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Mehmet Oz, M.D.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244–1850
Re: CMS Request for Information – Medicare Part D Reasonable and Relevant Pharmacy Contracting Standards

Dear Administrator Oz:

The undersigned members of the Pharmacy Coalition appreciate the opportunity to provide comments to the Centers for Medicare and Medicaid Services' (CMS') *Request for Information; Medicare Part D Reasonable and Relevant Pharmacy Contracting Standards*. The Pharmacy Coalition brings together six national organizations: the National Community Pharmacists Association (NCPA), American Pharmacists Association (APhA), National Association of Chain Drug Stores (NACDS), American Society of Consultant Pharmacists (ASCP), National Association of Specialty Pharmacy (NASP), and FMI – The Food Industry Association (FMI), representing diverse pharmacy practice settings and the pharmacists who serve Medicare beneficiaries nationwide.

The Coalition convened to support effective implementation of the bipartisan pharmacy benefit manager (PBM) reforms enacted under the Consolidated Appropriations Act, 2026 (CAA 2026), with particular emphasis on establishing meaningful, workable, and enforceable standards for reasonable and relevant pharmacy contracting under Medicare Part D.

NCPA represents America's community pharmacists, including 18,900 independent community pharmacies. Almost half of all community pharmacies provide long-term care services and play a critical role in ensuring patients have immediate access to medications in both community and long-term care (LTC) settings. Together, our members employ nearly 230,000 individuals, and provide an expanding set of healthcare services to millions of patients every day. Our members are small business owners who are among America's most accessible healthcare providers. NCPA submits these comments on behalf of both independently-owned community and long-term care pharmacies.

NACDS represents stand-alone drug stores, supermarkets, and mass merchants with pharmacies. Chains operate approximately 32,000 pharmacies, and NACDS' member companies include regional chains, with a minimum of four stores, and national companies. As the most accessible healthcare destinations, and among the most trusted,

pharmacies help patients use medicines correctly and safely, while offering innovative services that improve patient health and healthcare affordability. NACDS members also include supplier partners that help to meet Americans' expectations by leveraging the total store for the total person.

APhA is the largest association of pharmacists in the United States advancing the entire pharmacy profession. APhA represents pharmacists in all practice settings, including community pharmacies, hospitals, long-term care facilities, specialty pharmacies, community health centers, physician offices, ambulatory clinics, managed care organizations, hospice settings, and government facilities. Our members strive to improve medication use, advance patient care, and enhance public health.

ASCP is the only international professional society devoted to age-friendly care focusing on optimal medication management and improved health outcomes for older adults, the medically complex and individuals living with intellectual and developmental disabilities. Representing 5,000 pharmacists and more than 1,200 long term care pharmacies nationally, ASCP member pharmacists manage drug therapies in various settings—including sub-acute and long-term care facilities (LTCFs), skilled nursing facilities (SNFs), assisted living communities, psychiatric hospitals, hospice programs, correctional facilities, and home and community-based care.

NASP is the leading national organization representing the full continuum of the specialty pharmacy industry, including independent, health-system, and other specialty pharmacies, along with the manufacturers, some pharmacy benefit managers, technology companies, group purchasing organizations, and other supply-chain partners that support specialty pharmacy patients. NASP's specialty pharmacy members serve patients who require complex, high-touch therapies for conditions such as cancer, multiple sclerosis, rheumatoid arthritis, cystic fibrosis, HIV, organ transplantation, and rare and orphan diseases. These patients depend on the clinical management, adherence support, financial assistance navigation, and rapid-access dispensing services that nationally accredited specialty pharmacies uniquely provide.

As the food industry association, FMI works with and on behalf of the entire industry (from grocery companies that operate retail pharmacies across the United States, to producers that supply food and other products) to advance safer and more efficient consumer supply chains for both food and pharmaceuticals. In total, FMI member companies operate more than 45,000 grocery stores, and FMI's retail members operate more than 12,000 supermarket pharmacies located inside those stores in communities nationwide, from major metropolitan centers to small and rural towns.

The Pharmacy Coalition thanks CMS for the opportunity to provide feedback, and we stand ready to work with the agency to offer possible solutions and ideas.

Summary of Key Issues and Overarching Considerations

The Pharmacy Coalition strongly supports Congress's and CMS's efforts to strengthen Medicare Part D's Any Willing Pharmacy (AWP) protections through the establishment of clear, meaningful, and enforceable standards for reasonable and relevant pharmacy contract terms and conditions.

An offer to join a Part D network does little to protect beneficiary access if the terms make it financially or operationally impractical for a qualified pharmacy to participate. CMS should judge its standards by whether they give pharmacies a viable way to participate and beneficiaries a real choice of pharmacy. As CMS develops these standards, the Coalition encourages the agency to prioritize the following overarching considerations:

- **Promote reasonable, transparent, and sustainable pharmacy reimbursement.** CMS should establish standards that account for pharmacies' actual drug acquisition and dispensing costs, recognize objectively justified differences in services and associated costs, and promote predictable reimbursement. These standards should address opaque pricing methodologies, inadequate dispensing fees, and retrospective adjustments that obscure or diminish final pharmacy payment.

  In particular, pharmacies should have sufficient information to understand and evaluate reimbursement terms before accepting a contract, as well as to determine the compensation they can reasonably expect when dispensing covered medications.

- **Ensure meaningful and fair network participation.** CMS should strengthen AWP protections by ensuring that qualified pharmacies can participate in Part D networks under objective, reasonable, and consistently applied terms. Network participation requirements should reflect legitimate clinical and operational considerations, rather than imposing unnecessary barriers or favoring PBM affiliates.

