NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

November 23, 2026

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–4217–NC
P.O. Box 8013
Baltimore, MD 21244–8013

Submitted via: https://www.regulations.gov/docket/CMS-2026-3037

Re: Request for Information; Medicare Part D Reasonable and Relevant Pharmacy Contracting Standards; File Code CMS–4217–NC; RIN 0938–AW08

Dear Administrator Oz:

I. Introduction and Statement of Interest

The National Association of Chain Drug Stores (NACDS) appreciates the opportunity to respond to the September 24, 2026 Request for Information (RFI) issued by the Centers for Medicare & Medicaid Services (CMS) regarding standards for "reasonable and relevant" pharmacy contract terms and conditions under the Medicare prescription drug benefit. Section 6223(a) of the Consolidated Appropriations Act, 2026 (CAA, 2026) amends section 1860D–4(b)(1)(A) of the Social Security Act (the Act) to require Part D plan sponsors to permit any pharmacy that meets the plan's standard contract terms and conditions to participate as a network pharmacy, and requires that, for plan years beginning on or after January 1, 2029, those standard terms and conditions be reasonable and relevant according to standards established by the Secretary.[1]

NACDS represents stand-alone drug stores, supermarkets, and mass merchants with pharmacies. Chains operate approximately 32,000 pharmacies, and NACDS' member companies include regional chains, with a minimum of four stores, and national companies. As the most accessible healthcare destinations, and among the most trusted, pharmacies help patients use medicines correctly and safely, while offering innovative services that improve patient health and healthcare affordability. NACDS members also include supplier partners that help to meet Americans' expectations by leveraging the total store for the total person.

For many years, unchecked horizontal and vertical integration among the largest pharmacy benefit managers (PBMs), whereby the same corporate family maintains simultaneous ownership and control over the PBM, a health insurance carrier, and affiliated pharmacies, has rendered the PBM market uncompetitive and given each of the largest PBMs nearly unchecked power over the pharmacies with which they contract. The three largest PBMs now process approximately 80 percent of all dispensed prescriptions in the United States, and the six largest control approximately 96 percent of the market.[2] Because the dominant PBMs are also vertically integrated with their own retail, mail-order, and specialty

[1] Medicare Part D Reasonable and Relevant Pharmacy Contracting Standards; Request for Information, 91 Fed. Reg. 60568 (Sept. 24, 2026) (RFI).
[2] Staff of H. Comm. on Oversight & Accountability, 118th Cong., The Role of Pharmacy Benefit Managers in Prescription Drug Markets 7 (Comm. Print 2024).

pharmacies, they function simultaneously as a supplier to, and a competitor of, the unaffiliated pharmacies whose contract terms they set. It is precisely this structure that makes Congress's directive to establish enforceable, objective contracting standards not only so important, but imperative to the sustainability of community pharmacy.

NACDS strongly supports enforceable "reasonable and relevant" standards that are maximally impactful for the fair treatment of pharmacies and pharmacists. We recognize that the RFI poses a broad set of questions, and that CMS likely already possesses or is legally entitled to collect much of the underlying contracting information it seeks. Rather than responding to every question, NACDS focuses these comments on the priorities that we believe are most essential to implementing the statute as Congress intended and in a manner that will ensure safe and convenient patient access to vital medications:

1. **Fair and equal treatment across pharmacy business models.** Standards should apply neutrally to all pharmacies, regardless of size or business model, and should prevent PBMs that are vertically integrated with an insurer from favoring their own pharmacies (Section II).
2. **A confidential data submission process.** CMS cannot set evidence-based standards from public comments that, by the RFI's own terms, may not include proprietary information; CMS should establish a *confidential submission* process and use its existing authority to obtain contracting documents directly (Section III).
3. **Clear, enforceable contracting standards.** CMS should establish objective standards governing the factors for reasonableness, similarly situated determinations, preferred network access, provider manuals and off-contract terms, review periods, mid-contract changes, dispute resolution, audits, claims data protection or performance measures, and enforcement (Section IV, responding to Section B of the RFI).
4. **A cost-based reimbursement floor.** At a minimum, reimbursement should cover the full ingredient cost of the drug as measured by the National Average Drug Acquisition Cost (NADAC) plus a professional dispensing fee, measured after all reconciliation and post-adjudication adjustments (Section V, responding to Section A of the RFI).

Consistent with CMS's request, each section below identifies the section of the RFI to which it responds.

II. Pharmacy Terminology, Market Structure, and the Need for Neutral Standards

A. Defining affiliated, unaffiliated, and independent pharmacies

Discussions of pharmacy contracting frequently conflate two distinct concepts: pharmacy size and pharmacy affiliation. Because CMS's standards will turn on how these concepts are defined, NACDS respectfully requests that CMS distinguish among the following categories:

- **Affiliated pharmacies:** pharmacies that are under simultaneous common ownership and control of both a PBM and a health insurance issuer, as defined in 42 U.S.C. § 300gg-91(b)(2).
- **Unaffiliated pharmacies:** all other pharmacies, including national and regional chains, supermarket and mass-merchant pharmacies, and independents, that contract with PBMs at arm's length and are not under simultaneous common ownership and control of both a PBM and a health insurance issuer as defined by 42 U.S.C. § 300gg-91(b)(2).

B. Why simultaneous insurer, PBM, and pharmacy ownership matters

The tripartite integration of insurer, PBM, and dispensing pharmacy under common ownership creates both the incentive and the ability to disadvantage unaffiliated competitors. An insurer-owned PBM has a captive insured population through which it can guarantee volume to its affiliated pharmacies; it can shift revenue among its insurance, PBM, and pharmacy segments through internal transfer pricing; and it can steer the most profitable prescriptions to its own dispensing channels. A pharmacy that is affiliated with a PBM, but where neither entity is under common ownership or control with a health insurance issuer lacks the captive insured population and the closed corporate loop that characterize the insurer, PBM, and pharmacy structure, and does not present the same structural self-dealing risks.

The empirical record confirms these concerns. An analysis of the Ohio Medicaid program found that CVS paid its own pharmacies nearly double what it paid large, unaffiliated providers for generic drugs.[3] A 2026 compliance audit by the Tennessee Department of Commerce and Insurance found that an audited market-dominant PBM paid its own pharmacies 18 percent more than non-affiliated Tennessee pharmacies for the same drug on the same day.[4] FTC staff found that the three largest PBMs reimbursed their affiliated pharmacies at higher rates than unaffiliated pharmacies on nearly every specialty generic drug examined, and DOL has recently highlighted FTC findings that PBMs reimbursed affiliated pharmacies at rates 20 to 40 times NADAC for two generic cancer drugs.[5]

C. Congress did not limit network access protections by pharmacy size

The any willing pharmacy requirement in section 1860D–4(b)(1)(A) of the Act extends to "any pharmacy" that meets the plan's standard contract terms and conditions. Congress did not limit this protection, nor did it distinguish among unaffiliated pharmacies based on size, number of locations, or business models. CMS's standards should do the same. As independent economic analysis has concluded, retail pharmacies of all sizes face acute financial injury from dominant PBMs that exercise concentrated buying power over a fragmented pharmacy provider market.

