or Medicare Advantage claim through the applicable standard claims process. Any resulting change to the MFP refund should then be identified and processed by CMS, the relevant MAC or MA organization, the MTF, and the Primary Manufacturer through the established payment infrastructure.

Infusion centers should not be expected to track manufacturer payments affected by a corrected claim, communicate directly with manufacturers, recalculate refund amounts, or initiate separate adjustment or recoupment transactions. This centralized approach would reduce administrative burden and ensure that MFP payment adjustments are handled consistently across manufacturers and providers.

80 MFP-Eligible Individuals in 2028

CMS proposes requiring cost sharing to be based on the MFP for selected Part B drugs furnished to MFP-eligible individuals enrolled in MA plans, consistent with how these drugs are treated under Original Medicare. CMS also solicits comment on whether the 50 percent out-of-network coinsurance cap for selected Part B drugs should be calculated based on the MFP.

NICA supports extending MFP-related cost-sharing protections to Medicare Advantage beneficiaries receiving selected Part B drugs. However, MA organizations should be solely responsible for implementing and administering these requirements. Infusion centers should not be tasked with determining a patient's eligibility for MFP-based cost sharing, calculating the applicable MFP or beneficiary liability, or correcting and reconciling cost-sharing amounts when an MA organization does not apply the policy correctly.

Community-based infusion centers play a key role as the most efficient setting for drug administration, compared to hospital outpatient departments and, in many cases, even compared to the home. Thus, it is clearly beneficial to advance policies that support our nation's in-office drug administration capacity to further the Administration's goals to reduce the overall cost of prescription medications for both the federal government and for patients.

Thank you for the opportunity to comment on this important issue. We would welcome the opportunity to connect with you if we can provide any other information about our concerns. Please do not hesitate to contact me, should you have any questions or wish to further discuss this issue: Brian.nyquist@infusioncenter.org

Sincerely,

A handwritten signature in black ink that reads "Brian Nyquist". The signature is written in a cursive, flowing style.

Brian Nyquist, MPH

Chief Executive Officer
National Infusion Center Association