November 23, 2026

Submitted electronically via www.regulations.gov

The Honorable Mehmet Oz, M.D.
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-4217-NC
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Request for Information; Medicare Part D Reasonable and Relevant Pharmacy Contracting Standards (CMS-4217-NC; Docket No. CMS-2026-3037)

Dear Administrator Oz:

Introduction

I write to you today on behalf of American Pharmacy Cooperative, Inc. (APCI), a cooperative of more than 1,300 community pharmacies across thirty states. APCI appreciates the opportunity to respond to CMS's Request for Information on reasonable and relevant pharmacy contracting standards.

Section 6223(a) of the Consolidated Appropriations Act, 2026 presents CMS with a historic opportunity. Congress directed that, "[n]otwithstanding any other provision of law," Part D contract terms and conditions be reasonable and relevant according to standards CMS establishes. In doing so, Congress empowered, and indeed directed, CMS to ensure that Part D contract terms, including pharmacy reimbursement and dispensing fees, are reasonable and relevant, and identified whether reimbursement and dispensing fees "sufficiently cover the ingredient and operational costs" of network pharmacies as central to establishing those standards. Reimbursement that fails to cover those costs cannot be reasonable and relevant. Congress then charged CMS with enforcing the standards it sets.

The need is urgent. As set forth more fully below, with PBMs setting prices in Part D, reimbursement bears little relationship to what drugs actually cost. CMS's own Part D pricing files show massive variability in plan-level average prices for the same drugs, with many falling

well below NADAC and others far above it,[1] and independent pharmacists report that Part D reimbursement threatens the viability of their businesses. Retail pharmacy closures more than doubled between 2021 and 2025, and a growing share of Part D beneficiaries now live in ZIP codes with no pharmacy at all.[2] These outcomes are largely driven by opaque, PBM-controlled reimbursement methodologies, post-adjudication adjustments, and networks designed to steer patients toward PBM-affiliated pharmacies.

CMS does not need to start from scratch. It already maintains NADAC and approves state Medicaid dispensing fees, and both can anchor these standards. APCI urges CMS to adopt standards built on five pillars:

1. Market-based reimbursement. Ingredient cost reimbursement based on NADAC, plus a modest percentage, as both floor and ceiling, in place of trade-secreted methodologies such as MAC.

2. A fair dispensing fee. A professional dispensing fee based on the applicable state Medicaid fee, applied uniformly regardless of channel or PBM affiliation, with services beyond dispensing paid separately.

3. Finality at the point of sale. No post-adjudication adjustments, effective-rate reconciliations, cross-line offsets, or fees charged to pharmacies.

4. True any willing pharmacy. No preferred, narrow, or specialty networks closed to pharmacies willing to accept the same terms, and no tying of Part D participation to other lines of business.

5. Fair audits and enforceable rights. Recoupment limited to fraud, the stronger of federal or state audit protections, and decisions about a pharmacy's network participation and recoupment made by CMS, not the PBM.

These standards are not only fair; they are fiscally responsible. As a ceiling, NADAC eliminates the outlier payments documented throughout these comments, many at PBM-affiliated pharmacies. Georgia's repricing of state employee plan claims under NADAC plus a professional dispensing fee found that those savings more than offset higher dispensing fees.[3]

Congress has given CMS the authority and the mandate. With the standards it adopts, CMS can bring transparency to Part D pharmacy reimbursement, protect beneficiaries' access to the

[1] APCI Insights, "The NADAC Model: A Blueprint for Fiscally Responsible Drug Pricing" (Mar. 2026) [hereinafter APCI NADAC Model].
[2] MedPAC, Preferred Networks and Pharmacy Access in Part D, staff presentation (Apr. 9, 2026) (preliminary) [hereinafter MedPAC Apr. 2026 Presentation].
[3] *See* APCI NADAC Model, *supra*.

pharmacies they choose, and ensure that taxpayers and patients pay a fair price for prescription drugs.[4]

A. Pharmacy Reimbursement and Dispensing Fees

- Information about Part D pharmacy reimbursement policies, including variations by pharmacy type, geographic location, drug type (for example, generic, brand, specialty), or other factors.

APCI Comment: Currently, Part D lacks meaningful reimbursement policies, including regulatory guardrails to ensure fair and transparent reimbursement. Instead, Part D sponsors and their subcontracted, often vertically integrated pharmacy benefit managers (PBMs) utilize opaque, complex, and often trade-secreted drug pricing methodologies to reimburse retail pharmacies. These methodologies are often AWP-minus based and may include maximum allowable cost (MAC) pricing and effective rate pricing, leaving retail pharmacies with post-adjudication adjustments, underwater reimbursements, and little recourse.

Fortunately, Section 6223(a) of the Consolidated Appropriations Act, 2026 tasks CMS with establishing standards for reasonable and relevant contract terms and conditions between Part D sponsors and network pharmacies, "[n]otwithstanding any other provision of law."

In doing so, Congress empowered, and indeed directed, CMS to ensure that Part D contract terms, including ingredient cost reimbursement and dispensing fees, are reasonable and relevant. Congress required CMS to seek input, "for purposes of establishing the standards," on whether reimbursement and dispensing fees "sufficiently cover the ingredient and operational costs of such pharmacies," as well as on the "use and application of pharmacy quality measures." Reimbursement that fails to cover those costs cannot be reasonable and relevant.

Importantly, CMS is tasked not only with establishing standards for reasonable and relevant contract terms and conditions between Part D sponsors and network pharmacies, but also with enforcing them. Congress further extended accountability to subcontracted PBMs, requiring that PBMs acting on behalf of Part D sponsors agree to reimburse sponsors for penalties arising from violations related to responsibilities delegated to them.

[4] APCI's comments respond to selected questions in the RFI and focus on the issues most relevant to fair and transparent pharmacy reimbursement. The absence of a response to any particular question should not be construed as agreement with, or acquiescence in, any practice or position described therein.

- How Part D reimbursement rates compare to pharmacy actual acquisition costs, which methodologies and pricing benchmarks most closely reflect actual acquisition costs, and whether rates vary for certain drugs or drug types, pharmacy types, or other factors.

APCI Comment: Part D reimbursement rates are untethered from acquisition costs. APCI's analysis of CMS's Q2 2025 Part D pricing files found 29,523 distinct average prices for fifteen commonly prescribed generics in a single quarter, with the highest price for each drug ranging from 633% to 19,630% above NADAC.[5] Atorvastatin 20 mg (90 count), for example, ranged from $1.00 to $404.19 against a NADAC of $2.85. These overpayments and underpayments occur for the same drug in the same period.

Current PBM methodologies, including AWP-minus, MAC, and effective rate pricing, overwhelmingly fail to reflect acquisition costs. Pharmacy-specific acquisition cost reimbursement does, but it requires pharmacies to disclose proprietary data, often to PBMs that own competing pharmacies, and creates significant administrative burden.

NADAC, which CMS itself maintains for Medicaid, is the right benchmark for Part D. It is public, regularly updated, grounded in invoice costs, and independent of the contracting parties. Although it is drawn from a voluntary survey of retail pharmacies and can be improved, it remains the best national index available and should anchor reasonable and relevant ingredient cost reimbursement in Part D.

- The feasibility and utility of network pharmacies sharing their actual acquisition costs with Part D plan sponsors, either directly or via wholesalers, and whether that transparency would be a sufficient alternative to benchmarks or similar methodologies to establish a reasonable cost-based reimbursement methodology for ingredient costs.

