Submitted electronically to regulations.gov

November 23, 2026

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Department of Health and Human Services
7500 Security Boulevard
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Re: CMS Request for Information – Medicare Part D Reasonable and Relevant Pharmacy Contracting Standards [CMS–4217–NC]

Administrator Oz,

The National Community Pharmacists Association (NCPA) appreciates 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*. Section 6223(a) of the Consolidated Appropriations Act, 2026 (CAA, or The Act) amends section 1860D– 4(b)(1)(A) of the Social Security Act (the Act), which requires Part D plan sponsors to permit any pharmacy that meets standard contract terms and conditions under the plan to participate as a network pharmacy of the plan. Section 6223(a) of the CAA further requires that, notwithstanding any other provision of law, for plan years on or after January 1, 2029, such standard contract terms and conditions offered by Part D plan sponsors must be reasonable and relevant according to standards established by the Secretary of the Department of Health and Human Services. Finally, section 6223(a) of the CAA requires the Secretary to issue this RFI for purposes of establishing such standards.

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.

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It is critical that CMS properly regulate reasonable and relevant contracts in Medicare Part D, considering that vertical integration continues to harm pharmacy and patients alike. A May 2026 OIG report[1] reveals several key takeaways, including that patients covered by vertically integrated health plans pay substantially higher drug out of pocket costs. Another key takeaway is that vertically integrated health insurance corporations continue to, at best, make it difficult to analyze the full cost impact on purchasers of health care. The OIG highlighted "data limitations pertaining to pharmacy payments" that made the full impacts of vertical integration on pharmacies unknown. What is known is that the vertically integrated health plans/PBMs make it difficult even for the Federal Trade Commission (FTC) to investigate their impact on consumers and competition. In comments to the FTC, NCPA has highlighted the unholy trinity of health plans, PBMs and affiliated pharmacies under one ownership, making health care less affordable due to the conflicts of interest inherent in common ownership.

More than any other segment of the pharmacy industry, independent pharmacies are often located in the underserved and rural areas that are home to many Medicare and Medicaid beneficiaries. In fact, nearly two-thirds of independent pharmacies collectively serve areas with a population of less than 50,000. Pharmacists have more medication-related education and training than any other health care professional. Pharmacists can and do assist patients in optimizing the impact of medications and decreasing patients' costs by providing essential services, including medication therapy management, immunizations, chronic disease management, and preventive care screenings, helping patients manage their health conditions and avoid costly hospitalizations. A 2022 JAMA study found that patients on average visit their pharmacist almost twice as often as their primary care provider.[2]

PBMs are systematically eradicating their competition through forced economic duress and burying them in red tape. Pharmacies in the United States are closing at an unprecedented rate. Just in the last four years, consumers have over 4,100 *fewer* pharmacies from which to choose — a more than 7 percent decrease in pharmacy choice for patients across the nation — and that pattern of pharmacy deserts is *increasing*.[3] The closures of these pharmacies harm patients, many of whom rely on their local pharmacy for first-line medical care.

The primary driver of pharmacy deserts is below-cost pharmacy reimbursements. Pharmacy deserts are areas in the country where pharmacies have disappeared and patients are stranded without a local pharmacist, who often serves as the only health care provider. Adequate reimbursements ensure healthy competition and, therefore, more choices for patients. However, in many states, the PBM market is highly concentrated both in commercial coverage but also in public programs (Medicaid managed care and Medicare Part D). A February 2026 study evaluated market concentration of PBMs using the Herfindahl-Hirschman Index (HHI), a measure of market

[1] Impacts of Vertical Integration in Medicare Part D on Sponsors' Drug Costs, Pharmacy Reimbursement, and Enrollee Cost Sharing. OIG HHS May 2026.

[2] Valliant SN, Burbage SC, Pathak S, Urick BY. Pharmacists as accessible health care providers: quantifying the opportunity. J Manag Care Spec Pharm. 2022 Jan;28(1):85-90. doi: 10.18553/jmcp.2022.28.1.85. PMID: 34949110; PMCID: PMC8890748.

[3] 2022 NCPA Digest, 2023 NCPA Digest, 2024 NCPA Digest, 2025 NCPA Digest.

concentration used by the U.S. Department of Justice merger guidelines. This study showed that 46 out of 50 states were highly concentrated in their PBM markets in Medicaid managed care and Medicare Part D. In many cases, one of the top 3 PBMs accounted for at least 50% of the market in many cases.

These concentrations result in outsized leverage, giving the PBM-insurers the ability to under-reimburse pharmacies who they often compete with. That outsized market power also enables the PBMs to steer patients to their own pharmacies, force unconscionable contract terms, conduct unfair and punitive audits, charge excessive fees, manipulate pharmacy-generated data for their own benefit, use coercive marketing tactics, and exploit undisclosed conflicts of interest. PBM data is so opaque that in its first interim staff report on PBMs, the FTC stated, "The failure of certain respondents to timely produce data and documents has hindered the ability of the Commission to perform its statutory mission and noted that the FTC would pursue a court order if needed to get that data."[4]

Pharmacy shortage areas (pharmacy deserts) affect nearly 1 in 8 people living in the United States.[5] A 2024 Health Affairs study showed that of the 88,930 retail pharmacies operating during 2010–20, 29.4 percent had closed by 2021.[6] Pharmacies continue to close in the United States with non-preferred networks in Medicare Part D being at higher risk of closure than in preferred Part D networks. Independent pharmacies are often not part of preferred networks due to PBM constraints or issues with reimbursement forcing them to opt out. The Health Affairs study highlighting this also shows that pharmacies located in Black, LatinX, and low-income areas are more likely to close.[7]

NCPA provides the following information in direct response to the RFI:

A. Pharmacy Reimbursement and Dispensing Fees

CMS seeks information about whether pharmacy reimbursement and dispensing fees paid by Part D sponsors to network pharmacies sufficiently cover the ingredient and operational costs of such pharmacies. Specific areas of interest include, and NCPA comments are within:

NCPA Policy Recommendations to this Section Generally

- Section 6223 applies "notwithstanding any other provision of law," which allows CMS to set payment-related standards despite the Part D noninterference provision in section 1860D-11(i).

[4] See Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies, July 2024.

[5] Rozelle, J.W., Vos, R.O., Guadamuz, J.S.; Veetil, S.K.O.; & Qato, D.M. (YEAR, MONTH DATE). Pharmacy Shortage Areas Map (Version 2.3) University of Southern California and National Community Pharmacists Association (USC-NCPA) Pharmacy Access Initiative. https://pharmacydeserts.com

[6] https://schaeffer.usc.edu/research/more-us-pharmacies-closed-than-opened-in-2018-21-independent-pharmacies-those-in-black-latinx-communities-most-at-risk/.

[7] https://www.healthaffairs.org/doi/10.1377/hlthaff.2024.01452.

- CMS should define pharmacy types by what a pharmacy does, not by labels a PBM assigns, and should allow terms to differ between types only where costs or services differ. This is consistent with CMS's position that standard terms, particularly payment terms, may vary by geographic area or pharmacy type, provided all similarly situated pharmacies are offered the same standard terms (91 FR 60568, citing 70 FR 4254).

NCPA Responses to Specific Bullets in the RFI

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

Part D sponsor reimbursement varies significantly by pharmacy type, geographic location, and drug type (brand vs. generic vs. specialty). Variation occurs among pharmacy types, as long-term care and specialty pharmacies have different fee schedules. Rural pharmacies can also have different fee schedules, but often it is the PBMs and plans that define which pharmacies are rural. Different payers will also reimburse differently for the same drug. There can be different reimbursement price points, determined by PBMs and plans, across a network for the same NDC, Additionally, partially due to the lack of regulatory definitions for these terms, "brand" and "generic" and specialty designations can vary, often times across agreements developed by the same PBM for different networks, even assuming the same claim, NDC and quantity.

• *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;*

NADAC as a benchmark. While NADAC is not a perfect benchmark, it is the most reflective of retail community pharmacy acquisition cost. NADAC may not be appropriate for all pharmacy types.

PAC is not a fair benchmark. While NADAC is a publicly available benchmark, PAC is proprietary and pharmacies must pay a fee to access this information. PBMs often use PAC as a benchmark to pay pharmacies less. PAC benchmarking thus results in significant costs to pharmacies.

NCPA Policy Recommendations

- NADAC most closely reflects retail pharmacy acquisition cost because it is derived from a national survey of pharmacy invoice prices and is updated weekly.
- NADAC should account for variations like purchase volume and class of trade.
- Where NADAC is not available or not applicable to a pharmacy type, another transparent acquisition-cost benchmark should apply.
- NCPA supports NADAC reporting by store type. Any reimbursement floor should use the NADAC for the pharmacy's own store type.

- CMS should set a minimum reimbursement methodology: ingredient cost no lower than NADAC (or, where NADAC is unavailable, another transparent acquisition-cost benchmark), plus a dispensing fee that covers the cost of dispensing. Sponsors could pay more.
- The total minimum reimbursement for the drug's acquisition cost (separate from dispensing fees) must at least meet the price a pharmacy can readily acquire the drug from a distributor that is capable and willing to provide that drug to the pharmacy. PBMs must be required to consider (1) the region of the country where the pharmacy is located; (2) whether a drug is brand or generic; and, (3) current market for the drug. Without an enforceable floor PBM's routinely reimburse below acquisition cost.
- CMS should treat terms that routinely pay below acquisition cost for a drug as a barrier to enrollee access and pharmacy access to networks, because they push pharmacies to stop carrying that drug or forego participation in a network altogether.
- Reimbursement below the pharmacy's cost to acquire and dispense a drug should not be considered reasonable and relevant. Retail benchmarks don't fit LTC pharmacy; NADAC, for example, is built from a survey of retail community pharmacies and therefore not appropriate for LTC pharmacy reimbursement. Any acquisition-cost standard that CMS applies to LTC pharmacies should rest on LTC pharmacy data.
- Part D LTC terms should be offered in a standalone LTC contract or a clearly separate LTC schedule. A PBM should not require an LTC pharmacy to sign both LTC and retail contracts and then move LTC patients' claims to the retail contract.
- For LTC pharmacies and retail pharmacies in urban, rural, and underserved areas, delivery distance and frequency are significant cost drivers, particularly when serving rural or geographically dispersed facilities. Dispensing fees for these pharmacies must reflect these higher costs, consistent with CMS's existing definition of dispensing fees, which recognizes delivery as a pharmacy cost.
- CMS's reasonable and relevant contracting standards should apply to every drug type. Some pharmacies have relied on small brand margins to offset losses on generics, and negotiated prices for selected drugs are eroding those margins. Terms should cover cost on each claim.

• 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;

Infeasibility of sharing actual acquisition costs. Pharmacies cannot share their actual acquisition costs with PBMs due to restrictive covenants with wholesalers. Further, PBMs and plans, who own and control pharmacies, are direct competitors to independent pharmacies, so it would be anticompetitive if independent pharmacies shared this information with PBMs and plans. Additionally, actual acquisition cost can fluctuate and can impact the cost to fill prescriptions.

And Part D regulations do not define actual acquisition cost (the definition at 42 CFR 447.503 applies only to Medicaid), and PBMs and plans define it differently for contracting purposes.

Infeasibility of sharing invoice cost data. Additionally, it is infeasible for pharmacies to share invoice cost data; as pharmacies can purchase from 3-5 sources a day, asking to compile all these invoices would be a significant administrative burden.

