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September 18, 2026

Dr. Mehmet Oz
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8016
Baltimore, MD 21244-8016

Submitted electronically via regulations.gov

Re: Medicare Drug Price Negotiation Program: Draft Guidance, Manufacturer Effectuation of the Maximum Fair Price in 2028

Dear Administrator Oz:

The Academy of Managed Care Pharmacy (AMCP) thanks the Centers for Medicare & Medicaid Services (CMS) for the opportunity to provide comments in response to *Medicare Drug Price Negotiation Program: Draft Guidance, Manufacturer Effectuation of the Maximum Fair Price in 2028* (Draft Guidance). CMS issued this draft guidance to describe the processes and requirements for manufacturer effectuation of the maximum fair price (MFP) in 2028 for selected drugs payable under Medicare Part B and/or covered under Medicare Part D.

AMCP is the nation's leading professional association dedicated to increasing patient access to affordable medicines, improving health outcomes, and ensuring the wise use of healthcare dollars. Through evidence and value-based strategies and practices, AMCP's nearly 8,000 pharmacists, physicians, nurses, and other practitioners manage medication therapies for the 270 million Americans served by health plans, pharmacy benefit management firms, emerging care models, and government health programs.

AMCP offers these comments from the perspective of managed care pharmacy professionals responsible for designing and administering prescription drug benefits, supporting formulary and utilization management, coordinating with pharmacy and provider networks, and implementing payment and data-exchange requirements that affect beneficiary access. Because the 2028 effectuation framework will operate across Part D dispensing, Part B furnishing and administration, original Medicare, Medicare Advantage,

manufacturers, pharmacies, providers, and data intermediaries, CMS should finalize guidance that is operationally precise, enforceable, and workable for the entities responsible for ensuring beneficiaries can obtain clinically appropriate medications without avoidable disruption.

AMCP's recommendations focus on making MFP effectuation reliable in practice. CMS should preserve beneficiary access to the MFP while making clear that MFP access does not create a coverage mandate or displace evidence-based formulary and utilization management. CMS should also require standardized and privacy-protective data exchange, transparent refund and remittance processes, prompt correction of errors, meaningful complaint and dispute pathways, and clear accountability for manufacturers and technology vendors. Without these operational safeguards, payment delays, inaccurate claim identification, incomplete remittance, uncertain 340B status, or unclear direct member reimbursement rules could create avoidable access risks for beneficiaries and the pharmacies, providers, and plans that serve them.

40.4 Providing Access to the MFP in 2028

AMCP supports CMS's efforts to ensure that eligible beneficiaries have reliable access to the maximum fair price (MFP) for selected drugs in 2028. The Inflation Reduction Act established the Medicare Drug Price Negotiation Program in sections 1191 through 1198 of the Social Security Act, and the draft guidance sets forth policies for manufacturer effectuation of the MFP in 2028 for selected drugs payable under Part B and/or covered under Part D. CMS should finalize policies that make MFP access operationally reliable while avoiding interpretations that unintentionally displace evidence-based benefit design, formulary management, utilization management (UM), or clinical decision-making.

CMS should clarify that requiring MFP access for "all dosage forms, strengths, and package sizes" of a selected drug is a manufacturer effectuation obligation, not a coverage mandate imposed on Part D sponsors, Medicare Advantage organizations, or pharmacy and therapeutics (P&T) committees. The statutory structure supports this distinction. Section 1191(c) defines negotiation-eligible and selected drugs, while section 1193(a) directs manufacturers to provide access to a price not greater than the MFP for MFP-eligible individuals and applicable pharmacies, providers, and suppliers. It does not direct plan sponsors to cover every dosage form, strength, or package size of a selected drug, nor does it override Medicare rules governing formulary design, coverage determinations, utilization management, or medical necessity.

That distinction is critical for managed care pharmacy. A manufacturer's obligation to ensure access to the MFP should mean that, when a selected drug is covered and appropriately dispensed, furnished, or administered to an eligible beneficiary, the applicable entity can obtain the benefit of the MFP effectuation process. It should not mean

that plans must cover every dosage form, strength, or package size in every circumstance, regardless of clinical evidence, patient-safety considerations, therapeutic alternatives, medical necessity, or plan formulary design. AMCP recommends that CMS expressly state that the MFP access requirements do not restrict Part D sponsors, Medicare Advantage organizations, or P&T committees from using clinically appropriate formulary tiers, prior authorization, step therapy, quantity limits, drug utilization review, or other UM tools consistent with Medicare law and CMS requirements.