APCI Comment: Pharmacy-specific acquisition cost reimbursement is feasible. Tennessee, for example, prohibits PBMs from reimbursing contracted pharmacies below the pharmacy's actual cost, enforced through a pharmacy appeals process.[6] As a primary reimbursement methodology, however, it has significant drawbacks. Because acquisition costs differ from pharmacy to pharmacy, it depends on pharmacy-specific appeals that are burdensome to administer. It raises threshold questions about how acquisition cost is defined, such as invoice price versus price net of post-purchase discounts. And whether data is shared directly or through wholesalers, it may require pharmacies to disclose proprietary purchasing information to PBMs that own competing pharmacies.

NADAC is significantly more compelling. It is publicly available, PBMs need not guess at a pharmacy's acquisition costs, and pharmacies need not reveal confidential information to PBMs that own competing pharmacies. As an objective, public benchmark, NADAC serves several purposes at once: it increases transparency, reduces administrative burden for pharmacies, Part D

[5] APCI NADAC Model, *supra*.
[6] Tenn. Code Ann. § 56-7-3206(c)(1)-(2).

sponsors, and CMS and its contractors, including in evaluating and enforcing compliance, and ensures reimbursement that is reasonable and relevant. Acquisition cost appeals may still serve as a valuable backstop, at the pharmacy's election, where NADAC falls short, the role Tennessee's law effectively plays.

Reasonable reimbursement, however, means more than avoiding a loss on ingredient cost. It also requires a professional dispensing fee that covers the costs of dispensing. And because NADAC is an average and many pharmacies acquire drugs above it, ingredient cost reimbursement should be set at NADAC plus a modest percentage, serving as both floor and ceiling. Finally, that reimbursement must be final at the point of sale. As discussed below, fees and post-adjudication adjustments, which allow PBMs to manipulate an otherwise transparent price, should be prohibited.

- Whether, and how, pharmacy margins on ingredient costs differ for certain drugs or drug classes (for example, brand-name drugs versus generics).

APCI Comment: As set forth above, margins on ingredient costs can differ dramatically for the same drug, in the same period, depending on the plan, the PBM, and the pharmacy. Because reimbursement can be reconciled after the fact through effective rate guarantees, a pharmacy may not know at the point of sale whether a given claim will be reimbursed above or below its acquisition cost.

Generic reimbursement swings widely, with some plan-level average prices well above NADAC and many below it. The largest margins are found in generic "specialty" drugs, which PBMs often steer to their affiliated pharmacies.[7] In CMS's Q2 2025 Part D pricing files, the highest plan-level average price for abiraterone 250 mg (120 count) was $9,115.36 against a NADAC of $129.06.[8]

[7] See FTC, "Specialty Generic Drugs: A Growing Profit Center for Vertically Integrated Pharmacy Benefit Managers," Second Interim Staff Report (Jan. 2025) (finding that PBM-affiliated pharmacies dispensed 72 percent of commercial prescriptions for the most highly marked-up specialty generic drugs, suggesting "the Big 3 PBMs may be steering highly profitable prescriptions to their own affiliated pharmacies," and that the three largest PBMs paid their affiliated pharmacies more than unaffiliated pharmacies for nearly every specialty generic drug examined); APCI Insights, "American Postal Workers Union Health Plan: Mail-Order Pharmacy More Expensive Than Independent Pharmacy on 79% of Commonly Prescribed Medications Reviewed" (Nov. 2024) (documenting generic specialty drugs that could not be filled at an independent pharmacy and were directed to the PBM-owned specialty pharmacy).

[8] APCI NADAC Model, *supra*.

- **Maximum Allowable Cost pricing**
    - The frequency of plan updates to maximum allowable cost (MAC) pricing lists, communication regarding such updates, and related dispute resolution mechanisms;
    - Industry standards or common practices for establishing MAC prices and whether there are alternatives that are more transparent to pharmacies.

APCI Comment: In APCI's experience, MAC lists are set unilaterally by PBMs, treated as proprietary, and updated on the PBM's own schedule. Pharmacies generally learn a MAC price only at adjudication, and disputes must first be appealed to the same PBM that set the price, creating delays that thwart effective enforcement.

Many states have attempted to regulate MAC updates, disclosure, and appeals, with little success. The core problem is that MAC is not a benchmark but a trade-secreted methodology based on undisclosed information. It is subject to manipulation and can result in underwater reimbursement. MAC pricing tied to wholesaler pricing may bear little relationship to what a given pharmacy pays, as wholesaler prices vary significantly based on volume and near-exclusive supply contracts. In part for these reasons, some states are moving toward transparent, index-based pricing.[9]

The state experience is instructive. Standards regulating MAC updates and appeals would place CMS at the end of a drug-by-drug, pharmacy-by-pharmacy dispute process that has proven burdensome and largely ineffective at the state level. APCI recommends that CMS prohibit trade-secreted methodologies such as MAC and require reimbursement based on a transparent, market-based index such as NADAC, against which compliance can be measured objectively.

- The use of "lesser of" pricing methodologies, including the use of usual and customary (U&C) pricing and how U&C is defined.

APCI Comment: "Lesser of" provisions tied to usual and customary (U&C) pricing drive up costs for cash-paying patients. Because a pharmacy that lowers its cash price is then paid that price on insured claims, pharmacies are effectively forced to keep U&C prices high, and uninsured and underinsured patients pay the difference. The interplay between U&C and discount card programs can further distort pharmacy pricing. More broadly, "lesser of" logic layers multiple pricing benchmarks, such as AWP-minus, MAC, and U&C, making it difficult for pharmacies to predict which will control, which can result in opacity and underwater reimbursement. APCI recommends that CMS prohibit U&C-based "lesser of" provisions.

[9] *See, e.g.,* Ga. H.B. 196 (2025) (replacing PBM reimbursement methodologies, including MAC pricing, with NADAC-based reimbursement plus a professional dispensing fee for the State Health Benefit Plan and University System of Georgia).

- **Machine learning and Artificial Intelligence**
    - The use of machine learning to estimate acquisition costs;
    - Opportunities for the use of artificial intelligence (AI) with respect to Part D pharmacy reimbursement.

APCI Comment: NADAC, administered by CMS, is the gold-standard national index for market-based pharmacy acquisition costs. While opportunities exist to make NADAC more robust, as Minnesota has done through mandatory pharmacy participation in acquisition cost surveys,[10] the solution to reasonable and relevant reimbursement already rests with CMS. Likewise, state Medicaid cost-of-dispensing surveys already measure what it costs pharmacies to dispense.

Allowing Part D sponsors or PBMs to estimate acquisition costs through machine learning would simply replace one opaque, PBM-controlled pricing model with another, perpetuating the very opacity these standards are meant to address. A black-box estimate is neither transparent nor objective, cannot be meaningfully appealed, and invites the same manipulation as MAC pricing. Estimating what NADAC already measures adds error and opacity, not information. To the extent AI has a role, it is in oversight: helping CMS identify claims paid well above or below NADAC and reimbursement patterns that favor PBM-affiliated pharmacies.

- The relationship, if any, between Part D reimbursement rates and the presence of "pharmacy deserts" in rural, urban, or other underserved areas;

APCI Comment: Pharmacy deserts are a growing reality for Medicare beneficiaries. MedPAC reports that retail pharmacy closures more than doubled between 2021 and 2025, with declining reimbursement among the drivers, and that a growing share of Part D beneficiaries live in ZIP codes with no pharmacy.[11]

Part D is central to this trend. In a January 2025 survey, 96.5 percent of independent pharmacists said PBM and plan reimbursement for Medicare Part D threatened the viability of their business.[12] As set forth above, Part D reimbursement frequently falls below NADAC; in Q2 2025, the lowest plan-level average price for amoxicillin 500 mg (21 count) was $0.36, against a NADAC of $1.74.[13] PBM practices, including reimbursement and the use of preferred networks,

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[10] *See* Minn. Dep't of Human Servs., Minnesota Actual Acquisition Cost Program: Frequently Asked Questions (Apr. 2026) (pharmacies receiving survey requests are "required by DHS to provide the requested information," surveys are conducted quarterly, and "each pharmacy will be selected at least once every year"); see also Minn. Dep't of Human Servs., *2020 Minnesota Fee-for-Service Cost of Dispensing Survey* (Dec. 2020) (surveying enrolled independent, chain, long-term care, specialty, and 340B pharmacies; participation required under Minn. Stat. § 256B.0625).