- **Strengthen transparency, predictability, and fairness in pharmacy contracting.** Pharmacies should receive complete, understandable contract terms, including all material financial and operational requirements, with sufficient time to evaluate proposed agreements and amendments. CMS should examine practices that permit unilateral modifications, deemed acceptance, or material changes through provider manuals and other ancillary documents without meaningful pharmacy consent. Clear disclosures, reasonable review periods, and appropriate safeguards against unilateral changes can promote informed participation decisions and more balanced contractual relationships.

- **Establish objective, relevant, and consistently applied quality and performance requirements.** Pharmacy quality measures should reflect evidence-based

standards, account for differences in patient populations and settings, and evaluate factors that pharmacies can meaningfully influence. CMS should promote transparent methodologies, appropriate approaches to validation and risk adjustment, timely access to performance data, and substantive opportunities to challenge inaccurate determinations. Performance-related arrangements should not function as pretextual, de facto mechanisms for reducing pharmacy reimbursement.

- **Promote fair, proportionate, and transparent auditing and dispute resolution.** CMS should establish safeguards that distinguish administrative or clerical errors from conduct involving fraud, improper billing, or patient safety concerns. Audit and recoupment practices should follow clearly disclosed standards, provide reasonable opportunities for correction, and impose consequences proportionate to substantiated findings. Pharmacies should also have access to timely, meaningful, and impartial procedures for challenging reimbursement determinations, audit findings, contract disputes, and adverse network participation actions.

- **Develop an administrable framework for oversight, enforcement, and accountability.** The effectiveness of Congress's reforms will ultimately depend on CMS's ability to translate reasonable-and-relevant standards into consistent oversight and meaningful enforcement. CMS should establish objective requirements that support verification of compliance, clear expectations for plan sponsors and PBMs, and accessible procedures for submitting and resolving allegations of violations. The agency should also implement meaningful anti-retaliation safeguards and appropriate mechanisms for obtaining commercially sensitive information necessary to evaluate contracting practices and enforce the standards.

As CMS advances these priorities, the agency should evaluate both individual contractual provisions and their cumulative effects on pharmacy participation, financial sustainability, and beneficiary access.

The Coalition's recommendations reflect shared principles applicable across pharmacy practice settings and business models. Individual Coalition member comment submissions provide additional detail regarding the distinct services, operational requirements, and contracting challenges their members encounter. We encourage CMS to consider those submissions alongside this letter as the agency develops standards that recognize legitimate differences in pharmacy capabilities while ensuring consistent treatment of similarly situated pharmacies.

Finally, the Coalition encourages CMS to coordinate implementation of section 6223 with the complementary PBM compensation and transparency reforms enacted under section

6224 of CAA 2026. These provisions address distinct but interconnected aspects of Part D pharmacy contracting and PBM business practices. Coordinated oversight can help CMS identify unintended consequences, prevent problematic practices from shifting into alternative contractual or financial arrangements, and advance Congress's broader objectives of transparency, competition, affordability, and beneficiary access.

At the same time, coordination should not drive conflation of these policies or their requirements. CMS should not, for instance, treat a PBM or affiliate's compliance with the parameters of section 6224 as presumptive evidence or an implicit signal of compliance with the separate standards set out in accordance with section 6223. Some contracting terms, to that end, could comport with the former while falling short of the standards for reasonableness and relevance issued and enforced under the latter.

The following sections provide more detailed comments on selected topics and information requests identified in CMS's RFI, with particular emphasis on issues that warrant consideration as the agency develops reasonable-and-relevant contracting standards.

Responses to Specific Requests for Information

A. Pharmacy Reimbursement and Dispensing Fees

Reimbursement Adequacy and Acquisition-Cost Benchmarks

Information Request: CMS seeks information on whether Part D reimbursement sufficiently covers pharmacies' actual drug acquisition costs, how reimbursement varies across pharmacy and drug types, and which pricing benchmarks or methodologies most accurately reflect acquisition costs. CMS also asks about the feasibility of pharmacy-specific acquisition-cost disclosures, the relationship between reimbursement and pharmacy access, and whether it should establish reimbursement methodologies or rates.

Coalition Response:

The Coalition encourages CMS to establish meaningful standards that promote reimbursement sufficient to cover pharmacies' reasonable costs of acquiring and dispensing covered Part D drugs. Reimbursement methodologies that routinely fall below these costs can undermine pharmacies' financial sustainability, create an inability to stock certain medications, and ultimately threaten beneficiary access, particularly in underserved areas and for patients requiring specialized therapies.

For purposes of setting concrete and enforceable standards, CMS should consider requiring ingredient-cost reimbursement based on transparent, independently verifiable acquisition-cost benchmarks, such as the National Average Drug Acquisition Cost (NADAC), where appropriate. Where NADAC does not include information on drug

acquisition costs or lacks sufficient data for a particular drug or pharmacy setting (limited data recorded that is not representative of the pharmacy market), CMS should provide for objective, transparent, and reasonable benchmarks or methodologies, such as wholesale acquisition cost (WAC), and account for legitimate differences in acquisition costs. Any use of WAC must also ensure a payor respects WAC as a floor and does not reimburse at WAC minus a percentage. The use of a benchmark alone should not automatically deem reimbursement as satisfying reasonable-and-relevant standards. CMS should also evaluate whether the overall methodology adequately accounts for drug dispensing and relevant patient service costs and supports sustainable pharmacy participation.

The Coalition cautions against requiring pharmacies to disclose proprietary acquisition-cost information directly to PBMs or plan sponsors as a condition of network participation. Such requirements could expose competitively sensitive information to vertically integrated entities that are simultaneously owned by both a health insurer and a PBM and that own competing pharmacies, while imposing substantial administrative burdens on pharmacies. Moreover, acquisition costs may reflect rebates, discounts, or other adjustments that pharmacies cannot reasonably attribute to individual claims at the point of sale.

CMS should favor transparent benchmarks and, where necessary, consider alternative mechanisms for validating acquisition costs independently without requiring disclosure of proprietary pharmacy-level information to competing entities. This approach would mitigate considerable complexity and operational hurdles for both the agency and stakeholders.

