November 23, 2026

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The Honorable Mehmet Oz, MD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-4217-NC
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

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

Dear Administrator Oz:

On behalf of the National Association of Specialty Pharmacy ("NASP"), thank you for the opportunity to comment on the "Medicare Part D Reasonable and Relevant Pharmacy Contracting Standards" Request for Information ("RFI"),[1] which solicits input for purposes of establishing standards for reasonable and relevant pharmacy contract terms and conditions under the Medicare prescription drug benefit, as Section 6223 of the Consolidated Appropriations Act, 2026 requires. NASP's comments below respond to the topics on which the RFI seeks information, beginning with an executive summary of NASP's positions and a description of how the record supporting these comments was built.

Executive Summary and Methodology

A. General background section on NASP and how the record of information informing this RFI response was built

The National Association of Specialty Pharmacy (NASP) is a 501(c)(6) non-profit trade association, founded in 2012, and is the only national association representing all stakeholders in the specialty pharmacy industry.[2] Its mission is to empower specialty pharmacy stakeholders to advance the standard of patient care. NASP has more than 4,000 members, including specialty pharmacies, practicing pharmacists, pharmacy technicians, and nurses, as well as manufacturers, wholesalers, distributors, patient advocacy organizations, data and technology providers, protective packaging, cold chain management and logistics providers and other industry participants.[3] NASP provides continuing education and certification for specialty pharmacy professionals, develops clinical practice recommendations, and advocates at the federal and state level on policy and legal matters affecting patient access to specialty pharmacies and on specialty pharmacy business matters. It supports a free-market health care system in which all specialty pharmacies compete on a fair and level playing field and patients have access to the specialty pharmacy of their choice.

NASP's specialty pharmacy members represent the full breadth and diversity of specialty pharmacy practice, encompassing a wide range of practice settings, care delivery models, and patient populations. They include independent (non-affiliated) specialty pharmacies, health-system and hospital-based specialty pharmacies, including those serving 340B covered entities, home and alternate-site infusion providers, oncology and other disease-focused pharmacies, rare and orphan disease-focused pharmacies and those focused on cell and gene therapy, and specialty pharmacies of various size that are independent (non-affiliated) or affiliated with other healthcare market participants. Across its prior comments to CMS and other policymakers, NASP has consistently advocated for a clear, objective recognition of specialty pharmacy based on accreditation by a single nationally recognized, independent third-party specialty pharmacy accreditor. NASP has also urged that network participation and contracting standards recognize the distinct clinical, operational, and patient care services specialty pharmacies provide.[4] This RFI response maintains that consistent position, and advocates for "reasonable and relevant" contracting standards that can be applied consistently to all specialty pharmacies serving Part D beneficiaries, as some PBMs have previously ignored or misinterpreted Part D standards to the disadvantage of such pharmacies.

To prepare this response, Frier Levitt, a national boutique healthcare and life sciences law firm, surveyed NASP member pharmacies. All survey submissions were made directly to Frier Levitt, and NASP never received survey responses directly. Frier Levitt compiled and aggregated the responses and de-identified the data, so the results reported in this response describe member pharmacies' experience in the aggregate and do not identify any individual pharmacy. Frier Levitt also followed up with, and spoke directly to, individual pharmacies, without participation by NASP personnel. The survey responses therefore reflect NASP member pharmacies across a diversity of specialty pharmacy practice models, and the observations here reflect that range.

B. **Should CMS Define Specialty Pharmacy**

Yes. Consistent with NASP's July 2026 comments on Section 6224, CMS should define a specialty pharmacy for Part D contracting as a pharmacy that is currently accredited by one nationally recognized, independent third-party specialty pharmacy accreditor, such as URAC, ACHC, or The Joint Commission.[5] Accreditation provides an objective, independent means of identifying pharmacies with the comprehensive clinical and operational capabilities and longitudinal patient-care services necessary to deliver comprehensive, coordinated, and ongoing care to patients with complex health conditions. Through accreditation, pharmacies demonstrate their ability to meet established specialty pharmacy standards and provide the specialized services these patients require. A single, objective definition would end the current practice in which each PBM decides for itself which pharmacies count as "specialty," often to the advantage of its own affiliates (see Section II.E). NASP seeks a rule clarifying that a plan sponsor or its PBM may not deny any specialty pharmacy-accredited pharmacy (regardless of the pharmacy's practice setting) specialty network participation, specialty terms, or access to a drug the pharmacy can lawfully acquire, and may not require a second accreditation, proprietary credentialing, or fees in order to participate in a network.

C. **Short Answer on How to Define "Reasonable and Relevant"**

Whether a pharmacy's contract term is "reasonable and relevant" must be judged in relation to the pharmacy. NASP asks CMS to adopt a two-part test and to apply it to every standard. A

term is **reasonable** when a pharmacy with equal bargaining power could agree to it. Reimbursement is reasonable where it covers the cost of acquiring and dispensing the drug and of the care the patient requires, is predictable at the point of sale, is complete when offered, is mutual, and is backed by meaningful due process. A term is **relevant** when it fits the pharmacy's type and services, the drugs it dispenses, and where it serves a legitimate Part D purpose. Relevance turns on whether a pharmacy can safely dispense a drug and manage the patient's therapy, not on its volume of that drug, its ownership, or the drug's price. CMS should provide that a term that fails either prong is void.

The above test is needed because the conditions that once allowed pharmacies and PBMs to arrive at fair terms on their own no longer exist. Three PBMs manage nearly 80 percent of U.S. prescriptions, each sits within a conglomerate that also owns insurers and specialty pharmacies, and their affiliated pharmacies now take roughly 68 to 70 percent of specialty dispensing revenue (see Section II.A). The same enterprise that writes an non-affiliated specialty pharmacy's contract, sets its reimbursement, audits its claims, and decides whether it stays in the network also owns the pharmacy competing with it for the same patients. No specialty pharmacy can walk away from a network that covers most of its patients, and CMS itself has recognized that pharmacies "often do not have the ability to meaningfully negotiate" (see Section I.C). The result is a market in which certain PBMs pay non-affiliated pharmacies below cost, use "specialty" designations and proprietary credentialing to narrow networks and exclude independent (non-affiliated) specialty pharmacies, penalize pharmacies for the patient concentration that specialization naturally produces, and steer patients to their own affiliated pharmacies (see Sections II and III). These practices do not reward better care. They reward ownership, and they erode the independent and other non-affiliated specialty pharmacies on which Medicare beneficiaries with complex and rare conditions depend.

The reasonable-and-relevant requirement has been in CMS's regulations since 2005, but without defined standards it has rarely, if ever, been enforced (see Section IX.E). Congress has now directed CMS to establish those standards "[n]otwithstanding any other provision of law" (see Section X). A standard built solely for retail pharmacies will fail specialty pharmacies and the Medicare patients they serve. NASP therefore asks CMS to adopt standards that offer the same terms to every capable pharmacy regardless of ownership, measure each term against the pharmacy and the drug to which it applies, and give pharmacies a real remedy when a Plan or PBM falls short. The sections that follow apply that test to the specific questions CMS has asked.

Any rule from this process should do three things. **First, it should recognize the practice of specialty pharmacy as distinct and validated, by nationally recognized, independent third-party specialty pharmacy accreditation,** so it can't be folded into retail or traditional mail-order standards that do not fit the care model specialty pharmacies provide (see Sections I.A and II.E). Specialty pharmacy status should be determined by a pharmacy's demonstrated clinical and operational capabilities, rather than the cost of the medications it dispenses, and no plan sponsor or PBM should be permitted to layer duplicative or PBM-owned credentialing on top of that accreditation to narrow its network (see Sections II.D and II.E). Nor should a similarly situated specialty pharmacy be excluded because it lacks volume in that drug or penalized because its patients are concentrated in the conditions it specializes in treating (see Sections II.C and II.F).

Second, it should evaluate cost the way specialty pharmacies actually incur it. Acquisition cost for specialty drugs depends on distribution channels, special handling, bona fide services and inventory risk. Pharmacy acquisition cost must be benchmarked to NADAC, an

objective, publicly reported measure that is not maintained by a PBM that owns competing pharmacies, with WAC +0.00% as the fallback for any drug NADAC does not cover or does not cover in a statistically representative way (see Sections I.A, III.A, and V.A). Specialty pharmacies cannot be expected to provide their confidential purchasing terms and invoices to PBMs (who own competing pharmacies), and acquisition cost cannot be net of purchasing rebates and discounts fairly earned through good purchasing practices, consistent with the protection Congress gave customary purchasing discounts in Section 6224 (see Sections I.A and V.A).

Third, if a network is being billed as "cost plus," the "plus" must reimburse for specialty care. The dispensing fee, or any amount above cost, must cover the services specialty pharmacies already provide but typically aren't paid for by the PBM separately: complex administration; side-effect management; special handling; benefits investigation and coverage support; expanded pharmacy availability; and specialized patient education, including especially initial patient education about the drug prescribed and its therapeutic value, monitoring, nursing and other clinical services (see Sections IV.A and IV.B). A flat fee designed for retail dispensing of oral generics bears no relationship to the cost of dispensing a cold-chain biologic with REMS reporting and patient training (see Section I.A). And because a PBM-affiliated pharmacy can absorb an inadequate rate when its corporate family recovers the difference elsewhere, while an non-affiliated pharmacy cannot, an inadequate "plus" operates in practice as one more advantage for the PBM's own pharmacies (see Section II.D).

To ensure reasonable reimbursement to pharmacies of any type, a floor, not a payment rate or a ceiling must be established. NASP isn't asking CMS to set prices or prescribe a payment methodology. NASP urges CMS to prohibit contractual terms that reimburse specialty pharmacies below their actual acquisition costs for specialty medications and to ensure separate, adequate reimbursement for the costs of dispensing those medications and providing the specialized patient care services necessary to support patients receiving these therapies. Under a floor, a term would not be reasonable if it paid a network pharmacy less, for a given drug, than the acquisition cost benchmark for that drug (NADAC, or WAC +0.00% where NADAC is unavailable or insufficient), plus a dispensing fee that covers the cost of dispensing for that pharmacy type plus a reasonable margin, with the services the network requires paid for separately (see Sections I.A, IV, and V.A). The floor should apply drug by drug, so that a below-cost rate on one drug cannot be excused by margin on another (see Sections III.D and V.A). Congress directed CMS to consider whether pharmacy reimbursement and dispensing fees "sufficiently cover the ingredient and operational costs of such pharmacies," and CMS guidance already requires sponsors to offer reasonable and relevant reimbursement terms for all Part D drugs. A floor implements that requirement without creating a fee schedule (see Section V.A). Above that floor, sponsors and PBMs remain free to negotiate any rate, benchmark, or methodology, and any cost-plus arrangement in Part D should keep pharmacies competing: a pharmacy that purchases efficiently or exceeds service standards should keep that benefit, and the "plus" must account for the working capital specialty pharmacies commit to high-cost drug inventory. CMS should also make clear that the floor is a protection, not a cap, so that it does not become the rate PBMs offer every pharmacy and eliminate the incentive to compete on service and quality (see Section IV.A).

D. How This Response Is Organized

The remainder of this response follows CMS's questions, grouped into ten sections that reflect how specialty pharmacies experience Part D contracting:

I. What "Reasonable and Relevant" Should Mean
II. Open Access and Equal Treatment Regardless of Ownership
III. Reimbursement Below Cost
IV. Dispensing Fees and Unpaid Services
V. What CMS Should Do About Reimbursement
VI. 340B-Specific Terms
VII. Contract Integrity
VIII. Audits and Terminations
IX. Enforcement and Implementation
X. Related Issues and Legal Authority

Section I provides the framework for the rest of the response: a two-part test under which a contract term must be both reasonable and relevant to the pharmacy that is asked to accept it. Sections II through VIII apply that test to the issues that most affect specialty pharmacies and their patients, from network access and reimbursement to contract changes, audits, and terminations. Section IX explains how the standards can be made enforceable and implemented on CMS's statutory timeline and includes model contract terms. Section X addresses CMS's remaining legal and coordination questions, including how these standards interact with Section 6224 PBM reforms.

Within each section, each subsection opens with CMS's question, quoted from the RFI, followed by NASP's answer. Where CMS asked several closely related questions, we quote them together and answer them once. NASP has focused on the questions where specialty pharmacies have direct experience and a distinct perspective. NASP's silence on any question should not be read as agreement with current practice.

I. What "Reasonable and Relevant" Should Mean

A. **What "reasonable and relevant" should mean:** CMS asks *"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;"*

What "Reasonable and Relevant" Should Mean

NASP asks CMS to adopt a two-part test and to use it as the framework for every standard that follows: a term must be both reasonable and relevant, and each recommendation in this response is tied to one prong or to both. In brief, a term is reasonable when a party with equal bargaining power could agree to it under all circumstances, which means it covers the pharmacy's costs, is predictable at the point of sale, is complete at the time of offer, is mutual, and carries meaningful due process. A term is relevant when it fits the pharmacy: its type and services, the drugs it dispenses, and a legitimate Part D purpose.

"Reasonable"

A term is reasonable when a party with equal bargaining power could reasonably agree to it under all circumstances. This standard borrows from the settled law of unconscionability, which is applicable in this context because it is typically applied in situations where, as here, there is a

significant disparity in bargaining leverage between two parties.[6] A term is substantively unconscionable when, viewed at the time of contracting, it is unreasonably favorable to the stronger party, meaning overly harsh, unduly oppressive, or so one-sided as to shock the conscience. A term is procedurally unconscionable when the contracting process deprived the weaker party of meaningful choice through oppression or surprise, such as a take-it-or-leave-it presentation, unequal bargaining power, hidden terms, or fine print.[7] A reasonable Part D term is neither substantively nor procedurally unconscionable. Because the Part D contracting process is, by CMS's own account, one in which pharmacies "often do not have the ability to meaningfully negotiate"[8] (see Section I.C), the lack of procedural fairness exists in nearly every network offer and, therefore the "reasonable and relevant" standards must police the substance of the terms themselves. NASP proposes five components.

Covers cost. Reimbursement must separately cover three things: the cost to acquire the drug, the cost to dispense, and the clinical and operational services that specialty patients require (see Sections IV.A and IV.B). Base reimbursement must cover the gross (not net) cost a pharmacy actually pays for the drug. This must be the gross amount because discounts a pharmacy earns through good purchasing practices are what make it competitive. Congress recognized as much in Section 6224 of the Consolidated Appropriations Act, 2026, which restricts the remuneration that PBMs and their affiliates may receive in connection with Part D drugs. A rule of construction in that provision states that nothing in it prohibits "reimbursement or payment for ingredient costs," including "customary, industry-standard discounts directly related to drug acquisition that are retained by pharmacies or wholesalers."[9] Congress thus treated these discounts as part of the legitimate ingredient-cost payment that pharmacies and wholesalers retain, not as PBM remuneration. PBMs therefore should not reimburse at "dead net" cost, because Congress has clearly recognized the importance of the legitimate competition these discounts provide to pharmacies. Instead, acquisition cost should be an objective benchmark applied fairly across similarly situated pharmacies.