Chain pharmacies play an essential role in patient access. One recent study concluded that a greater portion of the population relies on chain pharmacies for convenient access (20.2 percent) than on smaller independents (5.0 percent), and recent chain closures – including hundreds of Rite Aid locations following its 2023 bankruptcy and Walgreens' announced closure of approximately 1,200 stores through 2027 – disproportionately affect underserved communities.[6]

Accordingly, NACDS urges CMS to:

- apply contracting standards consistently to chain, independent, regional, supermarket, mass-merchant, and other retail pharmacy models;
- avoid categorical assumptions that pharmacy size or ownership determines whether a contracting term is reasonable, and avoid using business model as a proxy for reimbursement adequacy or operating costs;

[3] Marty Schladen & Cathy Candisky, *CVS Paid Itself Far More Than Some Major Competitors, Report Says*, The Columbus Dispatch / USA Today Network (Jan. 20, 2019).
[4] Tennessee Department of Commerce and Insurance, Report on audit of Caremark, L.L.C., Caremark PhC, L.L.C., and CaremarkPCS Health, L.L.C.: PBM compliance section audit as of December 31, 2024 (Jan. 22, 2026), at 6 (Finding #4).
[5] Federal Trade Commission, Specialty Generic Drugs: A Growing Profit Center for Vertically Integrated Pharmacy Benefit Managers (Jan. 2025) ("FTC Specialty Generic Drugs"); Department of Labor, Improving Transparency Into Pharmacy Benefit Manager Fee Disclosure, Final Rule, 91 Fed. Reg. 69092 (Nov. 2, 2026) ("DOL Final Rule"), at 69150–51.
[6] Hernandez et al., *Role of independent versus chain pharmacies in providing pharmacy access: a nationwide, individual-level geographic information systems analysis*, Health Affairs Scholar, Volume 1, Issue 2, August 2023.

- distinguish between pharmacies that operate as extensions of an insurer-owned PBM and pharmacies that do not, and ensure that affiliated pharmacies receive no preference over unaffiliated pharmacies;
- evaluate whether ostensibly neutral contracting requirements create disproportionate barriers for particular pharmacy types; and
- preserve the ability of pharmacies to compete on efficiency, service quality, convenience, and value.

To the extent CMS looks to the definition of "affiliate" in section 1860D–12(h)(7) of the Act in implementing these standards, NACDS urges CMS to apply it consistent with the tailored approach described above, so that heightened scrutiny is directed at pharmacies operating within the insurer, PBM, and pharmacy structure.

III. CMS Should Establish a Confidential Data Submission Process to Develop Evidence-Based Standards

A. The RFI's data requests cannot be met through public comments

The RFI encourages commenters to provide "quantitative data and empirical analyses; contract language (de-identified as appropriate); information disaggregated by pharmacy type, geographic location, drug category, or other relevant factors; and evidence regarding Part D enrollee access and outcomes." At the same time, the RFI instructs that commenters "should not include proprietary or confidential information in their submissions," and advises that all comments received – "including any personally identifiable or confidential business information that is included in a comment" – will be posted publicly. CMS further notes that it may publicly post comments or a summary of them.

These instructions are irreconcilable. The information most probative of whether current contract terms are reasonable and relevant – pharmacy acquisition costs, contracted and reconciled reimbursement rates, effective-rate guarantees, fee schedules, rate sheets, and the specific terms PBMs impose – is precisely the information that pharmacies cannot disclose publicly. Pharmacy acquisition costs are competitively sensitive, and their disclosure to PBMs that own competing pharmacies would itself distort competition. Many PBM contracts also contain confidentiality provisions that restrict disclosure of their terms. Additionally, pharmacies reasonably fear retaliation from PBMs on which they depend for access to a substantial share of their patients. As a result, the public record CMS develops through this RFI will necessarily be incomplete, and will systematically understate the evidence of below-cost reimbursement and unreasonable contracting practices.

B. CMS has existing authority, and established models, for obtaining this information confidentially

As the RFI acknowledges, Part D sponsors and their first tier, downstream, and related entities are independently obligated to make available such documentation as the Secretary deems necessary to enforce CMS's contracts, including documents setting out the terms and conditions offered to pharmacies. *See* 42 C.F.R. § 423.505(e)(2) and (i)(2). CMS therefore need not rely on public comments to understand what PBMs actually require of pharmacies; it can obtain the contracts, amendments, rate sheets, provider manuals, reconciliation schedules, and fee arrangements directly.

C. Recommendations

NACDS respectfully recommends that CMS:

1. Establish a secure portal through which pharmacies and their representatives may submit confidential cost, reimbursement, and contracting information, and confirm that such submissions will be treated as confidential commercial information exempt from public disclosure, including under Exemption 4 of the Freedom of Information Act, 5 U.S.C. § 552(b)(4).
2. Provide a supplemental submission period following the November 23, 2026 comment deadline, or alternatively an opportunity to meet with CMS staff, so that pharmacies can provide confidential information through that process.
3. Exercise its existing authority under 42 C.F.R. § 423.505(e)(2) and (i)(2) to obtain from Part D sponsors and their PBMs the complete set of documents that determine pharmacy reimbursement, including executed contracts, amendments, rate sheets, provider manuals, effective-rate and reconciliation terms, and fee schedules.
4. Use only aggregated, de-identified results of confidential submissions in any public rulemaking record and ensure that no pharmacy's acquisition cost information is disclosed to PBMs, plan sponsors, or competitors.

NACDS is prepared to work with CMS to facilitate confidential submissions from its members.

IV. Section B — Current Contracting Practices

Congress directed CMS to establish reasonable and relevant standards as part of a broader set of PBM reforms. Those standards should promote competition, patient access, transparency, and fair treatment of pharmacies regardless of size or business model, while giving plans, PBMs, and pharmacies clear rules and parameters. Existing regulations require Part D sponsors to contract with any pharmacy that meets their standard terms and conditions, and require those terms to be reasonable and relevant, see 42 C.F.R. §§ 423.120(a)(8)(i) and 423.505(b)(18); but, as the RFI acknowledges, CMS has never established additional requirements for what constitutes reasonable and relevant terms. In the absence of objective standards, the largest PBMs have been free to impose unreasonable and inequitable terms that comply with the any willing pharmacy requirement in form while defeating it in substance.