Dispensing Fees and Differences among Pharmacy Types

Information Request: CMS seeks information about the costs encompassed by dispensing fees, whether Part D dispensing fees sufficiently cover those costs, how fees vary across pharmacy settings and services, and whether dispensing fees should independently cover dispensing costs or account for margins on ingredient-cost reimbursement.

Coalition Response:

The Coalition encourages CMS to establish standards that recognize the full range of reasonable costs pharmacies incur when dispensing covered Part D drugs. These costs extend beyond drug acquisition and include pharmacist and technician labor, quality assurance, packaging, technology, regulatory compliance, facilities, and other operational expenses associated with dispensing and patient care.

CMS should require dispensing fees to independently cover reasonable dispensing costs, rather than allowing plans or PBMs to rely on uncertain and often non-existent ingredient-cost margins to make up the difference. Such an approach would improve transparency,

reduce reliance on opaque cross-subsidization, and more clearly distinguish payment for acquiring a drug from compensation for dispensing it.

CMS should examine dispensing-fee methodologies that reduce fees based on days' supply without adequately accounting for fixed costs incurred per prescription. The Coalition encourages CMS to consider objective cost-of-dispensing methodologies, including relevant state Medicaid experience, while accounting for demonstrable differences in the services provided and costs incurred. The agency should consult individual Coalition members' comment letters for additional, more granular insights into the scope of services provided by various pharmacy types.

MAC Pricing, Transparency, and Appeals

Information Request: CMS seeks information regarding maximum allowable cost (MAC) pricing methodologies, the frequency and transparency of MAC updates, available dispute mechanisms, and alternatives that may better reflect acquisition costs. CMS also requests information about lesser-of pricing methodologies, usual and customary (U&C) pricing, and the potential use of machine learning or artificial intelligence in reimbursement determinations.

Coalition Response:

The Coalition encourages CMS to strengthen transparency and accountability in MAC pricing, particularly where PBM-controlled methodologies produce reimbursement amounts that pharmacies cannot independently verify or reasonably challenge. Pharmacies should have sufficient information to understand the basis for MAC determinations, assess whether reimbursement reflects prevailing acquisition costs, and pursue timely corrections when pricing benchmarks fail to reflect market conditions.

CMS should consider standards requiring disclosure of MAC pricing methodologies, regular updates reflecting acquisition-cost changes, and meaningful appeal procedures. Successful appeals should result in appropriate reimbursement corrections, including retroactive adjustments to affected claims where warranted. CMS should also clarify how existing Part D requirements governing pricing-standard updates apply to MAC lists and whether additional safeguards would improve compliance.

Finally, any use of machine learning or artificial intelligence to establish reimbursement amounts should remain subject to transparent, explainable methodologies and meaningful review. Automated pricing determinations should not diminish pharmacies' ability to understand or challenge reimbursement decisions.

Effective-Rate Guarantees and Post-Adjudication Adjustments

Information Request: CMS seeks detailed information about the relationship between negotiated prices reported at claim adjudication and pharmacies' final reimbursement, including the use of Brand Effective Rate (BER), Generic Effective Rate (GER), and similar aggregate guarantees. CMS also asks about reconciliation methodologies, payment predictability, negotiability, and the effects of retrospective adjustments on pharmacy operations and drug selection.

Coalition Response:

The Coalition encourages CMS to establish standards that promote predictable, transparent, and verifiable pharmacy reimbursement at the point of sale. Although CMS's prior reforms sought to ensure that negotiated prices would reflect the lowest possible reimbursement pharmacies receive, aggregate effective-rate arrangements and subsequent reconciliation processes continue to create uncertainty regarding final payment amounts.

BER, GER, and similar arrangements can involve retrospective adjustments across broad populations of claims, pharmacies, or reporting periods. These methodologies may obscure individual-claim reimbursement, complicate pharmacies' financial planning, and produce substantial reconciliation obligations long after pharmacies dispense medications.

CMS should consider requiring complete disclosure of effective-rate methodologies, including applicable drug classifications, included and excluded claims, reconciliation periods, calculation methods, and the treatment of payments across pharmacies and networks. Pharmacies should receive sufficiently detailed remittance and reconciliation information to verify calculations, identify adjustments attributable to particular claims, and pursue meaningful disputes. CMS should require plan sponsors to verify that reconciliations comply with the disclosed methodologies and applicable reimbursement protections, including when a PBM performs the calculations, and retain supporting records for CMS review.

CMS must also strengthen oversight, auditing, and enforcement to ensure that plans and PBMs properly apply pharmacy price concessions at the point of sale and accurately reflect applicable financial arrangements in plan sponsor bids and required reporting. Plans and PBMs should not be permitted to circumvent these requirements through retrospective reconciliations or alternative contractual arrangements. CMS should require sufficient documentation to verify compliance, conduct targeted audits, and require corrective action, including repayment of improperly recouped amounts and appropriate enforcement measures when violations occur.

The Coalition urges CMS to require BER, GER, and similar effective-rate reconciliation arrangements to permit additional payments to pharmacies while prohibiting retrospective

reductions to previously established reimbursement. Such a standard would reinforce CMS's point-of-sale transparency reforms, promote predictable pharmacy reimbursement, and prevent reconciliation mechanisms from recreating the financial uncertainty those reforms sought to address. At a minimum, CMS should prohibit reconciliations that reduce a pharmacy's reimbursement for a covered Part D claim below the higher of the amount established at the point of sale or the ingredient cost of the drug plus a fair and adequate dispensing fee, while preserving legitimate corrections of billing or payment errors.

CMS should also evaluate whether effective-rate guarantees create incentives that undermine beneficiary access or competition.