NCPA Policy Recommendations

- The standards should ensure invoice-based payment can work as a backstop for drugs without a reliable benchmark, but it should not replace a public benchmark. Invoice prices are often confidential under wholesaler agreements.
- Pharmacies should not be required to disclose their actual drug acquisition costs directly to Part D plan sponsors because those sponsors or their PBMs could own pharmacies that compete directly with them, creating a competitive harm.
- Any sharing of acquisition costs should go to CMS or a neutral third party, not to a PBM that owns competing pharmacies.

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

Margins vary widely by drug type. Generics, which account for about 90 percent of prescriptions, are often reimbursed at or below acquisition cost. Pharmacies have historically relied on small margins on brand drugs to offset those losses, and negotiated prices for selected drugs are now eliminating those margins on some of the highest-volume brands. Margins also vary with specialty designation, single- versus multi-source status, and launch timing, and many pharmacies report reimbursement below cost on high-cost classes such as GLP-1s. Pharmacies cannot manage this mix, which is why NCPA recommends that terms cover cost on each drug.

• *Whether, and how, reimbursement policies impact pharmacy decisions to stock certain drugs or drug classes (for example, high-cost drugs);*

Generally speaking, community pharmacies cannot afford to have high cost drugs that are poorly reimbursed sitting on their shelves, given their high carrying costs. For that reason, pharmacies will often wait to get such prescriptions before ordering these drugs, which is not an option for LTC pharmacies. Additionally, some drugs have high storage costs, for example those that have cold-chain implications. Such considerations also influence the quantity of such drugs that pharmacies have on stock. Drugs with a negotiated maximum fair price add to this pressure: pharmacies buy them at or near list price, are paid by the plan at roughly the maximum fair price, and must wait for the manufacturer's refund to make up the difference. That gap ties up cash on every fill, and it will grow as more drugs become subject to negotiated prices each year. Pharmacies now also need to consider if they can afford to stock MFP drugs. If the manufacturers are not refunding at the SDRA and the PBMs are not paying enhanced dispensing fees, having to

wait on average 23 days for payment is unsustainable. This unsustainability problem will continue to grow with more drugs being included in the Medicare Drug Price Negotiation Program.

NCPA Policy Recommendations

- The standards should apply to every drug type. A pharmacy should not be expected to cover losses on one category of drugs with margins on another.
- Reasonable terms should cover costs for each drug rather than rely on cross-subsidies across drug categories that pharmacies cannot control.

• 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;

MAC pricing lists are proprietary, arbitrary, inefficient, and not useful for pharmacies. The appeals process is very opaque and time consuming, and in the rare instance a pharmacy will be successful on appeal, the PBMs will often take money away from another drug.

MAC list disclosure has largely become a compliance exercise rather than a meaningful transparency mechanism. Some PBMs maintain thousands of different proprietary MAC lists, requiring pharmacies to navigate complicated portals and processes, at great confusion and administrative burden, just to identify the list applicable to their pharmacy.

MAC lists don't necessarily explain where the pricing information originated, what market data was considered, how the reimbursement amount was calculated, or whether the pharmacy could actually purchase the medication at that price. Giving a pharmacy a list of reimbursement prices does not give that pharmacy the information necessary to evaluate whether those prices are reasonable, challenge an inaccurate price, or hold the PBM accountable for its pricing decisions.

NCPA policy recommendations

- CMS already requires sponsors to update any pricing standard used to pay network pharmacies at least every 7 days and to disclose its source (42 CFR 423.505(b)(21)). The standards should make clear this extends to MAC lists and add: updates within **[3]** business days of a documented market price increase; appeal decisions within **[7]** business days; and, when an appeal is granted, correction of the pharmacy's affected claims, and of the same drug's claims for all other network pharmacies.
- MAC appeals should follow uniform CMS-established standards and be subject to independent review and CMS oversight.
- An incorrect payment due to an incorrect MAC list should not allow a PBM to reduce the reimbursement of a claim after point of sale.

- MAC methodology is opaque to pharmacies. A transparent alternative would be for PBMs and plans to pay generic ingredient cost at no less than NADAC. While we believe MAC lists without a drug-specific floor to be unreasonable, at a minimum, PBMs and plans should disclose the MAC methodology and list with the contract offer.
- Transparency should mean more than access to a spreadsheet. It should mean access to the information necessary to understand and validate the decisions represented in that spreadsheet.
- Bottom line: MAC lists should be prohibited, and/or the MAC should be no less than NADAC.
- All drugs should be reimbursed at a price which is at or above the price at which the pharmacy can acquire the drug from a distributor that is capable and willing to provide that drug to the pharmacy. In addition, PBMs must allow pharmacies to appeal MAC prices (to the extent that MAC prices are allowed or are needed) that fail to meet that standard and to receive the increased MAC price that meets the standard on a going-forward and retroactive basis. CMS should also specify that reimbursement for drug ingredient costs based upon an effective rate of reimbursement is unreasonable, and not permissible in Part D any willing pharmacy agreements.
- To be reasonable, definitions of drugs/claims as generic, brand, specialty, or any other category used for reimbursement purposes under the agreement must be clear and based only on criteria that are publicly available (e.g., specific Medi-Span identifiers), so as to permit the pharmacy or any third party to determine exactly what drugs/claims fall within or outside of the definition and perform any related reimbursement calculations. Plans and their PBMs must administer the agreement in accordance with these definitions and provisions.

• The use of ‘‘lesser of’’ pricing methodologies, including the use of usual and customary (U&C) pricing and how U&C is defined;

Usual and customary (U&C) pricing tends to be broadly defined by the PBMs as the cash price that a pharmacy charges the uninsured, or cash pay patients on the day of dispensing. That being said, PBMs differ widely on what discounts are included in and excluded from this price. In the broadest inclusions, discounts include zero-dollar, price matching, senior discounts, frequent shopper, and pharmacy discounts with or without enrollment fees.

In “lesser of” pricing methodologies, PBMs pay the lowest of the pharmacy's U&C price, its submitted charge, and the contract rate, and some PBMs also add the maximum fair price to that comparison for selected drugs.

<u>Industry Understanding Supports that U&C Refers to Pharmacy Retail Prices, Not Discount Card or Other Program Prices</u>

- CMS regulations define U&C only for out-of-network pharmacies (42 CFR 423.100), so each contract typically sets its own definition.
- Those contract definitions never sought to capture prices other than the retail price. For example, PBMs have testified under oath in public proceedings that they did not and do not view pharmacy savings club prices as the pharmacy's U&C prices. PBMs have repeatedly explained that they view pharmacies' retail prices, not their club prices, as the pharmacies' U&C prices. Further, PBMs' testimony as to the meaning of key terms found in many Part D contracts, including "cash transaction" and "applicable discount," is consistent with pharmacies' reporting their retail prices as their U&C prices under their pharmacy-PBM network agreements.
- As to third-party discount cards, a customer presenting a discount card pays a third-party program's negotiated price, not the pharmacy's retail price. The lower price accepted by many pharmacies when a customer presents a third-party discount card, which is often a lower price than the pharmacies' retail price, is negotiated with a third party and is subject to the terms of contractual arrangements with that third party. These third-party discount cards have similarities to the negotiated prices with PBMs and other payers.
- Finally, major PBMs often offer their own discount cards, and some automatically integrate third-party discount cards like GoodRx into the adjudication process at the point of sale for their insured beneficiaries. These offerings would not be necessary if pharmacies already reported these prices as U&C.

Federal Policy Supports that U&C Refers to Pharmacy Retail Prices, Not Discount Card or Other Program Prices

- Over two decades ago, the government published studies about discount cards that acknowledged that discount card prices are generally lower than, and therefore distinct from, pharmacies' usual or retail prices. *See, e.g.*, U.S. GAO, *Prescription Drugs: Prices Available Through Discount Cards and Other Sources* (2001), www.gao.gov/assets/gao-02-280r.pdf (finding discount card prices generally lower than pharmacy retail prices); U.S. GAO, GAO-03-912, *Prescription Drug Discount Card: Savings Depend on Pharmacy and Type of Card Used* 3 (2003), www.gao.gov/assets/gao-03-912.pdf ("For drugs purchased with PBM-administered cards, retail pharmacies accept a lower price from cardholders than their usual price[.]").
- CMS has repeatedly made distinctions between U&C prices and discount-program prices, showing the federal government did not think that discount cards affect U&C prices. Even before the creation of Medicare Part D, CMS encouraged pharmacies to offer discount-card programs to Medicare beneficiaries. In doing so, CMS distinguished between discount-card prices and "usual and customary" prices and ensured that Medicare beneficiaries could receive the lower of the two, without ever suggesting that these discount cards affected the U&C price.
- For example, CMS required pharmacies offering discount-card programs to ensure that participating Medicare beneficiaries received "the lower of the discounted price available through the program or [the] price the pharmacy would charge a 'cash' paying customer (commonly called the Usual & Customary price)[.]" 66 Fed. Reg. 37564, 375647 (July 18,

2001). Under the Medicare-Endorsed Prescription Drug Card Assistance Initiative final rule, CMS stated "the beneficiary is to get the lower of the negotiated discount price or the usual and customary price[.]" 67 Fed. Reg. 56618, 56636 (Sept. 4, 2002). CMS said beneficiaries should receive "the lower of the discounted price available . . . or the price the pharmacy would charge a 'cash' paying customer at that time." *Id.* at 56631; *see also* 68 Fed. Reg. 69840, 69862 (Dec. 15, 2003) (card enrollees should receive "the lower of the negotiated price or the pharmacy's usual and customary price for a covered discount card drug").

The Only Court Opinion to Address Third-Party Discount Cards Found These Separate Price Lists Did Not Affect U&C

- The only court opinion to address whether third-party discount card prices are U&C prices held: "The plain meaning of 'discount' does not capture the savings offered under . . . third-party discount programs." *See Nat'l Ass'n of Chain Drug Stores, Inc. v. Young*, No. 07-23-00175-CV, 2024 Tex. App. LEXIS 4091, at *20-21 (Tex. App.—Amarillo June 12, 2024, pet. denied). The Texas appellate court held that a state U&C regulation seeking "discounts" as U&C did not include third-party discount cards or pharmacy clubs because each had "their own price lists and structures;" these third-party discount cards and pharmacy clubs did not reduce the pharmacy's regular retail prices. *See id.* at *21, n.7.

Practical Considerations

- If Medicare Part D or other payers seek the prices of third-party discount cards as U&C, then pharmacies may be financially unable to continue to accept discount cards. Many patients depend on GoodRx, SingleCare, Blink, or other discount cards when their copays are too high or their drugs are not covered by their insurance at all.
- For consumers on tight budgets who rely on discount cards to pay for their medications, losing access to lower-priced medications would be devastating. Elimination of an option that provides lower-priced medication to the underinsured and uninsured would directly contravene the Administration's policy to promote affordable access to prescription drugs.

NCPA policy recommendations

- CMS regulations define usual and customary (U&C) only for out-of-network pharmacies (42 CFR 423.100), so each contract sets its own definition. The standards should define U&C as the pharmacy's own cash price to the general public, excluding discount cards, manufacturer direct to consumer cash prices and PBM-administered cash programs.