[11] MedPAC Apr. 2026 Presentation, *supra.*

[12] *See* NCPA, "Report for January 2025 Survey of Independent Pharmacy Owners/Managers" (Jan. 2025).

[13] APCI NADAC Model, *supra*.

contribute to these closures. Research has found that pharmacies "not preferred by most plans were 70–350 percent more likely to close than other pharmacies."[14]

State protections cannot fill this gap because Part D is largely beyond their reach. Kentucky, for example, requires NADAC plus a professional dispensing fee for pharmacies but excludes Part D.[15] Only CMS can establish reasonable reimbursement in Part D, and the standards it adopts under Section 6223(a) will directly affect whether pharmacies in underserved communities remain open. As set forth in Section B, preferred networks closed to any willing pharmacy are a regulatory construct the statute does not require. Reasonable reimbursement standards, together with reconsidering preferred networks, will drastically reduce closures.

- **Dispensing fees**
    - Costs that are considered within the scope of dispensing fees, and whether dispensing fees paid by Part D sponsors sufficiently cover those costs;
    - How dispensing fees are determined in Part D and outside of Part D; Whether dispensing fees should be required to cover the cost of dispensing irrespective of the ingredient cost reimbursement or whether reimbursement of the ingredient cost may be factored into the dispensing fee calculation;
    - Whether and how dispensing fees vary by pharmacy type, pharmacy services, or other factors;

APCI Comment: A dispensing fee should cover the full cost of dispensing, including. without limitation, labor, overhead, technology, and inventory carrying costs. In Part D, dispensing fees are set by PBMs and bear no required relationship to those costs.

A better model already exists within CMS's own programs. In Medicaid fee-for-service, states pay professional dispensing fees grounded in cost-of-dispensing surveys and approved by CMS. Outside of Medicaid, some states are beginning to similarly separate ingredient cost reimbursement from the costs associated with dispensing. For example, Georgia's state employee plan is required to pay NADAC plus $11.50 for independent pharmacies and $10.50 for chain and mail-order pharmacies, and Kentucky requires a minimum dispensing fee for independent pharmacies in the commercial market.[16]

APCI recommends that the state Medicaid professional dispensing fee, based on a current cost-of-dispensing survey and adjusted for inflation between surveys, serve as both the floor and the ceiling for Part D dispensing fees. CMS should retain flexibility to adjust that base fee for defined access considerations, such as higher costs for rural or low-volume pharmacies, as states

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[14] Jenny S. Guadamuz et al., Medicare Part D Preferred Pharmacy Networks and the Risk for Pharmacy Closure*, 2014–23*, 44 Health Affairs 539 (2025).
[15] Ky. S.B. 188 (2024); *see* Frier Levitt, "Kentucky's S.B. 188: A New Frontier in PBM Reform and the AG's OAG 25-11 Opinion" (Oct. 10, 2025) (describing SB 188's carve-out of Medicare Part D).
[16] APCI NADAC Model, *supra* (describing Ga. H.B. 196 signed into law in 2025); Ky. S.B. 188 signed into law in 2024.

like Tennessee have done.[17] Dispensing fees should not, however, vary by channel, network status, or PBM affiliation. Channel-based differentiation has too often been used to pay retail pharmacies less than PBM-affiliated mail-order and specialty pharmacies.

Dispensing fees and ingredient cost reimbursement should each cover their own costs. Allowing one to offset the other obscures what pharmacies are actually paid and leaves them underwater on one component or the other.

Likewise, services pharmacies provide beyond dispensing, whether in retail, long-term care, home infusion, or other settings, should be compensated through separate reimbursement line items, not folded into the ingredient cost of a drug or the cost to dispense. Pharmacies should be paid for the services they provide, transparently and on their own terms.

- **Post adjudication adjustments and effective rates**
    - Impacts of post-adjudication adjustments on net reimbursement rates;
    - The extent to which negotiated prices reported on pharmacy claim responses reflect a pharmacy's final reimbursement for Part D claims versus an aggregate guarantee such as a generic effective rate (GER), brand effective rate (BER), or similar reimbursement methodologies reconciled after the point of sale; the magnitude of the difference between negotiated prices reported on pharmacy claim responses and end of-year reconciled effective rates; and whether claim-level reimbursement is meaningfully predictive of the amount the pharmacy actually receives over the contract year.
    - The extent to which the use of aggregate guarantee reimbursement methodologies, or the parameters of such methodologies, are negotiable between pharmacies and Part D sponsors.

APCI Comment: Part D sponsors and PBMs retain the ability to adjust pharmacy reimbursement after the point of sale, whether on individual claims, across a pharmacy's claims through effective rate reconciliations, or in aggregate across pharmacies, plans, and lines of business. Under effective rate methodologies, reimbursement for the same drug may also fluctuate at the point of sale throughout the year with no change in the drug's underlying cost.

The scale of these adjustments has been significant. MedPAC documented $12.6 billion in pharmacy DIR in 2021.[18] By redefining the negotiated price used to calculate cost sharing as the lowest possible reimbursement, CMS removed the incentive for retroactive fees, but not the ability to adjust reimbursement after adjudication. GAO's 2026 report identified effective rate arrangements in Part D pharmacy contracts and acknowledged that effective-rate true-ups could

[17] Tenn. Code Ann. § 56-7-3206(f) (requiring payment of the TennCare enhanced dispensing fee to pharmacies that would qualify as low-volume pharmacies under TennCare standards).
[18] MedPAC, *Report to the Congress: Medicare and the Health Care Delivery System*, ch. 2, fig. 2-2 (June 2023) [hereinafter MedPAC June 2023 Report].

be substantially lower than point-of-sale payment rates.[19] In FEHBP, OPM's Inspector General identified more than $415 million in spread generated through aggregate pharmacy discount guarantees that was not passed through to plans.[20]

Because PBMs can adjust reimbursement across claims, pharmacies, and plans, pharmacies have little way of knowing whether the point-of-sale price is final, and claim-level reimbursement is not reliably predictive of what they ultimately receive. Even where effective rate reconciliations result in upward adjustments, pharmacies are effectively forced to float the difference until reconciliation, subsidizing underpayment in the interim, and the process lacks transparency. The potential magnitude of these adjustments reaches billions of dollars.

Pharmacies have limited ability to negotiate these terms. Because federal antitrust law generally prohibits competing independent pharmacies from collectively negotiating reimbursement, pharmacy services administrative organizations typically function as messengers, conveying PBM contract offers rather than bargaining over reimbursement on pharmacies' behalf.

CMS standards must therefore prohibit post-adjudication adjustments to pharmacy reimbursement, whether claim-specific, pharmacy-specific, or aggregate, and prohibit tying Part D effective rates or reimbursement to reimbursement in non-Part D plans. Standards should likewise prohibit transaction, network participation, and other fees charged to pharmacies, which reduce net reimbursement just as post-adjudication adjustments do; in FEHBP alone, OPM's Inspector General identified more than $100 million in retail pharmacy transaction fees that were not passed through to plans.[21] The reimbursement adjudicated at the point of sale should be final.