That objective benchmark should be NADAC,[10] which represents a price determination not influenced by payer interests, with wholesale acquisition cost (WAC +0.00%) as the fallback where no NADAC price exists, which is a benchmark many existing state Medicaid statutes already require.[11]

When a new specialty drug launches, PBMs commonly apply the network's default brand reimbursement rate until drug-specific terms are negotiated. Because these rates do not account for the unique acquisition costs and service requirements associated with specialty medications, pharmacies may be required to dispense these medications at a financial loss until terms are renegotiated, sometimes while the PBM negotiates access for its own affiliate. CMS should provide that the drug-by-drug floor applies from the first claim. Because NADAC will not exist for a newly launched drug, the floor should be measured against at least WAC +0.00%. CMS should also require that any non-affiliated pharmacy be offered drug-specific terms, no less favorable than those offered to the PBM's affiliate, within a fixed period after launch, so the default rate is a short bridge and not a standing price. Until those terms are in place, the default reimbursement rate for a new specialty, limited- or exclusive-distribution drug should be such that the PBM is given a reason to negotiate rather than a reason to delay.

Predictable at dispensing. The adjudicated reimbursement for a drug should not be reduced after the point of sale through negative performance adjustment, direct and indirect remuneration (DIR) fees, MAC adjustments, effective-rate reconciliation, or any other mechanism. PBMs have

repeatedly used these contractual devices to reduce payment after the sale. Although PBMs largely removed DIR fee programs in 2024 following final Part D rulemaking, pharmacies are wary of negative adjustments categorized as DIR or performance fees over which they have little control, and which wreak havoc on pharmacy finances. "Effective rate reconciliation," in which a PBM periodically negatively reconciles point-of-sale payments against an aggregate rate and "adjust[s] future reimbursement," sometimes including a "dispensing fee effective rate," remains a challenge in this respect.[12] Such effective rate reconciliation is a commonly used tool by PBMs in both direct contracts and in PSAO networks, and injects significant unpredictability into pharmacy reimbursement, as reported by NASP members. Effective rate agreements should serve only as a floor and not a ceiling on pharmacy reimbursements and should not form the basis of reduced reimbursement after adjudication. Lack of predictability can have adverse effects on financing arrangements, where both the borrowing pharmacy and the lending financial party must be able to rely on a drug's reimbursement at the point of sale.

More recent acquisition-cost PBM contracts achieve post adjudication rate reduction using enforced acquisition cost reductions. One 2026 network amendment offered to specialty pharmacies, for example, allows the PBM to demand documentation whenever a pharmacy's reported cost varies by more than five percent from "similarly situated pharmacies" and to recover the difference on all prior claims for that drug.[13] Such terms are not reasonable because a single pharmacy cannot predict its own cost against "similarly situated pharmacies," and because that pharmacy has no visibility into those other pharmacies' acquisition costs, nor does the PBM provide the identity of those pharmacies. Predictability means terms that are transparent, consistently applied, and clear enough for a pharmacy to evaluate the financial and operational effect of participation before it signs. This is impossible when the bases for rate reduction include factors the pharmacy cannot control.

Complete at offer. The contract must contain every term that will govern the contract year and may not leave material terms to PBM discretion or to change during the plan year, especially by unilateral amendment. NASP members reported being given as little as roughly one week to review a proposed contract or amendment before acceptance was required or deemed and reported material changes that took effect with no advance notice and changes applied retroactively within the past 24 months.[14]

Mutual. A reasonable term is one the parties actually negotiated. A rejected proposal should be met with a reasoned explanation, and a unilateral mid-year amendment, with or without notice, is not mutual. Of the NASP survey respondents, none said it could decline a material change and remain in the network.[15]

Due process. A pharmacy must have meaningful recourse, including a neutral third-party dispute process in place of PBM self-help remedies, except where patient harm is imminent and provable or where there is credible evidence of fraud, waste, or abuse (see Section IX.A).

"Relevant"

A term is relevant when it fits the pharmacy. CMS has long applied that principle. Its guidance confines drug-by-drug requirements to "special handling and dispensing that may be required for a particular 'specialty' drug and not to reimbursement or other standard contracting terms and conditions," and warns that "[o]ffering pharmacies unreasonably low reimbursement rates for certain 'specialty' drugs may not be used to subvert the convenient access standards."[16] Relevance has three parts.

Fits the pharmacy's type and services. A term must not exclude a pharmacy because it does not provide services unrelated to its practice and must not penalize it for the services it does provide. For example, a specialty network that requires a pharmacy to dispense drugs in every therapeutic class, when the pharmacy concentrates in oncology, is not relevant to that oncology pharmacy. Equally, a term may not exclude a pharmacy that can safely dispense a drug and manage the patient's condition because it lacks volume in that drug or drug class. CMS recognizes this concept and already requires terms "reasonable and relevant to the pharmacy practice functions performed by the specific pharmacy's business and service delivery model."[17] Pharmacy type is also distinct from licensure type: state licensing categories often group specialty and mail-order pharmacies under general retail licenses, and specialty pharmacies are frequently treated as mail-order simply because they deliver medications, so a term keyed to license category or how the medication is delivered will not reliably reflect the services and clinical care a pharmacy actually provides. This principle should be codified in the new rule and subject to enforcement by CMS through civil monetary penalties and sanctions.

Fits the drugs it dispenses. Reimbursement terms built for retail dispensing are not necessarily relevant to specialty dispensing. A cost-plus network paying a flat dispensing fee of roughly $5 to $6, as current acquisition-cost network offers do,[18] may be relevant to a retail pharmacy filling oral generics but it bears no relationship to the cost of dispensing a cold-chain biologic with REMS reporting, benefits investigation, and patient training, for example, as with a specialty pharmacy.

Serves a legitimate Part D purpose. Part D exists to give beneficiaries convenient access to covered drugs through any willing pharmacy.[19] CMS has "always interpreted the any willing pharmacy requirement to require Part D sponsors to offer reasonable and relevant contract terms and conditions to minimize barriers to pharmacy network participation."[20] A term that serves no access, quality, or program-integrity purpose, and instead operates principally to narrow the network to solely PBM-affiliated specialty pharmacies is not relevant. Convenient access should be judged the same way. For specialty patients, many of whom receive their drugs by delivery, it means access to a pharmacy capable of dispensing the drug and managing the therapy, not only geographic proximity.

B. **Compliance documentation:** CMS asks *"What documentation CMS should require to demonstrate compliance with standards for reasonable and relevant standard contract terms and conditions once finalized;"*

Compliance documentation

CMS should require each sponsor to file its standard specialty terms and reimbursement methodologies and to attest that they meet the reasonable and relevant standards. CMS already has this authority, as sponsors and their first tier, downstream, and related entities must make available "any books, contracts, records and documentation … that pertain to any aspect of services performed … or as the Secretary may deem necessary to enforce the contract."[21] CMS oversight, however, is only half of the requirement. The filed terms and methodologies must also be detailed and accessible enough that a pharmacy can determine its expected reimbursement, understand any adjustment, and evaluate the financial consequences of participation before it accepts. Sponsors may not prohibit a pharmacy from submitting contract offers and related correspondence to

CMS.[22] The criteria for determining whether pharmacies are similarly situated are addressed in Section II.C, and enforcement in Section IX.

C. **Negotiating leverage:** CMS asks *"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;"*

Negotiating leverage

Pharmacies cannot decline to participate in a network with any of the "Big Three" PBMs when those PBMs manage nearly 80 percent of prescriptions.[23] CMS has itself recognized that pharmacies "often do not have the ability to meaningfully negotiate with or demand clear information from PBMs and plans regarding contracting terms."[24] NASP's survey is consistent: only one respondent reported successfully negotiating any material Part D term since 2023.[25] NASP members report that where there is any negotiation with any PBM, it is reflected in only marginal change in reimbursement or, in the case of some government-related entities, where the law would not allow them to agree to certain terms. To ensure continued and robust patient access, CMS should set baseline protections that apply regardless of the parties' relative size, including transparent terms, reasonable notice, and a real opportunity to review and respond; by acting promptly on complaints; and by giving pharmacies access to a neutral determination of whether a term is reasonable and relevant once the standards are defined (see Section IX).

II. Open Access and Equal Treatment Regardless of Ownership

A. **Vertical integration:** CMS asks *"Vertical integration, that is, the control within a single corporate structure of various roles in the prescription drug supply chain, including insurance plans, pharmacy benefit managers (PBMs), and pharmacies."*

Vertical integration gives the largest PBMs both the ability and the incentive to favor the pharmacies they own, and CMS's standards should neutralize that incentive. Three PBMs manage nearly 80 percent of U.S. prescriptions, each sits within a conglomerate that also owns insurers and specialty pharmacies, and their affiliated pharmacies now take roughly 68 to 70 percent of specialty dispensing revenue.[26] In Part D, six vertically integrated organizations accounted for about 82 percent of 2023 spending, and eight of the fifteen largest sponsors, covering about 70 percent of enrollment, were integrated with PBMs and pharmacies.[27] CMS itself has warned plans and PBMs that this integration can disadvantage pharmacies the PBM does not own.[28]

The disadvantage is not confined to rate tables. The enterprise that owns the competing pharmacy also controls coverage and formulary decisions, benefits investigation and prior authorization, appeals, and the communications among pharmacy, prescriber, and patient. These same entities leverage their position to extract significant rebates from drug manufacturers, inflating costs across the system. Each is a point where friction can be applied to a non-affiliated pharmacy and waived for an affiliate (redirection mechanics are addressed in Section II.B). Recent federal reviews also show why CMS cannot rely on aggregate payment data. The Government Accountability Office (GAO) found that, for about half of the highest-cost Part D drugs, payments to owned pharmacies were higher, while cost sharing was lower at owned pharmacies for most drugs, and neither GAO nor the Office of the Inspector General (OIG) could observe post-sale

adjustments at the pharmacy level, meaning reimbursement may have been even lower for those pharmacies.[29]

NASP therefore asks CMS to provide that a term is not reasonable and relevant unless rates, terms, and administrative requirements are the same for the same drug and similarly situated pharmacy regardless of ownership (see Section II.C); to verify, rather than accept, reimbursement and administrative data from PBMs affiliated with network pharmacies, using Section 6224 reporting (see Section X.B); and to share its findings with the FTC and the DOJ, which police the same conduct.[30]

B. **Steering to affiliated pharmacies:** CMS asks *"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;"* and separately 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."*

Congress directed CMS to examine sponsor "restrictions or limitations on the dispensing of covered part D drugs by network pharmacies" and, from 2029, to require terms that are "reasonable and relevant."[31] Steering[32] to PBM-affiliated pharmacies is one such limitation that is both a beneficiary-access issue and a contracting issue. Diverting a prescription from the patient's pharmacy of choice to a PBM-affiliated pharmacy through agreements between the PBM and its affiliated plan can cause therapy disruption, unnecessary extra handoffs, delayed starts or refills, and loss of continuity of care. Selecting pharmacies qualified to dispense a particular drug is not the concern, rather, routing patients to the PBM's own pharmacy when a similarly situated non-affiliated pharmacy is available is merely favoring the PBM's affiliated pharmacies without regard to patient care.

To illustrate how steering works in practice, consider a typical sequence reported by specialty pharmacies and documented by federal regulators. A Medicare beneficiary is newly prescribed an oral oncolytic, and the prescriber sends the prescription to an accredited, non-affiliated specialty pharmacy. That pharmacy runs the benefits investigation and submits the claim. The PBM rejects it because "prior authorization required." The pharmacy then works with the prescriber's office to assemble and submit the prior authorization. These are the most labor-intensive and expensive steps in onboarding a specialty patient.[33] While the request sits in the PBM's review queue, the PBM passes the claim information to its own specialty pharmacy. That pharmacy then contacts the patient, the prescriber, or both, using the PBM's claims data, to have the prescription filled there instead.[34] The outreach is often presented as helpful information about the plan's "preferred" pharmacy or a special program for the patient's condition. In other cases, it suggests that the patient must switch or risk losing coverage.[35] In documented cases the affiliated pharmacy has told the prescriber that the patient asked for the transfer when the patient had not.[36] In others, a PBM letter falsely told a patient that their pharmacy had been terminated from the network and that they would "need to select a new specialty pharmacy."[37] When the non-affiliated pharmacy resubmits the approved claim, it is rejected again because the drug "must" be filled at the PBM-owned pharmacy, or because it has already been filled there.[38] Variations include

waiving the prior authorization only if the patient uses the PBM's pharmacy, and the affiliated pharmacy dispensing while the claim is "under review."[39] The patient, often seriously ill, is left confused about where the next dose will come from. Therapy is delayed. The pharmacy that did the clinical and administrative work loses the patient after bearing the cost of the first fill.[40] None of this turns on the quality of care the patient was receiving. It turns on who owns the pharmacy.

Patients should always have alternatives, so they are not locked into a singular pharmacy absent clinical need. Network participation protections must extend beyond initial eligibility to ensure that beneficiaries can meaningfully access otherwise similarly situated pharmacies. While not all affiliated organizations are bad actors and ownership is not the only source of misaligned incentives, transparency, pass-through arrangements, and bona fide services should guide program operations and take priority over affiliation or ownership. Thus, CMS should establish standards prohibiting plans and PBMs from using discriminatory network designs, mandatory prescription transfers, claims-processing restrictions, administrative barriers, misleading patient communications, or other practices that effectively direct patients to particular pharmacies without legitimate clinical, operational, or patient-safety justification. These protections should preserve permissible preferred network arrangements and transparent differential cost-sharing that provide legitimate value to beneficiaries, while preventing such arrangements from being used to circumvent reasonable and relevant contracting standards or effectively eliminate meaningful pharmacy choice.

Section 1860D-12(h) already requires PBMs to disclose benefit designs that "encourage plan enrollees to fill prescriptions at pharmacies that are an affiliate."[41] The reasonable and relevant standards in the Any Willing Provider Law should prohibit the kinds of steering activities discussed above at the contract level and use the same definition of "affiliate."[42]

CMS has warned that one-sided payment arrangements increase "market share for the sponsors' or PBMs' own pharmacies."[43] The FTC further found the largest PBMs "may be steering highly profitable prescriptions to their own affiliated pharmacies."[44] These arrangements represent a dire risk for competition in the drug channel space, further limiting beneficiary choice, where more choice is clearly needed, and where no legitimate clinical, operational, or patient-safety justification exists.