A. Factors for determining whether terms are reasonable and relevant

NACDS implores CMS to evaluate standard contract terms against the following objective factors:

- **Effect on competition.** Whether the term facilitates or hinders competition among pharmacies, including whether it has the purpose or effect of advantaging pharmacies affiliated with an insurer-owned PBM over unaffiliated competitors. CMS should evaluate terms such as a "affiliate-only network" and "mandatory use of affiliated mail or specialty pharmacies" through a lens of being inherently unreasonable.
- **Relevance to pharmacy services.** Whether the term is objectively related to the safe and effective dispensing of covered Part D drugs and enrollee access, rather than a pretextual requirement – such as proprietary software, delivery capabilities, or equipment that only a PBM's own pharmacies currently possess – designed to keep a network effectively closed while technically complying with the law.
- **Financial reasonableness.** Whether reimbursement, measured after all reconciliation and post-adjudication adjustments, at minimum covers the pharmacy's ingredient cost plus a fair and adequate professional dispensing fee (see Section V).

- **Transparency and completeness.** Whether all terms that determine what the pharmacy will be paid and/or reimbursed are disclosed in the contract documents at the time of offer, rather than in separate documents that the PBM may change unilaterally.
- **Consistency and nondiscrimination.** Whether the term is offered on the same basis to all similarly situated pharmacies, including affiliated and unaffiliated pharmacies. Because pharmacies cannot determine whether or not PBMs offer their affiliates better terms, CMS should verify parity directly, such as through an annual random audit sample, with significant penalties for violations.
- **Procedural fairness.** Whether the contract provides adequate time to review terms, advance notice of material changes, and an accessible and timely means to challenge reimbursement and contract disputes.

As commentators have observed, CMS has already recognized that unreasonably low reimbursement terms are inconsistent with the federal any willing pharmacy requirement.[7] Establishing objective standards of this kind would give CMS a workable framework for implementing the statute and reduce uncertainty for plans, PBMs, and pharmacies alike.

B. Similarly situated pharmacies

CMS's 2005 Part D final rule clarified that standard terms may vary to accommodate geographic areas or types of pharmacies, provided that all similarly situated pharmacies are offered the same terms.[8] CMS should now give that concept objective content. Whether pharmacies are similarly situated should be determined by objective, service-related criteria—such as licensure, dispensing capability, and the clinical services offered—and should not rely upon or consider the pharmacy's size, number of locations, or corporate form.

In particular, CMS should make clear that (1) affiliated and unaffiliated pharmacies meeting the same objective criteria are similarly situated and must be offered the same terms; (2) pharmacies meeting objective specialty criteria must be given the opportunity to participate in specialty networks on the same terms as a PBM's affiliated specialty pharmacy; and (3) sponsors must document and consistently apply the criteria they use to classify pharmacies, and may not unilaterally reclassify a pharmacy to apply less favorable terms. Neutral standards of this kind address the competitive concerns associated with vertical integration without creating preferential treatment for one pharmacy business model over another.

C. Any willing pharmacy access to preferred and non-preferred networks

Any willing pharmacy protections should provide a meaningful opportunity to participate, not merely the ability to accept a standard contract with commercially unreasonable terms. The FTC has found that PBMs may use network design, including preferred and narrow networks, to steer patients to their own affiliated pharmacies "even if a rival unaffiliated pharmacy may provide the same or better pricing and terms to the PBM for its pharmacy services."[9] Because preferred networks carry lower enrollee cost sharing, exclusion from them effectively eliminates a patient's ability to select their own preferred pharmacy and can be as consequential for a pharmacy as exclusion from the network altogether.

[7] See Frier Levitt, Pharmacy Benefit Managers and Their Impact on Cancer Care (Feb. 2022), at 52.
[8] Centers for Medicare & Medicaid Services, Medicare Program; Medicare Prescription Drug Benefit, 70 Fed. Reg. 4254 (Jan. 28, 2005).
[9] Federal Trade Commission, Interim Staff Report, Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies (July 2024) ("FTC Interim Report"), at 11.

NACDS therefore recommends that CMS require that the terms and conditions for participation in preferred networks be offered to any pharmacy willing to meet them, on the same objective basis as the PBM's affiliated pharmacies, and that *preferred network terms themselve*s be subject to the reasonable and relevant standards. This approach supports patient choice and competition while preserving the ability of plans to offer differentiated pharmacy networks.

D. Provider manuals and other documents used to modify contract terms

Contracting standards will be difficult to enforce if PBMs can circumvent them through documents that they can change unilaterally and with no transparency. PBMs commonly incorporate ever-changing provider manuals, policy bulletins, and similar documents by reference, effectively reserving the right to change material contract terms at any time and without the pharmacy's consent. The FTC has documented PBMs' use of "passive contracts" that take effect without affirmative consent or signature, and amendment provisions under which continued claim submission after an effective date is deemed acceptance of new terms.[10] CMS needs visibility into the full set of documents and arrangements that determine pharmacy reimbursement in order to assess whether statutory protections are meaningful.

At the state level, NACDS members have observed that PBMs frequently comply with reforms in form rather than substance, continuing problematic practices through changes to provider manuals that are subject to little or no regulatory oversight and that effectively undermine the intent of the reforms. If CMS does not establish clear requirements and enforceable guardrails, the same behavior will undermine the effectiveness of the Part D standards.

NACDS recommends that CMS:

- prohibit the use of provider manuals, policy bulletins, or other unilaterally modifiable documents to establish or change material contract terms, including reimbursement methodologies, fees, network participation requirements – taking particular care to ensure the prohibition of network participation requirements that seek pharmacy acquisition cost disclosures, performance measures, audit and recoupment provisions, and termination rights;
- require that any change to a material term be made only through a formal contract amendment subject to the notice, disclosure, meaningful negotiation, and acceptance requirements described below; and
- require sponsors to make available to CMS, upon request, all provider manuals and incorporated documents in effect at any point during the contract year.

E. Pretextual Pharmacy Audits and Due Process Guardrails

Each of the anticompetitive contracting mechanisms dominant PBMs impose on rival, unaffiliated pharmacies is backstopped by an arbitrary and opaque audit system. While PBMs defend audits as necessary to ensure program integrity and quality, NACDS members report that they are routinely used to claw back legitimately earned reimbursements. These audits focus overwhelmingly on high-reimbursement medications (such as insulin) and hyper-technical clerical discrepancies rather than genuine threats to patient health, clinical safety, or actual fraud. CMS should note that nothing in the below standards should be perceived as relieving a pharmacy of its obligation to correct inaccurate claims and return identified overpayments.

