[Date]

*Submitted electronically via regulations.gov*

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

**Re: Request for Information; Medicare Part D Reasonable and Relevant Pharmacy Contracting Standards (CMS-4217-NC; 91 FR 60568)**

Dear Administrator Oz:

## Summary of Key Recommendations

- **Set an enforceable reimbursement floor.** Standard terms should pay pharmacies no less than a transparent measure of acquisition cost, such as NADAC, plus a dispensing fee that covers the cost of dispensing.
- **Make final payment knowable at the point of sale.** Prohibit reconciliations that reduce payment after a claim is paid, and bar effective rate guarantees that blend Part D with commercial business.
- **Require complete terms, time to review them, and our signature.** Full rate information with every offer, a minimum review period, affirmative acceptance, and no unilateral mid-year changes.
- **Open preferred and specialty networks.** Any pharmacy that meets published, objective criteria should be able to participate on the same terms in all the Part D plan's networks.
- **Set reasonable audit standards.** No recoupment for clerical errors that caused no financial harm, no extrapolation without evidence of fraud, and an independent appeals process.
- **Hold affiliated and unaffiliated pharmacies to the same terms.** No term should favor pharmacies owned by the plan or its PBM.
- **Make the standards enforceable.** Write them as measurable requirements, bar contract terms that keep pharmacies from sharing their contracts with CMS and use the allegation process and civil monetary penalties Congress provided.

**All recommendations**

A. Pharmacy Reimbursement and Dispensing Fees

- 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).
- 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' 2005 statement that terms may vary by pharmacy type only if all similarly situated pharmacies are offered the same terms (70 FR 4254).
- 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.
- NADAC most closely reflects retail pharmacy acquisition cost because it is derived from a national survey of pharmacy invoice prices and is updated weekly. Where NADAC is not available or not applicable to a pharmacy type, another transparent acquisition-cost benchmark should apply.
- 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.
- 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.
- 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. Any sharing of acquisition costs should go to CMS or a neutral third party, not to a PBM that owns competing pharmacies.
- Reasonable terms should cover costs for each drug rather than rely on cross-subsidies across drug categories that pharmacies cannot control.

- 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 covers 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 claims for all similarly situated pharmacies.
- 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. At a minimum, PBMs and plans should disclose the MAC methodology and list with the contract offer.
- 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.
- 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 have ownership and oversight of any machine learning used in a federal program like Medicare Part D.
- 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.
- Terms should not reduce payment on the assumption that a claim is a 340B claim.
- 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 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.
- 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.
- 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.

- The cost of dispensing should be surveyed and adjusted annually based on consumer price index (CPI) and cost-of-living adjustments (COLA).
- Short-cycle dispensing fees should be paid as drugs are dispensed, not as a roll up at the end of the month.
- Every post-adjudication adjustment should be disclosed claim by claim, explained, and open to appeal. Adjustments that reduce payment after the point of sale should be prohibited.
- 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.
- Aggregate guarantees are offered on a take-it-or-leave-it basis. That imbalance is why the standards should set minimum terms rather than rely on negotiation.
- Aggregate guarantees can push pharmacies away from high-cost generics, which the FTC has found to be a growing profit center for PBM-affiliated specialty pharmacies. Claim-level payment would remove that distortion.
- Pharmacies should know what they will be paid when they dispense. Final claim-level payment and complete terms at offer would achieve this.
- Remittance advice should show, for each claim, the amount paid at the point of sale and every later adjustment, with a reason code.
- 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.

B. Current Contracting Practices

- Standard terms for preferred networks should be available to any pharmacy willing to accept them.
- 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.
- Standard terms should state the complete reimbursement methodology at the time of offer.
- PBMs and plans should give at least **[60]** days to review initial and subsequent offers and amendments.

- 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.
- 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.
- 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.
- 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 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.
- CMS should align the two sets of requirements: use PBM disclosures under section 1860D-12(h) to check compliance with the pharmacy contracting standards, apply the same definition of "affiliate," and make clear that complying with one does not satisfy the other.
- CMS should treat terms that routinely pay below acquisition cost for a drug as a barrier to enrollee access, because they push pharmacies to stop carrying that drug. 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.
- 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.
- 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.