Any audit recoupment should be limited to fraud, with no recoupment for clerical errors. CMS should establish this as a federal floor and require PBMs to also comply with the audit laws of the state in which the pharmacy is located, whichever is more protective of the pharmacy. PBMs already comply with these state laws in other lines of business, so this imposes no new administrative burden.

- The extent to which a pharmacy's Part D reimbursement rates are set or adjusted in relation to the same pharmacy's commercial reimbursement rates, including . . .

APCI Comment: Public data on cross-line arrangements in Part D is limited, but the record in other federal programs shows that PBMs have reserved, and exercised, the ability to reconcile pharmacy reimbursement across plans and lines of business. Express Scripts has represented in federal litigation that it does not negotiate separate TRICARE or FEHBP agreements with retail

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[19] U.S. Gov't Accountability Office, GAO-26-107393, *Medicare Part D: Payments and Contracts Between Pharmacies and Plan Sponsors That Are Vertically Integrated* (Sept. 2026, revised Oct. 6, 2026) [hereinafter GAO-26-107393].
[20] APCI Insights, "Discrepant: How OIG Audits Exposed Federal Subcontractor PBMs Diverting Hundreds of Millions in Taxpayer Dollars Under FEHBP Contracts" (Sept. 2026) (summarizing OPM OIG audit reports) [hereinafter APCI Discrepant].
[21] *Id.*

pharmacies and instead performs retail network services across federal and non-federal plans on an "undivided" and "indivisible" basis.[22]

A retail pharmacy contract quoted at a July 2026 Senate Armed Services subcommittee hearing reserves the right to use an aggregate reimbursement reconciliation and offset methodology.[23] And in responding to an OPM Inspector General audit, Express Scripts acknowledged that it "may maintain non-client specific aggregate guarantees with pharmacies and may realize positive margin."[24]

These arrangements can be both non-claim-specific and non-client-specific, and they enable PBMs to take spread after adjudication. The Inspector General found that pharmacies allow PBMs to fluctuate claim pricing so long as total business across all clients meets the negotiated discount, describing this as a practice "used by PBMs under traditional spread pricing arrangements, not transparent pricing arrangements."[25]

Across three FEHBP audits, the Inspector General identified more than $415 million in spread generated through aggregate pharmacy discount guarantees. Caremark, defending its "Overall Effective Rate" arrangements, told auditors there is "no way to untangle the mass of claims and data down to a specific claim, member, and/or client."[26]

The same dynamics can undermine Part D. GAO's 2026 review of vertically integrated Part D sponsors found effective rate arrangements in sponsors' pharmacy contracts, with true-ups that "could be substantially lower than point-of-sale payment rates," but could not determine net pharmacy payments because post-sale adjustments are reported to CMS in aggregate, not by pharmacy.[27]

Aggregate reporting also leaves no way to tell from CMS data whether a guarantee spans Part D and other lines of business, allowing a PBM to overpay on one line and recoup on another. Where it does, CMS would be unable to verify that reported Part D negotiated prices reflect what pharmacies were actually paid for Part D claims, or that the requirement that negotiated prices reflect the lowest possible reimbursement is being met. Beneficiary cost sharing, CMS subsidy calculations, and plan bids all rest on those prices.

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[22] *APCI Insights, "TRICARE Pharmacy Program: Pass-Through in Name Only?" (Oct. 2026) [hereinafter APCI TRICARE] (quoting Brief for Defendants-Appellants, Ohio ex rel. Yost v. Ascent Health Servs., LLC, No. 24-3033 (6th Cir. Apr. 30, 2025)).*
[23] TRICARE Pharmacy Program: Hearing Before the Subcomm. on Personnel of the S. Comm. on Armed Services, 119th Cong. (July 15, 2026); *see also* Greg Reybold, APCI, Responses to Questions for the Record (Sept. 2, 2026).
[24] APCI Discrepant, *supra*.
[25] *Id.*
[26] *Id.*
[27] GAO-26-107393, *supra.*

Some PBMs may carve out specific lines of business, such as Medicare, from their effective rate arrangements. But effective rate practices are widespread, and the ability to tie Part D reimbursement to other lines of business must be addressed directly. As set forth above, CMS standards should require Part D reimbursement to be claim-specific, plan-specific, and Part D-specific, and should prohibit any guarantee, reconciliation, or offset that spans Part D and any other line of business.

Reimbursement grounded in NADAC, plus a modest percentage to account for pharmacies acquiring above the national average, plus a professional dispensing fee, final at the point of sale, would make each Part D claim's reimbursement transparent and verifiable on its own terms, leaving no aggregate target against which to reconcile across lines of business.

- The predictability of final reimbursement at the time of dispensing.

APCI Comment: As set forth above, under effective rate and other post-adjudication methodologies, final reimbursement is not predictable at the time of dispensing. The point-of-sale price may be reconciled months later, and where reconciliation occurs at a non-claim-specific, and in some cases non-plan-specific, level, final reimbursement for any given claim becomes almost unknowable. Tying reimbursement to performance or outcome measures assessed further undermines predictability and transparency, because a pharmacy's payment for a claim depends on metrics measured across many claims and often outside its control. Reimbursement that is final at the point of sale, with any payment for services itemized separately, would make reimbursement fully predictable.

- Whether the remittance advice provided to network pharmacies include sufficient claim level detail for the pharmacy to determine how much it was reimbursed for each claim, including after point-of-sale adjustments;

APCI Comment: No. Adjustments reconciled at a non-claim-specific, and in some cases non-plan-specific, level cannot, by their nature, be attributed to individual claims on remittance advice. As one PBM told federal auditors in defending its effective rate arrangements, there is "no way to untangle the mass of claims and data down to a specific claim, member, and/or client."[28] A pharmacy cannot determine what it was paid for a claim when the PBM itself says it cannot. Greater remittance detail is not the solution; as set forth above, post-adjudication adjustments and fees charged to pharmacies should be prohibited. Remittance advice should then identify, for each claim, the ingredient cost, dispensing fee, and any separately itemized payment for services.

[28] APCI Discrepant, *supra*.

- Whether CMS should establish reimbursement methodologies or rates as part of the standards for reasonable and relevant pharmacy contract terms and conditions.

APCI Comment: Yes. As set forth above, Section 6223(a) of the Consolidated Appropriations Act, 2026 requires that, "[n]otwithstanding any other provision of law," Part D contract terms and conditions be reasonable and relevant according to standards established by CMS. Congress empowered, and indeed directed, CMS to establish standards that address whether reimbursement and dispensing fees "sufficiently cover the ingredient and operational costs" of network pharmacies. Leaving reimbursement methodology to Part D sponsors and their PBMs has produced the variability, below-cost reimbursement, and opacity documented throughout these comments.

CMS already has the tools to fix this. APCI recommends that the standards for reasonable and relevant contract terms and conditions establish:

1. Ingredient cost reimbursement based on NADAC, plus a modest percentage to account for pharmacies acquiring above the national average, serving as both floor and ceiling, in place of trade-secreted methodologies such as MAC and U&C-based "lesser of" provisions;

2. A professional dispensing fee based on the applicable state Medicaid fee, derived from a current cost-of-dispensing survey and adjusted for inflation, serving as both floor and ceiling, with CMS flexibility to adjust for defined access considerations such as rural or low-volume pharmacies, but not by channel, network status, or PBM affiliation;

3. Separately itemized payment for services beyond dispensing, not folded into ingredient cost or the dispensing fee;

4. Finality at the point of sale, prohibiting post-adjudication adjustments, whether claim-specific, pharmacy-specific, or aggregate; any guarantee, reconciliation, or offset spanning Part D and other lines of business; and fees charged to pharmacies; and

5. Audit recoupment limited to fraud, with no recoupment for clerical errors, under a federal floor that yields to state pharmacy audit law where state law is more protective.