[10] FTC Interim Report at 50–51.

NACDS members report pervasive procedural traps designed to manufacture technical noncompliance, including:

- **Clerical Pretext Penalties:** Deeming claims noncompliant for failure to produce the "front and back" of a purely electronic prescription (which possesses no physical reverse side) or claiming prescriber signatures are absent when verifiable electronic or wet signatures appear on the face of the order.

- **Artificial Submission Deadlines:** Establishing rigid response windows with postmark deadlines falling on Sundays or federal holidays when the U.S. Postal Service does not operate, and summarily rejecting timely responses mailed the following business day.

- **Packaging Mismatches:** Penalizing pharmacies for dispensing manufacturer-mandated, unbroken packaging (such as full boxes of insulin pens) where the PBM's rigid system rules specify a lesser days' supply, clawing back the entire claim despite the pharmacy's regulatory inability to break the container.

- **Disproportionate Full-Year Recoupments:** Forfeiting reimbursement across an entire year of therapy (e.g., all twelve refills of a valid maintenance script) because of a single administrative defect alleged on one fill, leaving the pharmacy entirely uncompensated for medications already acquired and safely dispensed to the patient.

- **One-Sided Small-Sample Extrapolation:** Auditing a handful of isolated claims and extrapolating alleged clerical error rates across an entire broad universe of non-audited claims without demonstrating statistical validity or sample representativeness.

To ensure standard contract terms are reasonable and relevant under Section 1860D-4(b)(1)(A), CMS should establish clear, enforceable audit standards:

1. **Limit Financial Recoupment:** Prohibit financial clawbacks for clerical, typographical, or administrative errors where a covered drug was legitimately dispensed to an eligible Part D beneficiary pursuant to a valid prescription and ensure that any recoupment that is deemed appropriate be limited to the actual overpayment. Further, assurance that any document review that can potentially lead to recoupment be treated as an audit, regardless of the terminology used to describe it.

2. **Require Advance Notice and Appropriate Disclosures:** Require disclosure of audit criteria, including frequency, scope, and targeted drug categories. Require advance notice of reasonable notice and limits on audit frequency and claim volume. Prohibit auditor compensation that depends on or is incentivized by recoveries and require disclosure of the recovery tied to each audited claim.

3. **Allow Opportunity to Support Claims**: Require PBMs to allow pharmacies an opportunity to support their claims by necessitating auditors accept reliable supplemental records, including, but not limited to signature logs, attestations, and prescriber statements. Recoupment should be prohibited while a timely appeal is pending.

4. **Prohibit One-Sided Extrapolation:** CMS should not allow extrapolation.

5. **Mandatory Due Process and Cure Rights:** Guarantee network pharmacies a minimum of 60 days to respond to audit findings, an automatic right to cure technical documentation defects before penalties attach, and access to an independent, neutral appeals adjudicator.

F. Protection of Competitor Claims Data and Anti-Steering

When an unaffiliated pharmacy submits a claim for adjudication, that transaction contains confidential prescriber and patient data that belongs to the dispensing event. Dominant PBMs can and do harvest this platform data to identify lucrative specialty, maintenance, and high-margin generic prescriptions filled at unaffiliated community pharmacies. NACDS members have found PBMs bypass patient consent by sending members misleading communications falsely alleging network exclusions, or contacting physicians under false pretenses to redirect refills to the PBM's wholly owned mail-order or specialty pharmacies. This anticompetitive conduct mirrors marketplace platform self-preferencing and subverts patient choice.

CMS should establish that standard terms must strictly prohibit PBMs from utilizing competitor claims data for commercial patient-solicitation or steering campaigns, and mandate strict data firewalls between PBM claims-adjudication units and affiliated dispensing channels.

G. Contract Review Periods, Complete Upfront Disclosure, and Affirmative Consent at the Time of Offer

The statutory guarantee that Part D plans must permit "any pharmacy" to participate on standard terms and conditions presupposes that a pharmacy is afforded a genuine, commercially reasonable opportunity to evaluate whether to accept those terms. Under current PBM practices, however, the contracting process at the point of offer is systematically engineered to deny pharmacies that opportunity. PBMs routinely deliver contract offers, renewal packets, and comprehensive rate schedules on compressed deadlines – often mere days before an election deadline or plan year begins – while withholding the underlying financial formulas necessary to assess whether the offered rates cover drug acquisition and dispensing costs.

Compounding this disadvantage, PBMs frequently employ "passive contracting" constructs and negative-consent clauses at the point of offer. Under these provisions, a pharmacy is deemed to have accepted an entire network agreement simply by failing to return an opt-out form within an abbreviated window, or by continuing to submit routine claims for existing patients on or after an arbitrary effective date.

These practices subvert arm's length negotiation and deprive pharmacies of procedural due process before contractual obligations attach. While Section IV.D addresses the separate problem of PBMs using extrinsic provider manuals to alter terms *after* an agreement is executed, CMS should establish distinct baseline guardrails governing the **initial offer, renewal, and acceptance process** under Section 1860D–4(b)(1)(A):

1. **Mandatory 60-Day Prospective Review Period:** CMS should require Part D plan sponsors and their PBMs to provide pharmacies (and/or their designated PSAOs) a minimum of **60 calendar days** to review proposed standard terms, network agreements, and rate schedules before any formal election or acceptance is required. Standard terms offered on shorter timeframes should be deemed per se unreasonable.

2. **Complete Upfront Financial Disclosure at the Point of Offer:** Standard terms and conditions cannot be considered "reasonable" if essential financial terms are withheld or disclosed only in fragments after execution. CMS should mandate that every contract offer include complete, unbundled pricing terms at the time of tender, including:

- The specific ingredient cost methodology (e.g., exact NADAC or public benchmark basis) and any applicable discount formulas;
- The precise, fixed professional dispensing fee per claim;
- The full parameters, mathematical formulas, and reconciliation timelines of any aggregate pricing guarantees (such as GER, BER, or DFER);
- All quality, performance, or Star Ratings measures that could affect net reimbursement, including measure specifications, benchmark percentiles, and potential financial exposure; and
- An itemized disclosure of all pharmacy-facing fees – including any network participation, technical, or administrative service fees – and their precise value, that may be assessed against claims.