CMS should also clarify how the "all dosage forms, strengths, and package sizes" standard applies when a particular form or package size is not clinically appropriate, is not routinely stocked by a network pharmacy or provider, is subject to safety-related dispensing limitations, or is not covered because an alternative form or strength better supports adherence, dosing accuracy, or value-based care. Without this clarification, stakeholders may incorrectly read a manufacturer access obligation as a plan coverage obligation, creating confusion for beneficiaries and operational risk for plans and pharmacies. CMS should avoid that ambiguity by clearly separating the manufacturer's statutory responsibility to make the MFP available from the plan sponsor's responsibility to manage the benefit in a manner that promotes safe, effective, and affordable medication use.

40.4.1 Retrospective Refund Amount to Effectuate the MFP and the Standardized Default Refund Amount

AMCP supports allowing manufacturers and dispensing entities or Part B providers to use actual acquisition cost or a mutually agreed adjusted metric in place of the standardized default refund amount where that approach improves accuracy and preserves access. CMS should make clear that voluntary reconciliation should not compel disclosure of proprietary acquisition costs, negotiated purchasing arrangements, wholesaler terms, or confidential contracting information beyond what is necessary to validate payment. Acquisition cost can vary across entities because of purchasing channel, inventory timing, provider type, distribution arrangement, and contract terms. A rigid approach that requires disclosure or assumes uniform acquisition cost could discourage participation, create unnecessary legal and operational risk, or produce refunds that do not reflect real-world acquisition economics.

CMS should standardize the evidence needed to support disputes and corrections while preserving confidentiality. For example, CMS could permit use of attestations, transaction-level documentation, or agreed adjusted metrics without requiring routine disclosure of underlying proprietary price terms to unrelated parties. CMS should also ensure that underpayment is corrected quickly because insufficient reimbursement can affect

pharmacy and provider willingness to stock selected drugs, particularly high-cost products for which delayed or inaccurate refunds may create significant cash-flow exposure.[1]

40.4.1.1 Retrospective Refund Amount to Effectuate the MFP and the Standardized Default Refund Amount for Drugs Covered Under Part D

AMCP supports continuity in CMS's use of a wholesale acquisition cost (WAC)-based standardized default refund amount (SDRA) for Part D where that approach provides predictable administration and timely MFP access. However, CMS should recognize that WAC is a list-price benchmark and may not reflect net acquisition cost, dispensing-entity economics, or the effect of negotiated arrangements. CMS should therefore validate the WAC data source, specify the date and unit basis used for the calculation, publish examples, and establish correction procedures when WAC data are inaccurate, delayed, or inconsistent with the claim-level information transmitted through the Medicare Transaction Facilitator (MTF). CMS should also monitor whether the WAC-based SDRA systematically over- or under-refunds dispensing entities and whether those differences create access concerns.

CMS should also provide operational examples showing how the WAC-based SDRA would be calculated for common Part D scenarios, including partial fills, reversals, amended claims, multiple package sizes, and claims later determined to involve an ineligible beneficiary. These examples would help plan sponsors, dispensing entities, manufacturers, and vendors understand whether the applicable unit, date of service, submitted quantity, package configuration, or corrected claim controls the refund calculation. CMS should further clarify whether and how the SDRA is recalculated when WAC changes after the date of service but before refund payment, and how stakeholders should reconcile claims when a claim is reversed after a manufacturer has already transmitted payment.

CMS should also consider the cumulative cash-flow implications of refund accuracy for dispensing entities. Even when a WAC-based SDRA is administratively simple, systematic under-refunds could require pharmacies to absorb costs that may not be sustainable for high-cost selected drugs, while systematic over-refunds could create later recoupment risk and administrative burden.[2] CMS should monitor these outcomes using aggregate payment data and should establish a process for revisiting the Part D SDRA methodology if

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[1] Mattingly II, TJ, Esterly, AA, and Kaltenboeck, A. *Implementing Maximum Fair Price Without Hurting Pharmacies*, JAMA Health Forum. 2024;5(5):e240921. doi:10.1001/jamahealthforum.2024.0921, https://jamanetwork.com/journals/jama-health-forum/fullarticle/2818378

[2] *Id.*

evidence shows recurring discrepancies that affect pharmacy participation or beneficiary access.[3]