• The use of machine learning to estimate acquisition costs;

• Opportunities for the use of artificial intelligence (AI) with respect to Part D pharmacy reimbursement;

NCPA and our members are concerned that PBMs and plan sponsors will use AI to drive down reimbursement.

NCPA policy recommendations

- Estimates, whether produced by machine learning or other models, should not replace observed acquisition costs. If a sponsor uses a model, its method and inputs should be disclosed to the pharmacy and subject to appeal.
- CMS should oversee any machine learning or other model used to set pharmacy payment in Medicare Part D, including by reviewing its methods and inputs. Any AI tool used to set or adjust pharmacy payment, or to select claims for audit, should be disclosed to the pharmacy, explainable, and subject to the same appeal rights as any other payment decision.

• Information on standard Part D pharmacy contract terms and conditions relating to dispensing covered Part D drugs to 340B patients enrolled in Part D, including whether such 340B specific terms and conditions are common, and whether and how Part D plan sponsors determine when a claim is for a 340B patient for which the pharmacy acquisition cost is less than the plan's negotiated price;

NCPA views 340B specific terms and conditions as not common, as we generally have not seen many (if any) 340B-specific terms to date in pharmacy network contracts with PBMs administering Part D plans. We are also not aware of 340B-specific terms in the draft cost-plus contracts circulating in the market.

We also generally have not seen Part D plan sponsors often ask pharmacies for support in determining when a claim is for a 340B patient for which the pharmacy acquisition cost is less than the plan's negotiated price. We have seen a few PBMs explore asking for pharmacies to include 340B identifiers at the point of sale, which pharmacies have challenged as not practicable given the retroactive identification, generally outside of the drafting of the base agreements or any formal amendments.

We do think we could potentially see more of a demand and pressure for these terms in pharmacy network contracts, which may arise both from emerging cost-plus models and potentially indirectly from increasing manufacturer efforts for there to be identification of 340B drug claims, particularly in the context of Part D.

- First, between the potential "rebate model" for Part D drugs subject to negotiated prices, as well as the data-driven mechanisms for excluding 340B utilization from Part D inflation rebates, federal program business under Part D is perceived to provide greater flexibility to implement claims identification mechanisms, without regard to state limits that may apply.
- Second, although manufacturer rebate contracts often exclude 340B units from rebate-eligible utilization, those contracts generally have not proscribed specific standards or

actions PBMs must take to identify 340B claims. As a result, manufacturers have become increasingly concerned with duplicative rebate claim exclusion and processes in the context of very significant disputes, and some have recently sought to introduce refined standards into their standard rebate contracts. These concepts include dispute limits, agreed-upon contractual standards to "define" a 340B claim for identification purposes, enhanced data sharing, and enhanced finality in audits and disputes.

- Third, we believe these manufacturer pressures could increase given that, in parallel with the rollout of their cost-plus model to pharmacies, PBMs are also rolling out new models under which manufacturer rebate funds would be paid up front, through a revolving fund of sorts, and then applied to payment amounts due to pharmacies from PBMs. Putting these two models together, manufacturers may be sensitive to the risks of "pre-funding" rebates for potentially duplicative (or at least, cost-priced) 340B claims or of their ability to claw back pre-funded amounts that have been paid on 340B claims that may be contractually ineligible for discounts.

Although these changes may be forthcoming, pharmacies have difficulty identifying which prescriptions are 340B prescriptions at the point of sale, since that information is typically known by the hospital/provider and not the contract pharmacy.

NCPA policy recommendations

- Terms should not reduce payment on the assumption that a claim is a 340B claim.
- Contract pharmacies should not be required to identify 340B claims.
    - NCPA supports CMS not requiring pharmacies to identify 340B claims, and re-emphasizes the inability of pharmacies to identify those claims either proactively or retroactively. NCPA has found that the N1 transaction is not feasible as it is not adopted by pharmacy information systems. For details of NCPA's position, see our July 2024 comments to CMS' Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027, as well as our March 2023 comments to CMS' Medicare Part D Drug Inflation Rebates Paid by Manufacturers: Initial Memorandum, Implementation of Section 1860D-14B of Social Security Act, and Solicitation of Comments

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

In a 2024 *Health Affairs* study, the researchers found that of the 88,930 retail pharmacies operating during 2010–20, 29.4 percent had closed by 2021, and pharmacies in predominantly Black and Latinx neighborhoods faced a higher risk of closure than those in White neighborhoods. Independent pharmacies were at greater risk for closure than chain pharmacies across all

neighborhood and market characteristics. Pharmacies in neighborhoods with more Medicaid and Medicare patients were also more likely to close.

A 2025 follow-up tied those closures directly to Part D. Pharmacies not preferred by any Part D plan were 3.1 times more likely to close, and pharmacies entirely out of network were 4.5 times more likely to close.[8] Although 4 in 10 pharmacies were independently owned in 2023, just 0.8 percent of them were preferred by most plans, compared with 70 percent of chain pharmacies. The gaps are geographic as well: 171 counties, home to 1.1 million people across 26 states, had no pharmacies participating in Part D preferred networks.

NCPA policy recommendations

- CMS must retain and strengthen both the convenient access standard for long-term care pharmacies and the standards for convenient access to network pharmacies.
- CMS should closely review the Essential Retail Pharmacy data reported by Part D sponsors and PBMs for preferred pharmacy access and reimbursement, especially amongst non-affiliated pharmacies.
- CMS should use its essential retail pharmacy reports under section 1860D-42(e) to test whether its standards preserve access where few pharmacies remain and should review reimbursement to those pharmacies as part of enforcement.
- Below-cost reimbursement is a leading cause of pharmacy closures. CMS should use its essential retail pharmacy reports under section 1860D-42(e) to track whether its standards slow or reverse closures.

• Costs that are considered within the scope of dispensing fees, and whether dispensing fees paid by Part D sponsors sufficiently cover those costs;

CMS's definition of dispensing fees includes pharmacist time, quality assurance, packaging, delivery, salaries, and facility and technology costs (42 CFR 423.100). Often times, Part D sponsors pay a zero or negligible dispensing fee, which does not sufficiently cover those costs. Absent an explicit requirement that dispensing fees actually cover such costs, pharmacies provide dispensing and filling services below cost and struggle to find alternative means to offset losses. In Medicare Part D, dispensing fees for retail pharmacy averages less than $1.00. Oftentimes, PBMs pay a $0 dispensing fee in Medicare Part D.

NCPA policy recommendations

- For retail pharmacies, dispensing fees must be at a level no less than the Medicaid fee-for-service dispensing fee for the given pharmacy type in the applicable state. States set these fees from cost-of-dispensing data that CMS reviews and approves (42 CFR 447.518(d)), so they offer a ready-made, state-specific floor.

[8] https://schaeffer.usc.edu/research/pharmacy-networks-closures-medicare-pbms/.

- Dispensing fees should cover the cost of dispensing on their own. CMS defines dispensing fees as paying for costs "in excess of the ingredient cost" (42 CFR 423.100). A margin on the drug, which a sponsor can eliminate at any time by changing its MAC list, cannot substitute for a fee that covers the cost of dispensing.
- CMS's definition of dispensing fees includes pharmacist time, quality assurance, packaging, delivery, salaries, and facility and technology costs (42 CFR 423.100). Standard terms should pay a dispensing fee that covers those costs, informed by cost-of-dispensing studies like many states use to set Medicaid dispensing fees.
- Dispensing fees must be based on the cost of dispensing, considering the geographic location of the pharmacy.
- Dispensing fees must align with the level of service and operational cost of community retail and long-term care pharmacies, respectively.
- CMS must require PBMs to disclose the rates that they pay to pharmacies in advance.
- To ensure NADAC figures are accurate, CMS should publish any change to the NADAC methodology in the Federal Register for notice and comment.

• *How dispensing fees are determined in Part D and outside of Part D;*

In Medicaid, states still rely heavily on state-based or regional-based, cost of dispensing surveys to benchmark dispensing fees.

Medicaid fee-for-service pharmacy reimbursement provides an established framework for recognizing the cost of dispensing a prescription separately from the cost of acquiring the medication. The professional dispensing fee is only one component of a two-part formula used to reimburse pharmacies for drugs dispensed to Medicaid beneficiaries; the other component covers the drug's ingredient cost. Under the 2016 CMS Covered Outpatient Drugs Final Rule, states must establish professional dispensing fees through their Medicaid state plans that are data-driven and reflect the actual costs associated with dispensing these drugs and the associated professional services. When proposing changes to either the acquisition cost or professional dispensing fee reimbursement, states must evaluate both components and submit supporting information demonstrating that the proposed reimbursement reflects actual acquisition and dispensing costs and maintains sufficient access to pharmacy services. State cost of dispensing studies providing data to inform these payment decisions.

As of October 2026, Medicaid professional dispensing fees for standard, non-specialty prescription drugs range from as low as $8.30 for high volume pharmacies in Ohio (with lower volume pharmacies receiving a higher dispensing fee) to as much as $22.17 for off the road, non-tribal pharmacies in Alaska. NCPA's review of publicly available state cost-of-dispensing studies conducted over the past five years found that the average of the reported weighted means for non-specialty pharmacies was $11.25 per prescription. These figures reflect different study populations, time periods, and methodologies and should not be interpreted as a direct measure of cost growth or as the dispensing fees currently paid by Medicaid programs.

State and national data illustrate the true costs associated with dispensing prescriptions. A national study published by NACDS, NASP, and NCPA in 2020 found that the mean overall cost of dispensing a prescription based on 2018 data was $12.40. Adjusted for inflation, this makes the current cost of dispensing approximately $16.64. Further, according to our *2026 NCPA Digest*, in 2025, the cost of dispensing for the average independent community pharmacy is $14.74. These figures provide context for the professional and operational costs pharmacies incur beyond purchasing the medication.

Part D dispensing fees for LTC pharmacies have commonly been $1 or less for generics, which make up about 90% of LTC prescriptions, and around $4.50 for brands. A 2024 cost analysis found an LTC cost to dispense of about $17.65, before the added pressures of the Inflation Reduction Act. Even state Medicaid dispensing fees are multiples higher, averaging $10-$12 in dispensing fees. CMS's definition of dispensing fees already includes pharmacist time, special packaging, delivery, and the incremental costs of LTC dispensing (42 CFR 423.100). CMS should establish a minimum payment standard for LTC dispensing fees, informed by a cost survey specific to LTC pharmacy.

• *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;*

NCPA policy recommendations

- Yes, dispensing fees should be required to cover the cost of dispensing irrespective of the ingredient cost reimbursement.
- Standard terms should pay a dispensing fee that covers dispensing costs, informed by cost-of-dispensing studies like those states use to set Medicaid dispensing fees.
- State Medicaid programs pay ingredient cost based on acquisition cost plus a professional dispensing fee (42 CFR 447.512), and many set that dispensing fee from cost-of-dispensing surveys. That is a workable model for Part D.
- The cost of dispensing should be adjusted annually based on consumer price index (CPI) and cost-of-living adjustments (COLA).
- Ingredient cost calculations for the drug must be based on a public and transparent benchmark or methodology to establish a reasonable reimbursement methodology for ingredient cost.

• *Whether and how dispensing fees vary by pharmacy type, pharmacy services, or other factors;*

NCPA policy recommendations

- Dispensing fees should reflect the cost of the service. CMS's definition already recognizes incremental costs of different dispensing methods and of LTC dispensing (42 CFR 423.100). Compounding, LTC dispensing, and specialty handling cost more and should be paid accordingly.