This framework relies on benchmarks CMS already maintains and states already use. It is transparent, objective, and enforceable claim by claim, which allows CMS to carry out the enforcement responsibilities Congress assigned it without adjudicating pharmacy-by-pharmacy pricing disputes. It is also fiscally responsible. As a ceiling, NADAC eliminates the outlier ingredient cost payments documented above, many at PBM-affiliated pharmacies, and those savings can offset the cost of adequate dispensing fees. Georgia's experience confirms this: a state repricing of 2023 claims under NADAC plus a professional dispensing fee identified savings of approximately $10.9 million for the State Health Benefit Plan and $6 million for the University System of Georgia, as savings from bringing outlier claims down to NADAC more

than offset higher dispensing fees.[29] CMS should establish this framework as the standard for reasonable and relevant reimbursement in Part D.

B. Current Contracting Practices

- The factors CMS should consider in determining the reasonableness and relevance of contract terms and conditions between prescription drug plans and network pharmacies, including whether such terms and conditions facilitate or hinder competition, promote enrollee access to Part D drugs, and align with evidence-based quality metrics.

APCI Comment: Contract terms foster competition when reimbursement is aligned with market prices and patients can choose a pharmacy based on the care and service it provides, rather than being steered by restrictive networks.

In determining reasonableness and relevance, CMS should consider, at a minimum, the following factors, and should address each in the standards themselves:

1. Whether reimbursement is based on a transparent, objective benchmark and covers the cost of acquiring and dispensing the drug, as set forth in Section A;

2. Whether reimbursement is final at the point of sale, without post-adjudication adjustments, cross-line offsets, or fees of any kind charged to pharmacies, as set forth in Section A;

3. Whether terms apply uniformly to all network pharmacies, regardless of network status or PBM affiliation;

4. Whether terms enable steering. Preferred and narrow network designations allow sponsors to steer enrollees toward affiliated pharmacies and to extract concessions from pharmacies seeking preferred status.[30] APCI does not accept the premise of preferred or narrow networks in Part D. The statute permits plans to reduce enrollee cost sharing for drugs dispensed through network pharmacies,[31] but nothing in it limits that opportunity to a subset of pharmacies selected by the sponsor. Read together with the any willing pharmacy requirement, any network pharmacy willing to accept the applicable terms should have the opportunity to participate on those terms. Preferred, narrow, and specialty networks closed to any willing pharmacy are a regulatory construct, inconsistent with the statutory structure Congress has now reinforced through Section 6223(a), and should be reconsidered, not assumed;

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[29] *See* APCI NADAC Model, *supra.*
[30] *See* MedPAC June 2023 Report, supra, ch. 2 ("Under Part D, plan sponsors cannot set up exclusive pharmacy networks, but they can include contract terms that try to achieve the same aims, often with postsale payments contingent on pharmacy performance."; pharmacies agree to these terms in part "to obtain preferred status in a plan's pharmacy network").
[31] Social Security Act § 1860D-4(b)(1)(B), 42 U.S.C. § 1395w-104(b)(1)(B).

5. Whether quality measures are evidence-based and transparent. Such measures are appropriate, but they cannot be tied to the ingredient cost reimbursement or dispensing fee; services they reflect should be compensated through separately itemized payments; and

6. Whether terms otherwise impose conditions that hinder competition or access, including but not limited to: modification of contractual terms through provider manuals, policy bulletins, or other communications outside formal contract amendment; accreditation or credentialing requirements beyond state licensure, particularly where the accrediting body's governance includes PBM or insurer representatives; and conditioning Part D network participation on participation in the sponsor's or PBM's non-Part D networks.

- With respect to the current requirements at § 423.505(b)(18), how Part D plan sponsors differentiate among the contract terms and conditions made available to pharmacies based on whether the pharmacies are "similarly situated" to other pharmacies, what criteria sponsors use to determine that individual pharmacies are similarly situated, and how sponsors ensure consistent application of those criteria;

APCI Comment: "Similarly situated" is undefined, and its application is left to sponsors and PBMs, which have an interest in differentiating terms in favor of affiliated pharmacies. For purposes of reimbursement and network participation, all pharmacies licensed to dispense under state law should be treated as similarly situated. Any differentiation should be limited to the defined access considerations CMS establishes, as set forth in Section A, and not based on channel, network status, or PBM affiliation.

- Whether Part D plan sponsors offer any willing pharmacy terms and conditions to participate in their non-preferred networks only, or if such terms and conditions are also offered to any willing pharmacy for participation in preferred networks;

APCI Comment: As set forth above, APCI does not accept the premise of preferred or narrow networks in Part D. Offering any willing pharmacy terms only for non-preferred participation allows sponsors to formally satisfy the any willing pharmacy requirement while evading its substance, since non-preferred status carries higher enrollee cost sharing that steers patients elsewhere. The use of preferred networks grew from 70% to 98% of stand-alone Part D plans between 2014 and 2023, yet in 2023 just 0.8% of independent pharmacies were preferred by most plans, compared with nearly 70% of chain pharmacies. Pharmacies not preferred by any Part D plan faced more than three times the risk of closure.[32]

Any willing pharmacy terms should apply to all network participation. CMS should not permit preferred networks closed to any willing pharmacy: any reduced cost sharing a plan offers must be available at every network pharmacy willing to accept the applicable terms.

[32] Guadamuz et al., *supra.*

- **Specialty networks**
  - Whether pharmacies meeting the same objective criteria (for example, accreditation, dispensing capability, clinical services) are offered the opportunity to participate as specialty network pharmacies under the same terms and conditions, and how "similarly situated" is determined for specialty pharmacy purposes;
  - The extent to which limited or exclusive specialty networks, manufacturer limited distribution designations, and PBM specialty pharmacy designations overlap with, or are influenced by, common ownership between the PBM and the designated specialty pharmacy;
  - The relationship between specialty pharmacy or specialty drug designation and reimbursement terms, including whether such designation results in materially different ingredient cost reimbursement, dispensing fees, performance measures, or audit treatment;
  - Whether CMS should establish standards related to the definition of "specialty pharmacy" in the context of Part D pharmacy contracting, including any standards for the criteria a network pharmacy must meet to be eligible for specialty designation.

APCI Comment: APCI does not accept the premise of specialty networks in Part D. Like preferred networks, specialty designations are constructs that lead to manipulation and exclusion. Sponsors and PBMs can designate drugs as "specialty," including low-cost generics, and route them to affiliated pharmacies that are reimbursed at hundreds to tens of thousands of percent above NADAC. In CMS's Q2 2025 Part D pricing files, for example, the highest plan-level average price for generic teriflunomide 14 mg (30 count) was $8,312.15, against a NADAC of $23.16.[33] As set forth in Section A, the Federal Trade Commission found that the three largest PBMs paid their affiliated pharmacies more than unaffiliated pharmacies for nearly every specialty generic drug examined. Specialty designation and common ownership are closely linked, and to the extent manufacturer limited distribution designations favor PBM-affiliated pharmacies, they warrant the same scrutiny.

This practice targets some of the sickest patients. It deprives them of the choice to use their local pharmacy, disrupts and fragments their care, and can cost them more out of pocket, since specialty-tier coinsurance of 25% to 33% is calculated on these inflated prices.[34]

Criteria such as accreditation are not objective when they are set by the sponsor or PBM, or by bodies whose governance includes PBM or insurer representatives. CMS should not establish a specialty pharmacy definition or eligibility criteria that would gate participation. Any pharmacy licensed to dispense a drug under state law should be considered similarly situated and permitted to dispense it on the same terms, under the same reimbursement standards set forth in Section A.

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[33] APCI NADAC Model, *supra*.
[34] MedPAC June 2023 Report, *supra*, ch. 2.