3. **Prohibition of Deemed Acceptance and Negative Consent:** Acceptance of a Part D standard contract or renewal must be active and informed. CMS should explicitly prohibit negative-consent, passive-contracting, and deemed-acceptance mechanisms. In particular, standard terms must not treat a pharmacy's continuation of claim submission for existing Medicare beneficiaries as constructive acceptance of a new or renewal agreement. Network participation should require an executed electronic or written signature from an authorized representative of the pharmacy.

4. **Pre-Execution Dispute and Negotiation Window:** To prevent "take-it-or-leave-it" standard contracts that violate the statutory intent of the Any Willing Pharmacy requirement, CMS should clarify that pharmacies have the right during the 60-day review period to seek written clarification or formally challenge non-compliant standard terms without forfeiting their network eligibility for the upcoming plan year.

H. Alignment of Pharmacy Performance and Quality Measures

Standard contract terms that condition pharmacy reimbursement or network placement on performance scores must be grounded in transparent, clinically meaningful measures. Today, PBMs frequently construct performance-based mechanisms and quality incentive programs like a game where the house always wins. Rather than evaluating a pharmacy against clear, achievable clinical baselines, PBMs grade pharmacies against opaque, shifting peer-percentile curves. Under this relative-ranking structure, it is mathematically impossible for all high-performing network pharmacies to retain full reimbursement, ensuring that the PBM claws back substantial funds regardless of how diligently pharmacies improve patient outcomes.

Furthermore, PBMs frequently apply health-plan-level population adherence measures—such as Proportion of Days Covered (PDC) for diabetes, hypertension, or cholesterol medications—to individual pharmacy locations with small, unadjusted patient sample sizes. These measures lack statistical

validation at the provider level and fail to risk-adjust for patient socioeconomic status or complex health disparities.

NACDS urges CMS to establish that pharmacy performance terms are neither reasonable nor relevant unless they:

- Align directly with standardized, non-proprietary measures developed by recognized consensus stewards (such as the Pharmacy Quality Alliance) and harmonize with CMS contract-level Part D Star Ratings;
- Are evaluated against fixed, transparent benchmark targets disclosed in advance and updated no more than annually, entirely eliminating relative-percentile ranking systems that guarantee penalties;
- Incorporate rigorous clinical and socioeconomic risk-adjustment methodologies that eliminate the penalization of pharmacies serving vulnerable or medically underserved populations; and
- Provide real-time, claim-level performance attribution and monthly reporting so pharmacies can actively track and improve patient adherence before performance periods close.
- Claim-level performance attribution should be based on objective, transparent, and clinically appropriate measures that are reasonably within the pharmacy's ability to influence or control. Pharmacies should not be held financially accountable for factors outside their control, including patient behavior, prescriber decisions, plan benefit design, or PBM-imposed restrictions.

I. Relative negotiating leverage of plans, PBMs, and pharmacies

The bargaining relationship between the largest PBMs and pharmacies is profoundly unequal if not nonexistent. As FTC staff found, "[b]ecause the Big 6 PBMs control over 90 percent of dispensing volume and the Big 3 cover approximately 270 million people, pharmacies often have little choice but to contract with the dominant PBMs to serve patients."[11] Concentration is even more pronounced in local markets: in twenty states, the single largest PBM held at least 50 percent of the market for retail pharmacy network management services for commercial plans, and in 35 states the largest PBM held at least 40 percent.[12] Multiple PBMs have referred during negotiations to a "no redlining policy" for their standard contract terms, even with large pharmacy services administrative organizations.[13]

This leverage disparity is magnified by PBMs' insistence on single national contracts. Where one PBM controls a dominant share of a single state—for example, 83 percent of retail pharmacy network management in South Carolina –a regional or national chain must either accept unfavorable terms across its entire footprint or *effectively exit that state*.[14] NACDS members have also observed that, when a state enacts minimum reimbursement protections, PBMs have reduced the reimbursement in neighboring states to preserve their margins –a particular burden on regional chains that must participate on an all-or-nothing basis across states. Recognizing these competitive realities provides a sound, competition-based rationale for nondiscriminatory contracting standards that do not treat all

[11] FTC Interim Report, at 48.
[12] *Id.*
[13] *Id.*
[14] Jose R. Guardado, *Competition in Commercial PBM Markets and Vertical Integration of Health Insurers with PBMs*, AMA Division of Economic and Health Policy Research (2023 update).

pharmacies as having identical business models, but also do not exclude any unaffiliated pharmacy from their protection.

J. Mid-contract modifications

Enforceable standards must apply throughout the contract period, not only when an agreement is signed. Standards that govern the initial contract can be readily evaded if it is allowable for PBMs to later change reimbursement methodologies, MAC lists, fees, or network requirements unilaterally, or shift pharmacies into nonstandard or alternative arrangements that fall outside the protections CMS establishes. NACDS strongly recommends that CMS establish standards governing material changes to reimbursement methodologies, fees, network participation requirements, and other significant provisions, including:

- advance written notice of no less than **90** days before any material change takes effect, with full disclosure of the change and its expected financial effect;
- an implementation delay until the next plan year of any discretionary mid-contract changes to reimbursement terms that would have a negative impact on pharmacy reimbursement;
- a meaningful opportunity to decline a material change without losing network participation for the remainder of the contract term;
- an opportunity to challenge material changes through the dispute resolution process described below;
- a prohibition on retaliation or conditioning network participation on acceptance of nonstandard or alternative contract terms that provide less protection than the standard terms; and
- A prohibition against a PBM terminating a pharmacy contract without cause, instead requiring that a termination be for cause, be based on defined grounds, be accompanied by written notice of the specific basis, and be reviewed by an independent third entity who was not a party to the original termination decision.

K. Dispute resolution procedures

A clear and accessible dispute resolution process can resolve contracting disagreements without requiring CMS to intervene in every individual dispute. Current processes fall far short. Pharmacies that appeal MAC determinations must appeal to the PBM itself, and NACDS members report MAC appeal success rates consistently below 10 percent. The Tennessee compliance audit found that nearly 30 percent of pharmacy appeals were rejected outright for incomplete paperwork, rather than on the merits, notwithstanding a state-law requirement that pharmacies be given an opportunity to cure.[15] Many PBM contracts also require binding arbitration, and some PBMs have required pharmacies to place funds in escrow as a precondition to initiating disputes.[16]

NACDS recommends that CMS establish minimum procedural requirements for dispute resolution under Part D pharmacy contracts, including:

[15] Tennessee Department of Commerce and Insurance, at 9 (Finding #6).
[16] National Association of Insurance Commissioners, Guide to Pharmacy Benefit Manager and Stakeholder Regulation (2025), at 21; FTC Interim Report, at 58 n.280.