This anti-competitive status quo also affects pharmacy oversight, as there is no evidence that PBM-affiliated pharmacies face the same scrutiny as independent (non-affiliated) pharmacies, because no neutral third party provides oversight over that relationship. Consistent with CMS's rule that "all similarly situated pharmacies are offered the same standard terms and conditions,"[45] no network pharmacy should face a term, requirement, performance measure, or audit practice that the PBM's affiliate does not.

The standard should cover unequal reimbursement, performance measures, or audit treatment tied to specialty designation, which can force the patient's current pharmacy to stop dispensing mid-therapy;[46] redirected prescriptions and mandatory transfers, which cause therapy disruption, delays, and lost continuity;[47] terms in "side letters, or unwritten understandings between affiliated entities,"[48] and sponsor validation of affiliated PBMs' pricing and DIR data, which will impact patients whose cost is based on the negotiated price.[49]

CMS should also bar PBMs from using non-affiliated pharmacies' claims data to redirect patients already on therapy (a regular practice as reported by NASP members), which causes

confusion and gaps in therapy, and should update Chapter 5, § 50.3 of the Prescription Drug Benefit Manual to reflect this change.[50]

C. **"Similarly situated" and equal treatment:** CMS asks *"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;"*

Part D participation is largely open and worth protecting. CMS should establish objective criteria for determining whether pharmacies are similarly situated, based on demonstrated clinical and operational capabilities, accreditation, the services provided, and the drug-handling and patient-care requirements of the drugs dispensed. For purposes of identifying similarly situated specialty pharmacies under Part D, CMS should recognize accreditation by any one nationally recognized, independent third-party specialty pharmacy accreditor as the objective standard for determining whether a pharmacy possesses the specialized clinical, operational, and patient-management capabilities necessary to care for patients with specialty conditions and manage their specialty drug therapies. A pharmacy meeting this standard and any applicable, clinically justified drug-specific requirements should be treated as similarly situated to other specialty pharmacies, regardless of its volume for that drug.

Ownership or affiliation alone should never determine network eligibility or reimbursement, but legitimate differences in the scope and complexity of services should be recognized. A sponsor must contract with any pharmacy that meets its standard terms, 42 C.F.R. § 423.120(a)(8)(i), and those terms must be "reasonable and relevant," *id.* § 423.505(b)(18). Terms may vary by pharmacy type only if "all similarly situated pharmacies are offered the same standard terms and conditions." Medicare Prescription Drug Benefit Manual, § 50.8.1. CMS has never defined "similarly situated," treating these as "fact-specific questions that are best left between negotiating parties." *Id.* § 50.5.3. Left to the parties, however, the question of which pharmacies are alike is answered by the PBM.

NASP recommends that CMS establish accreditation by a single nationally recognized, independent third-party specialty pharmacy accreditor as the foundational qualification standard for identifying similarly situated specialty pharmacies, rather than leaving that determination to individual plan sponsors or PBMs. This would establish a consistent, independently verified national standard for identifying similarly situated specialty pharmacies across Part D networks, rather than allowing individual plans and PBMs to define specialty pharmacy qualifications through differing or proprietary criteria. Third-party specialty accreditation independently validates a pharmacy's ability to provide the clinical, operational, and patient-management services associated with specialty pharmacy practice, including:(i) demonstrated clinical capabilities, such as clinical management, side-effect and adherence monitoring, and pharmacist or nursing access; (ii) demonstrated operational capabilities, such as specialized drug storage and cold-chain handling; (iii) the specialized services actually provided; (iv) the ability to manage patients with complex or rare conditions requiring specialty therapy; and (v) [51]the drug-handling and patient-care requirements of specialty therapies, such as a REMS program or infusion.

Accreditation should be recognized regardless of pharmacy ownership, size, or dispensing model, and plans and PBMs must be prohibited by CMS from imposing duplicative accreditation or proprietary credentialing requirements as barriers to specialty pharmacy network participation.

Plan sponsors and the PBMs they delegate authority to administer their respective programs must disclose, in each contract offer, the criteria used to classify the pharmacy, every term that will determine its reimbursement, and how its performance is measured, including pricing benchmarks, dispensing fees, effective-rate guarantees, performance measures and their scoring methodology, and pharmacy comparison groups. Plan sponsors must then apply those criteria and terms consistently and equally to similarly situated affiliated and non-affiliated pharmacies.

D. **Specialty designation and reimbursement:** CMS asks *"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;"*

A specialty drug label should change handling requirements, not the reimbursement. CMS guidance limits drug-by-drug specialty requirements to special handling and dispensing, "not to reimbursement or other standard contracting terms and conditions," and bars use of unreasonably low "specialty" rates to subvert access.[52] Yet PBMs decide which drugs are "specialty," keep expanding those lists, and, as CMS has recognized, can categorize drugs in ways that maximize the revenue they keep for themselves.[53] CMS should therefore provide that a specialty drug or pharmacy designation may not be used to pay a pharmacy less than the floor described in Section V.A. Matching the affiliated pharmacy's rate is not sufficient. An affiliated pharmacy can accept a below-cost rate because its corporate family makes up the loss elsewhere: through manufacturer rebates, through the spread between what the PBM charges the plan and what it pays the pharmacy, or at the plan level. A non-affiliated pharmacy has nowhere else to make it up, so a rate that is equal but below cost still pushes it out. Finally, specialty pharmacy designation must not be conditioned on credentialing, fees, or accreditation beyond accreditation by a single nationally recognized, independent third-party specialty pharmacy accreditor, as described in Section II.E.[54]

E. **Defining "specialty pharmacy":** CMS asks *"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."*

Specialty pharmacy must be recognized in Part D as a distinct model of care rather than a particular pharmacy type or ownership structure. Specialty pharmacy is recognized by a host of clinical, operational, and longitudinal patient-care capabilities that are validated through nationally recognized, independent third-party specialty pharmacy accreditors. CMS should therefore recognize "specialty pharmacy" for Part D contracting purposes as a pharmacy meeting all clinical, operational, and longitudinal patient-care capabilities required for specialty dispensing, as validated through accreditation by one nationally recognized, independent third-party specialty pharmacy accreditor, such as URAC, ACHC, or The Joint Commission.[55] The accreditation requirement validates specialty practice rather than defining it. Specialty pharmacy practice

consists of the comprehensive clinical, operational, and longitudinal patient-care services specialty pharmacies provide. Accreditation independently validates specialty pharmacy capabilities including, benefits investigation and prior authorization support, financial-assistance navigation, cold-chain and REMS handling, patient training, and ongoing clinical monitoring.[56] Without a recognized standard and the reporting that goes with it, consumers may have inadequate information to decide what specialty pharmacy is available within a given plan network. CMS declined to define specialty pharmacy in 2018 out of concern that a definition could "prematurely and inappropriately interfere with the marketplace."[57] The market has since answered that concern. Sponsors and PBMs already treat accreditation as a condition of specialty network participation, while any pharmacy can call itself "specialty" and each PBM decides for itself what counts.[5859] Section 6224's requirement that PBMs define "specialty drug" makes a consistent definition on the pharmacy side more pressing (see Section X.B).[60]

The definition should set both a minimum that sponsors may require and a limit on what they may require. A sponsor may require the single accreditation for specialty pharmacy designation, specialty pharmacy network participation, and specialty drug reimbursement terms. Where Chapter 5, § 50.3 permits a sponsor to limit a drug to a subset of pharmacies, accreditation is the objective standard the sponsor should apply.[61] A sponsor may not require a second accreditation, a PBM-owned accreditation, or proprietary credentialing or fees. It also may not deny an accredited specialty pharmacy specialty terms, or access to a drug the pharmacy can lawfully acquire.[62] Some drugs labeled "specialty" are also dispensed at retail, but dispensing such a drug does not make a retail pharmacy a specialty pharmacy, and neither does a drug's price or prior authorization support alone. Rather specialty pharmacy status must rest on the capabilities accreditation validates to ensure a pharmacy can support a Medicare Part D beneficiary on the dispensed medication. Specialty status should also carry compensation for the clinical services accreditation requires (see Sections IV and V.A). For purposes of completeness, CMS could put forward guidance on the meaning of "Specialty drug/biologic" that does not restrict growth in the market or drug/biologic innovation. For example, guidance could clarify that a specialty prescription drug or biological that, because of its clinical characteristics, treatment complexity, or requirements for safe and effective use, reasonably requires specialized pharmacy services beyond those routinely required for dispensing and managing non-specialty prescription drugs. Such characteristics may include one or more of the following: specialized handling, storage, or distribution requirements; complex administration or dosing; clinically significant monitoring requirements; management of serious, complex, chronic, or rare conditions; or a need for specialized patient education, care coordination, or adherence support.

These considerations demonstrate the importance of preserving the integrity of the specialty pharmacy care model and recognizing that specialty pharmacy services are an integral component of patient care, not simply a mechanism for dispensing medications. The specialty pharmacy care team functions as an extension of the physicians, specialists, and other health care professionals prescribing these complex therapies, providing specialized clinical expertise, patient education, monitoring, care coordination, adherence support, and other services necessary to support the safe, effective, and appropriate use of specialty medications.

Prescribers and specialists rely heavily on the expertise, accessibility, and consistent support of their specialty pharmacy clinical counterparts to help manage the complexities associated with specialty therapies and the patients who depend on them. This collaborative care model extends the capacity of the prescribing practice by supporting patients throughout the course

of therapy, identifying and helping address barriers to treatment, reinforcing the prescriber's care plan, and facilitating communication among patients, caregivers, providers, and other members of the care team.

The specialty pharmacy care model works to safeguard against delays in therapy initiation, interruptions in treatment, increased burden on prescribers and their staff, and additional barriers to accessing high-quality specialty and clinical care, supporting intended outcomes with the course of therapy.

Accordingly, CMS should ensure that policies affecting specialty pharmacy recognize and preserve the specialty pharmacy care team as an important extension of the patient's broader clinical care team. Requirements intended to advance access or choice should not inadvertently dismantle the clinical infrastructure, specialized expertise, and established provider-pharmacy relationships that enable patients with complex conditions to initiate, maintain, and successfully manage specialty therapies.

F. **Dispensing restrictions:** CMS asks *"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."*

Yes, such terms are prevalent in Part D and largely designed to favor PBM affiliates. Terms that expressly prohibit or limit the dispensing of particular drugs are common in Part D network agreements, and PBMs reach the same result through concentration-based penalties. NASP urges CMS to codify Chapter 5, §50.3's limits on restricting dispensing of covered Part D drugs to a subset of network pharmacies, and to extend those limits to all similarly situated pharmacies by expressly prohibiting concentration-based penalties. A ban limited to express restrictions would miss most of the practice. These penalties punish a specialty pharmacy for the patients it serves, not for anything it does wrong, and the PBM sets and changes the threshold, the comparison group, and the drug list. [63] [64]

Several PBMs expressly bar pharmacies from dispensing certain drugs, even drugs on the plan's formulary, and set percentage thresholds that pharmacies cannot exceed without risking termination.[65] Published descriptions of such terms include a provision stating in substance that a network pharmacy may not have more than twenty-five percent (25%) of its claim submissions or amount paid for a plan's members attributed to a single therapeutic class unless the PBM has approved an arrangement in advance, and a provision prohibiting "aberrant quantities" of a covered item or a high volume of claims within a therapeutic category, measured against a list of drugs that the PBM maintains and that the pharmacy must monitor without any definition of what is "aberrant."[66] Sponsors and PBMs set reimbursement rates for particular drugs or categories of drugs so low that dispensing them becomes financially untenable, which discourages pharmacies from stocking and filling those drugs without any formal restriction ever appearing in the contract. CMS's own guidance recognizes the problem.[67] The effect is well documented. In a January 2025 survey of independent pharmacists, 40.8 percent reported being paid below NADAC on more than 40 percent of their Part D prescriptions, and 96.5 percent said PBM and plan reimbursement threatens the viability of their business.[68]

PBMs also treat dispensing that looks "aberrant" or "abnormal" compared with other pharmacies as a breach of the pharmacy contract, regardless of the pharmacy's patient population or clinical focus.[69] A pharmacy that serves many patients with one condition is flagged as an "outlier" and penalized through recoupments, cease-and-desist demands, or breach notices. Each finding is then cited to justify the next, escalating to suspension or termination, even though the pharmacy's conduct (dispensing covered drugs to enrolled beneficiaries) never changed. Terminations resting on these comparisons have been reversed once challenged,[70] but the effect of the threat of termination is the same as an express restriction, though harder to see and to challenge. Because these terms are easily relabeled, CMS should prohibit the penalty itself.

NASP proposes that CMS adopt the following under 42 C.F.R. § 423.505(b)(18):

> "Concentration-based penalties prohibited. (A) A Part D plan sponsor, or any entity acting on its behalf, shall not terminate, suspend, recoup from, reduce payment to, issue a notice of breach to, or otherwise take adverse action against a network pharmacy based on (1) the share or volume of its claims for a drug, therapeutic class, condition, or manufacturer; (2) a comparison of the pharmacy's dispensing or patient population to other pharmacies; or (3) a prior finding based on (1) or (2). (B) Paragraph (A) applies however the term is labeled and wherever it appears, including in a network agreement, provider manual, policy, bulletin, or list. (C) This section does not limit action based on a credible and documented allegation of fraud or a documented risk of patient harm, or a drug-specific handling or dispensing requirement the pharmacy cannot meet, such as a requirement imposed by an FDA risk evaluation and mitigation strategy. (D) A contract term inconsistent with this section is void and unenforceable as to the pharmacy."