- For high-priced drugs above $500, regardless of setting, PBMs and plans should reimburse a handling fee of 3 percent, taking into account carrying cost involved, including the cost of capital, inventory risk, and, for selected drugs, waiting on the MFP refund.
- Short-cycle dispensing fees in LTC should be paid as drugs are dispensed, not as a roll up at the end of the month.
- Dispensing fees should follow the services provided, not the enrollee's setting. CMS's regulations define an LTC facility as a SNF or nursing facility (42 CFR 423.100), but CMS has told sponsors that specialized packaging and delivery for residents of ALFs and other non-LTC settings are allowable dispensing fee costs (December 15, 2021 memo; Prescription Drug Benefit Manual, Chapter 5, section 20.7). The standards should make clear that paying less for the same LTC pharmacy services because an enrollee lives in an ALF, group home, or other congregate setting is not reasonable and relevant.

• *Impacts of post-adjudication adjustments on net reimbursement rates;*

PBMs are often loading incorrect MAC lists and making what appear to be arbitrary post-adjudication adjustments against the pharmacy, even after CMS's 2022 rule requiring pharmacy price concessions to be reflected at the point of sale beginning in 2024. While states have limited the ability of PBMs to claw back payments in Medicaid and commercial payers, pharmacies do not have such protections in Medicare. Often pharmacies need to readjust or re-adjudicate claims within 30 days, which is a very tight timeline.

<u>NCPA policy recommendations</u>

- Every post-adjudication adjustment should be disclosed claim by claim, explained, and open to appeal. Arbitrary adjustments that reduce payment after the point of sale should be prohibited.
    - Arbitrary adjustments that cannot be verified or are unsubstantiated and reduce payment after the point of sale create unreasonable financial risk for pharmacies and are reflective of PBMs and plan sponsors leveraging their outsized market and operational power in uncompetitive ways.
- CMS must require that PBMs and plans make final payment to the pharmacy for the prescription at the point of sale and must prohibit reconciliations that reduce payment after a claim is paid. Otherwise, any standards established for reasonable reimbursement will be hindered by PBMs through clawbacks.
- Post-adjudication adjustments need to be transparent to the pharmacy.
    - PBMs should be prohibited from re-adjudicating a claim without pharmacy knowledge (i.e., the PBM should document the date and time and person).
    - Using 835 remittance advice is not sufficient to demonstrate pharmacy knowledge of re-adjudication.

• *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.

Our retail pharmacy members have noted that effective rates are generally no longer present in Medicare. Post-adjudication changes to reimbursement such as reversals and rebillings are present via the MAC list. LTC pharmacies still have GERs.

NCPA policy recommendations

- CMS defines the negotiated price as the lowest possible reimbursement the pharmacy will receive, in total (42 CFR 423.100). A later reconciliation that reduces payment means the price on the claim was not the lowest possible reimbursement. Standard terms should make claim-level payment final, prohibit downward reconciliations, and allow only upward adjustments disclosed in advance.
- Pharmacies should know what they will be paid when they dispense. Final claim-level payment and complete terms at offer would achieve this.
- Standard terms should state the complete reimbursement methodology at the time of offer. PBMs and plans should not vary payment for the same LTC pharmacy services based on the setting where the enrollee lives given the same set of services are being provided regardless of the enrollee's residence.
- CMS should eliminate generic effective rate (GER) and brand effective rate (BER) contracts, and other aggregate guarantees reconciled after the point of sale.

• 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:

++ The prevalence of contract provisions that tie Part D reimbursement rates to commercial reimbursement rates, and any variances across pharmacy types.

Many of our members have expressed that such contract provisions are very prevalent.

NCPA Policy Recommendations

- Participation in a Part D network should not be conditioned on participation in any other line of business, and Part D terms should not change based on it.
- Part D terms should stand on their own. A guarantee that blends Part D with commercial business lets a PBM shift payment between lines of business, which can raise Part D negotiated prices and, with them, enrollee cost sharing, and Medicare subsidies. As a result, this could lead to unreasonable and irrelevant terms for non-Part D lines of business that serve as barriers to participation in Part D networks. The standards should prohibit blended guarantees.
- Part D terms should be offered in a standalone Part D contract or a clearly separate Part D schedule, so they can be evaluated and enforced on their own.

• *The predictability of final reimbursement at the time of dispensing;*

Most of our members have indicated that final reimbursement is not predictable at the time of dispensing.

• *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; and*

Our members have expressed difficulty in understanding the remittance advice. Sometimes these files have fees and line items that our members do not understand, and members have expressed that PBMs and plan sponsors fail to specify what the service level adjustments are linked to.

If GER/BER is used in Part D contracts, the remittance advice likely does not have sufficient data to determine final claim-level reimbursement. It may be difficult for the pharmacy to determine which drugs are on either list (i.e., branded generics or authorized generics).

NCPA Policy Recommendations

- Remittance advice should show, for each claim, the amount paid at the point of sale and every later adjustment, with a reason code.

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

NCPA Policy Recommendations

- PBMs and plans should pay generic ingredient cost at no less than NADAC.
- For retail pharmacies, dispensing fees must be at a level no less than the Medicaid fee-for-service dispensing fee for the given pharmacy type in the applicable state. States set these fees from cost-of-dispensing data that CMS reviews and approves (42 CFR 447.518(d)), so they offer a ready-made, state-specific floor.
- CMS should establish a minimum payment standard for LTC pharmacy dispensing fees, informed by a cost survey specific to LTC pharmacy, or at a minimum make clear that reimbursement below the pharmacy's cost to acquire and dispense the drug is not reasonable and relevant. Section 6223 directs CMS to set these standards "notwithstanding any other provision of law."

B. Current Contracting Practices

CMS seeks information regarding current Part D plan and network pharmacy contracting practices. Specific areas of interest include:

• 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;

Credentialing process. The credentialling process of pharmacies by PBMs is not uniform, onerous, and contributes to significant administrative burden. Each PBMs credentialing requirements may vary. During the initial credentialing process, pharmacies are generally required to submit approximately 8 to 11 standard documents, although the exact number may differ based on factors such as the number of pharmacists employed by the pharmacy. For newly established pharmacies, additional onboarding and credentialing requirements typically apply. These requirements may range from a few pages to several pages of questions and attestations that must be completed. While some PBMs accept documentation maintained through the NCPDP DataQ platform, most require pharmacies to submit credentialing documentation directly to the PBM while also ensuring their information and supporting documents remain current within NCPDP.

Typically, PBMs require pharmacies to produce at least some of the following:

- Current State Board of Pharmacy License(s)
- Current General & Professional Liability Insurance Coverages
- Pharmacist-In-Charge (PIC) License
- All active pharmacist licenses
- Current DEA Certificate/License
- Federal Tax ID document (W9)
- IRS document showing EIN
- NPPES NPI Registry Verification, Confirmation Letter, or Email
- Managing Member List, if applicable
- Medicare Certification Letter, if applicable
- Accreditation Certificates and/or Certifications, if applicable

NCPA Policy Recommendations

- To be relevant, a contract term must directly relate to the pharmacy's provision of drugs to enrollees of Part D plans and the plan/PBM's payment for same in accordance with Part D requirements. Provisions that do not meet these criteria are irrelevant and should not be included in an any willing pharmacy contract.
- A term should be considered reasonable and relevant only if it (1) pays at least the pharmacy's cost to acquire and dispense the drug; (2) is fully disclosed at the time of offer and affirmatively accepted; (3) applies the same way to affiliated and unaffiliated pharmacies; (4) relates to the pharmacy's Part D services rather than unrelated business;

and (5) can be verified and enforced through CMS' allegation process. These factors serve the competition, access, and quality considerations CMS identified.

- All contracts for pharmacies currently in network, including complete terms, including all rates, fees, guarantees, and performance terms, should be executed by October 1 preceding the plan year.
    - The pharmacies that have these executed contracts must appear on plan finder by October 15, the first day of annual elections.
- PBMs should not have their own credentialling process.
- Any credentialling in Medicare Part D should be standardized, and should be at no cost to pharmacies.
- CMS should create standardized enrollment requirements, require use of reliable NCPDP data where available, establish onboarding and rate-loading deadlines, and prohibit unreasonable application fees. All fees should be the same no matter what region/area a pharmacy is in. PBMs charge more for pharmacies in high volume areas.
- PBMs should not have unilateral ability to re-classify a LTC closed door facility as a retail pharmacy and reimburse at retail rates, ignoring their class of trade.

• 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;

Members have expressed that this question is difficult for pharmacies and PSAOs to answer given the limited insights plan sponsors and their PBMs provide pharmacies on relative treatment of their pharmacies.

<u>NCPA Policy Recommendations</u>

- In general, PBMs shouldn't be allowed to arbitrarily designate a pharmacy as a particular type of pharmacy in order to preclude their participation in a specific network.
- CMS should ensure Part D sponsors and their PBMs are required to provide pharmacies and PSAOs clarity on "similarly situated" pharmacies, including which pharmacies they consider to be similarly situated, why, and how their treatment of similarly situated pharmacies complies with CMS requirements to treat all similarly situated pharmacies the same.

• 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;

Our members have indicated that they have only seen any willing pharmacy terms and conditions in non-preferred networks. Our members' experience makes it clear that Part D sponsors and

their PBMs attempt to reserve access to preferred networks for affiliated pharmacies, creating an uncompetitive dynamic that not only increases short term costs, but also impacts long term access to pharmacy services as independent competitors are squeezed out.

NCPA Policy Recommendations

- Given the use of preferred networks across Part D sponsors and the concentration of affiliated pharmacies in those networks relative to that for independent pharmacies, it is critical for CMS to ensure that standard terms for preferred networks should be available to any pharmacy willing to accept them, and that those standard terms be reasonable and relevant.
- The "any willing pharmacy" standard should apply to preferred networks as well as non-preferred networks. A pharmacy that accepts a preferred network's standard terms, which must be reasonable and relevant, should be allowed to join it.
- CMS must require that any pharmacy that meets published objective criteria should be able to participate in the Part D plan standard or preferred network on the same terms and conditions.
- CMS must require that PBMs and plans hold PBM-affiliated and unaffiliated pharmacies (like independent pharmacies) to the same terms.
- CMS should closely review the Essential Retail Pharmacy data reported by Part D sponsors and PBMs for preferred pharmacy access and reimbursement, especially amongst non-affiliated pharmacies.

• 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;

NCPA Policy Recommendations

- Specialty network terms should be available to any pharmacy that meets published, objective criteria, such as accreditation, and demonstrated capability to handle the drug, on the same terms offered to other participating pharmacies.
- CMS should set objective criteria for deciding which pharmacies are similarly situated (services offered, licensure, accreditation), and sponsors should publish how they apply them. Affiliation with the sponsor or its PBM should never be a criterion.

• 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;

Members have expressed difficulty in filling specialty medications, as PBMs are steering such medications to their affiliated pharmacies.

• 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.

PBMs and plans do not have a uniform definition of "specialty pharmacy."

NCPA and its members are concerned with defining "specialty pharmacy" as this could create a broad definition that would be abused by PBMs and plans, and further facilitate PBMs and plans to exclude pharmacies from networks, or alternatively allowing PBMs and plans to exclude and manage specialty drugs exclusively, and apply distinct fee schedule rates to specialty drugs. Additionally, PBMs and plans could use such a definition to establish onerous accreditation requirements on pharmacies.