Cross-Line Reimbursement, Pharmacy Access, and Other Considerations

Information Request: CMS seeks information about reimbursement arrangements spanning Part D and commercial lines of business, including blended guarantees, cross-line offsets, and the implications for pharmacy reimbursement, Medicare spending, and beneficiary cost sharing. CMS also requests information about how reimbursement practices influence pharmacy access and decisions to stock particular medications.

Coalition Response:

The Coalition encourages CMS to ensure that Part D reimbursement arrangements remain independently identifiable, transparent, and subject to meaningful oversight. Contractual structures that combine Part D and commercial reimbursement through blended effective-rate targets or cross-line reconciliations may obscure the compensation pharmacies ultimately receive for Part D claims and complicate CMS's ability to assess compliance with program requirements.

CMS should consider requiring sponsors and PBMs to separately identify Part D reimbursement methodologies, financial adjustments, performance guarantees, and reconciliation amounts, even where pharmacies participate in broader agreements covering multiple lines of business. Performance guarantees should be measured and enforced based on actual results within the applicable pharmacy channel and line of business, rather than aggregated across channels or commercial and Part D business in ways that obscure underperformance or allow unmet guarantees to escape financial accountability. Such safeguards would improve transparency, prevent inappropriate cross-line offsets, ensure that Part D performance guarantees are independently enforceable, and support accurate program reporting.

More broadly, CMS should consider the relationship between reimbursement adequacy and meaningful network participation. Pharmacies may technically qualify for network participation while facing reimbursement terms that make continued participation financially untenable. The Coalition encourages CMS to evaluate whether such arrangements undermine the practical operation of AWP protections and contribute to

reduced medication availability, pharmacy closures/acquisitions, or diminished beneficiary access.

Taken together, these considerations underscore the importance of reasonable-and-relevant standards that address not only the nominal terms of pharmacy reimbursement, but also their transparency, predictability, and cumulative effects on pharmacies' ability to serve Medicare beneficiaries.

B. Current Contracting Practices

Meaningful Network Participation and Consistent Application of Contracting Standards

Information Request: CMS seeks information on the factors that should inform reasonable-and-relevant contracting standards, including the treatment of similarly situated pharmacies, participation in preferred and specialty networks, the influence of PBM ownership relationships, and the extent to which network requirements promote competition and beneficiary access.

Coalition Response:

The Coalition encourages CMS to establish clear, objective standards for determining when pharmacies are similarly situated, grounded in their demonstrated qualifications, capabilities, and services provided. These standards should recognize legitimate clinical and operational requirements without allowing pharmacy size, ownership, business model, or classification alone to justify different contractual treatment. Pharmacies possessing comparable qualifications and capabilities should have meaningful opportunities to participate in Part D networks under consistent terms and conditions.

CMS should require plan sponsors and PBMs to establish, document, disclose, and consistently apply objective criteria governing pharmacy network participation and classification, including within preferred and specialty networks. These criteria should reflect legitimate drug-specific handling, clinical, operational, and patient-service requirements rather than arbitrary distinctions or preferential treatment of insurer/PBM-affiliated pharmacies. Plans and PBMs should not use network designations or additional participation requirements to circumvent reasonable-and-relevant standards or exclude otherwise qualified pharmacies.

To promote objective qualification standards, CMS should recognize accreditation by an independent, nationally recognized third-party specialty pharmacy accreditor as evidence of relevant specialty pharmacy capabilities. Where accreditation appropriately reflects the services involved, plans and PBMs should recognize comparable accreditations and avoid duplicative, proprietary, or unnecessary requirements that restrict participation by otherwise qualified pharmacies. Accreditation should inform assessments of

demonstrated capabilities rather than serve as an unjustified barrier to network participation.

Contract Transparency, Review Periods, and Affirmative Acceptance

Information Request: CMS seeks information about the availability and completeness of standard pharmacy contract terms, the use of bundled agreements and ancillary documents, review periods, deemed acceptance, unilateral amendments, and whether pharmacies have sufficient information and time to evaluate participation decisions.

Coalition Response:

The Coalition encourages CMS to establish standards requiring timely disclosure of complete, understandable contract terms and meaningful opportunities for pharmacies to evaluate proposed agreements before accepting them. These protections should extend to all material financial and operational provisions, including reimbursement methodologies, rate schedules, performance measures, audit requirements, dispute procedures, and network participation conditions.

Pharmacies frequently encounter arrangements in which material terms appear outside the executed contract, including provider manuals, policy bulletins, rate sheets, fax blasts, and other documents subject to modification by the plan sponsor or PBM. CMS should ensure that pharmacies receive all material terms at the time of network offer and that plans and PBMs cannot impose new substantive obligations through ancillary documents without appropriate notice, review, and active agreement by the pharmacy.

The Coalition also recommends at least 60 days to review new standard terms and at least 60 days to review material amendments, in each case starting when the pharmacy receives the complete contract or amendment package. Initial contracts and material amendments should require affirmative acceptance. Deemed acceptance, negative-consent provisions, and unilateral changes to reimbursement or operational requirements can undermine informed participation decisions, particularly when pharmacies receive incomplete information or face compressed implementation timelines.

CMS should consider requiring material changes to receive affirmative pharmacy acceptance before taking effect, while preserving reasonable procedures for routine, previously disclosed updates that do not fundamentally alter contractual obligations. Pharmacies should also receive sufficient information about the plans and networks covered by an agreement to evaluate likely financial and operational consequences.

Bundled Contracts, Cross-Line Participation, and Contracting Leverage

Information Request: CMS seeks information on the extent to which Part D network participation depends on participation in other lines of business, whether contracts bundle

multiple networks or payment arrangements, and how bargaining leverage differs among sponsors, PBMs, pharmacies, and pharmacy services administrative organizations (PSAOs).

Coalition Response:

The Coalition encourages CMS to ensure that Part D network participation does not depend on contractual obligations unrelated to the pharmacy's provision of Part D services. Agreements that condition Part D participation on acceptance of commercial, Medicaid, or other network arrangements may prevent pharmacies from independently evaluating the terms governing their Medicare business and undermine meaningful participation.