A specialty pharmacy's claims mix grows out of how it specializes. Some specialty pharmacies focus on a narrow set of patients or conditions given the expertise and clinical pharmacy staffing and infrastructure needed to support these patients and conditions. Others build core competencies few other pharmacies possess and where patient volume for a given condition and its treatment is often limited, and it would not make business sense for a retail high volume pharmacy business to store and manage all the requirements associated with these drugs. A high concentration is the expected result of specialization, not evidence of misconduct. The above proposed rule preserves plan sponsors' ability to act to prevent fraud, documented patient harm, and drug-specific requirements such as REMS or what is otherwise necessary to appropriately manage a patient on a complex therapy. The proposed rule also gives CMS the ability to audit whether an adverse action rested on concentration. Finally, the rule protects the access that the any willing pharmacy requirement exists to protect, since a rule that penalizes a pharmacy for serving patients with a particular condition directly reduces the number of pharmacies able to serve them.[71]

NASP also asks CMS to implement a rule that a sponsor's network include a robust set of specialty pharmacies, not affiliated with the sponsor or its PBM, that are able to dispense the specialty drugs on the sponsor's formularies, with adequacy measured by capability to dispense and manage patients on specialized treatments and not by the geographic proximity of the pharmacy to the enrollee. A network made up mostly of the PBM's affiliates that routinely ship specialty medications can meet any distance standard and still leave enrollees no independent choice. CMS's access data for specialty should measure whether enrollees can reach a capable pharmacy of their choice, including one that delivers to the home, rather than geographic distance

alone. CMS should also require that each sponsor's network include non-affiliated specialty pharmacies able to dispense the specialty drugs on its formulary.[72]

III. Reimbursement Below Cost

A. **Reimbursement below acquisition cost:** CMS asks *"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;"*

Reimbursement Below Cost

A material share of specialty Part D claims is paid at or below acquisition cost, sometimes by thousands of dollars per fill. Most NASP survey respondents reported that a significant percentage of their 2025 Part D specialty claims were paid at or below invoice cost, with at least one reporting 50 percent or more, and every respondent reported a single-claim shortfall of at least $300, reaching $1,000 or more.[73] Member records show a PBM denying pricing appeals on specialty brands, including biologics with unit costs above $20,000, on the ground that the claim was paid "at your contracted rate" rather than MAC, even though the pharmacy documented payment below its invoice cost.[74]

Regarding how reimbursement is typically handled, and what is the most accurate measure of cost, brand specialty drugs are generally paid at AWP less a percentage, and specialty generics on "lesser of" logic in which the PBM's MAC usually sets the price. MAC is problematic for reasons discussed in Section III.C, below. Invoice cost, while an accurate measure of acquisition cost, discloses purchasing terms that pharmacies are contractually bound to keep confidential, and requiring them to be produced to PBMs that own competing specialty pharmacies (as some new "cost-plus" contracts, applicable to commercial networks and possibly to Part D, purport to require) would hand those competitors the pharmacy's only source of competitive advantage. The existing PBM acquisition-cost contracts illustrate the point. One 2026 cost-based reimbursement contract requires a pharmacy to submit quarterly cost files "inclusive of any rebates, discounts and/or other price adjustments" and to attest annually to its wholesaler pricing.[75] This same contract requires pharmacies to obtain discounts on drug acquisition costs and lowers reimbursement yearly regardless of whether pricing actually lowers. This is untenable. Even if a cost-based reimbursement accurately reflected acquisition cost, the total reimbursement must cover costs to dispense, plus a reasonable margin.

NADAC, while imperfect, is the most common public alternative and provides the objective and neutral benchmark that would best capture acquisition. NASP therefore recommends that CMS require PBMs to utilize NADAC, weighting results so the largest purchasers do not set the price for everyone else, and excluding 340B acquisition costs, with WAC +0.00% as the fallback where NADAC does not supply data.

B. **Effect on stocking and patient access:** CMS asks *"Whether, and how, reimbursement policies impact pharmacy decisions to stock certain drugs or drug classes (for example, high-cost drugs);"*

Effect on stocking and patient access

Below-cost rates may force pharmacies to transfer patients to a pharmacy able to dispense, thus delaying therapy and negating the patient's choice of provider. Survey respondents reported transferring Part D prescriptions because reimbursement would not cover cost, some of them frequently, and each reported that transfers usually went to a plan- or PBM-affiliated pharmacy.[76] Those respondents that track access reported a median of four to five days from referral to first fill and a 10 percent abandonment rate, and reported that five percent of patients were transferred out to another specialty pharmacy because of Part D reimbursement or network restrictions.[77] Respondents identified transfers in generic oral oncology, dermatology, gastroenterology, neurology, and rheumatology drugs (with many of these being in a protected class), and documented the effects on patients that followed contracting and dispensing restrictions: longer time to treatment, treatment delays and interruptions, broken continuity of care, and weakened or lost clinical coordination.[78] Reimbursement terms also shape what pharmacies can stock and the services they can provide; respondents reported that, because of those terms, they had stopped dispensing certain drugs, reduced inventory, delayed purchasing, and withdrawn from a network.[79] For specialty, a "pharmacy desert" is a network and reimbursement problem, not a matter of distance: a patient may live near a similarly situated pharmacy that cannot afford to dispense the drug. That effect falls hardest on rural and low-income beneficiaries, who depend on the pharmacy already managing their care.

C. **MAC pricing for specialty generics:** CMS asks *"The frequency of plan updates to maximum allowable cost (MAC) pricing lists, communication regarding such updates, and related dispute resolution mechanisms;"*

MAC pricing for specialty generics

MAC prices are undisclosed, change often, can sit hundreds of dollars below cost, and are effectively visible only at adjudication. Most survey respondents that dispense specialty generics reported claims paid on MAC below acquisition cost in 2025–26, with single-claim shortfalls ranging from about $100 to several hundred dollars.[80] Respondents typically learn of a MAC change only when a claim adjudicates; and their MAC appeals succeeded usually for some pharmacies but only sometimes or rarely for others.[81] Part D already requires drug-cost pricing standards to be updated at least every seven days "to accurately reflect the market price of acquiring the drug,"[82] but it says nothing about disclosure, sourcing, or appeals.

Multiple states have filled that gap, and CMS should adopt the strongest of their protections as Part D standards. Georgia requires MAC lists to be updated at least every five business days.[83] Iowa requires an update within seven days after an increase of 10 percent or more in pharmacy acquisition cost.[84] Colorado requires the PBM to disclose its pricing sources within ten days of request and to place on a MAC list only drugs that are A- or B-rated and generally available from a national or regional wholesaler.[85] Maryland requires a denied appeal to identify the NDC, the wholesaler from which the drug was available at or below MAC, and "the mathematical calculation used to determine the maximum allowable cost," and requires an upheld appeal to be paid without reversing and rebilling.[86] New Jersey and Indiana require that a successful appeal adjust the price for all similarly situated pharmacies, with Indiana making the correction effective from the initial date of service.[87] Virginia bars a PBM from terminating or refusing to renew a pharmacy for invoking these rights.[88] CMS should require, for every specialty generic priced on MAC, a published list available to the pharmacy before adjudication, disclosed sources, a seven-day or shorter update cycle and prompt updates when acquisition costs rise, enforceable appeal rights that apply to any reimbursement below acquisition cost whether or not the PBM labels the rate "MAC,"

written denials identifying the NDC and wholesaler, network-wide correction from the date of service, and protection against retaliation.

D. **Limited-distribution drugs and common ownership:** CMS asks *"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;"*

They often do. While both the FDA and manufacturers have required distribution controls that may reflect legitimate clinical, supply, data reporting, or patient-support requirements, NASP's concern is PBM restrictions that go beyond those controls. When a non-affiliated pharmacy holds the manufacturer's limited-distribution drug ("LDD") designation, it has already shown it can provide the services the drug requires. PBMs nonetheless often pay a default brand rate that does not cover acquisition cost, or leave the pharmacy with little margin above acquisition cost, while paying their own affiliates more. This can happen even where the PBM's affiliate cannot dispense the drug. Where a non-affiliated pharmacy holds an exclusive or ultra-narrow designation, a PBM seeking access for its affiliate may cut reimbursement to near or below cost while that access is negotiated. If the affiliate gains access, rates may improve but stay below typical levels for these drugs. If it does not, rates often return to typical levels. The FTC found a similar pattern for specialty generics that the largest PBMs reimbursed affiliates at higher rates "on nearly every specialty generic drug examined."[89] Below-cost LDD rates effectively act as a steering provision, which push prescriptions to the PBM's affiliate.

Congress already requires cost-based pricing standards "to accurately reflect the market price of acquiring the drug." Social Security Act § 1860D-12(b)(6), 42 U.S.C. § 1395w-112(b)(6); see 42 C.F.R. § 423.505(b)(21). Congress also directed that, beginning in 2029, standard terms be "reasonable and relevant" under standards set by the Secretary, "[n]otwithstanding any other provision of law." Social Security Act § 1860D-4(b)(1)(A)(ii), 42 U.S.C. § 1395w-104(b)(1)(A)(ii). CMS should therefore adopt a drug-by-drug floor of the NADAC (or WAC +0.00%) acquisition cost benchmark plus dispensing cost for LDDs (see Section I.A). This would be a minimum, not a CMS-set rate. CMS should also require that any pharmacy holding the manufacturer's designation receive the same terms as the PBM's affiliate. *See* 42 C.F.R. §§ 423.120(a)(8)(i), 423.505(b)(18); Medicare Program; Medicare Prescription Drug Benefit, 70 Fed. Reg. 4194, 4254 (Jan. 28, 2005). Parity alone is not enough. An affiliated pharmacy can accept a below-cost rate because its corporate family recovers the loss elsewhere (see Section II.D), so the floor must apply regardless of what the affiliate is paid.

E. **Shift from DIR to lower point-of-sale rates:** CMS asks *"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;"*

Between 2016 and 2023, many PBMs (including, specifically, the big three) charged pharmacies fees based on various performance metrics. These performance-based payment arrangements ("PBPA") were developed and administered by PBMs on behalf of their Part D plan sponsor clients. PBMs and Part D plan sponsors considered the fees generated under these PBPAs to be pharmacy price concessions, which is a form of direct and indirect remuneration ("DIR").

Each PBM had its own proprietary method for administering these PBPAs. Some PBMs collected the fee at the point of sale, which pharmacies could earn back if they met certain performance metrics. Some PBMs, including, specifically, Caremark, collected the fee *after* the point of sale (sometimes many months after) and after the pharmacy's "performance" was determined.[90] The fee itself was only one component of the pharmacy's overall reimbursement. The other component included the point-of-sale reimbursement itself (e.g., AWP discount) for the drug(s) at issue. A pharmacy's net reimbursement was the sum of the AWP discount and the performance-based fee.[91] The problem with this reimbursement method, among other things, was that pharmacies could not predict how well they would ultimately perform and, consequently, how that performance would impact the fees clawed back by PBMs.

In 2024, CMS changed the definition of "negotiated price," causing PBMs and Part D plan sponsors to abandon the PBPAs described above. This shift away from PBPAs was due to the fact that, under the new definition of "negotiated price," CMS required Part D plan sponsors to include all pharmacy price concessions at the point of sale to reduce the "negotiated price." This, in turn, resulted in Part D plan sponsors and PBMs paying pharmacies substantially less at the point of sale than what pharmacies received prior to the rule change. While the payment methodology changed, the pharmacy economics remained roughly the same or, in many cases, got worse.

Specialty pharmacy contracts reviewed in preparing this response suggest that PBMs offset the elimination of performance-based DIR fees by lowering point-of-sale rates. Under the Contract Year 2023 final rule, beginning January 1, 2024, the Part D "negotiated price" must reflect "the lowest possible reimbursement" a network pharmacy will receive, "in total," inclusive of "all price concessions."[92] CMS intended this change to bring transparency to the point of sale. It did not require that overall reimbursement be any lower, yet it was.[93]

One major PBM's Medicare Part D performance network enrollment forms for plan years 2020 through 2023 illustrate the point. Each form paired a modest point-of-sale AWP discount with a post-sale, performance-based DIR fee. Depending on performance, that DIR fee could range from roughly 2 percent to 17 percent of brand ingredient cost and reach as much as 37 to 43 percent of generic ingredient cost (these and all other rates in this Section are fictionalized for the purpose of this response).[94] Each form also provided that, if changes to the Part D rules made the program infeasible, the DIR fee would "no longer apply" and the brand AWP discount would be replaced by a specified, deeper discount.[95]

In nearly every form, that replacement discount equals almost exactly the net rate a pharmacy would have received at an average performance score. To illustrate with fictionalized rates: if a network paired a base reimbursement of somewhere between AWP-8% and AWP-10% with a DIR fee of between 10% and 14%, a pharmacy with an average performance score would net between approximately AWP-19% and AWP-21%, and the contract's replacement rate would be set within that same range, at the net rate the pharmacy would have received. That is the relationship the underlying contract reflects.[96] In the other networks reviewed, the replacement rate likewise matched the average-performance net rate to within a few hundredths of a percentage point.[97] In at least one network, the replacement rate was deeper than the average-performance net rate. Again using fictionalized rates, a base reimbursement of between AWP-15.5% and AWP-18.5% paired with a DIR fee of between 2% and 5% would net approximately AWP-19.9% at the midpoint, while the replacement rate would be set at approximately AWP-20.5%.[98] Put simply, the PBM fixed in advance that the DIR fee would be folded into a lower base rate. The pharmacy's average economics were preserved at best.

The later contracts cut reimbursement further. For plan year 2025, the same PBM's standard Medicare Part D retail network set a maximum brand discount of between AWP-22% and AWP-24% and a maximum non-MAC generic discount of between AWP-52% and AWP-57%, with a dispensing fee of between $0.05 and $0.20 (fictionalized rates).[99] Even at the low end of its range, that brand rate is deeper than the average-performance net rate in every pre-2024 network reviewed (a fictionalized range of approximately AWP-18% to AWP-21%), and the generic rate is at or beyond the deepest pre-2024 generic net rate (a fictionalized range of approximately AWP-35% to AWP-52%). At the midpoints of these fictionalized ranges, the pharmacy's reimbursement on a $1,000-AWP brand claim falls roughly 4 percent compared with its pre-2024 average net.[100]

A second PBM's contract history with a specialty pharmacy follows the same pattern. Its 2019 Medicare network exhibit paid brands at a base reimbursement of between AWP-14.5% and AWP-17% plus a dispensing fee of between $0.80 and $1.50, less a post-sale DIR fee of between $11 and $16 per claim at an average performance rating, plus a separate specialty DIR fee of between 0.25 and 0.85 percent of AWP (fictionalized rates).[101] The 2024 exhibit that replaced it dropped the DIR fees but cut the brand rate to between AWP-17.5% and AWP-20.5% and the dispensing fee to between $0.30 and $0.80 (fictionalized rates).[102] At the midpoints of these fictionalized ranges, net reimbursement declines on every brand claim above approximately $400 AWP, and the decline grows with the drug's cost: about 2.4 percent on a $1,000 claim and 3.6 percent on a $5,000 claim.[103] The pharmacies least able to absorb that shift, specialty pharmacies dispensing high-cost brands and biologics, bear the most.

These examples show why moving price concessions to the point of sale, standing alone, does not make reimbursement reasonable. NASP therefore asks CMS to recognize, in defining "reasonable and relevant" terms, that a PBM may not recreate eliminated DIR fees through base-rate reductions, "maximum" discount ranges that vary by plan sponsor, or effective-rate reconciliation. Every such term should be measured against the reimbursement floor described in Section V.A.

Any rule by CMS regarding the terms of participation in pharmacy networks must require that terms of reimbursement be transparent and predictable. The general approach adopted by most PBMs is that once pharmacies agree to participate as a network provider, they must participate for the entire plan year. In other words, pharmacies generally cannot terminate their participation if they learn the net reimbursement paid by the PBM or Part D plan sponsor is inadequate once the retroactive adjustment (i.e., performance clawback) is applied. Therefore, when defining "reasonable and relevant," CMS should consider language that requires terms of reimbursement to be clear and unambiguous at the time those terms are offered. CMS should further consider language prohibiting retroactive adjustments to pharmacy reimbursement that would materially alter the pharmacy's reasonable expectations at the time they agree to participate as a network provider.