- **Part D contracting tied to other lines of business**
    - The extent to which a pharmacy's participation in a Part D plan sponsor's non-Part D pharmacy network impacts its ability to participate in the plan sponsor's Part D network, the terms of its contract for participation in the plan sponsor's Part D network, or both;
    - Whether current Part D pharmacy contracting practices differ from non-Part D pharmacy contracting practices and, if so, information about such differences;
    - Whether standard Part D pharmacy contract terms and conditions are offered as standalone Part D contracts or as part of a broader network agreement covering multiple lines of business (for example, Medicaid managed care, commercial, exchange), and whether the multi-line structure affects the terms applicable to Part D specifically.

APCI Comment: As set forth in Section A, PBMs have reserved the ability to contract with pharmacies across lines of business through a single agreement. Express Scripts has represented that it does not negotiate separate TRICARE or FEHBP agreements with retail pharmacies but instead "negotiates a single network agreement with each pharmacy."[35] To the extent Part D terms are, or may be, embedded in a multi-line agreement between a PBM and a pharmacy, Part D participation and reimbursement can be tied to, and reconciled against, a pharmacy's participation in other lines of business.

The consequences are concrete. In response to a pharmacy that cited a state prohibition on credentialing fees, one PBM wrote:

> "The re-credentialing process is a component of [PBM]'s standard terms and conditions for network participation. It applies to pharmacies that participate in networks across [PBM]'s entire book of business (e.g., fully insured commercial plans, self-funded ERISA plans, and government programs, such as Medicare, Medicaid, TRICARE, etc.). [PBM] is willing to waive the fee if you are only seeking to service beneficiaries of plans subject to [state] law. However, this may impact your ability to fill claims for beneficiaries of plans not subject to [state] law, such as Medicare and TRICARE."

In other words, a fee prohibited by state law is conditioned on, and enforced through, Medicare participation. Absent CMS standards, a single multi-line agreement allows PBMs to use Part D as leverage to impose terms that state law prohibits elsewhere. The PBM's ability to distinguish between state-regulated and federal plans when it suits its interests also demonstrates that standalone Part D terms are entirely feasible.

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[35] APCI TRICARE, *supra* (quoting Brief for Defendants-Appellants, Ohio ex rel. Yost v. Ascent Health Servs., LLC, No. 24-3033 (6th Cir. Apr. 30, 2025)).

CMS should close off the ability for PBMs to tie Part D contracting to other lines of business. Standard Part D terms and conditions should be offered in a standalone Part D contract, Part D participation should not be conditioned on participation in any non-Part D network, and Part D terms should not be affected by a pharmacy's participation, or terms, in any other line of business.

- **Provider manuals and rate exhibits**
  - The use of provider manuals, policy bulletins, or other Part D plan sponsor or PBM communications to modify or supplement standard contract terms and conditions outside of formal contract amendment;
  - The extent to which the financial terms that ultimately determine pharmacy reimbursement are contained in documents other than the executed contract (for example, rate sheets, internal budget files, side letters, or unwritten understandings between affiliated entities), and whether and how transparency about such documents could be improved.

APCI Comment: In APCI's experience, PBMs commonly reserve the right to modify contract terms through provider manual updates and routinely do so. This practice should be prohibited. All terms and conditions governing a pharmacy's network participation and reimbursement should be set out in the executed contract. Provider manuals and similar documents may restate or implement terms already agreed to, such as notice procedures, but should not create new obligations or modify existing ones.

Separately, in APCI's experience, the financial terms that determine pharmacy reimbursement are frequently set out in rate exhibits rather than in the executed contract itself, where they can be changed or replaced without formal amendment. Offsetting a pharmacy's performance under one rate exhibit against another raises the same concerns as the effective rate reconciliations addressed in Section A. Rate exhibits and all other financial terms should be part of the executed contract, modified only through formal amendment agreed to by both parties, and not subject to unilateral amendment or offset across exhibits.

- **Negotiating leverage**
  - The role and impact of PBMs, pharmacy services administrative organizations (PSAOs), and other entities on the Part D pharmacy contracting process;
  - The relative leverage Part D plan sponsors, PBMs, and pharmacies have in negotiations over contract terms and conditions and network participation; the variation of such leverage by pharmacy type, geographic location, or other factors; and the extent to which CMS rules and guidance affect, or could affect, this balance.

APCI Comment: The leverage in Part D contracting rests almost entirely with sponsors and their PBMs. In 2021, the four largest PBMs served nearly 90% of Part D enrollment, and each owns mail-order and specialty pharmacies that compete with the network pharmacies whose terms it sets.[36] Pharmacies are offered standard terms on a take-it-or-leave-it basis. The re-credentialing letter quoted above illustrates the point: a pharmacy that invoked a state-law protection was told that doing so could cost it access to Medicare patients.

As set forth in Section A, PSAOs do not alter this balance: because federal antitrust law generally prohibits competing independent pharmacies from collectively negotiating prescription drug reimbursement, PSAOs typically function as messengers, conveying PBM contract offers rather than bargaining over reimbursement on pharmacies' behalf.

CMS rules have reinforced this imbalance by permitting preferred and specialty networks closed to any willing pharmacy, which give PBMs additional leverage over pharmacies seeking access to enrollees. The standards CMS adopts under Section 6223(a) are the most direct means of restoring balance. Objective, enforceable standards for reimbursement, uniform terms, and contracting practices would make network participation depend on willingness to serve patients rather than on accepting whatever terms a PBM dictates.

- **Recoupment, suspension, and termination**
  - With respect to pharmacy contract provisions that permit Part D plan sponsors to recoup or suspend pharmacy payment or terminate a pharmacy contract: the prevalence of such provisions; the conditions necessary to invoke such provisions, such as a credible allegation of fraud or other inappropriate billing or risk of patient harm; whether such provisions include an appeal process and, if so, the extent to which such appeal process is utilized and the outcomes of such appeals.

APCI Comment: In APCI's experience, PBM contracts commonly reserve broad, unilateral rights to recoup or suspend payment and to terminate network participation. Access to Medicare patients cannot rest on a PBM's discretion. Termination of network participation should be permitted only upon an objective government determination: exclusion under

[36] MedPAC June 2023 Report, *supra*, ch. 2.

Sections 1128 or 1128A of the Act, revocation of Medicare enrollment, or loss of state licensure. Termination without cause should be prohibited.

Suspension of payment should be permitted only where CMS, the HHS Office of Inspector General, or law enforcement has determined that a credible allegation of fraud exists. Any suspension should be limited in duration and subject to prompt review by CMS or its designee. As set forth in Section A, recoupment should be limited to fraud, with no recoupment for clerical errors. Pharmacies should have the right to appeal any recoupment to CMS or its designee, not the PBM that imposed it. Because recoupment would be limited to fraud, such appeals should be infrequent, and determinations of fraud are appropriately made by the government rather than by a contracting party.

State pharmacy audit laws already provide a workable model. Kentucky and Georgia both limit recoupment for clerical errors.[37] Georgia's protections also include, but are not limited to, a prohibition on extrapolation in calculating recoupments, limits on the number of prescriptions and frequency of audits, recoupment of disputed funds only after the audit's final disposition, including appeals, and a prohibition on paying auditors based on the amount recovered.[38] CMS already requires Part D sponsors, by contract, to "comply with State law to the extent that it is not preempted by Federal law."[39] As set forth in Section A, CMS should establish audit protections as a federal floor and require PBMs to also comply with the pharmacy audit laws of the state in which the pharmacy is located, whichever is more protective of the pharmacy. CMS should state this requirement affirmatively in its regulations and in Part D sponsor contracts, so that protections states have adopted are not lost to preemption, or to uncertainty about its scope, in Part D.