CMS should consider requiring plans and PBMs to disclose Part D-specific terms separately, even where a broader agreement encompasses multiple lines of business. Such transparency would allow pharmacies to assess their Part D obligations independently and help CMS evaluate compliance with reasonable-and-relevant standards.

The Coalition also encourages CMS to account for the substantial differences in negotiating leverage among contracting parties. Pharmacies may have limited practical ability to reject standard terms without risking access to significant prescription volume. PSAOs can facilitate contracting for participating pharmacies, but their involvement should not eliminate individual pharmacies' access to material contractual information or meaningful dispute procedures.

CMS should therefore consider standards that promote transparent contracting and protect pharmacies' ability to evaluate and challenge terms, regardless of whether they negotiate directly or through an intermediary.

Contract Termination, Payment Suspension, and Dispute Resolution

Information Request: CMS seeks information on contract provisions permitting payment recoupment, suspension, or termination; the grounds and procedures for invoking such remedies; and the availability, accessibility, and effectiveness of contractual dispute resolution mechanisms.

Coalition Response:

The Coalition encourages CMS to establish clear procedural safeguards governing adverse contractual actions, including payment suspension, recoupment, and network termination. Such actions can have substantial financial and operational consequences for pharmacies and may disrupt beneficiaries' access to medications and services.

CMS should consider requiring objective grounds for material adverse actions, timely written notice identifying the basis for the relevant determination, reasonable opportunities to respond or correct deficiencies, and meaningful access to independent review. Immediate suspension or termination may warrant different treatment where credible evidence establishes fraud, imminent patient harm, or another serious program-integrity concern.

The Coalition also encourages CMS to establish objective standards governing network termination, including a requirement that plans and PBMs provide a written explanation identifying the contractual or regulatory basis for termination and a meaningful opportunity for independent review. Where pharmacies satisfy applicable participation requirements, unilateral termination rights should not permit plans or PBMs to circumvent reasonable-and-relevant standards. This approach would institute important protections while allowing CMS to preserve narrowly tailored exceptions for credible fraud allegations or imminent patient-safety risks.

More broadly, CMS should establish expectations for timely, accessible, and impartial dispute resolution. Pharmacies should have meaningful opportunities to challenge reimbursement determinations, contractual interpretations, network participation decisions, and other adverse actions without facing unreasonable procedural barriers, excessive costs, or retaliatory consequences.

Preventing Preferential Treatment and Other Barriers to Pharmacy Participation

Information Request: CMS seeks information about specialty network participation, ownership relationships between PBMs and pharmacies, network designations, contracting practices that affect competition, and other factors that may impede meaningful pharmacy participation or beneficiary access.

Coalition Response:

The Coalition encourages CMS to examine contracting practices that may favor insurer/PBM-affiliated pharmacies or disadvantage unaffiliated competitors through network design, participation requirements, reimbursement terms, or other operational conditions. Such practices may restrict beneficiary choice even where unaffiliated pharmacies technically qualify for network participation.

CMS should require plans and PBMs to apply the same objective criteria to similarly situated pharmacies when setting participation, reimbursement, and performance terms, regardless of affiliation. The agency should also evaluate whether network restrictions, specialty designations, credentialing requirements, or other contractual provisions create unnecessary barriers to participation or direct prescription volume toward affiliated entities without legitimate clinical or operational justification. Specialty designations

should be evaluated against the objective accreditation standard described above, rather than used as an additional barrier to participation.

The Coalition further encourages CMS to consider how contracting practices affect the accuracy and timeliness of network participation information available to beneficiaries, including through Medicare Plan Finder. Delays in processing network agreements, inaccurate pharmacy listings, lack of recognition of accredited specialty pharmacies, and inconsistent network-status communications can preclude beneficiaries from identifying otherwise qualified pharmacies and disrupt access to care.

These considerations underscore the importance of evaluating not only individual contract provisions, but also their cumulative effects on pharmacy competition, meaningful network participation, and beneficiary access.

C. Trends in Contract Terms and Conditions

Evolving Financial Arrangements and Contracting Complexity

Information Request: CMS seeks information about trends in pharmacy reimbursement methodologies, payments between pharmacies and plans or PBMs, performance-based arrangements, contract complexity, and the use of effective-rate guarantees across multiple lines of business.

Coalition Response:

The Coalition encourages CMS to examine how evolving pharmacy contracting arrangements affect reimbursement transparency, predictability, and meaningful network participation. As plans and PBMs modify reimbursement methodologies and financial arrangements, pharmacies may encounter new administrative charges, network participation fees, performance adjustments, or other contractual mechanisms that affect the compensation they ultimately retain.

CMS should evaluate these arrangements based on their economic substance rather than contractual labels, including whether fees compensate for identifiable services, whether pharmacies receive adequate disclosures, and whether the cumulative effects of multiple charges undermine reasonable reimbursement. The agency should pay particular attention to arrangements that introduce new financial obligations outside the scope of executed contracts, or that obscure the allocation of payments across Part D and other lines of business. CMS should prohibit arrangements that circumvent the standards in purpose or practical effect, considering the cumulative economic and operational obligations imposed on pharmacies. Uniform wording, nominally voluntary participation, or designation as an alternative contracting arrangement should not, by itself, establish compliance.

As discussed in Sections A and B of this letter, reasonable-and-relevant standards should promote transparent financial terms, predictable reimbursement, and meaningful opportunities for pharmacies to evaluate and accept contractual obligations. The Coalition encourages CMS to monitor emerging practices that could circumvent these protections.

Clinical Services and Emerging Payment Arrangements

Information Request: CMS seeks information about contract terms applicable to pharmacies operating across multiple lines of business, compensation for non-dispensing services, and the effects of Medicare Drug Price Negotiation Program implementation, including maximum fair prices (MFPs), on pharmacy contracting and reimbursement.