IV. Dispensing Fees and Unpaid Services

A. **Dispensing fees:** CMS asks several questions about what they cover, how they're set, and the standard CMS should adopt: *"Costs that are considered within the scope of dispensing fees, and whether dispensing fees paid by Part D sponsors sufficiently*

cover those costs;" "How dispensing fees are determined in Part D and outside of Part D;" and *"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;"*

Dispensing Fees and Unpaid Services

Part D defines the dispensing fee to cover costs "associated with ensuring that possession of the appropriate covered Part D drug is transferred to a Part D enrollee," including pharmacist time, delivery, special packaging, and overhead.[104] In practice the PBM sets the fee in the rate exhibit as a flat per-claim amount untied to the actual cost or medication complexity, and the amount varies by PBM and between direct and PSAO contracts. GAO found dispensing fees in the 2023 contracts it reviewed "ranged from $0 to $2."[105] NASP's respondents reported typical specialty dispensing fees of $0, under $1, and $1 to $5.[106] Currently, in Part D, drug margin, not the fee, pays for dispensing and patient care, and that margin often rests on only a few drugs the pharmacy dispenses, with the rest being reimbursed at essentially cost or at a loss.

NASP recommends a three-part structure. The first part is ingredient reimbursement measured by NADAC or WAC +0.00% as described in Section III.A, assuring that pharmacies will at least cover the cost to purchase drugs. The second is a dispensing fee that covers only the transactional cost of dispensing for that pharmacy type, tiered by handling complexity (for example, cold chain, REMS, limited distribution, and infusion) rather than set as one flat amount, thus covering the cost to dispense. The third is a separate payment for the clinical and patient-management services that the patient, disease, and drug require, described in Section IV.B, covering the additional costs required in specialty patient care and management. This is a structure, not a rate. CMS should require that each component be present and adequate, and leave the economics above that baseline to negotiation; the baseline must not become a ceiling.

B. **Non-dispensing services:** CMS asks *"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;"*

Non-dispensing services

Specialty pharmacies provide services that Part D does not pay for directly, including benefits investigation and prior authorization support, financial-assistance navigation, cold-chain packaging and shipping, infusion supplies, patient training, nursing, toxicity and adverse-event monitoring, prescriber coordination, and after-hours clinical access. Every survey respondent reported that these services are not compensated in Part D.[107] These services are what accreditation validates and what keeps patients on therapy, and a term that requires them without paying for them is not reasonable. CMS should require that standard terms identify the services the network requires and pay for them separately at fair market value, using ranges for core and enhanced services of the kind already common in manufacturer service agreements, with a neutral process to resolve disputes over value.

C. **Inflation Reduction Act and negotiated prices:** CMS asks *"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;"

Inflation Reduction Act and negotiated prices

Negotiated-price drugs expose the fragility of the current model on two separate fronts. The first is cash flow. Pharmacies acquire selected drugs at full price and wait for manufacturer refunds to bring them back to the maximum fair price, carrying the difference in the meantime. The second is payment adequacy. Once the margin on a selected drug disappears, the dispensing fee is all that remains, and it does not cover the cost to dispense. Multiple survey respondents said the dispensing fee on these claims does not cover their cost, and one reported a $1 fee, adding that "[t]hese fees are irrelevant to our margin/profitability."[108] CMS should treat these as distinct problems and refund timing should not leave the pharmacy financing the program, and the dispensing fee must stand on its own.

V. What CMS Should Do About Reimbursement

A. **Whether CMS should set reimbursement methodologies:** CMS asks *"Whether CMS should establish reimbursement methodologies or rates as part of the standards for reasonable and relevant pharmacy contract terms and conditions."*

No. CMS should not set rates or prescribe a payment methodology. It should instead build a structural floor into the reasonable-and-relevant standard that covers acquisition cost, real costs to dispense under a range of complexities and a margin for dispensing pharmacies. Under that floor, a term is not reasonable if it pays a network pharmacy less, for a given drug, than (1) the acquisition cost benchmark for that drug (NADAC, or WAC +0.00% where NADAC is unavailable) (see Section I.A), plus (2) a dispensing fee that covers the cost of dispensing for that pharmacy type, plus (3) a reasonable margin (see Sections III.D and IV). Sponsors and PBMs would stay free to negotiate any rate, benchmark, or methodology above the floor. NASP proposes the structure, not a dollar figure.

Congress asked CMS to examine this question. Section 6223 directs the RFI to consider "whether pharmacy reimbursement and dispensing fees … sufficiently cover the ingredient and operational costs of such pharmacies" for purposes of establishing the standards, and it makes the standards apply "[n]otwithstanding any other provision of law."[109] CMS guidance already requires sponsors to "offer reasonable and relevant reimbursement terms for all Part D drugs."[110] A floor implements that rule. It does not create a fee schedule or "institute a price structure" (see Section X).[111]

Two design points matter for specialty. First, acquisition cost should be measured by NADAC, with WAC +0.00% as the fallback where NADAC does not supply a price, not by requiring a pharmacy to hand confidential invoices and purchasing terms to a PBM that owns competing pharmacies, which is an untenable proposition. It also should not be reduced by customary purchasing discounts the pharmacy earns, which Congress expressly protected in Section 6224.[112] Because NADAC is survey-based and is unavailable for most specialty generics, the WAC +0.00% fallback is essential (see Section III.A). [113] Second, the floor must apply drug by drug, so that below-cost payment on one limited-distribution drug cannot be excused by margin

on another (see Section III.D). NASP raised this gap when CMS moved pharmacy price concessions to the point of sale. CMS said it would consider safeguards guaranteeing a reasonable rate of reimbursement, but none followed.[114]

B. **Point-of-sale finality:** CMS asks *"Impacts of post-adjudication adjustments on net reimbursement rates;"* CMS also asks *"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."* and *"The predictability of final reimbursement at the time of dispensing;"*

What CMS Should Do About Reimbursement

Point-of-sale finality

The governing principle is that final reimbursement should be transparent and determinable at the point of sale, and that no PBM may recreate retroactive reductions under a different label. Since the 2024 point-of-sale rule, specialty pharmacies see fewer performance-based clawbacks; PBMs instead cut point-of-sale rates or substituted reconciliations. Asked what changed after January 1, 2024, NASP membership shared examples representing lower up-front reimbursement in place of retroactive fees, reported effective-rate reconciliation in place of prior DIR fees, and that fees are still assessed after the point of sale.[115] Respondents described after-the-fact adjustments on specialty claims since 2024 as occurring rarely or only sometimes, except for rate guarantees.[116] Generic and brand effective-rate guarantees remain in use, and any term that reduces payment after the point of sale through reconciliation against an aggregate guarantee should be treated as not reasonable and relevant.[117] An effective-rate guarantee should operate as a floor, never a ceiling. In more precise words, an effective rate should guarantee the minimum amount a pharmacy shall receive in aggregate reimbursement, and the pharmacy shall receive any amount in excess of that guarantee, as determined by point-of-sale reimbursement.

VI. 340B-Specific Terms

A. **340B-specific terms:** CMS asks for *"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;*"*

340B-specific terms are common in the standard agreements certain PBMs offer, especially in agreements with covered entity owned or affiliated pharmacies. Under the 340B product replenishment model used by most contract pharmacies, the pharmacy generally does not know at the point of sale whether a patient is 340B-eligible or whether the drug will be replenished at the 340B price. The covered entity, working with a 340B third-party administrator, makes that

determination only after the drug is dispensed. The pharmacy may then flag the claim as a 340B claim after the point of sale in NCPDP field 420-DK with a submission clarification code of "20."

PBMs reduce 340B payment in three ways. First, some pay flagged claims under separate "340B" rate schedules. Second, some pay entity-owned or affiliated pharmacies lower rates on every claim, so payment is reduced even on claims with no connection to the program.118 Third, some achieve the same result indirectly through network tiers, effective-rate guarantees, or retroactive "true-up" mechanisms that never mention 340B (see Section V.B). In some cases, the resulting reimbursement falls below fair market rates or even below the drug's acquisition cost.

NASP urges CMS to make clear that a term paying a pharmacy less for a covered Part D drug because it is a 340B claim is not reasonable and relevant. The drug, the patient, and the pharmacy's work are identical either way, and the 340B discount belongs to the covered entity, not the contract pharmacy. Sponsors and PBMs should not be able to use standard contract terms to exclude or penalize willing pharmacies on grounds unrelated to the pharmacy's services.

These practices harm not only the pharmacy but also the covered entities, including disproportionate share hospitals and other safety-net providers. Those entities rely on 340B revenue from in-house and contract pharmacies to fund care for low-income and uninsured patients. Congress created 340B so that these providers could "stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services" (H.R. Rep. No. 102-384, pt. 2, at 12 (1992)). Lower reimbursement on 340B claims moves those savings to plan sponsors and PBMs instead. Recognizing PBM profiteering off funds that Congress intended for those in need, covered entities have begun to challenge these practices in court. Six hospital systems recently sued Caremark and CVS Specialty, alleging an under-reimbursement and discriminatory pricing scheme that deprived them of hundreds of millions of dollars in 340B savings (Mount Sinai Hospital, et al. v. CVS Health Corp., et al., No. 1:26-cv-4143 (S.D.N.Y.)). In support of Congress's goals for 340B, CMS should not let the Part D contracting process serve as a path around the federal purpose of 340B or the policy reflected in state law.

The practice of diverting these funds to PBM profits also conflicts with a fast-growing body of state law. Many states have enacted 340B anti-discrimination statutes that bar PBMs and health insurers from paying covered entities or their contract pharmacies less for 340B drugs than for non-340B drugs. These statutes also bar added fees, chargebacks, claim identifiers, or network exclusions imposed because a drug was purchased under 340B (see, e.g., Illinois (215 ILCS 5/513b1); Indiana (Ind. Code Ann. § 27-1-24.5-19.5); Iowa (Iowa Code ch. 510D); Michigan (MCL § 550.926); Ohio (Ohio Rev. Code § 3902.71)). These laws reflect a clear and consistent policy judgment. To our knowledge, no court has yet addressed whether these 340B-specific statutes reach Part D plans.

NASP respectfully asks CMS to expressly prohibit, as not reasonable and relevant, any standard contract term that: (a) sets lower reimbursement, or imposes additional fees or chargebacks, for a covered Part D drug based on whether it was purchased under 340B; (b) sets reimbursement for covered-entity-owned pharmacies or the covered entity's contract pharmacies below the NADAC (or WAC +0.00%) acquisition cost benchmark (see Section I.A) on the expectation that 340B discounts will make up the shortfall, consistent with the general reimbursement floor NASP proposes in Section V.A; (c) uses a 340B claim identifier for any purpose other than statutory compliance, including setting reimbursement or network status; or (d) excludes a pharmacy from a network, assigns it to a less favorable network tier, or otherwise

conditions its participation based on the pharmacy's ownership by, affiliation with, or contract with a covered entity.

VII. Contract Integrity

A. **Changing terms through provider manuals:** CMS asks *"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;"* and *"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;"*

Contract integrity is a threshold condition for every other standard CMS adopts. A term cannot be "reasonable" if it is not predictable at the time of dispensing and complete at the time it is offered. The any willing pharmacy guarantee means little if the "standard terms and conditions" a pharmacy must meet can be rewritten after the pharmacy has signed. The most egregious example is also a matter of public record. On August 2, 2023, a major PBM notified its network pharmacies that a revised provider manual, which their provider agreements incorporate by reference, would take effect on August 10, eight days later, and would move the forum for every dispute with a major PBM from the American Arbitration Association to JAMS and significantly limit a pharmacy's ability to gain access to discovery as well as significantly limited the time available to present the dispute to an arbitrator. A major PBM's own pleading describes its manual as amended simply by giving notice of the amendment and its effective date.[119] A change to the forum in which a pharmacy may ever vindicate its rights is as material as a term can be, yet it required no signature, negotiation, or consent. That PBM's current manual still provides that, "notwithstanding any other provision in the Provider Agreement," it "may amend the Provider Agreement, including the Provider Manual or other Caremark Documents, by giving notice . . . of the terms of the amendment and specifying the date the amendment becomes effective."[120]

NASP urges CMS to adopt a clear rule that a PBM may not change a material term of a provider agreement through a provider manual, policy bulletin, portal notice, or any other unilateral communication, and that any such change is effective only if set out in a written amendment signed by both parties, delivered to the pharmacy at least ninety (90) days before its effective date, and that a pharmacy that declines to sign an amendment may not be terminated, suspended, or otherwise penalized for declining. Network pharmacies and other providers cannot meaningfully negotiate with a counterparty that can rewrite the deal at will. Critically, a manual that is revised on the PBM's schedule, at the PBM's discretion, and often with little notice is not a contract term in any meaningful sense. For the same reason, CMS should expressly prohibit a PBM from treating continued claim submission as acceptance of a modified term, a practice that is common among PBMs.[121] A provider that continues to fill prescriptions for Part D enrollees is meeting its obligations to its patients and to the program, and is not thereby manifesting assent to terms it never signed, particularly where the only alternative is to abandon the patients it serves. CMS should also clarify that contract recitals declaring the PBM's policies and manuals to be "reasonable and relevant" have no legal effect for purposes of the any willing pharmacy and

reasonable and relevant standard. NASP's position is supported by the simple fact that a term cannot satisfy a regulatory requirement merely because its drafter says that it does.

Finally, NASP emphasizes that these protections must apply with equal force to financial terms. Reimbursement rates, fees, clawbacks, reconciliation and DIR-related adjustments, and other economic provisions contained in rate sheets, fee schedules, addenda, or other side documents should be subject to the same signed-amendment requirement, so that a PBM cannot avoid the rule by moving such changes out of the agreement and into a separate document. Any financial term that is not contained in the executed agreement or in a document expressly incorporated into it and provided to the pharmacy, including any unwritten understanding between a plan sponsor and an affiliated PBM or pharmacy, should be unenforceable against the pharmacy.

Further, NASP urges CMS to address the incorporation-by-reference clauses through which most of these changes are made. Network agreements commonly incorporate the PBM's provider manual and policies "as modified from time to time," which allows a manual revision to operate as a contract amendment.[122] CMS should provide that an incorporated document binds the pharmacy only in the version in effect when the agreement or amendment was signed, and that a PBM that revises an incorporated document must provide each network pharmacy with active notice and a redlined or otherwise marked version identifying every change. Manual updates currently occur at the PBM's absolute discretion, without a set schedule or standard notification, and often without any redline that would allow a pharmacy to identify what changed. CMS should issue a clear rule that (1) an incorporated provider manual, policy, or other document binds a pharmacy only in the version in effect when the agreement or amendment was signed; (2) any change to an incorporated document is a material amendment subject to the signed-amendment, ninety (90) day notice, and no-penalty-for-refusal requirements described above; and (3) every revision must be delivered with a redline identifying each change, and no revision takes effect until that redline has been delivered.