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

Identifying MFP-eligible Part B claims

CMS should select the most accurate and least burdensome method for identifying whether a Part B claim is for a selected drug subject to MFP effectuation. Whether CMS uses claim modifiers, National Drug Code 11-digit format (NDC-11) reporting, separate Healthcare Common Procedure Coding System (HCPCS) codes, or another approach, the final policy should be tested with Medicare Administrative Contractors, Medicare Advantage organizations, providers, suppliers, manufacturers, and data vendors before implementation. CMS should evaluate each option against several criteria: whether it reliably distinguishes selected from non-selected products; whether it can identify the applicable National Drug Code (NDC), dosage form, strength, and package size; whether it can be implemented in existing billing workflows; whether it creates new burden for small, rural, or safety-net providers; and whether it supports timely corrections when claim information changes.

AMCP recommends that CMS avoid relying on an identifier that is technically available but not operationally reliable for the intended purpose. Inaccurate identification could lead to erroneous MFP treatment, incorrect beneficiary cost sharing, delayed or missing refunds, duplicate discounts, or inappropriate manufacturer liability. CMS should require end-to-end testing, publish error-resolution procedures, and specify how providers, plans, manufacturers, and CMS will correct affected claims when an identifier is missing, inaccurate, or later amended.[4]

Part B SDRA

CMS should select and validate the SDRA metric that most closely approximates acquisition cost while minimizing payment instability and administrative complexity. Because section 1847A of the Social Security Act uses average sales price (ASP) and other payment benchmarks for Part B drug payment, CMS should explain how any WAC-based, ASP-based, NDC-level, or HCPCS-level approach aligns with existing Part B payment data and where it may diverge from actual acquisition experience. WAC-based metrics may be available and administratively straightforward but may not reflect discounts or acquisition variation. ASP-

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[3] Hernandez, I, Gabriel, N, Kaltenboeck, A, et al. *Reimbursement to Pharmacies for Generic Drugs by Medicare Part D Sponsors*, JAMA. 2023;330(24):2390–2392. doi:10.1001/jama.2023.21481, https://jamanetwork.com/journals/jama/fullarticle/2812780.
[4] AMCP, *Use of Technology*, https://www.amcp.org/legislative-regulatory-position/use-technology.

based metrics may align with Part B payment policy but may lag market conditions or obscure NDC-level differences. HCPCS-level metrics may fit billing workflows but may be insufficient when a code contains selected and non-selected products or multiple NDCs with different acquisition costs.

AMCP recommends that CMS publish a machine-readable, versioned Part B SDRA file that includes complete HCPCS and NDC identifiers, billing units, effective dates, metric type, update dates, correction dates, and archive files. A transparent file is necessary for plans, providers, manufacturers, and vendors to build reliable systems and reconcile payments. CMS should provide advance notice of file-layout changes, maintain prior versions for audit purposes, and rapidly correct errors that could affect payment timing or beneficiary cost sharing.[5] CMS should treat the Part B SDRA file as an operationally critical source of truth and should establish governance procedures for maintaining it. At a minimum, CMS should identify the official publication location, update cadence, version numbering convention, effective-date rules, archive process, correction process, and stakeholder notice process. CMS should also specify whether corrected files apply prospectively only or require retrospective reconciliation, how users will be notified of material corrections, and whether CMS will provide a change log that identifies affected HCPCS codes, NDCs, billing units, and effective dates. Without these governance standards, stakeholders may rely on different file versions, creating avoidable disputes and inconsistent MFP effectuation.

40.4.2 Medicare Transaction Facilitator Data Facilitation

AMCP supports CMS's proposal to use the Medicare Transaction Facilitator Data Module (MTF DM) to facilitate claims and payment data exchange and to prohibit manufacturers or vendors from charging providers for effectuation services. Fee-free participation is essential to avoid creating administrative barriers that could reduce pharmacy or provider participation. Because the MTF is central to effectuation, CMS should establish measurable service-level standards, including uptime requirements, outage notice timeframes, maximum processing times, batch rejection rules, error-rate thresholds, help-desk response times, and escalation procedures.[6] These protections are consistent with AMCP's support for health information technology that promotes efficient use of healthcare resources, improves quality, and reduces administrative burden.[7]

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[5] AMCP, *Use of Technology*, https://www.amcp.org/legislative-regulatory-position/use-technology.
[6] Walker, DM, Tarver, WL, and Jonnalagadda, P, et al. *Perspectives on Challenges and Opportunities for Interoperability: Findings from Key Informant Interviews with Stakeholders in Ohio*, JMIR Med Inform. 2023 Feb 24;11:e43848. doi: 10.2196/43848, https://pmc.ncbi.nlm.nih.gov/articles/PMC10007006/
[7] AMCP, *Use of Technology*, *supra* note 7.