Coalition Response:

The Coalition encourages CMS to ensure that reasonable-and-relevant standards account for the evolving range of dispensing, clinical, and patient-support services pharmacies provide. Contract terms should reflect objectively demonstrable differences in the services performed and costs incurred, without relying on pharmacy classifications alone. Individual Coalition members' comment submissions offer additional context, granularity, and examples regarding the services that particular pharmacy types provide.

CMS should also examine whether contracts adequately distinguish reimbursement for dispensing covered drugs from compensation for separately identifiable clinical and patient-support services. Clear contractual treatment of these services can improve transparency and help ensure that payment arrangements reflect the responsibilities pharmacies undertake as required for drug and patient management.

Reasonable-and-relevant standards should discourage contractual practices that impose inappropriate financial risks on pharmacies or interfere with beneficiary access to negotiated medications.

D. Pharmacy Quality and Performance Measures

Information Request: CMS seeks information about the use of pharmacy quality and performance measures in Part D contracting, including how plans and PBMs select, validate, and apply measures; whether measures appropriately account for differences across pharmacy types and patient populations; how performance affects reimbursement and network participation; and whether pharmacies receive sufficient information and opportunities to review or appeal performance determinations.

Coalition Response:

The Coalition supports the use of meaningful, evidence-based quality and performance measures that promote improved patient outcomes and recognize pharmacies'

contributions to medication management and care delivery. However, such measures should reflect factors within a pharmacy's reasonable control, account for differences across pharmacy practice settings that are based on the drugs dispensed and managed by a pharmacy, and avoid imposing financial or operational consequences unrelated to actual performance.

CMS should establish standards requiring pharmacy quality measures to undergo validation by a credible, objective third party independent of the plan sponsor or PBM applying the measures and qualified to address quality measures for all types of pharmacy (including retail, specialty, and long-term care), using transparent, evidence-based methodologies and recognized measure specifications, with appropriate risk adjustment, pharmacy stakeholder consultation and input, and minimum sample-size requirements. Where plans or PBMs adapt broader Part D quality measures, including Star Ratings measures, for pharmacy-level application, they should demonstrate that the resulting measures have undergone independent validation for their intended pharmacy-level use, rather than simply applying plan-level metrics to individual pharmacies without adequate validation.

Importantly, pharmacy performance measures should account for the medications dispensed, services provided, patient populations served, and factors within pharmacies' reasonable control. Measures developed for one population or setting may not appropriately assess performance in another without additional validation or adjustment. Individual Coalition members' submissions offer examples of these dynamics. Pharmacies should not face adverse performance determinations based on factors outside their reasonable influence, including prescriber decisions, beneficiary affordability constraints, or clinical treatment changes.

The Coalition also encourages CMS to strengthen transparency and procedural safeguards surrounding performance-based contracting. Plans and PBMs should disclose applicable measures, calculation methodologies, performance thresholds, and potential financial consequences before contract acceptance. Pharmacies should receive timely access to sufficiently detailed performance data to identify deficiencies, support quality improvement, and challenge inaccurate calculations or patient attributions.

Finally, CMS should ensure that pharmacy performance-based payment arrangements genuinely reward improvements in patient care rather than function primarily as mechanisms for reducing reimbursement. The Coalition encourages CMS to require such arrangements to operate through upside-only incentives, rewarding qualifying performance through additional payments rather than reductions to otherwise applicable pharmacy reimbursement. These protections should preserve reasonable base reimbursement, prevent performance adjustments from reducing payment below any applicable minimum standard, and guard against arrangements that recreate retrospective pharmacy price concessions or apply performance requirements inconsistently across similarly situated pharmacies.

E. Auditing Practices

Transparency, Consistency, and Proportionality in Pharmacy Audits

Information Request: CMS seeks information about pharmacy audit frequency, methodologies, common findings, and financial and operational impacts, including the distinction between clerical errors and fraud or improper billing. CMS also requests information about extrapolation methodologies, recoupment practices, and how sponsors verify claim-level pricing and direct and indirect remuneration (DIR) data received from PBMs.

Coalition Response:

The Coalition recognizes the important role of pharmacy audits in safeguarding Medicare program integrity, identifying improper payments, and protecting beneficiaries. However, audit practices should follow transparent, consistently applied standards and distinguish substantive compliance violations from minor administrative or clerical errors that do not affect patient care or result in improper payment.

CMS should consider prohibiting plan/PBM-imposed pharmacy recoupment based solely on technical or documentation deficiencies where pharmacies appropriately dispensed the prescribed medication and the error caused no financial harm to the plan or beneficiary, absent evidence of fraud or other material noncompliance. Audit remedies should reflect the nature and severity of substantiated findings rather than impose disproportionate financial penalties for minor discrepancies.

The Coalition also encourages CMS to prohibit audit extrapolation. Auditors should apply the contractual and regulatory requirements in effect when the pharmacy dispensed the medication, rather than retroactively enforcing subsequently adopted standards. Likewise, inventory audits should recognize documented lawful drug purchases and avoid arbitrary restrictions that create artificial discrepancies.

Finally, CMS should promote consistent audit treatment across similarly situated affiliated and unaffiliated pharmacies and strengthen sponsor oversight of PBM-reported reimbursement and DIR information submitted during the plan bid process. These safeguards would help ensure that audits advance legitimate program-integrity objectives rather than function primarily as mechanisms for reducing pharmacy reimbursement.

Notice, Corrective Action, and Meaningful Appeal Rights

Information Request: CMS seeks information about opportunities for pharmacies to correct audit deficiencies, challenge findings, and appeal recoupment determinations, including

whether existing procedures provide adequate due process and distinguish administrative errors from material compliance concerns.