B. **Acceptance of standard terms:** CMS asks *"The amount of time pharmacies (and their PSAOs) are given to review proposed standard terms, rate sheets, and amendments before acceptance is required or deemed;"* CMS also asks *"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);" "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;"* and *"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;"*

No, pharmacies are not given a reasonable opportunity to evaluate and accept terms. Most notices changing standard terms, rate sheets, MAC lists, or provider manuals ask for no response at all, and PBM treats the pharmacy's continued participation as acceptance. One major PBM's manual provides that, "[e]ven if Provider has not signed a rate schedule, Provider is deemed to have accepted reimbursement and participation terms" in any network in which it submits a claim that is not rejected, and that if a pharmacy "submits claims to Caremark after the effective date of any notice or amendment, the terms of the notice or amendment is accepted by Provider."[123] Basic contract law treats silence as acceptance only in limited circumstances.[124] Where a response is invited, it is usually an "acknowledgment" due within about ten business days, and declining likely

means termination. Nor do offers reliably include the complete reimbursement terms CMS lists. Section I addresses this, and Section II.C proposes the disclosures each offer should contain.

Simply put, a pharmacy cannot stop dispensing to a plan's enrollees while it considers new terms without cutting patient off from their medications and losing a meaningful share of its business. Its "acceptance" therefore reflects the lack of any realistic alternative, not genuine assent, and it should not be treated as evidence that a term is reasonable and relevant. See Section I.A. Unilateral changes through provider manuals are addressed in Section VII.A, and NASP's recommended review period, affirmative acceptance, and right to decline in Section VII.C.

C. **Minimum review periods and affirmative acceptance:** CMS asks *"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;"*

Yes, CMS should establish and adopt these requirements together. A review period is meaningless without the information needed to evaluate the change. Disclosure is meaningless if the pharmacy can be bound without agreeing. Any requirements fail the purpose of a reasonable contract if refusing PBM-driven change ends the pharmacy's participation. Any review period must also allow appropriate time to consult outside counsel. This requirement is reasonable as Federal law already gives consumers, franchisees, and employees time to review terms and consult counsel before they are bound to agreements. [125]

NASP recommends that CMS require:

1. Ninety days' notice of any material change. That is the practical minimum to review the change against the existing agreement, model its financial effect, consult counsel, and negotiate, given that NASP members report PBM responses to even routine inquiries commonly take a week or more. It also fits the Part D calendar, under which standard contracts are available by September 15 for January 1, about 108 days. This is consistent with related state law analogues. [126]
2. Material changes take effect only at the start of a plan year, so a pharmacy's refusal of a mid-year amendment cannot lead to termination. MAC updates may be excepted, subject to the MAC protections in Section III.C.
3. No retroactive changes to rates, fees, or other economic terms for claims already adjudicated (see Section V, Point-of-sale finality). [127]
4. Complete reimbursement information in every proposal, as described in Sections I and II.C, including any effective-rate guarantee and how it is reconciled. [128]
5. Affirmative acceptance: the pharmacy's express agreement, not consent presumed from silence, the lapse of time, or continued claim submission.
6. Reciprocal notice: a pharmacy may exit a changed arrangement on the same notice the PBM must give, not the longer exit periods pharmacies are often held to. [129]

Two further points makes these protections work. First, CMS should define "material change" broadly and objectively, so that the protections cannot be avoided by arbitrarily characterizing a change as administrative or immaterial. At a minimum, a change should be treated as material if it affects any of the following: reimbursement, fees, or post-adjudication adjustments;

audit, recoupment, credentialing, or accreditation requirements; dispensing obligations or restrictions; termination rights; or dispute resolution, and any doubt should be resolved in favor of materiality. Second, CMS should provide that a pharmacy that declines a proposed change may continue to participate in the network on its existing terms through the end of the current contract term, without retaliation, and that a change implemented in violation of these requirements is void as to the pharmacy, with any amounts withheld or recouped under it repaid.

NASP further urges CMS to adopt its own CY2026 proposals (proposed in December 2024 but not finalized),[130] including bilateral without-cause termination and an October 1 network-status notice. NASP emphasizes that bilateral termination gives real force to the right to decline, as a pharmacy that can exit on the same terms as the PBM is not forced to accept a change to continue serving its patients. The October 1 network-status notice likewise affords pharmacies and enrollees advance notice of network participation before the plan year begins. Of note, these protections matter to beneficiaries as much as they do to pharmacies since enrollees select plans, in part, based on the pharmacies in network. A mid-year change that forces a specialty pharmacy out of network disrupts therapy for patients whose care that pharmacy is actively managing. Compliance with each protection can be shown from a dated notice, a redline, and a signed amendment, which makes them transparent, objective, and enforceable.

VIII. Audits and Terminations

A. **Recoupment, suspension and termination:** CMS asks, with respect to *"pharmacy contract provisions that permit Part D plan sponsors to recoup or suspend pharmacy payment or terminate a pharmacy contract,"* about *"The prevalence of such provisions;"* and *"The conditions necessary to invoke such provisions, such as a credible allegation of fraud or other inappropriate billing or risk of patient harm;"*

CMS asks about the prevalence of recoupment, suspension, and termination provisions and the conditions necessary to invoke them. These provisions are nearly universal in pharmacy network agreements. Therefore, the conditions for invoking them are critical. A pharmacy that can be suspended or terminated on thin grounds has no practical protection against arbitrary action, and the patients who rely on that pharmacy lose access to their medications whenever it is cut off. For specialty patients, that harm is magnified. An oncology patient on an oral anticancer therapy, a transplant recipient on immunosuppressants, or a patient with a rare disease will often depend on a single pharmacy that has built the clinical program, prior authorization support, and manufacturer coordination for that therapy, and many of these drugs are available only through a limited number of pharmacies, so there may be no immediate alternative that can fill the next prescription. This has resulted in missed treatment cycles, delays in care at a critical point, and avoidable hospitalizations, which is why termination is categorically more serious for specialty pharmacies as compared to retail.[131]

CMS should therefore promulgate a rule that a suspension or termination of a pharmacy is not reasonable or relevant except where there is a credible, established allegation of fraud or a risk of patient harm. Although many contracts and state laws use the "credible" language to limit such actions, PBMs and plans are under no obligation to establish such credibility with tangible evidence; the mere recitation that the allegation is "credible," without evidence, currently suffices.[132] This swallows the rule, and permits suspensions and terminations on the PBM or plan's

word alone, without substantiation. Moreover, such actions should be permitted only upon notice to the pharmacy, along with substantiating evidence, except that a PBM may suspend a pharmacy immediately where there is a documented, imminent risk of patient harm, provided that notice is given at the same time and review by a neutral decision-maker follows promptly. No other findings should qualify as cause for suspension or termination. In particular, NASP emphasizes that therapeutic-class concentration reflects the patient population a specialty pharmacy serves rather than any wrongdoing (see supra Section II.F), and that clerical errors (such as a missing signature or a typographical error in a required record)[133] are not indicative of fraud or patient harm. Treating either as grounds for suspension or termination necessarily turns an ordinary feature of a pharmacy's business into a pretext for its removal from the network, and is used by PBMs as a tool to undermine negotiated network access for independent pharmacies.

This issue is especially acute for a pharmacy that specializes in managing patients within a disease category, such as oncology or a rare or orphan condition. Such pharmacies are expected to have a high concentration of the drugs used to treat that condition, and where access to such drugs is limited or exclusive, a high concentration is the evidence that the pharmacy is fulfilling its mission.[134] A rule that treats concentration as cause removes the pharmacies with the deepest expertise. This bears directly on the conditions necessary to invoke these provisions: if concentration can serve as cause, then specialization alone can, and that is untenable for specialty patient care. Specialization should not, but presently is, used as the reason to terminate a pharmacy and, thus, to steer patients to PBM affiliates, circumventing network access negotiations.

These proposed limits must apply equally to terminations directed by the plan sponsor, as PBM agreements permit plan sponsors to do. The any willing pharmacy obligation belongs to the sponsor under 42 C.F.R. § 423.120(a)(8)(i), and a sponsor cannot avoid that obligation by directing its PBM to remove a pharmacy that the sponsor itself could not remove directly. This is common: plans have terminated commonly owned pharmacies in their own name, in actions rescinded after the pharmacies objected, and where pharmacies are identified by shared characteristics, including pharmacies with no apparent connection to the conduct alleged.[135] Critically, if the conditions for termination differ depending on which entity initiates it, these protections may be bypassed simply by routing the decision through the sponsor.

B. **Appeals:** CMS asks *"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."*

Appeal rights rarely change outcomes. The PBM decides the appeal, and the result is rarely different from the original decision. Where a termination is directed by the sponsor, the pharmacy is often afforded no appeal at all. Accordingly, every termination or suspension should be reviewed by a neutral decision-maker, independent of the entity that made the original determination, before termination takes effect. The sole exception should be a documented risk of patient harm, in which case immediate action may be warranted, provided that a review follows promptly. Termination should not take effect immediately in any other case. A sponsor owes its enrollees notice of network changes and help moving to another pharmacy. CMS should therefore provide that a termination take effect no earlier than thirty (30) days after the final determination on any appeal, so enrollees receive written notice and a transition to another pharmacy can be arranged without interruption in therapy, consistent with the thirty-day enrollee notice CMS already requires for provider terminations in Medicare Advantage.[136] Without such a structure, an appeal is merely a formality that offers the appearance of fairness without substance.

C. **Audit volume:** CMS asks *"The frequency and type of pharmacy audits conducted;"*

CMS asks about the frequency and type of pharmacy audits. For many pharmacies, the burden stems from audit volume alone. NASP's members report frequent desk audits, audits of roughly one hundred (100) claims, inventory audits reaching back two (2) years, and on-site audits that disrupt operations and divert staff from patient care. In NASP's survey, respondents reported 50 or more Part D desk audits in 2025 alone, in addition to larger claim audits with inventory review and on-site audits, and one estimated that its audits consumed roughly 500 staff hours.[137] Each audit demands time and documentation, and the cumulative effect of repeated audits can be significant even where none identifies a problem. To that end, NASP urges CMS to set reasonable limits on audit frequency, lookback periods, and the number of claims reviewed in a single audit. NASP recommends limits that states have already adopted and found workable: no more than one audit of a pharmacy in any twelve (12) month period absent credible evidence of fraud; a lookback of no more than twenty-four (24) months from adjudication; no more than one hundred (100) prescriptions per audit and no more than two hundred (200) in any twelve (12) month period; written notice of at least fourteen (14) business days before any on-site audit, together with the list of claims to be audited; and, for invoice audits, review confined to verification of purchases specific to the claims at issue.[138] CMS should also require 14 business days' advance notice before any on-site audit, so that a pharmacy can prepare and continue to serve its patients while the audit takes place. These limits would not prevent PBMs from detecting genuine fraud, waste, or abuse. Rather, they would prevent audit authority from being used as a continuous drain on pharmacy resources that should otherwise be focused on patients.

D. **Clerical findings and full-claim recoupment:** CMS asks *"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;"* and *"Use of audits to recoup payment based on errors, including minor errors;"*

CMS asks how often audits identify administrative or clerical issues and how often they are used to recoup payment based on errors, including minor errors. Most audit findings are clerical in nature, yet they frequently result in recoupment of the full value of the claim and, in some cases, termination under the label of "fraud, waste and abuse."[139] One survey respondent attributed all of its roughly $200,000 in 2024–25 Part D audit recoupments to clerical or technical findings rather than fraud or patient harm, and respondents reported recoupment of the full value of claims where the patient received the drug, in one case extending to fills before and after the date of service under review, without being offered a corrective action plan.[140] NASP emphasizes that a missing signature, a documentation inconsistency, or a similar technical deficiency is not fraud. Characterizing it as such misstates the facts and inflates the consequences. Accordingly, recoupment in such circumstances should be limited to overpayment, if any, while full-claim recoupment and termination should remain available where fraud is confirmed upon credible and supported evidence of intent to defraud. This approach corrects genuine errors while keeping the consequence in proportion to the conduct. It also prevents PBMs from collecting windfalls on claims for drugs or services of which patients otherwise received the full benefits.

E. **Audit transparency and fees:** CMS asks *"Transparency of audit and recoupment methodologies, including whether pharmacies are provided with information on a per claim basis;"*

The amount of information provided through PBM auditor reports depends entirely on the PBM and what (if any) context they see fit to provide. At the worst, an audit report identifies alleged invoice shortages without disclosing why the pharmacy's purchase records were not credited. In one published account, the actual basis, that a wholesaler's license could not be verified, was not stated in the findings and emerged only after repeated inquiries, by which point the PBM had already withheld funds to offset the claimed shortages.[141] A report that does not disclose which invoices were considered, why an invoice was not credited, or how the dollar amount was computed gives the pharmacy nothing to rebut. Because no federal standard specifies what an audit report must contain, pharmacies are often left to contest findings without the information needed to do so, which makes it more likely that recoupments and clawbacks will stand. Accordingly, CMS should require PBMs to disclose their audit and recoupment methodologies and to provide claim-level findings, so that a pharmacy can identify which claims are at issue, why, and how the amount at issue was calculated. CMS should also prohibit any arrangement in which an auditor's compensation, or any fee charged to the pharmacy, depends on the amount recouped. This is a practice among certain PBMs and their audit vendors, which is why a number of states have prohibited auditors from being paid a percentage of the amount recovered.[142] Critically, compensation tied to recoveries gives the auditor a direct financial incentive to identify errors and maximize recoupment, which necessarily undermines the objectivity that an audit is intended to provide.

F. **Invoice audits:** CMS asks *"Information about common audit findings and financial and other impacts on pharmacies and plans;"*

During invoice audits specifically, the appearance of shortfalls or reconciliation irregularities is often the result of PBMs' refusal to accept evidence of acquisition that does not take a particular form, and then recoup claims for drugs that the pharmacy did in fact acquire and dispense.[143] For example, published accounts describe a PBM that refused to credit a pharmacy's invoices because of a minor clerical error, producing a recoupment of more than $700,000 for drugs the pharmacy had purchased, and PBMs that rejected pharmacy-to-pharmacy transfer documentation and demanded other documents instead, including for claims where the patient received the medication.[144] PBMs should be required to accept any reliable evidence that a drug was lawfully acquired, including records maintained under the Drug Supply Chain Security Act, and that recoupment should be available only where there is no evidence that the drug was acquired and dispensed. A rule that rejects authentic records based on their format (for example, rejecting a Drug Supply Chain Security Act transaction record, a pharmacy-to-pharmacy transfer record, or an invoice from a licensed wholesaler because the PBM prefers a different document or a different supplier)[145] penalizes the pharmacy for a technicality, deprives the pharmacy of payment for a drug the patient in fact received, and does nothing to protect the program.