- clearly written procedures, available to pharmacies at the time of contracting, for challenging reimbursement discrepancies, MAC and effective-rate determinations, recoupments, contract changes, and alleged discriminatory treatment;
- defined, timely deadlines for decisions, and adjustment of all similarly situated claims when a pharmacy's appeal succeeds;
- A prohibition on required binding arbitration;
- review by a decision-maker independent of the personnel who made the challenged determination;
- no fees, escrow, or other financial preconditions to filing a dispute, and an opportunity to cure technical deficiencies before a dispute is rejected; and
- documentation and periodic reporting to CMS of dispute volumes, outcomes, approval and denial rates, and resolution times.

L. Enforcement

Clear rules of the road will help prevent problems, but only if they are vigorously and consistently enforced. The record of PBM compliance with existing law underscores the need for robust enforcement. When the FTC issued compulsory orders to the six largest PBMs in 2022, press reports indicated that, twenty months later, none of the companies had complied.[17] In Tennessee's first-ever PBM compliance audit, the audited PBM submitted late responses to 41 percent of information requests and delayed the production of core claims data by nearly two months, requiring consent orders to compel compliance.[18]

NACDS urges CMS to make clear, beginning with the plan bid process and throughout each plan year, that it will use its authority under section 1857(g) of the Act, as applied to Part D sponsors through section 1860D–12(b)(3)(E), to impose intermediate sanctions –including suspension of enrollment –and civil money penalties on sponsors that fail to comply with the reasonable and relevant standards, and, where warranted, to terminate their Part D contracts. CMS should also establish a process for pharmacies to submit complaints regarding noncompliance and should use those complaints to target oversight and audits. Finally, CMS should require sponsors to document their compliance with the standards and to retain, and make available to CMS on request, all contract documents in effect during the contract year.

M. Coordination with the PBM remuneration and disclosure requirements

CMS has asked how the reasonable and relevant standards will overlap with implementation of section 1860D–12(h) of the Act. As NACDS explained in its response to CMS–4218–NC, pharmacy reimbursement arrangements –including spread pricing, retroactive effective-rate clawbacks, reconciliation adjustments, and pharmacy-facing fees such as "network access" and "technical" fees – are a significant source of PBM compensation. The two sets of requirements should therefore be implemented together: arrangements that reduce net pharmacy reimbursement below a cost-based floor should be treated both as unreasonable contract terms and as remuneration subject to scrutiny under section 1860D–12(h). DOL's final rule provides a useful model, requiring disclosure of copay clawbacks and "any other retroactive adjustment to pharmacy reimbursement," as well as of

[17] Maya Goldman, *First Look: PBM probe update*, Axios (Feb. 26, 2024).
[18] Tennessee Department of Commerce and Insurance, at 13 (Observation #1).

arrangements that direct patients to PBM-affiliated pharmacies.[19] In addition to ensuring the aforementioned coordination, when CMS is evaluating network access and technical fees, NACDS recommends that CMS prohibit network participation and claim processing fees unless it is for an itemized service that the pharmacy itself requested and received.

V. Section A – Pharmacy Reimbursement and Dispensing Fees

A. CMS should establish NADAC plus a professional dispensing fee as a reimbursement floor

NACDS supports fair and adequate reimbursement standards that are cost-based and enforceable, and include, at a minimum, reimbursement to the pharmacy or pharmacist for the full ingredient cost of the drug plus a fair and adequate professional dispensing fee that reflects at least the true cost of dispensing the drug, to ensure that PBMs no longer use their market power to force pharmacies to accept below-cost reimbursement that threatens their sustainability. Consistent with that position, NACDS urges CMS to establish, as part of the reasonable and relevant standards, a minimum reimbursement floor equal to NADAC plus a professional dispensing fee.

That floor should be a floor, not merely a benchmark against which reasonableness is assessed while leaving the underlying rate to private negotiation. Unconstrained private negotiation marred by an undeniable leverage disparity between pharmacies and the PBMs holding the market power described above is what produced and subsequently perpetuated today's frequent below-cost reimbursement scenarios. Plans and pharmacies would remain free to negotiate reimbursement above the floor, but no standard contract term should be considered reasonable if it results in reimbursement below it.

NADAC is an objective, publicly available benchmark administered by CMS and derived from actual pharmacy invoice data. It stands in contrast to the proprietary, "black box" benchmarks that PBMs increasingly use, such as Elsevier's Predictive Acquisition Cost, which are not used by the federal government in Medicare or Medicaid reimbursement and which PBMs have deployed as a one-way ratchet to reduce pharmacy payment.

In the Medicaid program, CMS has defined the professional dispensing fee to encompass the pharmacy costs of transferring a covered drug to the patient, including the pharmacist's time checking coverage and performing drug utilization review, filling the container, beneficiary counseling, delivery, special packaging, and the overhead associated with maintaining the facility and equipment necessary to operate the pharmacy.[20] CMS should adopt a comparable definition for Part D that accounts for instances when dispensing requires additional handling, delivery and clinical support, as well as differing equipment and compliance requirements. CMS should consider permitting evidence-based dispensing fee adjustments where documented requirements create materially different dispensing costs.

As of the quarter ending September 2026, most state Medicaid programs reimbursed retail pharmacies a professional dispensing fee of between $10.00 and $12.50 per prescription, and many states reimbursed substantially more to lower-volume or remote pharmacies.[21] West Virginia's experience is

[19] DOL Final Rule (29 C.F.R. § 2550.408b–22(e)(3)(ii)(C), (e)(3)(iii)).
[20] 42 C.F.R. § 447.502. In August 2025, CMS reminded all Part D plan sponsors that it expects dispensing fees "to sufficiently compensate network pharmacies so that enrollees can be assured network access," and that dispensing fees cover costs incurred at the point of sale in excess of ingredient cost, including "salaries, time associated with checking for coverage, filling the container, packaging, and overhead (including IT)." Ctrs. for Medicare & Medicaid Servs., Memorandum to All Prescription Drug Plans, Medicare Advantage-Prescription Drug Plans, Section 1876 Cost Plans, Medicare-Medicaid Plans, and PACE Organizations, *Network Adequacy Requirements and Dispensing Fees for Selected Drugs* (Aug. 25, 2025). citing 42 C.F.R. § 423.100.
[21] Ctrs. for Medicare & Medicaid Servs., *Medicaid Covered Outpatient Prescription Drug Reimbursement Information by State, Quarter Ending September 2026*.

instructive: after the state moved Medicaid pharmacy claims to fee-for-service reimbursement at NADAC plus a $10.49 professional dispensing fee, an actuarial assessment commissioned by the state estimated SFY 2018 savings of approximately $54.5 million, even as dispensing fees paid to pharmacies increased.[22]

PBM arguments that large retail chain efficiencies justify dispensing fees as low as $2.00 collapse under empirical examination. Recent state cost-of-dispensing surveys found weighted average costs exceeding $12 per claim.[23] These operational overhead costs—encompassing specialized cold-chain refrigeration, mandatory electronic prescribing infrastructure, regulatory compliance, clinical counseling, and licensed pharmacy staff—largely do not vary with the ingredient cost of the drug. A $2.00 dispensing fee leaves the average dispensing pharmacy at least $10 underwater on operating expenses for virtually every generic prescription dispensed.