CMS should require robust pre-implementation testing with manufacturers, Part D sponsors, Medicare Advantage (MA) organizations, dispensing entities, Part B providers, and data vendors. Testing should include routine claims, reversals, amended claims, missing identifiers, 340B status changes, rejected transmissions, late payments, and outage scenarios. CMS should also publish aggregate performance metrics so stakeholders can assess whether the MTF is functioning as intended. When the MTF fails or is unavailable, CMS should specify contingency processes that preserve MFP access and prevent affected entities from bearing financial consequences caused by system failure.

40.4.2.1.3 MFP Payment Window

AMCP supports a 14-day prompt-payment period for retrospective MFP refunds after MTF transmission, but cautions that CMS needs to create the operational accountability necessary for that standard to function in practice. CMS should define precisely when the 14-day clock starts, including whether the period begins upon MTF transmission, manufacturer receipt, successful validation, or another auditable event. CMS should require visible timestamps for data transmission, receipt, payment initiation, and payment completion; tolling during documented MTF outages; late-payment remediation; and monitoring of whether delayed refunds affect provider cash flow, selected-drug stocking, dispensing, furnishing, or administration. Clear payment accountability is necessary to ensure that MFP implementation advances affordability without introducing access risks.

CMS should require a payment-status tracking mechanism that allows dispensing entities and Part B providers to determine whether a refund has been transmitted, rejected, delayed, or disputed. CMS should also specify remedies for late or incomplete payments, including escalation, interest or other late-payment measures where legally available, and prompt correction when payment failure affects beneficiary access. For high-cost selected drugs, even short delays can create meaningful cash-flow pressure for pharmacies and providers, particularly if multiple claims are affected at the same time.

90.2.1 Manufacturer Plans for Effectuating the MFP

CMS should require manufacturer effectuation plans to provide sufficient operational detail for CMS and affected stakeholders to assess readiness, identify access risks, and resolve problems quickly. Plans should address effectuation method, use of the MTF DM and MTF Payment Module, operational contacts, dispute contacts, 340B handling, treatment of claim reversals and amendments, payment timing, remittance content, contingencies, outage procedures, change notices, and performance metrics. CMS should require updates when manufacturers materially change their approach and should publish nonproprietary summaries so that plans, dispensing entities, Part B providers, and other stakeholders can prepare without requiring disclosure of confidential commercial terms.

CMS should also require manufacturer plans to describe readiness testing, expected transaction volumes, fallback processes when the MTF is unavailable, procedures for rejected or disputed claims, late-payment remediation, and communication processes for affected entities. Because effectuation failures can directly affect beneficiary access, plans should not be treated as static compliance documents. CMS should require manufacturers to maintain current plans and to notify CMS and affected stakeholders before operational changes that could affect payment timing, claim routing, or 340B nonduplication.

90.2.2 Centralized Intake System for Complaints and Disputes Related to MFP Availability and MTF Functionality

AMCP supports a centralized intake system for complaints and disputes involving MFP availability and MTF functionality, but CMS should specify response timeframes, resolution timeframes, escalation standards, appeal rights, urgent access handling, and public reporting of aggregate metrics. The centralized system should distinguish among data-transmission errors, delayed or missing payments, incorrect claim eligibility determinations, 340B nonduplication disputes, MTF outages, manufacturer noncompliance, and beneficiary access issues. A complaint system that only collects concerns without enforceable service expectations will not adequately protect beneficiaries, dispensing entities, Part B providers, or plans when payment or data failures threaten access to medications.

CMS should provide complainants with status tracking, confirmation of receipt, expected resolution timelines, and written explanations of outcomes. CMS should also establish an urgent-access pathway when a payment or data issue may prevent a beneficiary from obtaining a selected drug or may cause a pharmacy or provider to decline to stock, dispense, furnish, or administer the drug. Aggregate public reporting should include complaint volume, category, average response time, average resolution time, recurring system issues, late-payment trends, and corrective actions. Public metrics would allow CMS and stakeholders to identify whether implementation problems are isolated or systemic.