G. **Corrective action and due process:** CMS asks *"Opportunities for corrective action;"* and *"Due process provisions."*

NASP contends that, absent fraud, a corrective action plan should be available, and should be accepted by the PBM, before any recoupment or termination based on a first-time clerical finding. A pharmacy that identifies and corrects an identified issue has addressed the concern, and removing it from the network or recouping payment at that point serves no Part D purpose. NASP further emphasizes that due process should include notice (at least thirty (30) days before any recoupment, suspension, or termination takes effect, except where there is a documented, imminent risk of patient harm), supporting documentation, review by a neutral decision-maker

(that is, a reviewer who took no part in the original determination and is not employed by, or compensated based on recoveries for, the PBM, the plan sponsor, or the auditor, such as an independent arbitrator or an external reviewer like the Insurance Commissioner review Delaware now provides for reimbursement appeals),[146] and reasonable deadlines (at least forty-five (45) days to respond to a preliminary audit report, as Delaware and Minnesota already require)[147] for the pharmacy to respond. These protections ensure that a pharmacy can understand and contest the allegations against it before suffering adverse consequences.

Finally, PBMs sometimes deny network participation to or terminate pharmacies on the basis of their "affiliation" (a relationship short of common ownership or control, such as membership in the same pharmacy services administrative organization, use of the same management or consulting vendor, a shared landlord, or a family relationship among owners) with another pharmacy that has had compliance issues. One major PBM's manual, for example, permits it to deny enrollment or terminate a pharmacy "in its sole discretion" based on adverse findings against "[a]nother provider with any common association, ownership, or relationship to Provider."[148] Any such denial should require actual common ownership or control. Without that limit, a pharmacy may be penalized for the conduct of an entity it neither owns nor controls. That is the logic of group-based action, which has been taken against pharmacies identified only by the drug they dispense and the program through which it was acquired, including pharmacies with no apparent connection to the alleged wrongdoing.[149]

IX. Enforcement and Implementation

A. **Dispute resolution:** CMS asks *"Whether a mechanism is provided to resolve disputes about such terms, and the adequacy of such mechanisms;" and "What limitations, if any, are placed on a pharmacy's ability to file disputes;"*

Many barriers exist to challenging the conduct of PBMs. First, most PBMs require that pharmacies submit their disputes to confidential arbitration.150 The arbitral venues (e.g., AAA and JAMS) that these agreements call for are incredibly costly, especially when the PBM requires that the arbitration panel consist of three (3) arbitrators, all of whom charge hourly rates that commonly exceed $1,000 per hour. PBMs like Caremark require that arbitrations be limited to one (1) NCPDP location only, and that each pharmacy location deposit into escrow no less than $50,000 to cover Caremark's attorneys' fees and costs. PBM agreements also include significant discovery limitations designed to prevent pharmacies from obtaining potentially relevant documents. For example, one large PBM has included language in their arbitration agreement prohibiting pharmacies from requesting documents located in backup servers, tapes, or other media.151 This limitation, if enforced, would prevent pharmacies from receiving claims level data that is a necessary component of the pharmacy-PBM relationship, and often the basis of claims that pharmacies might bring against PBMs to enforce payment terms. In practice, these limitations apply unilaterally primarily because PBMs do not commence arbitration against pharmacies when the pharmacy breaches the agreement. Instead, the PBM suspends, terminates, or withholds reimbursement to remedy alleged breaches of the agreement. In other words, pharmacies are forced to submit disputes to costly arbitration while PBMs engage in self-help without commencing arbitration and subjecting themselves to the discovery limitations they wrote into the agreement.

Reasonable and relevant terms and conditions must include a fair, timely, and impartial dispute process, with appropriate transparency, reasonable costs, and protections against retaliation. Importantly, no contractual provision should prevent a pharmacy from communicating potential violations of CMS requirements to the agency or other appropriate regulatory authorities, in addition to the contractual dispute process. CMS should ensure that terms between PBMs and pharmacies that deprive pharmacies of a fair and meaningful dispute process, and that threaten termination or other sanctions against pharmacies for communicating with regulators, are void under Part D.

B. **Validation of PBM data and recoupments:** CMS asks *"Whether and how Part D plan sponsors audit, verify, or otherwise validate the claim-level pricing data and DIR data they receive from PBMs …"*

Pharmacies have no visibility into the black box of agreements between PBMs and Part D plans. In the commercial space, it is common that, for example, employer plan sponsors receive claims data that relates to the drug costs and patient/member co-payments made to PBMs for Part D drug claims. In that instance, plan sponsors use the claims data to identify generic and brand drug spend, specialty drug spend, compare the total ingredient cost for brand claims to rebates received, and overall whether the drug spend meets the contract guarantees with the PBM. The audits are limited to the drug spend and the PBM performance. Such plan sponsors do not receive any claims data or visibility into the pharmacy reimbursement data and DIR data. PBMs claim that the network agreements that they have with pharmacies are confidential and proprietary and therefore cannot be shared with employer plan sponsors. Thus, plan sponsors have no idea whether they are truly receiving pass-through pricing or whether the PBM is taking a "spread" on the amount paid by the Plan for the drug and the amount reimbursed to the pharmacy. Similarly, plan sponsors have no visibility into PBM clawbacks or DIR fees extracted from pharmacies. Whether this is the state of affairs between PBMs and their Part D plan sponsor clients, including their affiliated plans, is not known, and further elucidates the need for greater transparency in Part D.

CMS should require PBMs to provide claims-level pharmacy pricing data to plan sponsors for visibility and verification of the amounts paid that actually flow to the pharmacy. In situations where the PBM is affiliated with network pharmacies, the need for visibility is even greater because the reimbursement is often manipulated for profits.152

Sponsors should validate PBM pricing data, but often plan sponsors do not receive the pharmacy reimbursement data and DIR data. CMS should verify and report to plan sponsors in situations where the PBM is affiliated with network pharmacies, and audit recoupments should flow back to plan sponsors and be reflected in PDE adjustments.

a. Evidence: FTC reports; § 6224 audit rights.

C. **Regulatory clarifications:** CMS asks *"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."*

CMS should make clarifications that reimbursement is a term subject to § 423.505(b)(18) and that below-cost reimbursement fails it; that the standards are incorporated into every PBM-

pharmacy contract; that "similarly situated" is defined; and that Chapter 5, § 50.3 of the Medicare Prescription Drug Benefit Manual is codified and enforced.

Reimbursement is a term. Section 423.505(b)(18) requires "a standard contract with reasonable and relevant terms and conditions of participation."[153] CMS guidance already states that "Part D sponsors must offer reasonable and relevant reimbursement terms for all Part D drugs as required by 42 CFR 423.505(b)(18)."[154] The final rule should say so expressly, and should state that reimbursement below the cost structure described in Sections III through V is not reasonable.

The standards are contract terms. Every contract between a sponsor and its first tier, downstream, and related entities must contain "[a] provision requiring that any services or other activity performed by a first tier, downstream, and related entity in accordance with a contract are consistent and comply with the Part D sponsor's contractual obligations," and must specify that those entities "comply with all applicable Federal laws, regulations, and CMS instructions."[155] The reasonable-and-relevant requirement is therefore a term of every PBM-pharmacy contract, enforceable through the parties' dispute resolution process. Confirming this reduces the burden on CMS to adjudicate every dispute and is consistent with CMS's view that these are "fact-specific questions that are best left between negotiating parties."[156] The standards supply the objective measure that courts and arbitrators will apply, and the statute preserves pharmacies' other legal remedies.[157]

Define "similarly situated." Terms may vary by pharmacy type only if "all similarly situated pharmacies are offered the same standard terms and conditions,"[158] but the phrase is undefined and has been used to exclude specialty pharmacies from specialty networks. The definition should allow any willing specialty pharmacy that can serve a subset of specialty patients, such as oncology or transplant patients, to participate, so that accredited specialty pharmacies are treated as similarly situated for any-willing-pharmacy purposes (see Section II.C for the objective criteria).

Codify Chapter 5, § 50.3. Sponsors may restrict a drug to a subset of pharmacies only where "[t]he FDA has restricted distribution of the drug" or dispensing "requires extraordinary special handling, provider coordination, or patient education that cannot be met by a network pharmacy."[159] PBMs nonetheless create exclusive specialty networks open only to their affiliates. An accredited specialty pharmacy has demonstrated the extraordinary handling, coordination, and education capability the guidance describes, and should be permitted to dispense any drug it can lawfully acquire to any Part D patient. This guidance should be codified, and CMS should state that it will enforce it using the civil monetary penalty and sanction authority Congress provided.[160]

D. **Model terms:** CMS asks *"Examples of pharmacy contract terms and conditions or similar frameworks that could be viewed as models;"*

Model Terms

The table below sets out model terms that satisfy both prongs of the test in Section I.A. Each is reasonable because it covers cost, is predictable at dispensing, is complete at offer, is mutual, and carries due process; each is relevant because it fits the pharmacy's type, the drugs it dispenses, and a legitimate Part D purpose. Where current PBM contracts or provider manuals already contain workable language, the model term restates it; where current language works against the pharmacy, the right-hand column identifies the language the model replaces. The terms

are structural. They fix floors, processes, and definitions and leave rates above those floors to negotiation, consistent with Section X.

NASP asks CMS to adopt these terms as minimum standard terms under 42 C.F.R. § 423.505(b)(18) and to provide that a sponsor's standard contract that omits or contradicts them is not reasonable and relevant. Bracketed text identifies items for the parties to complete or for CMS to specify.

Term	Model Contract Language	Existing Language Modeled
1. Reimbursement		
1(a) Ingredient Cost	**Ingredient Cost.** For each Covered Drug dispensed, PBM shall reimburse Pharmacy an ingredient cost not less than the Acquisition Cost Benchmark for that drug on the date of dispensing. **"Acquisition Cost Benchmark"** means for a drug, the per-unit National Average Drug Acquisition Cost (NADAC) most recently published by CMS as of the date of dispensing or, where CMS publishes no NADAC for that drug, the drug's wholesale acquisition cost (WAC +0.00%). **"Independent Benchmark Source"** The Acquisition Cost Benchmark shall be measured on a gross basis and shall not be reduced by customary, industry-standard discounts directly related to drug acquisition that are retained by Pharmacy or its wholesaler. PBM shall not require Pharmacy to produce invoices, purchase files, or wholesaler or manufacturer pricing terms as a condition of reimbursement, and shall not reduce reimbursement based on a comparison of Pharmacy's acquisition cost to that of any other pharmacy. PBM shall update the Acquisition Cost Benchmark not less than every seven (7) days and shall apply it drug by drug, so that a shortfall on one drug is not offset by margin on another.	Current acquisition-cost offerings define cost as the pharmacy's actual cost "inclusive of discounts and rebates," require quarterly cost files and annual attestations, and fall back to NADAC, WAC, or PBM-selected prices (restates contract term as collected from pharmacy). Medicaid rate exhibits sequence NADAC, then WAC, then AWP based discounts (restates contract term as collected from pharmacy). The model replaces pharmacy-specific invoice disclosure with the publicly reported NADAC benchmark, with WAC +0.00% as the fallback, consistent with Part D's protection of retained acquisition discounts and its seven-day pricing-update requirement.[161]
1(b) Professional Dispensing Fee	**Dispensing Fee.** PBM shall pay a professional dispensing fee for each claim not less than the Cost to Dispense for Pharmacy's class, and tiered by handling complexity. **"Cost to Dispense"** means the cost of the activities described in the definition of "dispensing fees" at 42 C.F.R. § 423.100, as determined by an independent cost-of-dispensing study performed by a person not affiliated with Plan Sponsor or PBM, using data from pharmacies of Pharmacy's class, and refreshed not less than every three (3) years. **Annual Adjustment.** On January 1 of each contract year, each dispensing fee shall increase by not less than the percentage increase over the preceding twelve months in [the Consumer Price Index for All Urban Consumers, Medical Care Services component] [other index designated in Exhibit __]. No dispensing fee shall decrease during the term. A dispensing fee of $0.00, or below the Cost to	Current Part D rate exhibits commonly pay $0.00 to $1.00 per claim (restates contract terms as collected from pharmacies). GAO found 2023 fees "ranged from $0 to $2."[162] Annual escalators already exist but run against the pharmacy (restates contract terms as collected from pharmacies). The model reverses the direction and ties it to an index. Specialty-tiered fees are already used in other lines (restates contract term as collected from pharmacy).