- A "specialty" label for a drug should not by itself justify lower reimbursement, different performance measures, or stricter audits for unaffiliated pharmacies.
- Plan sponsors/PBMs cannot decrease reimbursements of Medicare Drug Price Negotiation Program (MDPNP) drugs in response to manufacturer refunds.
- CMS should define specialty pharmacy by capability, such as accreditation by a recognized body and the ability to handle, store, and support patients on complex therapies, not by PBM designation.
- 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 well as 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.
- 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.
- Independent pharmacies have essentially no leverage with the three largest PBMs, which together processed nearly 80 percent of U.S. prescriptions in 2025,[1] and each own competing pharmacies. That is why minimum standards, rather than negotiation, must set the floor. That is because PBMs do not “negotiate” with pharmacies.
- 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)). 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.

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

- 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.
- 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.

C. Trends in Contract Terms and Conditions

- CMS should watch for terms that recreate retroactive fees in new forms, such as low base rates paired with incentive payments the pharmacy may never earn.
- 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.
- Uniform terms are not a problem in themselves; uniformly below-cost terms are. The standards should set a floor that applies across all sponsors.
- Contracts should include terms suited to each line of business a pharmacy operates, rather than forcing specialized dispensing into a retail contract.
- Non-dispensing services should be paid separately under terms disclosed in the standard contract, not folded into dispensing fees or performance measures.
- 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.
- Reasonable terms should ensure that, for selected MFP drugs, plan payment plus the MFP refund covers the pharmacy's acquisition cost and a dispensing fee, and that sponsors do not cut reimbursement on other drugs to offset lower negotiated prices on selected drugs.

D. Pharmacy Quality and Performance Measures

- Measures are currently in separate contracts. Pharmacy quality and performance measures should be identified in the contract, and their financial effect should be stated in the contract at the time of offer.
- Measures should be limited to those with a recognized steward, a published specification, and evidence that pharmacies can influence the result.

- 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.
- 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.
- Sponsors should be required to show that their pharmacy performance programs improve enrollee outcomes. Programs that mainly move money should not qualify as reasonable.
- Pharmacies should receive performance data at least monthly, with patient-level detail, so they can act on it.
- Pharmacy measures should align with Star Ratings specifications and be re-specified at the pharmacy level only through a transparent, published method.
- CMS should require sponsors to analyze and report whether their measures disadvantage particular types of pharmacies.
- Pharmacies should be able to appeal measure calculations, including patient attribution, before any payment effect.

E. Auditing Practices

- The standards should limit audit frequency and volume, require at least **[14]** days' notice for on-site audits, [30] days for desk and invoice audits and limit the look-back period for claims adjudicated in the **[2]** years immediately preceding all audits.
- Every audit report should list each claim, the finding, the amount, and the contractual or regulatory basis for the discrepancy.
- CMS should require sponsors to report audit recoupments by finding type, so it can see how much is recovered for clerical issues.
- 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.
- 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.
- 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.
- Audit terms should provide written notice, a preliminary report within [30] days of the documentation due date, at least 30 days to respond, an independent appeal, and no

recoupment until the appeal is decided. Auditors should not be paid based on the amounts they recover.

- Preliminary reports for invoice audits must include sufficient detail for what purchases were accepted or rejected.
- Documentation standards should not exceed existing law or that required of affiliated pharmacies.
- If the PBM recoups a claim in full, it should be removed from the PDE.
- PBMs and plans should have an affirmative burden to show fraud, waste and abuse when categorizing audits accordingly.
- Part D audits should be stand-alone, separated from other types of lines of business, like Medicaid or commercial payor audits.
- 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.

F. Limitations

- 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).

G. Current Regulations and Guidance

- 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

- 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)).

## Conclusion

Thank you for considering these comments. [Pharmacy name] would welcome the opportunity to discuss our experience further. Please contact [name] at [business email or phone].

Sincerely,

[Name]
[Title]
[Pharmacy name]
[City, State]