40.4.3.3 Pass Through Payment to a Dispensing Entity When a Primary Manufacturer Participates in the MTF PM for drugs covered under Part D

AMCP supports use of the MTF Payment Module to transmit manufacturer refunds and remittance information to enrolled Part D dispensing entities when the module improves payment efficiency and traceability. CMS should require prompt electronic payment, complete remittance information, unique claim linkage, payment-status visibility, and metrics for rejected, delayed, returned, or incomplete payments. CMS should also require contingency processes, including paper-check or alternative electronic payment options, when an enrolled dispensing entity cannot receive payment through the primary channel.

Remittance information should be detailed enough to reconcile the refund to the claim, but should not require disclosure of unnecessary proprietary or patient information.

CMS should specify the minimum remittance content that must accompany each MFP refund to a Part D dispensing entity. The remittance should include, at a minimum, a unique payment identifier, claim or prescription linkage, date of service, drug identifier, quantity or unit basis, refund amount, payment date, payment status, reason code for any adjustment, manufacturer identifier, and information sufficient to resolve rejected or disputed payments. CMS should also require standardized reason codes for underpayment, overpayment, duplicate payment, reversal, amendment, rejected transaction, and 340B-related nonduplication issues. Complete and standardized remittance is essential because a payment that cannot be reconciled to the underlying claim does not provide a workable operational solution for pharmacies.[8]

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

AMCP supports allowing payments outside the MTF Payment Module only if those payments are subject to equivalent transparency, timeliness, auditability, and access-protection standards. Manufacturers that elect outside payment arrangements should still meet the same 14-day payment expectation, provide claim-level reporting and complete remittance, avoid fees to dispensing entities or providers, maintain audit trails, participate in centralized complaint and dispute processes, and report performance metrics to CMS. CMS should not allow outside payments to become a less transparent channel that makes it harder for pharmacies, providers, plans, or CMS to determine whether MFP access was effectuated.

CMS should require manufacturers using outside payment arrangements to submit sufficient information to CMS to demonstrate parity with MTF Payment Module standards. That information should include payment method, payment timing, remittance format, dispute contact, rejected-payment process, amendment process, 340B nonduplication controls, no-fee certification, audit trail, and performance metrics. CMS should also clarify that outside payment arrangements remain subject to centralized complaints and disputes and that CMS may require corrective action if an outside arrangement produces delayed payments, incomplete remittance, access problems, or unresolved reconciliation issues. Outside payment flexibility should be preserved only if it does not weaken transparency or make MFP access less reliable.

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[8] Hernandez, et al. *Reimbursement to Pharmacies for Generic Drugs by Medicare Part D Sponsors*, *supra* note 3.

CMS should expressly state that manufacturer choice of payment channel should not determine the level of protection available to dispensing entities, Part B providers, plans, or beneficiaries. Whether payment is made through the MTF Payment Module or outside the module, the same substantive standards should apply for timeliness, remittance detail, no-fee access, rejected-payment handling, amendments, complaints, dispute resolution, auditability, and access remediation.[9] Aligning these standards would preserve operational flexibility while avoiding a fragmented system in which stakeholders must learn different rules for each manufacturer or selected drug.

40.4.5 Nonduplication with 340B Ceiling Price

AMCP supports CMS's implementation of the statutory nonduplication rule in section 1193(d)(1) of the Social Security Act, which prevents duplicate application of the MFP and the 340B ceiling price. CMS should require prospective, standardized identification of 340B status wherever feasible, clear correction rules when status is uncertain or later corrected, and monitoring to prevent both duplicate discounts and missed MFP access. This policy should be implemented in a manner that promotes 340B program transparency and accountability while avoiding disruptions in patient access.[10]

CMS should address both sides of the nonduplication problem. If 340B status is not identified accurately and prospectively, a claim may receive both 340B and MFP treatment, undermining program integrity and distorting manufacturer liability. Conversely, if a claim is incorrectly treated as 340B or remains uncertain for too long, an eligible beneficiary, dispensing entity, or Part B provider may miss timely access to the MFP. CMS should specify which stakeholder is responsible for identifying 340B status, what data source controls when multiple sources conflict, how corrections are made, and how CMS will audit and monitor the process. CMS should also ensure that nonduplication controls do not impose duplicative reporting obligations on plans or pharmacies when the relevant 340B information is held by covered entities or contract pharmacy arrangements.