Anchoring Part D reimbursement to an objective professional dispensing fee modeled on transparent state Medicaid determinations ensures that network pharmacies are fairly compensated for professional dispensing services without relying on artificial cross-subsidies. Importantly, CMS should consider defining standard terms for Maximum Fair Price drug claims to include a meaningful professional dispensing fee. Additionally, CMS should acknowledge that clinical services are performed separately and distinctly from professional dispensing and include a number of components including, but not limited to, patient assessments, screening, counseling, and documentation. CMS should require that reimbursement for clinical services separately from and in addition to a professional dispensing fee and the PBMs should be prohibited from utilizing clinical service reimbursements to offset ingredient cost or professional dispensing fees associated with the aforementioned rate floor.

B. Drugs without a NADAC

NADAC coverage is generally cited at approximately 98 percent of generic drugs and 99 percent of brand drugs. While this represents a relatively small share of covered drugs, CMS should explicitly establish clear requirements and enforceable guardrails governing reimbursement for them. Historically, drugs without a NADAC have been reimbursed using wholesale acquisition cost (WAC) or WAC-plus methodologies. Without clear standards for these drugs, PBMs will be free to establish reimbursement methodologies at their discretion, effectively leaving the door open for the reforms to be circumvented – especially for pharmacies that are not part of the aforementioned insurer, PBM, and pharmacy vertical integration schematic.

To establish an objective, operationally workable standard for the small percentage of drugs (primarily limited distribution and newly introduced specialty therapies) that lack a NADAC benchmark, CMS should adopt an explicit pricing hierarchy:

1. **Primary Benchmark:** Where a published NADAC exists, reimbursement for ingredient cost must not fall below 100 percent of NADAC.

2. **Fallback Benchmark for Non-NADAC Products:** For drugs without a published NADAC, ingredient cost reimbursement should be anchored to an objective, non-PBM-controlled public

[22] Navigant, *Pharmacy Savings Report: West Virginia Medicaid, Actuarial Assessment of the SFY18 Impact of Carving out Prescription Drugs from Managed Care for West Virginia's Medicaid Program* (Feb. 25, 2019), https://www.ncpa.co/pdf/state-advoc/west-virginia-report.pdf.
[23] Idaho Department of Insurance, *Survey of the Cost of Dispensing a Prescription in the State of Idaho* (Oct. 2025) (weighted average of non-specialty dispensing cost was $12.26 and the majority of pharmacies (approximately 70 percent) had average dispensing costs between $9 and $15); Oregon Health Authority, *Survey of the Average Cost of Dispensing a Medicaid Prescription for the State of Oregon* (July 2024) (finding weighted average dispensing cost of $12.15, the majority of pharmacies (approximately 70 percent) had average cost of dispensing between $8 and $25).

benchmark—specifically, **undiscounted Wholesale Acquisition Cost (WAC + 0%)**. CMS should expressly prohibit "WAC-minus" reimbursement formulas that assume wholesale discounts not available to retail community pharmacies.

3. **Acquisition Cost Appeal Right:** In the event that a pharmacy's verifiable wholesale invoice acquisition cost exceeds the fallback benchmark due to acute market shortages, specialty distribution surcharges, or geographical challenges, CMS should require PBMs to provide an expedited, binding reimbursement true-up to cover the pharmacy's acquisition cost plus the professional dispensing fee that does not require a pharmacy to disclose acquisition costs when they are subject to a confidentiality agreement. Any dispute requiring disclosure of acquisition cost should be resolved by an unaffiliated, neutral third party under a nondisclosure agreement, not the PBM."

C. The floor must apply after reconciliation and all post-adjudication adjustments.

A reimbursement floor will be meaningless if reimbursement appears reasonable on an individual claim but falls below cost after reconciliation. PBMs commonly use Generic Effective Rates, Brand Effective Rates, and Dispensing Fee Effective Rates to impose aggregate discount targets across a year's worth of claims and to claw back reimbursement retroactively. DOL has recently described this practice of "effective rate reconciliation," under which the PBM periodically reconciles point-of-sale payments against an aggregate effective rate and adjusts future reimbursement accordingly.[24] The history of direct and indirect remuneration (DIR) fees –which CMS estimated increased by more than 107,400 percent from 2010 to 2020,[25] with final settlement as much as 18 months after dispensing –demonstrates how retroactive mechanisms can hollow out pharmacy reimbursement. And following the elimination of retroactive pharmacy DIR, PBMs have introduced new, non-negotiable "Network Access Fees," "Technical Fees," and "Pharmacy Administrative Service Fees" deducted from pharmacy payments.

CMS should extend the guaranteed transparency requirements of proposed § 423.2812 (CMS-4214-P) to pharmacy-facing effective-rate guarantees. This includes consistent definitions of generic, brand, biologic, biosimilar, and authorized generic; NDC-level lists and exclusions; and WAC-based equivalents.

CMS should therefore measure compliance with the reimbursement floor on a net basis, after all reconciliation payments, effective-rate adjustments, fees, recoupments, and other post-adjudication adjustments, and should prohibit any mechanism that reduces net reimbursement on a claim below the floor.

D. Predictability of final reimbursement and claim-level information

Pharmacies cannot manage their businesses, or evaluate whether contract terms are reasonable, if they cannot determine at the point of sale what they will ultimately be reimbursed. NACDS recommends that CMS require that (1) the negotiated price reported on the pharmacy claim response reflect the pharmacy's final reimbursement for that claim. This is consistent with the negotiated price definition at 42 C.F.R. § 423.100 and the 14-day prompt-pay requirement. Downward adjustments below the point-of-sale amount, including offsets against later remittances, should be prohibited as a return to retroactive pharmacy DIR. CMS should clarify how upward reconciliation payments are treated for negotiated price, PDE, and DIR reporting; (2) remittance advice provide sufficient claim-level detail for

[24] DOL Final Rule, at 69099–100.
[25] 87 Fed. Reg. 1842 (Jan. 12, 2022).

the pharmacy to determine how much it was paid for each claim, including after any adjustment; and (3) Part D reimbursement terms be established, reconciled, and reported separately from commercial and other lines of business, so that guarantees spanning multiple lines of business cannot be used to offset Part D reimbursement.