- **Contract acceptance and modification**
  - With respect to acceptance of standard Part D pharmacy contract terms and conditions. . .
  - How often standard terms and conditions, MAC lists, or other reimbursement parameters are modified mid-contract; the notice provided to network pharmacies before such modifications take effect; who has authority to make such changes; and whether pharmacies have a meaningful opportunity to decline modified terms without losing network participation;
  - Whether CMS should establish minimum review periods, disclosure requirements, or affirmative acceptance requirements (as opposed to deemed acceptance) for standard contract terms, amendments, and material reimbursement changes as part of the standards for reasonable and relevant pharmacy contract terms and conditions.

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[37] Ky. Rev. Stat. Ann. § 304.17A-741 (prohibiting recoupment for clerical or recordkeeping errors "unless the auditing entity can provide proof of intent to commit fraud"); O.C.G.A. § 26-4-118 (providing that a clerical or recordkeeping error does not by itself constitute fraud and limiting recoupment to the actual overpayment).
[38] O.C.G.A. § 26-4-118.
[39] CMS, Contract with Approved Entity for the Operation of a Voluntary Medicare Prescription Drug Plan; *see also* 42 C.F.R. § 423.505(b)(15).

APCI Comment: Pharmacies often cannot meaningfully evaluate proposed terms, for a variety of reasons, including short evaluation windows, delays in receipt, and failure to receive the requisite notice. Negative-consent provisions can work only if pharmacies receive actual notice and a genuine opportunity to evaluate and negotiate. CMS should therefore require a minimum review period of 60 days from confirmed receipt by the pharmacy, with the period beginning only once receipt is confirmed, and an extension of that period where the pharmacy is engaged in good-faith negotiation.[40]

Current regulations already require sponsors to make standard contracts available by September 15 for contracts effective January 1.[41] That requirement should extend to the complete contract, including rate exhibits and all financial and other contractual terms, so that pharmacies can evaluate the whole agreement rather than a shell. Updates to reimbursement under a transparent, agreed-upon index such as NADAC are not modifications to contract terms and should not require amendment.

Disclosure is not a substitute for the standards set forth in Section A. The RFI asks whether pharmacies receive information on effective-rate guarantees, performance measures, and DIR fee structures. Under reasonable and relevant standards, effective-rate guarantees, performance-based adjustments to reimbursement, and DIR fees should be prohibited, not disclosed. Likewise, MAC lists should be replaced by transparent, index-based reimbursement.

As addressed above, unilateral revisions and updates through provider manuals and other documents remain problematic and should be prohibited. Contract terms should be modified only through formal amendment agreed to by both parties.

- **Dispute resolution**
    - With respect to pharmacy contract terms and conditions, whether related to pharmacy reimbursement or otherwise, whether a mechanism is provided to resolve disputes about such terms, and the adequacy of such mechanisms. . .

APCI Comment: In APCI's experience, dispute mechanisms in PBM contracts are typically administered by the PBM itself, which decides disputes over terms it set and payments it made. MAC appeals, for example, are decided by the same PBM that set the price, as set forth in Section A. Contracts may also limit pharmacies' remedies through short filing windows, mandatory arbitration, confidentiality requirements, or restrictions on venue. Even where arbitration is available, its cost often exceeds the amount in dispute. A violation that is cost-prohibitive to arbitrate on a single claim can become a revenue stream for a PBM when repeated claim over claim and across pharmacies. A process in which one party adjudicates its own disputes, or in which the cost of a remedy exceeds the harm, is not an adequate mechanism.

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[40] *See, e.g.,* Ark. Code Ann. § 23-92-506(g)–(h), as amended by Act 775 of 2025 (S.B. 544) (requiring at least 60 days' notice of opt-out contracts, amendments, and renewals, delivery by both email and fax, and a follow-up notice by certified mail if no reply is received within 30 days).
[41] 42 C.F.R. § 423.505(b)(18)(i).

Pharmacies have also lacked an effective path outside the contract. Courts have held that the Part D any willing pharmacy requirement creates no private right of action for pharmacies.[42] Section 6223 provides a path. It requires CMS to establish a process for pharmacies to submit allegations of violations of the reasonable and relevant standards, prohibits sponsors from limiting a pharmacy's ability to submit contract offers and related documents to CMS, preserves pharmacies' other legal remedies, and prohibits retaliation against pharmacies that submit allegations.[43] CMS standards should make clear that no contract term, including any confidentiality, arbitration, or dispute resolution provision, may limit a pharmacy's access to that process or to other legal remedies.

Under the framework set forth in Sections A and B, the volume of disputes would fall significantly. Reimbursement tied to NADAC and a uniform dispensing fee, final at the point of sale, eliminates MAC appeals and leaves little to dispute claim by claim. Limiting recoupment to fraud would sharply reduce audit disputes. For the disputes that remain, pharmacies should have access to review by CMS or its designee, with clearly defined procedures and resolution timeframes.

- **Fostering a level playing field**
    - Incentives, if any, that help foster a level playing field between the parties;
    - Other ways to ensure transparency and fairness in Part D pharmacy contracting.

APCI Comment: The most effective way to level the playing field is not to add incentives, but to remove the levers that tilt it. As set forth above, those levers include opaque and trade-secreted reimbursement methodologies, post-adjudication adjustments, fees charged to pharmacies, preferred and specialty networks closed to any willing pharmacy, multi-line agreements that tie Part D to other lines of business, unilateral modification of terms, and dispute processes administered by the PBM itself.

Each of these levers is more powerful where a sponsor, its PBM, and pharmacies are vertically integrated. The entity setting the terms may also own the pharmacies competing for the same patients, and preferred and specialty networks can be used to steer patients to them. CMS should closely scrutinize how these conflicts of interest are leveraged, and should ensure that vertical integration cannot be used to create anticompetitive conditions. Section 6223 requires sponsors to identify pharmacies affiliated with the sponsor or its PBM.[44] CMS should use that information to compare the terms, reimbursement, and network status of affiliated and unaffiliated pharmacies, and should treat any differential treatment as a violation of reasonable and relevant standards.

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[42] *See, e.g.,* Life Star Pharmacy, Inc. v. Express Scripts, Inc., No. 4:23CV186 JAR (E.D. Mo. Mar. 4, 2024) (declining to recognize a private right of action for a pharmacy under 42 U.S.C. § 1395w-104(b)(1)(A) and 42 C.F.R. § 423.505(b)(18)).
[43] Social Security Act § 1860D-4(b)(1)(F)(i)(I), (III)(bb), (VII), (VIII), as added by Consolidated Appropriations Act, 2026, § 6223(c).
[44] Social Security Act § 1860D-42(e)(3)(B), as added by Consolidated Appropriations Act, 2026, § 6223(b).

Objective, enforceable standards addressing each of these levers, together with meaningful CMS enforcement under Section 6223, would make transparency and fairness the structure of Part D contracting rather than the exception.

C. Trends in Contract Terms and Conditions

- **Reimbursement and payment methodologies**
  - Reimbursement methodologies for dispensing services, including but not limited to the use of MAC pricing and other pricing benchmarks relied on for ingredient costs and incentive payments;
  - Payment methodologies for other payments made to network pharmacies by Part D plan sponsors or PBMs, and any payments from network pharmacies to Part D plan sponsors or PBMs (for example, network participation fees).

APCI Comment: As set forth in Section A, current methodologies, including AWP-minus, MAC, "lesser of," and effective rate pricing, are opaque and bear little consistent relationship to acquisition costs. CMS should replace them with reasonable and relevant standards based on NADAC plus a modest percentage for ingredient cost and the applicable state Medicaid professional dispensing fee. Payments to pharmacies for services beyond dispensing should be separately itemized. Payments from pharmacies to sponsors or PBMs, including network participation, transaction, credentialing, and other fees, should be prohibited.