80.1 Direct Member Reimbursement and Access to the MFP for Selected Drugs in 2028

AMCP supports direct member reimbursement processes. CMS should clarify the responsibilities of manufacturers, Part D sponsors, dispensing entities, and beneficiaries when a claim is paid outside the point-of-sale process and later submitted for reimbursement. The policy should ensure correct pricing without creating a coverage mandate, bypassing valid formulary or utilization management requirements, or

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[9] *Id.*

[10] AMCP, *340B Drug Pricing Program*, https://www.amcp.org/legislative-regulatory-position/340b-drug-pricing-program.

encouraging out-of-network purchases that fragment claims data and care management. CMS should provide examples addressing non-network pharmacy claims, paper claims, claims submitted after reversal or amendment, and claims involving coverage determinations or exceptions.[11]

CMS should provide beneficiary-facing and plan-facing examples explaining how MFP access applies when a beneficiary seeks direct member reimbursement after paying cash, using an out-of-network pharmacy, submitting a paper claim, purchasing a nonformulary drug, obtaining a drug before a coverage determination or exception was resolved, or submitting a claim after the plan's standard filing period. CMS should also clarify whether a manufacturer refund is owed to the dispensing entity, the plan, or another entity when the beneficiary has already paid the pharmacy directly. These examples are necessary to avoid beneficiary confusion and to ensure that direct member reimbursement does not inadvertently bypass valid coverage rules or create inconsistent payment flows.

CMS should preserve the integrity of Part D coverage rules when applying MFP access to direct member reimbursement. Direct reimbursement is an important beneficiary protection, but it should not become a mechanism for bypassing formulary placement, utilization management, network pharmacy requirements, safety edits, or coverage determinations that apply under Medicare rules. CMS should make clear that MFP access applies when an eligible beneficiary has a reimbursable covered claim, while leaving intact plan processes that determine whether a drug is covered, clinically appropriate, and payable under the benefit.

100.1 Failure of a Primary Manufacturer to Ensure Access to a Price Less Than or Equal to the MFP in 2028

AMCP supports accountability for manufacturers that fail to provide MFP access, but CMS should distinguish intentional or repeated noncompliance from correctable operational errors, disputed data, MTF outages, or errors caused by incomplete specifications. CMS should establish transparent enforcement standards, notice and cure opportunities where appropriate, proportional civil monetary penalties, and prompt remediation for beneficiaries, dispensing entities, Part B providers, and plans affected by failures. CMS should also use complaint and performance data to identify systemic issues before they result in access interruptions. Enforcement should promote reliable MFP access while avoiding punitive responses to good-faith implementation problems that are promptly corrected.

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[11] AMCP, *AMCP Position on Formulary and Utilization Management*, https://www.amcp.org/position-statements/amcp-position-evidence-based-clinical-practice-guidelines-cloned.

CMS should identify the factors it will consider when determining whether a manufacturer has failed to provide MFP access and whether civil monetary penalties are appropriate. Relevant factors should include the number of affected claims, duration of the failure, whether beneficiaries experienced access barriers, whether dispensing entities or providers experienced payment delays, whether the manufacturer had an approved effectuation plan, whether the failure resulted from MTF or data-source error, whether the manufacturer acted in good faith, and how quickly the manufacturer corrected the problem. CMS should also explain how affected beneficiaries, pharmacies, providers, plans, and manufacturers will be made whole when a failure is confirmed. Transparent enforcement factors would promote accountability while reducing uncertainty for good-faith implementation issues.

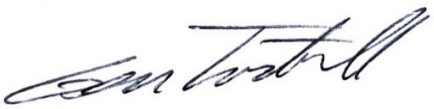
Conclusion

The final guidance should make MFP effectuation accurate, timely, and administratively workable across pharmacy, provider, manufacturer, plan, and vendor operations. AMCP urges CMS to finalize clear rules for claim identification, SDRA methodology, MTF data exchange, prompt payment, remittance content, manufacturer effectuation plans, complaint and dispute resolution, payment outside the MTF Payment Module, 340B nonduplication, direct member reimbursement, and manufacturer accountability. This is essential to ensuring the effectuation of the negotiated price without undermining clinically appropriate benefit design or shifting avoidable financial and administrative risk.

AMCP looks forward to continued engagement with CMS as the agency finalizes and implements the 2028 MFP effectuation framework. Ongoing stakeholder communication will be critical as CMS develops technical specifications, tests MTF functionality, monitors payment timeliness and dispute resolution, and evaluates whether implementation is protecting access for Medicare beneficiaries while supporting the wise use of healthcare dollars.

If you have any questions regarding AMCP's comments or would like further information, please contact me at etunstall@amcp.org or (703) 705-9358.

Sincerely,



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