<u>NCPA Policy Recommendations</u>

- The FTC's interim staff reports describe how the largest PBMs route specialty drugs to their own specialty pharmacies. CMS should require sponsors to report which pharmacies may dispense each restricted drug and whether those pharmacies are affiliates.
- CMS should not allow PBMs to define specialty pharmacy.
- CMS should establish a list of drugs which should be deemed to be "specialty." Sometimes PBMs do not pay specialty drugs at higher specialty rates if they are generic equivalents, even if the drug requires the same level of specialized handling. If a brand drug is a specialty drug, its generic equivalent should also be paid at specialty rates.

<u>Suggested definition of "specialty drug"</u>

NCPA suggests the following definition of "Specialty drug":

"Specialty drug" means any of the following prescription medications:

(1) A medication that is subject to restricted distribution by the United States Food and Drug Administration; or

(2) A medication that is subject to a bona fide limited distribution arrangement established by the drug manufacturer based on clinical, safety, handling, or regulatory considerations, under which the manufacturer limits the pharmacies authorized to dispense the medication.

A prescription drug shall not be considered a specialty drug solely because of its cost, reimbursement amount, route of administration, or designation as a specialty drug by a pharmacy benefits manager, health benefit plan, insurer, or pharmacy owned by or affiliated with any such entity.

Except where dispensing is prohibited or restricted by federal or State law, regulation, an applicable requirement of the United States Food and Drug Administration, or a bona fide limited distribution arrangement described in subdivision (2), any pharmacy licensed by the Board of Pharmacy may dispense any prescription drug, including a specialty drug, when dispensing the drug is within the pharmacy's license and scope of practice.

A pharmacy benefits manager, health benefit plan, or insurer shall not prohibit, restrict, or otherwise prevent a pharmacy from dispensing, or receiving reimbursement for dispensing, a prescription drug that the pharmacy is authorized to dispense by the Board of Pharmacy and that is within the pharmacy's license and scope of practice.

A pharmacy benefits manager, health benefit plan, or insurer shall not require a pharmacy to obtain any accreditation, credential, certification, designation, or other qualification **beyond those required by the Board of Pharmacy or by State or federal law** as a condition of dispensing or receiving reimbursement for a prescription drug.

A pharmacy benefits manager, health benefit plan, or insurer shall not require or induce a covered person to obtain a prescription drug exclusively from, or provide more favorable coverage or terms for obtaining the drug from, a pharmacy owned by, affiliated with, or under common ownership or control with the pharmacy benefits manager, health benefit plan, or insurer when another participating pharmacy is authorized to dispense the drug under this section.

A pharmacy benefits manager, health benefit plan, or insurer shall not impose, directly or indirectly, any network participation, credentialing, accreditation, certification, performance, technological, volume, ownership, or other requirement that has the purpose or effect of preventing or materially restricting a pharmacy otherwise authorized by the Board of Pharmacy from dispensing a prescription drug, unless the requirement is expressly required by State or federal law.

• *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;*

PBMs for a Part D sponsor may require that a pharmacy enter into a network contract under which it would provide products or services for plans or programs other than the Part D plans for which it is exercising its any willing pharmacy right, such as commercial health plans, Medicaid

managed care plans, discount programs, or unspecified Part D plans. Some PBM agreements provide that a pharmacy will be deemed to elect to join any PBM network that the PBM identifies as applicable to a claim that the pharmacy submits, without the pharmacy even knowing what plan or program applies to the claim, or the associated reimbursement terms to which the pharmacy is deemed to have agreed.

NCPA Policy Recommendations

- Participation in a Part D network should not be conditioned on participation in any other line of business, and Part D terms should not change based on it. A pharmacy should be able to accept a sponsor's Part D terms without accepting its terms for any other line of business, and declining, disputing, or terminating non-Part D terms should not affect the pharmacy's Part D participation or Part D terms.
- Tying Part D participation to non-Part D terms runs against the purpose of the any willing pharmacy requirement. CMS has long interpreted that requirement to call for reasonable and relevant terms that minimize barriers to pharmacy participation in Part D networks (83 FR 16440, 16590 (Apr. 16, 2018)), and section 6223 now directs CMS to set standards for those terms. When a PBM bundles Part D with commercial, Medicaid managed care, or exchange business, it can load terms onto the non-Part D side, such as below-cost rates, onerous audit and recoupment terms, or unilateral amendment rights, that would not be reasonable or relevant in a Part D contract. A pharmacy that cannot accept those terms loses access to the Part D network as well. CMS should treat any requirement to accept non-Part D terms as a condition of Part D participation as a Part D term subject to the standards.
- Part D terms should stand on their own. A guarantee that blends Part D with commercial business lets a PBM shift payment between lines of business, which can raise Part D negotiated prices and, with them, enrollee cost sharing and Medicare subsidies. As a result, this could lead to unreasonable and irrelevant terms for non-Part D lines of business that serve as barriers to participation in Part D networks. The standards should prohibit blended guarantees.
- Part D terms should be offered in a standalone Part D contract or a clearly separate Part D schedule, so they can be evaluated and enforced on their own. Multi-line agreements should not include cross-default, cross-termination, or cross-offset provisions that let a dispute, termination, audit finding, or recoupment under another line of business reduce Part D payment or end Part D participation.

• 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;

Many of our members have expressed that they are often offered standard Part D pharmacy contract terms and conditions as part of a broader network agreement covering multiple lines of business.

NCPA Policy Recommendations

- Participation in a Part D network should not be conditioned on participation in any other line of business, and Part D terms should not change based on it.
- Part D terms should stand on their own. A guarantee that blends Part D with commercial business lets a PBM shift payment between lines of business, which can raise Part D negotiated prices and, with them, enrollee cost sharing and Medicare subsidies. As a result, this could lead to unreasonable and irrelevant terms for non-Part D lines of business that serve as barriers to participation in Part D networks. The standards should prohibit blended guarantees.
- Part D terms should be offered in a standalone Part D contract or a clearly separate Part D schedule, so they can be evaluated and enforced on their own.
- Where a PBM uses one agreement for several lines of business, the Part D terms should be separately stated, separately accepted, and separately amendable, and a change to another line's terms should not change the Part D terms or the pharmacy's Part D participation.
- Differences between a pharmacy's Part D terms and its terms for other lines of business with the same PBM should reflect differences in cost or service, not the PBM's leverage.

• 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;

Contracts frequently incorporate all requirements of a pharmacy manual, and sometimes other materials, such as unspecified plan or PBM policies or payor sheets, into the contract by reference. Many plans/PBMs have moved various material terms out of the contract signed by the pharmacy and into a pharmacy manual, and provide in the contract that all terms of the pharmacy manual, as unilaterally modified by the plan/PBM from time to time, are incorporated into the contract. Manuals often contain onerous and unreasonable obligations of the pharmacy, including obligations that go beyond applicable law.

NCPA Policy Recommendations

- CMS must set minimum contract review periods, require clear disclosure, and affirmative acceptance of standard contract terms, amendments, and material reimbursement changes, and restrict any unilateral mid-year changes.
- CMS must also make clear that provider manuals, bulletins, and portal notices cannot change payment or other material terms outside a formal amendment.
- Every financial term that affects pharmacy payment should be in the executed contract or a schedule to it and given to the pharmacy. Terms that exist only in side letters or understandings between affiliated entities should be unenforceable against the pharmacy and reportable to CMS.
- A contract is not reasonable unless it contains all terms and conditions creating rights or obligations of the parties. Reference to a manual for certain operational information (e.g., help desk information or details of certain claims submission requirements) or regulatory requirements (such as Part D flow-down requirements) can be acceptable, so long as the requirements accurately describe the respective regulatory obligations of the plan/PBM and the pharmacy (i.e., without shifting plan obligations to the pharmacy).
- CMS should require notification to pharmacies of any updates to pharmacy manuals before they go into effect (at least 30 days in advance, except where the update relates to a change in applicable law that takes effect sooner), and provide that, except for changes required to be included in the contract due to a change in law, changes to any of the pharmacy's obligations to which the pharmacy objects (within 30 days of notice) will not be deemed to bind the pharmacy.
- Plans/PBMs should not have the right to terminate an agreement or the pharmacy's participation in any network due to its refusal to consent to manual changes as provided above.
- Contractual provisions should also supersede any conflicting pharmacy manual terms.

• 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;

Most contracts between PBMs and pharmacy do not contain the financial terms in the contract, which are contained in rate sheets or other exhibits to the contract. And under the terms of many rate sheets incorporated into base contracts, the reimbursement that the pharmacy is paid may be less than the price at which the drug is available for purchase from pharmaceutical distributors. This primarily occurs in two circumstances:

- The plan or its PBM sets a "maximum allowable cost" (MAC) reimbursement amount for the drug that is below the price at which the drug is available for purchase by the pharmacy; or

- The plan or its PBM does not agree to pay any minimum amount for any specific prescription dispensed by the pharmacy, and instead only agrees that, on average for all drugs within a given category (e.g., generic drugs) that are dispensed by the pharmacy over a given period (e.g., a year), reimbursement will not be less than (and, in some cases, not greater than) some percentage of an "effective rate" measured based upon a pricing benchmark (e.g., "average wholesale price" (AWP) or "wholesale acquisition cost" (WAC)), such as AWP-90%. A reconciliation between the amounts that the pharmacy was paid for drugs dispensed during the period and the effective rate is performed after the end of the period, and if the pharmacy's reimbursement was below (or above) the effective rate, then the pharmacy is paid (or must pay) the difference.

PBMs may re-classify drugs from brand to generic, or otherwise change drug classifications, with the effect of reducing pharmacy reimbursement. *See, e.g., Albertson's LLC et al. v. Express Scripts, Inc.,* Consol. C.A. No. N25C-12-001-KMM- CCLD (Del. Super. Ct.) at Consolidated Complaint, Dkt. 8, ¶¶ 61-62 (complaint alleging that PBM initially classified drugs as brands and reclassified them as generics during reconciliation, improperly lowering pharmacy reimbursement). This may include changing a classification made based on sources other than the pharmacy's own contract. *See id.* at Answer, Dkt. 56, ¶ 62 (PBM acknowledging it initially determines whether a drug is a brand or a generic ***using Sponsors' contracts***, and may reach a different brand/generic designation under the pharmacy's contract during reconciliation).

NCPA Policy Recommendations

- A term is not reasonable or relevant if it pays or treats an unaffiliated pharmacy less favorably than a pharmacy affiliated with the plan or its PBM for the same drug and service. CMS should use the definition of "affiliate" in section 1860D-12(h)(7), which section 6223 already uses for essential retail pharmacies.

• The role and impact of PBMs, pharmacy services administrative organizations (PSAOs), and other entities on the Part D pharmacy contracting process;

PBMs limit pharmacies' ability to use PSAOs for negotiation, which is unreasonable given that it allows the PBM more leverage and operational capacity at the expense of pharmacies.

NCPA Policy Recommendations

- Pharmacies should be able to select PSAO representation without retaliation, network exclusion, or mandatory dual-contracting arrangements that undermine that representation.

• 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;

• 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.