In particular, CMS should require that all claim-level pricing details—including the initial point-of-sale adjudicated rate, ingredient costs, dispensing fees, and any subsequent post-adjudication adjustments or reconciliations—be transmitted using standardized electronic data protocols (specifically ASC X12N 835 Electronic Remittance Advice files) with mandatory claim-level adjustment detail. CMS should explicitly ban the practice of deducting post-adjudication adjustments or fees through aggregate, lump-sum remittance write-offs that cannot be matched to individual prescription transactions and require that the reimbursement amount determined at adjudication be final, absent correction of documented claim errors. [26]Standardizing claim-level electronic remittance ensures transparent tracking by 11-digit National Drug Code (NDC) and pharmacy National Provider Identifier (NPI).

E. Proprietary reimbursement data

Detailed rate, acquisition cost, and margin information cannot reasonably be provided through public comments, for the reasons discussed in Section III. NACDS encourages CMS to obtain such information through the confidential process recommended above and through its existing authority to obtain contracting documents from sponsors and their PBMs.

F. Use of artificial intelligence and machine learning

CMS has asked about the use of machine learning to estimate acquisition costs and opportunities for the use of artificial intelligence (AI) in Part D pharmacy reimbursement. To the extent AI or machine-learning tools are used to set or adjust pharmacy reimbursement, CMS should, at a minimum, establish expectations for transparency, oversight, and pharmacy input.

CMS should establish mandatory regulatory guardrails governing any automated, algorithmic, or machine-learning tools used by Part D sponsors and PBMs:

- **Algorithmic Transparency and Auditability:** PBMs must provide CMS and network pharmacies meaningful disclosure of the methodologies, underlying data sources, and factors used in predictive models (such as Elsevier's Predictive Acquisition Cost) that affect acquisition cost estimates or reimbursement rates, while protecting legitimate proprietary information. Such models should be subject to appropriate oversight and auditability.
- **Prohibition of Algorithmic Margin Suppression:** Algorithmic pricing tools must not be used to circumvent applicable reimbursement protections or inappropriately suppress pharmacy reimbursement. AI-generated benchmarks should reflect acquisition costs, market conditions, and the cost of dispensing prescription drugs.
- **Mandatory Human Review for Denials and Appeals:** Adverse pharmacy reimbursement or maximum allowable cost (MAC) pricing decisions generated in whole or in part by automated

[26] *See* Nat'l Cmty. Pharmacists Ass'n, *Survey of Community Pharmacies: Impact of Direct and Indirect Remuneration (DIR) Fees on Pharmacies and PBM-Imposed Copay Clawback Fees Affecting Patients*, at 2 (June 2016) (finding that among pharmacies receiving fee disclosures, only about one-quarter received an itemized claim-level accounting); *see also* Inmar Intelligence, *Direct and Indirect Remuneration (DIR) White Paper*, at 13–14 & Ex. 9 (2020) (documenting that routine electronic remittance lacks claim-level itemization for the overwhelming majority of plans).

systems must be subject to timely, meaningful review, reconsideration, and correction by qualified personnel.

- **Anti-Bias and Parity Oversight:** AI-enabled reimbursement methodologies must be regularly evaluated to identify unintended bias, inappropriate manipulation, or systematic reimbursement disparities between PBM-affiliated and unaffiliated pharmacies.
- **Economically Responsive Reimbursement Methodologies:** AI-enabled reimbursement methodologies should account for changing acquisition costs, inflation, drug shortages, supply chain disruptions, and other market conditions to support predictable and economically sustainable pharmacy reimbursement.
- **Ongoing Validation and Accountability:** PBMs and Part D sponsors should maintain risk-based oversight, ongoing validation, and monitoring of AI-enabled reimbursement methodologies to address inaccurate data, model drift, and unintended consequences. Organizations must remain accountable for reimbursement decisions informed by AI.
- **Meaningful Pharmacy Engagement:** Pharmacies should have opportunities to participate in the development, implementation, evaluation, and ongoing oversight of AI-enabled reimbursement methodologies that materially affect reimbursement, network participation, and patient access.

VI. Conclusion

Congress directed CMS to ensure that the terms on which Part D plans contract with pharmacies are reasonable and relevant. Meeting that directive requires clear, enforceable standards that ensure pharmacies are fairly and adequately reimbursed, can meaningfully participate in Part D networks, and are subject to consistent and transparent contracting requirements regardless of size or business model. NACDS therefore urges CMS to:

- apply the standards neutrally to all pharmacies, while directing heightened scrutiny at pharmacies under common ownership and control of both a PBM and a health insurance issuer;
- establish a confidential process for submitting cost and reimbursement information, and use its existing authority to obtain contracting documents directly from sponsors and PBMs;
- adopt objective standards governing the factors for reasonableness, similarly situated determinations, and access to preferred networks;
- ensure that pharmacies receive complete terms, including all financial terms, at the time of offer, with an adequate review period and affirmative acceptance, and prohibit the use of provider manuals and other unilaterally modifiable documents, or unilateral mid-contract changes, to alter material terms;
- establish fair audit standards, including prohibitions on extrapolation and including a right to cure, and prohibit PBMs from using claims data submitted by unaffiliated pharmacies to steer patients to PBM-affiliated pharmacies;
- require that performance measures affecting reimbursement be transparent, clinically meaningful, and evaluated against fixed benchmarks;

- require independent and timely dispute resolution, backed by meaningful enforcement and coordinated with the PBM remuneration and disclosure requirements of section 1860D–12(h) of the Act;
- establish NADAC plus a professional dispensing fee as a reimbursement floor, with clear guardrails for drugs without a NADAC, measured after all reconciliation and post-adjudication adjustments and supported by claim-level remittance information; and
- ensure that any artificial intelligence or algorithmic tools used to set reimbursement are transparent, subject to oversight, and never used to reduce reimbursement below the floor.

NACDS implores CMS to strongly consider full implementation of the aforementioned recommendations. Without necessary implementation and enforcement, pharmacies across the nation will continue to close, resulting in beneficiary access challenges and increased healthcare costs. NACDS appreciates CMS's consideration of these comments and stands ready to serve as a resource as the agency develops its rulemaking. Please do not hesitate to contact Christie Boutte, NACDS Senior Vice President, Reimbursement, Innovation, and Advocacy, at CBoutte@nacds.org with any questions.

Sincerely,



Steven C. Anderson, FASAE, CAE, IOM
President and Chief Executive Officer