Coalition Response:

The Coalition encourages CMS to establish minimum procedural safeguards that provide pharmacies with meaningful opportunities to understand, respond to, and challenge audit findings before plans or PBMs impose adverse financial or network participation consequences.

Such safeguards should include reasonable advance notice, clearly defined documentation requirements, claim-level explanations of alleged discrepancies, and sufficient time to provide supporting information or correct deficiencies. Pharmacies should receive written preliminary findings identifying the applicable contractual or regulatory basis for proposed recoupments, along with access to a timely and impartial appeal process.

CMS should also consider prohibiting recoupment of disputed amounts until pharmacies have exhausted applicable administrative review procedures, subject to narrowly tailored exceptions for credible fraud allegations, imminent patient-safety risks, or other serious program-integrity concerns. Audit vendors' compensation arrangements should not create financial incentives to maximize recoupments irrespective of the validity or significance of findings.

These protections would promote consistent oversight, reduce unnecessary administrative burdens, and ensure that pharmacy audits appropriately balance program integrity with fair and predictable contracting practices.

F. Limitations on Dispensing Covered Drugs

Information Request: CMS seeks information about restrictions or limitations imposed by Part D plan sponsors or PBMs on network pharmacies' ability to dispense covered Part D drugs, including the nature, prevalence, and effects of such restrictions across pharmacy types and dispensing arrangements.

Coalition Response:

The Coalition encourages CMS to establish clear standards governing contractual and operational restrictions that limit otherwise qualified network pharmacies' ability to dispense covered Part D drugs. Such restrictions can undermine meaningful AWP participation, constrain beneficiary choice, and create competitive advantages for insurer/PBM-affiliated pharmacies, particularly where plans or PBMs impose requirements unrelated to legitimate clinical, safety, or operational considerations. A report prepared by House Committee on Oversight and Accountability staff identified internal PBM

discussions about shifting patients from medications nearing the end of patent exclusivity to higher-cost alternatives, substantiating claims that PBM dispensing decisions may be driven by financial incentives rather than patient needs.[1]

CMS should require dispensing limitations to rest on objective, transparent criteria tied to the clinical, safety, handling, or service requirements of the medication or patient population. Plans and PBMs should apply these criteria consistently to pharmacies with comparable capabilities, regardless of ownership or affiliation. Pharmacies that satisfy the applicable requirements should have a meaningful opportunity to dispense covered medications.

The Coalition also encourages CMS to examine practices that steer beneficiaries toward insurer/PBM-affiliated pharmacies through network restrictions, claims-processing requirements, or misleading communications about pharmacy participation. Such practices may include restrictions on initial fills or refills, mandatory use of particular dispensing channels, limitations on mail-order, or specialty dispensing by otherwise qualified, similarly situated pharmacies, as referenced above. CMS should evaluate whether dispensing restrictions serve legitimate patient-care objectives or unnecessarily disrupt existing pharmacy-patient relationships, and should establish additional safeguards where necessary.

The Coalition therefore encourages CMS to strengthen oversight of dispensing restrictions, require clear documentation of their clinical or operational justifications, and provide meaningful opportunities for pharmacies to challenge limitations that lack an objective basis or receive inconsistent application. These safeguards would reinforce existing beneficiary protections while promoting competition, continuity of care, and meaningful pharmacy access.

G. Current Regulations and Guidance

Information Request: CMS seeks information about existing Part D regulations, guidance, and contracting requirements that warrant clarification or additional specificity, including areas where inconsistent interpretation or application may affect pharmacy contracting and network participation.

Coalition Response:

The Coalition encourages CMS to incorporate the reasonable-and-relevant standards developed under section 6223 into the existing Part D regulatory framework, providing clear, enforceable requirements that promote consistent application across plan

[1] *The Role of Pharmacy Benefit Managers in Prescription Drug Markets*, House Committee on Oversight 30 (2024). Available at: https://oversight.house.gov/wp-content/uploads/2024/07/PBM-Report-FINAL-with-Redactions.pdf.

sponsors, PBMs, and pharmacy networks. In particular, several existing provisions warrant clarification or targeted modification:

- **AWP contracting requirements (42 C.F.R. § 423.505(b)(18)).** CMS should incorporate objective standards governing reasonable and relevant contract terms, including meaningful disclosure, review periods, and safeguards against unilateral amendments. The agency should also clarify how these requirements apply to similarly situated pharmacies and ensure that existing contract-availability deadlines afford pharmacies sufficient time to evaluate complete terms before the applicable plan year.
- **Network participation and pharmacy access (42 C.F.R. § 423.120(a)).** CMS should clarify how AWP requirements apply to preferred and specialty networks, including the use of objective participation criteria and consistent treatment of similarly situated pharmacies, as recommended above. CMS should also strengthen existing protections against inappropriate dispensing restrictions and patient steering while preserving legitimate clinical requirements and permissible preferred-network arrangements.
- **Pricing standards and pharmacy reimbursement (42 C.F.R. §§ 423.100 and 423.505(b)(21)).** CMS should clarify the application of existing negotiated-price and pricing-standard requirements to MAC methodologies (including their relationship to pharmacy costs), post-adjudication adjustments, and effective-rate guarantees. In particular, the agency should ensure that existing requirements for timely pricing-standard updates, disclosures, and reimbursement at the point of sale support transparent, predictable, accurate, and verifiable pharmacy payments that fairly reflect acquisition costs.
- **Prompt payment and contractual remedies (42 C.F.R. § 423.520).** CMS should examine whether additional clarifications would prevent payment adjustments, recoupments, or reconciliation practices from undermining existing prompt-payment protections. The agency should also consider how reasonable-and-relevant standards can establish appropriate notice, documentation, and dispute procedures for adverse payment actions.