Contract provisions may be drafted in such a way that allows PBMs to unilaterally determine that a payment to a pharmacy constituted an overpayment that can be recouped, without giving the pharmacy an opportunity to contest that recoupment. It is inappropriate for a PBM to unilaterally determine that an overpayment to a pharmacy has occurred and recoup on that basis, without giving the pharmacy a meaningful opportunity to contest the recoupment.

<u>NCPA Policy Recommendations</u>

- Termination requirements in contracts between PBMs/plans and pharmacies must be mutually agreed upon.
- Termination without cause should be disallowed for a pharmacy that has elected to accept the contract.
- Termination with cause should have opportunities for appeal and further documentation.
- Payment suspension and recoupment should require a credible allegation of fraud or risk of patient harm, written notice of the basis, and an independent appeal before any recoupment is final, except where patient safety requires immediate action.
- Any termination provision should identify the duration of exclusion, objective criteria for reinstatement, and a process and timeframe for reapplication.

• With respect to acceptance of standard Part D pharmacy contract terms and conditions:

++ The amount of time pharmacies (and their PSAOs) are given to review proposed standard terms and conditions, rate sheets, and amendments before acceptance is required or deemed;

<u>NCPA Policy Recommendations</u>

- PBMs and plans should give at least **[60]** days to review initial and subsequent offers and amendments.
- Standard terms should state the complete reimbursement methodology at the time of offer.

++ The use of deemed acceptance or negative-consent provisions (for example, terms treated as accepted if the pharmacy does not respond within a certain timeframe);

NCPA Policy Recommendations

- Regarding all contracts, modifications, and renewals, PBMs and plans should require affirmative acceptance by signature, with no deemed acceptance, and no mid-year changes without consent.

++ Whether pharmacies receive complete reimbursement information— including ingredient cost methodology, dispensing fees, applicable effective-rate guarantees, performance measures, and direct and indirect remuneration (DIR) fee structures—at the time the contract or amendment is offered;

Pharmacies do not receive complete reimbursement information because Part D plans and their PBMs often administer effective rate provisions in a manner that makes it difficult or impossible for the pharmacy to determine if it has been paid more or less than contractual guarantees, and whether the PBM correctly categorized drugs for purposes of applying different types of rates that apply to different categories of drugs.

NCPA Policy Recommendations

To the extent that CMS permits reimbursement effective rates, an effective rate reimbursement term is only reasonable if (1) the formula and procedure for reconciling amounts paid to the pharmacy against the effective rate are clear, unambiguous, and sufficient to accurately determine the amount (if any) by which amounts paid to the pharmacy are greater or less than the agreed effective rate; (2) the pharmacy receives the plan/PBM's reconciliation calculations and all underlying claims detail so as to enable the pharmacy to replicate the calculation; (3) the claims subject to the reconciliation (and, conversely, any exclusions (e.g., compounded or usual and customary claims)) are clearly defined in the agreement, and the data the plan/PBM provides enables the pharmacy to confirm the correct claims set was used; and (4) the plan/PBM identifies the network under which the claim was paid in its adjudication response (and related payment documentation) for the claim, to enable the pharmacy to independently perform the calculation with its own claims data. These calculations and associated data should be provided to the pharmacy within a reasonable period (no more than 60 days after the end of the period to which they relate) and the pharmacy should have a reasonable period (no less than 60 days) to review and object to the plan/PBM's reconciliation.

++ Whether the timing and completeness of disclosures are sufficient to constitute a reasonable opportunity to evaluate and accept terms within the meaning of section 1860D–4(b)(1)(A) of the Act;

Pharmacy network contracts may require a pharmacy to participate in one or more networks that fall into either of two problematic categories: (1) networks whose scope is undefined or unclear, such as a Part D national network; or (2) networks that are effectively subnetworks of the pharmacies already contracted to serve as network pharmacies for the plan, such as an extended days' supply or "specialty" pharmacy network. In some cases, PBMs unilaterally establish terms for a sub-network (e.g., a sub-network of a national network with reimbursement terms specific to a given plan sponsor) without pharmacy agreement to do so, or with that agreement "deemed" accepted unless the pharmacy declines, in which case, the agreement is terminated. These practices are not reasonable.

NCPA Policy Recommendations

- A reasonable and relevant contract must include a definition of each pharmacy network or sub-network to which the contract applies that enables the pharmacy to determine the specific plans, pharmacy types, existing network pharmacies, and prescription claims to which that network or sub-network applies, as well as any other terms defining the network (e.g., based upon number of pharmacies included or number of pharmacy chains having a given number of pharmacies that are included or excluded).
- No changes should be made to the scope of any network or sub-network or the terms or conditions of the pharmacy's participation in it without the express written agreement of the pharmacy.

• 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;

Contracts frequently give plans/PBMs the right to unilaterally amend the contract, including reimbursement rates, either without any right of the pharmacy to object or with the agreement being subject to termination by the plan/PBM if the pharmacy does object. Indeed, certain PBM contracts allow unilateral amendment without any notice to the pharmacy, or without a meaningful opportunity to object.

NCPA Policy Recommendations

- Any change that affects payment, audits, or network status should require a formal amendment to the already-signed contact, subject to the same notice and affirmative acceptance rules as the contract.
- Mid-year changes to rates or terms should be allowed only with advance notice and the pharmacy's affirmative consent. A pharmacy that declines should keep its existing terms through the end of the contract year. MAC updates under 42 CFR 423.505(b)(21) are the exception.

• 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;

NCPA Policy Recommendations

- To be relevant, a contract term must directly relate to the pharmacy's provision of drugs to enrollees of Part D plans and the plan/PBM's payment for same in accordance with Part D requirements. Provisions that do not meet these criteria are irrelevant and should not be included in an any willing pharmacy contract.
- A term should be considered reasonable and relevant only if it (1) pays at least the pharmacy's cost to acquire and dispense the drug; (2) is fully disclosed at the time of offer and affirmatively accepted; (3) applies the same way to affiliated and unaffiliated pharmacies; (4) relates to the pharmacy's Part D services rather than unrelated business; and (5) can be verified and enforced through CMS' allegation process. These factors serve the competition, access, and quality considerations CMS identified.
- CMS must set minimum contract review periods, require clear disclosure, and affirmative acceptance of standard contract terms, amendments, and material reimbursement changes, and restrict any unilateral mid-year changes.
- PBMs and plans should give at least **[60]** days to review initial and subsequent offers and amendments.
- Standard terms should state the complete reimbursement methodology at the time of offer.
- CMS should require notification to pharmacies of any updates to pharmacy manuals before they go into effect (at least 30 days in advance, except where the update relates to a change in applicable law that takes effect sooner), and provide that, except for changes required to be included in the contract due to a change in law, changes to any of the pharmacy's obligations to which the pharmacy objects (within 30 days of notice) will not be deemed to bind the pharmacy.

• 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;
++ What limitations, if any, are placed on a pharmacy's ability to file disputes;
++ Whether dispute resolution procedures are clearly outlined;
++ How disputes are adjudicated, and by whom;
++ Resolution timeframes; and
++ Approval and denial rates;

It is common for PBMs to require all disputes be raised behind the closed doors of arbitration. Although parties may agree to arbitrate, because PBMs have an unfair advantage due to their market power, pharmacies have no meaningful opportunity to refuse arbitration clauses and have not adequately consented to arbitration. Forcing a pharmacy to agree to arbitration in an any willing pharmacy contract is not a voluntary choice by the pharmacy, and an inappropriate condition upon a pharmacy's exercise of its any willing pharmacy right.

Certain PBMs also require the pharmacy, before initiating the arbitration, to place a substantial amount of funds (e.g., $50,000) in an escrow to cover the prevailing party's attorneys' fees and expenses. This effectively serves as a bar for certain pharmacies from even initiating a dispute, and a court has found this practice unconscionable. *Osterhaus Pharmacy Inc. v. CVS Health Corp.*, No. CV-24-01539-PHX-JJT, 2025 U.S. Dist. LEXIS 25142, at *30-32 (D. Ariz. Feb. 12, 2025), *aff'd by* Nos. 25-1467, 25-1843, 2026 U.S. App. LEXIS 14021 (9th Cir. May 15, 2026).

A contract may require pharmacies to raise disputes about remittance advices or reconciliation reports within a very short time frame, or to file an arbitration demand or litigation demand within a very short time after the parties conclude what the PBM deems to be the period for good-faith negotiations. Despite these short time frames applied to a pharmacy, the PBM often takes a protracted time to review and process disputes, to the extent it is willing to resolve them at all. Further, PBMs may require burdensome processes before pharmacies may commence an arbitration or litigation.

PBMs may impose requirements to bring a dispute that pharmacies cannot satisfy because only the PBM has the relevant information. For PBMs to require a pharmacy to provide information about a dispute (e.g., its calculation of a network rate reconciliation amount) for which it does not have access to the necessary data (e.g., the claims which the PBM used in its calculation, and how it classified them (such as brand vs. generic)) is unreasonable and an inappropriate reason to consider a pharmacy to have forfeited its right to challenge an action of the PBM, and arguably a violation of due process.

Most PBM agreements prohibit the pharmacy from asserting claims on behalf of a class or consolidating actions with others. The cost to litigate claims is high. Especially for an independent pharmacy, even if there is a clear breach of the parties' agreement by a plan/PBM, the pharmacy has little incentive to seek to recover those amounts if they may be exceeded by anticipated legal fees and costs, unless the claims may be pursued on a class or other consolidated basis. **This can be resolved by CMS characterizing these types of provisions as unreasonable.**

Any litigation may be required to be in the federal or state courts of the PBM's headquarters, not the pharmacy's headquarters or a neutral location. This practice unfairly advantages the PBM, and burdens the pharmacy, by requiring it to litigate outside of its state (potentially several time zones away) and on the PBM's home turf.

NCPA Policy Recommendations

- Contracts should include a written dispute process with a decision-maker independent of the PBM's network and pricing staff, a deadline for decisions, and no fees or waivers that deter pharmacies from using it. Sponsors should report dispute volumes and outcomes to CMS.
- A reasonable Part D contract should not impose time limitations upon the rights of pharmacies to assert breaches of the contract or related obligations (e.g., violations of applicable law); only the statute of limitations should impose those limitations. Any dispute resolution processes short of arbitration or litigation should be clearly outlined in the contract and should not preclude the pharmacy from initiating litigation or an arbitration for a period of more than 30 days.
- The PBM should be prohibited from requiring a pharmacy to provide any information relating to a dispute not in the pharmacy's possession in order to challenge an action of the PBM.
- Any litigation should take place where the pharmacy is located or headquartered unless the pharmacy is willing to agree otherwise (e.g., mutual agreement to Delaware courts).

• *Incentives, if any, that help foster a level playing field between the parties; and*

NCPA Policy Recommendations

- Independent pharmacies have essentially no leverage with the three largest PBMs, which together processed nearly 80 percent of U.S. prescriptions in 2025,[9] and each PBM owns competing pharmacies. That is why minimum standards, rather than negotiation, must set the floor. In practice, PBMs do not "negotiate" with independent pharmacies; they offer terms on a take-it-or-leave-it basis and leverage their outsized market power to coerce pharmacies to accept unreasonable terms.