- Performance-based pharmacy payment models.

APCI Comment: As set forth in Sections A and B, evidence-based, transparent quality measures are appropriate, but they cannot be tied to ingredient cost reimbursement or the dispensing fee. Performance-based models that reduce, withhold, or reconcile drug reimbursement after the point of sale undermine predictability and transparency and function as post-adjudication adjustments. Pharmacies should instead be compensated for the services those measures reflect through separately itemized payments. APCI addresses performance measures further in Section D.

- Terms and conditions for non-dispensing services (including information about what the non-dispensing services are and how they are compensated), and whether non-dispensing services generally are included in or negotiated outside of the standard contract terms and conditions referred to in section 1860D-4(b)(1)(A)(i) of the Act.

APCI Comment: As set forth in Section A, services pharmacies provide beyond dispensing should be compensated through separately itemized payments, not folded into ingredient cost reimbursement or the dispensing fee. Those services, and the terms on which they are compensated, should be included in the standard contract terms and conditions offered to any willing pharmacy, not negotiated selectively outside them. Otherwise, sponsors and PBMs can offer service opportunities to affiliated or preferred pharmacies while excluding others,

recreating the steering and differential treatment the any willing pharmacy requirement is meant to prevent.

- The complexity of Part D pharmacy contracting terms and conditions and issues related to transparency.

APCI Comment: The complexity of current Part D contracting is itself a transparency problem, as set forth throughout Sections A and B, and it is by design and not incidental. Layered pricing benchmarks, post-adjudication reconciliations, rate exhibits outside the executed contract, and provider-manual modifications make it difficult for pharmacies to know what they will be paid, and for CMS to verify it. History shows how complexity is used. When price concessions that could not be determined at the point of sale were excluded from the negotiated price, pharmacy price concessions grew more than 107,400 percent between 2010 and 2020, often tied to performance measures, and, as CMS itself found, shifted costs to beneficiaries through higher cost sharing.[45] The standards APCI recommends would replace that complexity with objective, claim-level terms.

- Impacts of the Inflation Reduction Act of 2022 on Part D pharmacy contracting, including the impact of maximum fair prices (MFPs) under the Medicare Drug Price Negotiation Program on Part D pharmacy reimbursement terms for both selected drugs and non-selected drugs.

APCI Comment: Requiring pharmacies to acquire selected drugs at full cost and then await manufacturer refunds to be made whole places the burden on the party in the transaction least able to bear it. Pharmacies should not be forced to float the cost of the Negotiation Program or subsidize it through delayed or incomplete refunds, and CMS should ensure they are made whole promptly. But the Negotiation Program demonstrates something important: when CMS negotiates a transparent, objective price, it can do more for program costs and beneficiaries than PBMs left to their own devices.

Section 6223(a) gives CMS a similar opportunity. Congress empowered, and indeed directed, CMS to establish reasonable and relevant standards, including standards addressing pharmacy reimbursement, "[n]otwithstanding any other provision of law." CMS can again increase transparency and lower costs, this time by grounding pharmacy reimbursement in NADAC, a market-based index it already maintains, plus a modest percentage, together with a professional dispensing fee.

[45] Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs, 87 Fed. Reg. 1842, 1910–11 (proposed Jan. 12, 2022); *see also* MedPAC June 2023 Report, *supra,* ch. 2.

- Trends related to the use of guarantees that utilize a single effective rate target for both Part D and commercial lines of business.

APCI Comment: As set forth in Section A, PBMs have reserved, and exercised, the ability to reconcile pharmacy reimbursement across plans and lines of business, including in other federal programs. Any guarantee, reconciliation, or offset spanning Part D and any other line of business should be prohibited.

D. Pharmacy Quality and Performance Measures

APCI Comment: APCI supports quality measures that are evidence-based, transparent, and within a pharmacy's control. But measures cannot be tied to the ingredient cost reimbursement or dispensing fee for a drug. Whether performance is applied as a post-adjudication clawback, as an amount a pharmacy must "earn back," or as a bonus it may "earn" on top of drug reimbursement, the effect is the same. The pharmacy's payment for dispensing a drug depends on metrics measured across many claims, often outside its control, and determined after the fact. The true price paid for the drug is obscured and can be manipulated, since a lower base rate can be offset by a bonus the pharmacy may never receive. And additional obligations are piled onto pharmacies without true additional reimbursement, as pharmacies perform added work simply to recover payment they should have received for dispensing the drug.

As set forth in Section A, services pharmacies provide should instead be compensated through separately itemized payments, offered on the same terms to every network pharmacy as part of the standard contract.

As currently applied, measures can penalize pharmacies for circumstances they cannot control, such as changes in a patient's care setting, therapy, coverage, or choice of pharmacy. Pharmacies may have no means to report these changes or correct the underlying data, even when it reduces their scores and their payments.

Where measures are used to determine separately itemized payments for services, CMS standards should, at a minimum, require that:

1. measures, their methodology, and their measure steward be disclosed in the standard contract and applied uniformly to all network pharmacies;
2. measures exclude circumstances outside the pharmacy's control;
3. pharmacies have a process to report changes in patient status or therapy and to correct inaccurate data before scores are finalized;
4. pharmacies receive timely, patient-level access to their performance data; and
5. pharmacies may appeal performance determinations to a neutral party.

These standards ensure that payments for services do not become a new channel for the opacity that reasonable and relevant standards are meant to eliminate.

E. Pharmacy Auditing Practices

APCI Comment: PBM audit practices are burdensome and frequently unfair. Problems include, without limitation, the size and frequency of audits; the mixing of Part D claims with claims from other lines of business in a single audit; recoupment based on clerical or recordkeeping errors that caused no harm to patients or the program; and recoupment of the full cost of drugs that were properly dispensed; and the use of reviews labeled as something other than audits, such as "validation reviews," "reconciliations," or "verifications," that impose the same burdens and recoupments without audit protections.

As set forth in Sections A and B, audit recoupment should be limited to fraud, with no recoupment for clerical errors, and pharmacies should have the right to appeal any recoupment to CMS or its designee rather than the PBM that imposed it. CMS standards should also:

1. limit the number of claims and frequency of audits;
2. require that Part D claims be audited separately from claims in any other line of business, consistent with standalone Part D contracting;
3. prohibit extrapolation in calculating recoupments;
4. permit recoupment only after the audit's final disposition, including appeals;
5. prohibit compensating auditors based on the amount recovered; and
6. define "audit" to include any review of pharmacy claims, records, or invoices conducted by or on behalf of a PBM or Part D sponsor, however labeled and whether desk or on-site, that may result in recoupment, chargeback, or other adverse action, including network termination.

Several states already provide these protections, and CMS already requires Part D sponsors by contract to comply with state law to the extent it is not preempted, as set forth in Section B. CMS should establish these protections as a federal floor, require PBMs to also comply with the pharmacy audit laws of the state in which the pharmacy is located, whichever is more protective of the pharmacy, and state this requirement affirmatively in its regulations and in Part D sponsor contracts.

Conclusion

Section 6223(a) gives CMS both the authority and the responsibility, "[n]otwithstanding any other provision of law," to ensure that Part D pharmacy contract terms, including reimbursement, are reasonable and relevant. Standards grounded in NADAC, a fair professional dispensing fee, finality at the point of sale, true any willing pharmacy participation, and fair audits would bring transparency to Part D reimbursement, protect beneficiaries' access to their pharmacies, and ensure that taxpayers and patients pay a fair price. APCI appreciates CMS's consideration of these comments and welcomes the opportunity to discuss them further.

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