Across these areas, CMS should clarify that Part D plan sponsors retain responsibility for compliance with applicable requirements, including when they delegate pharmacy contracting and related functions to PBMs or other entities. Clear regulatory obligations, supported by consistent guidance and effective oversight, would reduce uncertainty and provide a stronger foundation for implementing and enforcing section 6223's reasonable-and-relevant standards.

H. Implementation of Standards

Clear, Objective, and Administrable Standards

Information Request: CMS seeks information about implementation timelines, documentation necessary to demonstrate compliance, examples of model contract terms, and criteria for ensuring that reasonable-and-relevant standards are transparent, objective, and enforceable.

Coalition Response:

The Coalition encourages CMS to establish clear, measurable, and administrable standards that provide meaningful protections for pharmacies and a consistent basis for oversight and enforcement. General principles alone may leave pharmacies and plan sponsors uncertain about their respective obligations and complicate CMS's ability to identify and address violations. Accordingly, the standards should establish objective requirements, including, where appropriate, minimum notice and review periods, reimbursement transparency and adequacy safeguards, consistently applied network participation criteria, and defined procedural protections.

CMS should also provide sufficient implementation guidance and lead time for plan sponsors, PBMs, and pharmacies to incorporate the new requirements into their contracts and operations before the standards take effect in 2029. Plan sponsors should make complete, compliant standard terms available sufficiently early in the contracting cycle to permit meaningful pharmacy review and acceptance.

To facilitate oversight, CMS should consider requiring plan sponsors to maintain and, where appropriate, submit documentation demonstrating compliance, including standard contract templates, applicable rate schedules, provider manuals, network participation criteria, and relevant policies governing audits, performance measures, and dispute resolution. Such requirements would promote consistent application of the standards and help CMS identify contractual provisions that warrant additional scrutiny.

Accessible Allegation Submission and Meaningful Enforcement

Information Request: CMS seeks information about operational considerations and documentation necessary to implement and enforce reasonable-and-relevant contracting standards, including approaches that could serve as models for compliance and oversight.

Coalition Response:

The Coalition encourages CMS to establish a straightforward, accessible, and timely process through which pharmacies can report alleged violations of reasonable-and-relevant contracting standards. Congress's express direction to establish an allegation submission process reflects the importance of meaningful oversight and enforcement in strengthening existing AWP protections.

CMS should clearly identify submission requirements, applicable evidentiary standards, review procedures, and anticipated resolution timelines. Pharmacies should receive sufficient information to understand the status and disposition of their allegations, while plan sponsors and PBMs should have appropriate opportunities to respond to substantiated concerns. When CMS finds a violation, it should require the plan sponsor to correct it within a defined timeframe and demonstrate that the correction has been made, including when the underlying conduct was carried out by a PBM acting on the sponsor's behalf. Such oversight should assess compliance with the anti-circumvention principle described in Section C, including the cumulative effects of related terms and arrangements.

The Coalition also encourages CMS to clarify how the allegation process interacts with contractual dispute resolution and arbitration provisions. Such arrangements should not prevent pharmacies from communicating with CMS or submitting allegations under the statutory framework. Likewise, CMS should ensure that pharmacies can access the allegation process without first exhausting contractual remedies that may prove costly, inaccessible, or ineffective.

Anti-Retaliation Protections and Confidential Information

Information Request: CMS seeks information about implementation considerations and other practices that warrant evaluation as the agency develops reasonable-and-relevant contracting standards.

Coalition Response:

The Coalition encourages CMS to implement the statute's anti-retaliation and anti-coercion protections through clear, practical safeguards that enable pharmacies to report suspected violations without fear of adverse consequences. CMS should clarify how these protections apply to actions such as network termination, reimbursement reductions, heightened audit scrutiny, or other adverse contractual measures undertaken in response to protected reporting activity.

The Coalition also reiterates its previous recommendation that CMS establish an optional mechanism for receiving commercially sensitive information outside the public comment docket during standards development, consistent with applicable law. Although public submissions can identify important contracting practices and recommend appropriate standards, pharmacies may hesitate to disclose proprietary financial information, contract terms, or other sensitive documentation through a fully public process, particularly where disclosure could create competitive harm or retaliation risks. These concerns are heightened by a history, noted in a previous House Committee on Oversight and Accountability report, of PBMs and plan sponsors using their relationships with network

pharmacies as data intermediaries to obtain prescription claims data and steer patients toward affiliated pharmacies.[2]

A narrowly tailored confidential submission pathway would complement public comments and provide CMS with additional evidence to inform standard-setting, oversight, and enforcement. The Coalition encourages CMS to consider practical mechanisms for receiving such information, with appropriate safeguards for confidentiality, transparency, and lawful use.

Together, clear regulatory standards, meaningful oversight, accessible allegation procedures, and effective protections for reporting pharmacies would help translate Congress's reforms into durable, enforceable requirements that promote pharmacy participation and beneficiary access.

Conclusion

The Pharmacy Coalition appreciates CMS's thoughtful and comprehensive approach to gathering stakeholder input and developing reasonable-and-relevant pharmacy contracting standards under section 6223. Effective implementation of these bipartisan reforms presents an important opportunity to strengthen Medicare Part D's Any Willing Pharmacy protections, promote fair and sustainable pharmacy participation, and safeguard beneficiary access to medications and pharmacy services.

The Coalition encourages CMS to establish clear, workable, and enforceable standards that reflect the diverse operational realities of pharmacy practice and address the contracting challenges outlined above. We look forward to continued collaboration with CMS as the agency advances this important work.

Sincerely,

National Community Pharmacists Association
American Pharmacists Association
National Association of Chain Drug Stores
American Society of Consultant Pharmacists
National Association of Specialty Pharmacy
FMI – The Food Industry Association

[2] *The Role of Pharmacy Benefit Managers in Prescription Drug Markets*, House Committee on Oversight (2024). Available at: https://oversight.house.gov/wp-content/uploads/2024/07/PBM-Report-FINAL-with-Redactions.pdf.