- The any willing pharmacy requirement means little if a pharmacy cannot see and evaluate the terms before agreeing to them. CMS already requires sponsors to make standard contracts available by September 15 for the following year (42 CFR 423.505(b)(18)(i)), which CMS might need to re-evaluate. All contracts for pharmacies currently in network, including complete terms, including all rates, fees, guarantees, and performance terms, should be executed by October 1 preceding the plan year, ahead of the annual enrollment period that begins October 15.
- CMS must set clear standards around the timing of contract negotiations between PBMs and pharmacies so that Medicare Part D beneficiaries have a clear understanding of the pharmacies available to them during open enrollment. CMS must prohibit the practice of PBMs sending confusing letters to beneficiaries saying their pharmacy will be out of

[9] Drug Channels: The Top Pharmacy Benefit Managers of 2025: Market Share and Key Industry Developments

network for the coming year, when contract negotiations are not even finalized. PBMs continue to use this confusing tactic to steer patients to pharmacies the PBM prefers.

- PBMs should provide a plan list that ties to their associated plan contracts (BIN/PCN/group numbers/network reimbursement ID) at the time they provide their offer to their associated network. A fair negotiation involving reasonable and relevant terms and conditions must allow pharmacies clear visibility as to the full impact of those terms.
- Sponsors should certify compliance annually and submit their standard contracts, rate schedules, and pharmacy performance and audit program documents to CMS, along with data on reimbursement relative to NADAC by pharmacy type and affiliation. Section 6223 already requires sponsors to give CMS contract offers and related correspondence when a pharmacy files an allegation.
- CMS must retain and strengthen both the convenient access standard for long-term care pharmacies and the standards for convenient access to network pharmacies.

• *Other ways to ensure transparency and fairness in Part D pharmacy contracting.*

The MAC appeals process lacks transparency. PBMs will often respond, without reasonable justification, that MAC or reimbursement appeals are pre-empted, and they do not provide full and transparent information as required by the states. The MACs are not providing alternative sources, NDC numbers, no real reporting/complaint mechanism to CMS, whereas commercial insurers create more of a process for transparency.

NCPA Policy Recommendations

- If CMS allows MAC pricing and appeals, pharmacies should have a reimbursement floor and a fair appeals process.
- PBMs and plan sponsors should be prohibited from contacting residents of long-term care facilities about the network status of their long-term care pharmacy while negotiations are ongoing, as PBMs and sponsors are using this tactic increasingly to coerce pharmacies into accepting unreasonable and irrelevant terms and conditions. PBMs and plan sponsors should not only be prohibited from retaliating against pharmacy complaints, but they should be required to keep CMS apprised of any and all developments.

C. Trends in Contract Terms and Conditions

CMS seeks information regarding trends in Part D plan sponsor and network pharmacy contract terms and conditions. Specific areas of interest include—

• 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;

NCPA Policy Recommendations

- CMS should create a standard where terms that recreate retroactive fees in new forms are prohibited, such as low base rates paired with incentive payments the pharmacy may never earn. The standards CMS establishes should treat an incentive arrangement as reasonable only if the base payment, without any incentive, covers the pharmacy's cost to acquire and dispense the drug.
- Fees a pharmacy must pay to participate in a network reduce its net payment. CMS should confirm that they are price concessions that must be reflected in the negotiated price (42 CFR 423.100), count them against any reimbursement floor, and require their disclosure at offer. Any price concessions must be reflected in the price charged the beneficiary, and not be a kickback to the PBM.

• 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);

• Performance-based pharmacy payment models;

• The uniformity of terms and conditions offered by different Part D plan sponsors and plan types;

NCPA Policy Recommendations

- Uniform terms are not a problem in themselves; uniformly below-cost terms are. The standards should set a floor that applies across all sponsors.

• Terms and conditions offered to pharmacies with multiple lines of business (for example, retail, LTC, specialty), and how such terms and conditions accommodate the multiple lines of business;

NCPA Policy Recommendations

- Contracts should include terms suited to each line of business a pharmacy operates, rather than forcing specialized dispensing into a retail contract.

• 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;

NCPA Policy Recommendations

- Non-dispensing services should be paid separately under terms disclosed in the standard contract, not folded into dispensing fees or performance measures.

• The complexity of Part D pharmacy contracting terms and conditions and issues related to transparency;

NCPA Policy Recommendations

- Complexity itself hides the true terms. The standards should require a standardized summary of all payment terms for each contract; in a format CMS specifies.

• 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; and

Our members have expressed concern that manufacturers are using guidance stating that all GFIs should be resolved in 120 days to denying all or most of these claims in 120 days. Pharmacies then are unable to re-open the GFI or dispute this decision.

NCPA Policy Recommendations

- Reasonable terms should ensure that, for selected MFP drugs, plan payment plus the MFP refund covers the pharmacy's acquisition cost, while a dispensing fee covers the remaining cost to dispense. Sponsors and PBMs should not reduce reimbursement on other drugs to offset lower negotiated prices on selected drugs.
- Plan sponsors/PBMs cannot decrease reimbursements of Medicare Drug Price Negotiation Program (MDPNP) drugs in response to manufacturer refunds – those refunds are required to keep pharmacies whole, not reduce sponsor/PBM liability.
- CMS should require manufacturers to provide effectuation plans to pharmacies that are transparent, and include precise manufacturer refund amounts.
    - NCPA requests that CMS require that manufacturers pay pharmacies the standard default refund amount (SDRA)
- CMS should devise a permanent solution to solve the issue of misidentification of 340B claims to ensure prompt payment to pharmacies.
- CMS should monitor manufacturers to see if they are denying all or most claims within 120 days.

CMS should view drugs selected for MDPNP as a distinct category, and should require that PBMs reimburse pharmacies an enhanced dispensing fee for each selected drug dispensed.

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

NCPA Policy Recommendations

- CMS should prohibit single effective rate targets that span Part D and commercial business. A blended target obscures the true Part D price, lets a PBM recover concessions on one line of business through the other, and makes Part D participation contingent on non-Part D terms (see Sections A and B).

D. Pharmacy Quality and Performance Measures

CMS seeks information about the use and application of pharmacy quality measures (or other measures used to evaluate pharmacy performance) by Part D plan sponsors for network pharmacies. Specific areas of interest include—

- *How such measures are incorporated into network pharmacy contracts;*

NCPA Policy Recommendations

- Measures are currently in separate contracts from our understanding, speaking with PSAO representatives. Pharmacy quality and performance measures should be identified in the network pharmacy contract and subject to reasonable and relevant protections, and their financial effect should be stated in the contract at the time of offer.

- *What measures are used, including methodology and measure steward;*

NCPA Policy Recommendations

- Measures should be limited to those with a recognized steward, a published specification, and evidence that pharmacies can influence the result.

- *Whether measures are applied uniformly across pharmacies, or how specifications vary by pharmacy type or other pharmacy attributes;*

NCPA Policy Recommendations

- Measures should account for pharmacy type and patient mix. An LTC pharmacy, or a pharmacy with few attributed patients, should not be judged against retail adherence thresholds.

- *How such measures are used to monitor pharmacy performance, including success/failure performance threshold(s), or impact to pharmacy reimbursement or preferred network placement;*

NCPA Policy Recommendations

- Performance programs should be upside incentives paid on top of a reasonable base payment, not a way to reduce base payment. Measures used to set pharmacy payment should be validated at the pharmacy level, risk-adjusted, and applied only where the pharmacy has enough attributed patients for a reliable result.

- *Whether and how measures are validated or risk-adjusted;*

- *How performance impacts enrollee outcomes or the financial implications for Part D plan sponsors and pharmacies;*

NCPA Policy Recommendations

- Sponsors should be required to show that their pharmacy performance programs improve enrollee outcomes.

- *Whether and how often network pharmacies receive access to performance measure data;*

NCPA Policy Recommendations

- Pharmacies should receive performance data at least monthly, with patient-level detail, so they can act on it.
- CMS should require sponsors to analyze and report whether their measures disadvantage particular types of pharmacies.

- *Whether any measures are aligned with CMS' contract-level Part D Star Ratings measures, and how any measures have been re-specified at the pharmacy level;*

NCPA Policy Recommendations

- Pharmacy measures should align with Star Ratings specifications and be re-specified at the pharmacy level only through a transparent, published method.

- *Information about disproportionate impacts of pharmacy quality or performance measures on particular pharmacy types or pharmacy characteristics (for example, pharmacy size, setting, and non-chain type); and*

- *Appeal processes for pharmacies regarding their performance measures.*

NCPA Policy Recommendations

- Pharmacies should be able to appeal measure calculations, including patient attribution to pharmacy, before any payment effect.

E. Auditing Practices

CMS seeks information regarding Part D plan sponsor auditing practices for network pharmacies. Areas of interest include—

- *The frequency and type of pharmacy audits conducted;*

NCPA Policy Recommendations

- A pharmacy should have the same lookback period to challenge an underpayment or improper reimbursement determination that a Part D sponsor or PBM has to identify and recover an alleged overpayment.
- Advance Notice and Audit Transparency
    - Pharmacies should receive meaningful, written notice by email or certified mail before an audit begins
    - Audit Notice Must Include:
        - Scope and purpose of the audit;
        - Specific claims under review;
        - Prescription numbers and fill dates; and
        - Documentation requested
    - Allow the pharmacy to reschedule the audit for up to 14 calendar days from the original date designated in the audit notice or as reasonably requested.
- CMS should also:
    - Limit audits to no more than 50 prescription claims per pharmacy, and limit reviewed claims to those submitted or adjudicated within 1 year of the period covered by the audit.
    - Prohibit audits beginning within the first 5 days of the month.
    - Require audits to be claim-specific and date-specific.
    - Prohibit duplicate audits of the same claims unless fraud is substantiated.
    - Allow for tolling of an audit for pharmacies within the geographical boundaries of a declared disaster by a federal or state agency.
    - On-site audits should be limited to 2 per year.

- Documentation Standards
    - Required Acceptance of:
        - Redacted copies of supplier invoices in the pharmacist's or pharmacy's possession, without limitation to date or source
        - Invoices and supporting documents from state or federal authorized suppliers, subject to validation, without limitation to date or source of electronic records and other industry-standard documentation formats.
        - Records of a hospital, physician, or other authorized practitioner written or transmitted by any means of communication for purposes of validating the pharmacy record with respect to orders or refills of a prescription drug
    - Protections:
        - No retroactive documentation requirements
        - Upon request, PBMs must provide audit-related supporting materials within 5 business days of such request.
        - Electronic and industry-standard formats must be accepted.
- Audit Process, Timelines, and Appeals
    - Audits must follow a structured, time-bound process with due process protections.
    - Audits must be conducted based on how a drug is actually labeled and prescribed in terms of quantity and strength (e.g., a PBM cannot impose its own dispensing quantities that do not exist on the label for the drug or do not correspond to how the prescription was written)
    - Audits cannot require pharmacists to break open packaging labeled “for single-patient-use only.”
        - Packaging labeled “for single-patient-use only” shall be deemed to be the smallest package size available.
    - Audits should not interfere with the delivery of pharmacist services to a patient and should use every reasonable effort to minimize inconvenience and disruption to pharmacy operations.
    - Audit discrepancies should not be identified when:
        - the National Drug Code for the dispensed drug is in a quantity that is a sub-unit or multiple of the drug purchased by the pharmacist or pharmacy as supported by a wholesale invoice;
        - the pharmacist or pharmacy dispensed the correct quantity of the drug according to the prescription; and
        - the drug dispensed by the pharmacist or pharmacy shares all but the last two digits of the National Drug Code of the drug reflected on the supplier invoice.
    - A third-party auditing entity contracting with multiple PBMs shall not use audit reports or other information gained from an audit on a pharmacy to conduct another audit for a different PBM.

    - Recoupment determinations cannot be based on documentation requirements that exceed those of the relevant state board of pharmacy or applicable law.
    - Model Timeline
        - Pharmacy response period: at least 90 days to respond, submit additional documentation, or contest findings, with extensions as agreed or for good cause.
        - Final report: issued 30 days after review of the pharmacy's response and appeal submissions.
        - Appeal rights: mandatory appeal process, including electronic resubmission and reverse-and-rebill correction of errors.
- Recoupment:
    - Prohibited until the appeals process is exhausted.
    - Dispensing fee or actual invoice cost of the prescription dispensed should not be included in a recoupment unless a prescription was not actually dispensed or a physician denied authorization of a dispensing order.
    - prohibited for clerical or recordkeeping errors, absent proof of intent to commit fraud.

- *Transparency of audit and recoupment methodologies, including whether pharmacies are provided with information on a per claim basis;*

<u>NCPA Policy Recommendations</u>

- Every audit report should list each claim, the finding, the amount, and the contractual or regulatory basis for the discrepancy.

- *Information about common audit findings and financial and other impacts on pharmacies and plans;*

<u>NCPA Policy Recommendations</u>

- CMS should require sponsors to report audit recoupments by finding type, so it can see how much is recovered for clerical issues.

- *The extent to which pharmacy audits are used for or result in identification of administrative or clerical issues versus issues related to patient care or program integrity vulnerabilities such as fraud or other improper billing;*

NCPA Policy Recommendations

- Recoupment for clerical or documentation errors that caused no financial harm to the plan should be prohibited. PBMs and plans should allow for electronic resubmission of the claim, without imposing a financial penalty on the pharmacy.
- Where a plan sponsor or PBM has the information necessary to identify a claim defect at the point of adjudication, it should be required to reject or identify the defect prospectively rather than approve and pay the claim and later recoup payment through an audit.

- *Extrapolation methods used for recoupment;*

NCPA Policy Recommendations

- Extrapolation should be prohibited except where the sponsor has found a pattern of fraud, and then only with a statistically valid method disclosed to the pharmacy.

- *Whether and how Part D plan sponsors audit, verify, or otherwise validate the claim-level pricing data and DIR data they receive from PBMs, particularly when the PBM is affiliated with one or more network pharmacies;*

NCPA Policy Recommendations

- Sponsors should be required to audit claim-level pricing and DIR data from their PBMs, especially where the PBM owns network pharmacies, and to report the findings to CMS.
- Documentation standards should not exceed existing law or that required of affiliated pharmacies.

- *Use of audits to recoup payment based on errors, including minor errors; and*

- *Opportunities for corrective action; and*

NCPA Policy Recommendations

- CMS should
    - Allow pharmacies to correct non-fraudulent errors without automatic penalties.
    - Permit electronic resubmission and reverse-and-rebill correction of errors without penalty.
    - Require consideration of clinical judgment and clerical or recordkeeping errors.

- Require pharmacist reviewers, who are licensed in the relevant state, for clinical disputes.
- Not allow interest to accrue on the recoupment amount during the appeals process
- Require that PBM must reimburse pharmacy within 14 days if underpayment is found.

- *Due process provisions.*

NCPA Policy Recommendations

- CMS should
  - Establish a mandatory, accessible appeal process.
  - Permit either party to seek mediation or other legal relief based on outstanding audit disputes.
- Contract Transparency and Fairness
  - Audit, appeal, and recoupment procedures should be disclosed in advance and applied under identical standards, regularity, and parameters to similarly situated pharmacies.
  - All audit, appeal, and recoupment procedures must be clearly disclosed in the contract.
  - Standards must be written in plain language and easily accessible.
  - Undisclosed audit standards are unenforceable.
  - Similarly situated pharmacies should be subject to identical audit parameters, including pharmacies owned or managed by the PBM.
- Enforcement and Oversight
  - Strong standards require equally strong enforcement mechanisms.
  - CMS should investigate complaints and provide oversight of settlements, including itemized accounting sufficient to track restitution to impacted pharmacies.
- Financial Protections
  - Audits should not function as revenue-generating tools.
  - Recouped amounts should be disclosed and refunded back to the payor or plan sponsor, with safeguards against fee-based audit incentives.
  - Prohibited Practices:
    - Charging pharmacies audit-related fees
    - Recoupment based solely on clerical or recordkeeping errors.
    - Compensating auditors or audit agents based directly or indirectly on recoupment amounts or audit findings.
    - Contingency-fee auditors
    - Extrapolation-based recoupment

- Required Safeguards:
  - PBMs must bear reasonable administrative costs, including the cost of copies or records they request.
  - PBMs must disclose recouped amounts to affected plan sponsors or payors.
  - Recovered funds should be allocated first to patient-paid amounts, if included, and then to the plan sponsor

Other NCPA Policy Recommendations

- Preliminary reports for invoice audits must include sufficient detail for those purchases that were accepted or rejected.
- If the PBM recoups a claim in full, it should be removed from the PDE.
- An audit should not be characterized as an FWA, SIU, program-integrity, or investigative audit solely because of the amount at issue, dispensing volume, drug type, pharmacy type, or the existence of documentation discrepancies. Such characterization should require articulable facts supporting a reasonable suspicion of fraud, waste, abuse, or patient harm. Payment suspension and recoupment should require a credible allegation of fraud or risk of patient harm, written notice of the basis, and an independent appeal before any recoupment is final, except where patient safety requires immediate action.
- Part D audits should be stand-alone, separated from other types of lines of business, like Medicaid or commercial payor audits. Part D payments should not be offset to recover amounts claimed under other lines of business, and findings under another line of business should not trigger Part D recoupment or termination.

F. Limitations

CMS seeks information about Part D plan sponsor restrictions or limitations on the dispensing of covered Part D drugs by network pharmacies (or any subsets of pharmacies), including the nature and prevalence of such limitations.

NCPA Policy Recommendations

- A restriction on which network pharmacies can dispense a drug should be reasonable only if it rests on published, objective criteria, such as a manufacturer's limited distribution or a documented safety requirement, applied equally to affiliated and unaffiliated pharmacies. Terms that keep retail pharmacies from dispensing extended supplies available through mail order also undercut the level playing field requirement in section 1860D-4(b)(1)(D).
  - The use of an extended-day supply should not, by itself, result in reduced reimbursement when the pharmacy continues to provide the services required to

support the LTC patient. Payment methodology should appropriately recognize the LTC services provided and the population being served.

- LTC pharmacy is a distinct pharmacy type. CMS already requires sponsors to offer LTC pharmacies standard terms that include the LTC performance and service criteria CMS specifies (42 CFR 423.120(a)(5); Prescription Drug Benefit Manual, Chapter 5, section 50.5.2), requiring unique transition practices in LTC settings (Prescription Drug Benefit Manual, Chapter 6, Section 30.4.4.2) and authorizes plans to pay distinct LTC Pharmacy dispensing fees (Prescription Drug Benefit Manual, Chapter 5, Section 20.7). The standards should set a uniform definition of the LTC pharmacy class of trade, based on the services a pharmacy provides to patients with an LTC level of need, and require that terms for LTC pharmacies reflect those services rather than retail terms.

G. Current Regulations and Guidance

CMS seeks information about areas in current regulations or Part D program guidance related to contracting between prescription drug plans and network pharmacies that may require clarification or additional specificity. In responding to this topic, commenters should consider Part D regulations at 42 CFR part 423, the Medicare Prescription Drug Benefit Manual, and any other CMS regulations or guidance relevant to the topics included in this RFI.

NCPA Policy Recommendations

- CMS should clarify: (1) 42 CFR 423.505(b)(18), by tying "reasonable and relevant" to the new standards and requiring complete terms by October 1; (2) the negotiated price definition in 42 CFR 423.100, by stating that downward post-sale reconciliations are inconsistent with "the lowest possible reimbursement"; (3) the U&C definition in 42 CFR 423.100, by defining U&C for network pharmacies; (4) 42 CFR 423.505(b)(21), by applying it expressly to MAC lists and adding appeal and correction requirements; and (5) the "similarly situated" standard, by codifying objective criteria that exclude affiliation.

H. Implementation of Standards

CMS seeks information related to the implementation of reasonable and relevant standard contract terms and conditions not otherwise addressed in the topics included in this RFI. Areas of interest include—

• Operational considerations, including timelines needed for Part D plan sponsors, PBMs, and pharmacies to modify contracts to comply with new standards and implement other needed operational changes;

• What documentation CMS should require to demonstrate compliance with standards for reasonable and relevant standard contract terms and conditions once finalized;

• *Contracting practices not captured in this RFI that CMS should evaluate; and*

NCPA Policy Recommendations

Any recoupment should be limited to the actual financial loss sustained by the plan or actual overpayment received by the pharmacy. Recoupment should not be permitted for a clerical, recordkeeping, or documentation deficiency where the prescription was properly authorized, dispensed to the beneficiary as prescribed, and the deficiency did not cause an improper payment.

• *Examples of pharmacy contract terms and conditions or similar frameworks that could be viewed as models;*

• *Criteria CMS should consider to ensure standards are transparent, objective, and enforceable.*

NCPA Policy Recommendations

- The statute applies the standards for plan year 2029. All contracts for pharmacies currently in network, including complete terms, including all rates, fees, guarantees, and performance terms, should be executed by October 1 preceding the plan year.
- Standards should be written as measurable requirements, such as a payment floor, a minimum review period, or a prohibited term, rather than general principles, so a pharmacy can show a violation through the allegation process and CMS can enforce it.
- The standards should apply equally to PDPs and MA-PD plans.
- CMS should use its essential retail pharmacy reports under section 1860D-42(e) to test whether its standards preserve access where few pharmacies remain and should review reimbursement to those pharmacies as part of enforcement.
- Below-cost reimbursement is a leading cause of pharmacy closures. CMS should use its essential retail pharmacy reports under section 1860D-42(e) to track whether its standards slow or reverse closures.
- The most effective incentive is enforcement. CMS should use the allegation process and civil monetary penalty authority in section 6223 against sponsors whose terms fall below the standards, and report the results in the biennial enforcement report required by section 1860D-42(f).
- Confidentiality clauses keep pharmacies from telling CMS what their contracts say. The standards should bar terms that prohibit a pharmacy from sharing contract terms with CMS, extending to all communications with CMS the protection section 6223 already gives pharmacies that file allegations (section 1860D-4(b)(1)(F)(i)(III)(bb)).

NCPA implores CMS to establish reasonable and relevant Part D pharmacy contracting standards that promote transparency, predictability, and sustainable participation by independent community and long-term care pharmacies. The development of such standards will help us continue to provide pharmacy services to Medicare beneficiaries enrolled in Medicare Part D.

NCPA thanks CMS for the opportunity to provide feedback, and we stand ready to work with the agency to offer possible solutions and ideas. Please let us know how we can assist further, and should you have any questions or concerns, please feel free to contact me at steve.postal@ncpa.org or (703) 600-1178.

Sincerely,



Steve Postal, JD
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National Community Pharmacists Association