Term	Model Contract Language	Existing Language Modeled
	Dispense, is not permitted, and dispensing fees are not subject to any effective rate, reconciliation, or offset.	
1(c) Compensation for Required Services	**Required Services.** If this Agreement, any Network Exhibit, the Provider Manual, or Plan Sponsor requires Pharmacy to furnish any service other than dispensing, including benefits investigation, prior authorization support, financial-assistance navigation, patient training, nursing, clinical and adverse-event monitoring, REMS or manufacturer data reporting, or 24/7 pharmacist access ("Required Services"), PBM shall (i) list each Required Service and its performance standard in Exhibit [__]; and (ii) pay Pharmacy for each Required Service at fair market value. **Fair Market Value.** Fair market value shall be determined by an independent valuation firm **mutually agreed to** by the parties, expressed as a per-patient-per-month or per-service fee within published low, middle, and high ranges, and reviewed annually. FMV payments are in addition to, and shall not be offset against, ingredient cost or dispensing fees. A service not listed in Exhibit [__] may not be required of Pharmacy, and Pharmacy's failure to perform an unlisted service may not be the basis for any audit finding, breach, or adverse action.	FTC consent order with Express Scripts requires a standard retail offering that will "make additional payments for all Non-Dispensing Services."[163] Manufacturer enhanced-services agreements already pay core and non-core services at FMV ranges.
2. Generic, Brand, and Dispensing Fee Effective Rates		
2(a) Effective Rate as Floor; Point-of-Sale Finality	**Point-of-Sale Finality.** Reimbursement for each claim, as adjudicated at the point of sale (the "POS Amount"), is final and shall not be reduced after adjudication by any reconciliation, true-up, fee, offset, or other mechanism, however denominated. **Effective Rate Guarantee.** Any Generic Effective Rate, Brand Effective Rate, or Dispensing Fee Effective Rate in this Agreement (each, an "Effective Rate Guarantee") establishes only the minimum aggregate reimbursement Pharmacy shall receive for the Measurement Period. Within forty-five (45) days after the end of each Measurement Period, PBM shall calculate Pharmacy's aggregate POS Amounts for the claims subject to the guarantee. If aggregate POS Amounts are less than the Effective Rate Guarantee, PBM shall pay Pharmacy the shortfall. If aggregate POS Amounts exceed the Effective Rate Guarantee, Pharmacy shall retain the excess, as determined by point-of-sale reimbursement. **No "Managing To" the Guarantee.** PBM shall not recoup, offset, or withhold any amount, or reduce MAC prices, rates, or fees prospectively, in order to recover or offset any amount by which Pharmacy's reimbursement exceeds an Effective Rate Guarantee.	Current terms reserve post-sale clawback (restates contract terms as collected from pharmacies). Some exhibits already exclude claims from reconciliation (restates contract term as collected from pharmacy). State laws provide models.[164]
2(b) Measurement and Transparency	Each Effective Rate Guarantee shall (i) be measured on a Part D-only, Pharmacy-specific basis (by NCPDP number), (ii) use definitions of "brand," "generic," and "specialty" drug that are consistent with 42 C.F.R. § 423.4 and with the definitions PBM uses for guarantees under SSA § 1860D-	Section 6224 of the Consolidated Appropriations Act, 2026 requires PBMs to define "generic," "brand name," and "specialty" drug

Term	Model Contract Language	Existing Language Modeled
	12(h)(1)(B), and that are set out in the Agreement; (iii) identify every drug and claim excluded from the guarantee; and (iv) be supported by a claim-level reconciliation report delivered with any payment. Dispensing fees shall not be subject to any Dispensing Fee Effective Rate that operates to reduce the fee paid at the point of sale.	transparently and consistently for guarantee purposes; the model carries the same definitions into pharmacy contracts.[165] Dispensing Fee Effective Rates claw back fees after the fact.[166]
3. Contract Integrity		
3(a) Signed Amendments Only	No Material Term may be amended, supplemented, or superseded except by a written amendment signed by authorized representatives of both parties. PBM shall deliver any proposed amendment, with complete reimbursement information and a redline against the current terms, at least ninety (90) days before its proposed effective date. Material amendments may take effect only on January 1 of a plan year, except MAC list updates made in compliance with this Agreement. Pharmacy's silence, the lapse of time, continued participation, or submission of claims shall not constitute acceptance. Pharmacy may decline any proposed amendment and shall continue to participate on its existing terms through the end of the current term. PBM shall not terminate, suspend, reduce reimbursement to, audit, or take any other adverse action against Pharmacy because Pharmacy declined an amendment. An amendment implemented in violation of this Section is void as to Pharmacy, and any amount withheld or recouped under it shall be repaid.	Current terms permit deemed or unilateral acceptance, including automatic participation unless the pharmacy opts out and reserved rights to implement new rates at any time (restates contract terms as collected from pharmacies); and manual amendments effective on notice (common PBM provider manual term)[167].[168]
3(b) Incorporated Documents	A provider manual, policy, bulletin, payer sheet, rate sheet, or other document incorporated by reference binds Pharmacy only in the version in effect when this Agreement or the most recent signed amendment was executed. Any revision to an incorporated document that affects a Material Term is an amendment subject to Section 3(a), and no revision takes effect until PBM has delivered to Pharmacy, by active notice, a redline identifying each change, and the Pharmacy provides affirmative acceptance of such revision.	Network agreements incorporate manuals "as modified from time to time" (common PBM provider manual term).
3(c) Material Term; Complete Offer	**"Material Term"** means any term affecting reimbursement, fees, or post-adjudication adjustments; audit, recoupment, credentialing, or accreditation requirements; dispensing obligations or restrictions; termination rights; or dispute resolution. Any doubt shall be resolved in favor of materiality. Every offer and amendment shall state, in the document itself, the ingredient cost methodology, dispensing fees, Effective Rate Guarantees, performance measures and scoring methodology, fees, and comparison groups that will apply. Any financial term not contained in this Agreement or in a document incorporated and delivered to Pharmacy, including any side letter or unwritten understanding between	

Term	Model Contract Language	Existing Language Modeled
	Plan Sponsor and an Affiliate, is unenforceable against Pharmacy.	
3(d) No Retroactive Changes	No negative change to any rate, fee, MAC price, Effective Rate Guarantee, or other economic term shall apply to any claim adjudicated before the change's effective date.	
3(e) Reciprocal Termination; Network Notice	Pharmacy may terminate this Agreement, or any Network Exhibit, without cause on the same notice PBM is permitted to give Pharmacy, and in no event on more than ninety (90) days' notice. PBM shall notify Pharmacy by October 1 of each year of each plan and network in which Pharmacy will participate for the following plan year.	CMS proposed both measures in the CY2026 rule but did not finalize them.[169]
3(f) Compliance With Law; No Self-Certification	PBM shall comply with, and perform its obligations consistent with, SSA § 1860D-4(b)(1)(A), 42 C.F.R. §§ 423.120(a)(8) and 423.505(b)(18), the standards for reasonable and relevant contract terms established by the Secretary, and all other applicable Federal laws, regulations, and CMS instructions, and these obligations are enforceable by Pharmacy under [the parties' dispute resolution procedures]. A recital or statement that any term or policy is "reasonable and relevant" has no effect in determining whether it is.	Required by CMS regulations.[170] PBMs have argued that the flow-down binds pharmacies but "not the other way around."[171]
4. Audits and Terminations		
4(a) Audit Notice, Frequency, and Scope	PBM shall give Pharmacy at least fourteen (14) business days' written notice before any on-site audit, together with the list of prescriptions to be audited, and shall not schedule an on-site audit during the first five (5) business days of a month without Pharmacy's consent. Absent a credible and supported allegation of fraud, waste, or abuse, PBM shall not (i) audit Pharmacy more than once in any twelve (12) month period; (ii) review claims adjudicated more than twenty-four (24) months before the audit notice; or (iii) review more than one hundred (100) prescriptions in an audit or two hundred (200) in any twelve (12) month period. Any audit involving clinical or professional judgment shall be conducted by or in consultation with a licensed pharmacist. Pharmacy shall be audited under the same standards and parameters as other similarly situated pharmacies, including PBM's Affiliates.	Restates common PBM provider manual terms. Those protections appear only as state-law addenda, and several expressly exclude "audits of claims paid for by federally funded programs" (common PBM provider manual term). The model makes them Part D terms.[172]
4(b) Documentation; Invoice Audits	Pharmacy may validate any claim with any authentic and verifiable record, including medication administration records, electronic, facsimile, or documented telephone prescriptions, Drug Supply Chain Security Act transaction information, pharmacy-to-pharmacy transfer records, and invoices from any licensed wholesaler or manufacturer. Invoice audits shall be limited to verifying the purchase of the drugs on the claims under review. PBM shall not recoup any claim for which there is reliable evidence that the drug was lawfully acquired and dispensed.	Restates common PBM provider manual term ("any legal prescription" and "authentic and verifiable" records may validate a claim).
4(c) Findings and Recoupment	Any recoupment shall be limited to the actual overpayment on the claim, calculated without extrapolation, probability sampling, or projection. A clerical or recordkeeping error,	Restates common PBM provider manual terms (state-law addenda barring

Term	Model Contract Language	Existing Language Modeled
	including a typographical, scrivener's, or computer error, is not fraud, waste, or abuse, and where the correct drug was dispensed to the patient, shall not result in recoupment of the drug cost or dispensing fee; Pharmacy may correct or resubmit the claim. No interest shall accrue during the audit. PBM shall not charge any audit fee, and no auditor or agent shall be compensated, directly or indirectly, based on amounts identified or recouped.	extrapolation, limiting recoupment to actual overpayment, barring chargebacks for errors with no financial harm, and prohibiting contingency compensation for auditors).
4(d) Audit Reports; Timing of Recovery	PBM shall deliver a preliminary audit report within sixty (60) days after the audit, identifying for each claim the discrepancy, the specific basis (including the reason any record was not credited), and the calculation of any amount. Pharmacy shall have at least forty-five (45) days to respond. PBM shall deliver a final report within sixty (60) days after Pharmacy's response. No amount may be withheld, offset, or recouped until the dispute process in Section 5 is complete. Any recovery shall be returned to Plan Sponsor and reflected in the applicable prescription drug event data.	Restates common PBM provider manual terms (no recoupment until the appeal process is complete; final report with claim-level information).[173] See Sections VIII.E, VIII.G, IX.B.
4(e) Corrective Action	Absent a credible and supported allegation of fraud, waste, or abuse, PBM shall offer, and accept, a corrective action plan before any recoupment, suspension, or termination based on a first-time finding. Pharmacy's timely completion of the corrective action plan resolves the finding.	Restates common PBM provider manual term (errors subject to recovery only where pharmacy fails a formal corrective action plan).
4(f) Suspension and Termination for Cause	PBM or Plan Sponsor may suspend or terminate Pharmacy for cause only upon (i) a credible and supported allegation of fraud, waste, or abuse; (ii) a documented risk of patient harm; or (iii) loss of a required license. None of the following is cause: the proportion of Pharmacy's claims attributable to a drug, class, condition, or manufacturer; a comparison of Pharmacy to other pharmacies; a clerical finding; or the conduct of another pharmacy with which Pharmacy has no common ownership or control. Except in the case of a documented, imminent risk of patient harm, no termination shall take effect until thirty (30) days after the final determination under [Dispute Resolution] Section, so that affected enrollees can receive notice and a transition. These limits apply equally to any termination directed by Plan Sponsor.	Medicare Advantage already requires 30-day enrollee notice of provider terminations, and the any willing pharmacy obligation belongs to the sponsor.[174]
5. Dispute Resolution		
5(a) No Self-Help	PBM and Plan Sponsor shall not recoup, offset, withhold, or suspend payment; suspend or terminate Pharmacy; or impose any other disciplinary measure ("Self-Help") except where there is (i) a credible and supported allegation of fraud, waste, or abuse, meaning an allegation with indicia of reliability that is supported by documentary evidence disclosed to Pharmacy; or (ii) a documented risk of patient harm. Any Self-Help taken on those grounds requires contemporaneous written notice of the basis and supporting evidence, and Pharmacy may obtain expedited review by the arbitrator or court, which shall be completed within thirty (30) days.	Congress already limits Part D payment suspensions to "credible allegations of fraud";[175] CMS defines a credible allegation as one with "indicia of reliability."[176] Several state-law addenda bar recoupment until "final internal disposition of the audit, including the appeals process" (common PBM provider manual term).

Term	Model Contract Language	Existing Language Modeled
	All other disputes and proposed disciplinary action shall proceed exclusively through this Section. No recoupment, suspension, or termination may take effect unless authorized by the neutral arbitrator or court, as designated in this Agreement, after a full and fair hearing on the merits.	
5(b) Arbitration: Full and Fair Hearing	Any dispute not resolved within forty-five (45) days after written notice shall be resolved by binding arbitration administered by [the American Arbitration Association under its Commercial Rules] before a single neutral arbitrator with healthcare experience, selected jointly. PBM may not change the administrator, rules, or forum except by signed amendment under Section 3(a). **Discovery.** Each party shall be entitled to document requests, interrogatories, and not fewer than one (1) corporate representative deposition and two (2) fact depositions plus depositions of each disclosed expert, and the arbitrator may issue subpoenas to third parties under 9 U.S.C. § 7 and shall grant additional discovery for good cause. PBM shall produce claim-level data, pricing and benchmark data, and communications concerning the dispute. **Hearing.** The arbitrator shall hold an evidentiary hearing with live testimony and cross-examination, and shall issue a reasoned written award. The hearing shall take place in Pharmacy's home state or remotely. No shortened limitations period, bond, or minimum claim amount applies, and commonly owned pharmacies may consolidate claims. The arbitrator may award all remedies available at law or in equity, including reinstatement and repayment, and shall award a prevailing Pharmacy its reasonable attorneys' fees and costs. Either party may seek interim injunctive relief in court to preserve the status quo.	Current terms waive or limit discovery and aggregation, including waivers stating that "the right to discovery and the right to appeal are limited or eliminated" and limits of one NCPDP number per arbitration (common PBM provider manual term)[177], and single-arbitrator clauses with costs split equally (restates contract term as collected from pharmacy). PBMs also limit disputes through short limitations periods, bonds, and limits on discovery.[178]
5(c) No Confidentiality of Proceedings; Trade Secrets	Neither party may require that the existence, conduct, or result of any arbitration be kept confidential, and no arbitration, award, or pleading may be designated a trade secret. A party may designate specific materials exchanged in discovery or admitted into evidence as trade secrets only if it demonstrates to the arbitrator that the material meets the definition of "trade secret" under 18 U.S.C. § 1839(3) or the applicable state Uniform Trade Secrets Act; the designating party bears the burden, and the arbitrator shall resolve any challenge. Nothing in this Agreement restricts either party from disclosing this Agreement, any dispute, or any award to CMS, the HHS Office of Inspector General, the Department of Justice, a state regulator, or Congress.	Contrast with typical PBM confidentiality clauses barring disclosure of "the existence, content, or results of any dispute or arbitration" without both parties' consent (common PBM provider manual term).[179] A sponsor may not limit a pharmacy's submission of documents to the Secretary.[180]
6. Definitions		
6(a) Specialty Pharmacy	**Specialty Pharmacy.** "Specialty Pharmacy" means a pharmacy that meets the comprehensive clinical, operational, and longitudinal patient-care services that characterize specialty pharmacy practice, only as confirmed through current accreditation by one nationally recognized, independent third-party specialty pharmacy accreditor, such	PBM provider manuals do not define "specialty pharmacy," and PBMs do not treat the term consistently. Several manuals define a "retail" pharmacy in part by

Term	Model Contract Language	Existing Language Modeled
	as URAC, ACHC, or The Joint Commission. PBM and Plan Sponsor shall not deny a Specialty Pharmacy specialty network participation, specialty terms, or access to a drug the pharmacy can lawfully acquire, and shall not require a second accreditation, a PBM-owned accreditation, proprietary credentialing, or fees as a condition of specialty designation.	excluding pharmacies with high specialty-drug volume, without stating what makes a pharmacy "specialty," leaving that decision to each PBM.[181] One PBM manual lists "specialty pharmacy accreditation" among its specialty credentialing criteria,[182] and another recognizes, under state law, that a network may require national certification to be considered a specialty pharmacy.[183] The model term adopts the standard of accreditation by a single nationally recognized, independent third-party specialty pharmacy accreditor described in Section II.E.
6(b) Accreditation	**Accreditation.** "Accreditation" means current specialty pharmacy accreditation by a nationally recognized, independent third-party specialty pharmacy accreditor, such as URAC, ACHC, or The Joint Commission, that validates the specialized clinical, operational, and patient-management capabilities necessary to care for patients with specialty conditions and manage their specialty drug therapies, including benefits investigation and prior authorization support, financial-assistance navigation, cold-chain and REMS handling, patient training, and ongoing clinical monitoring.	PBM provider manuals do not define accreditation or identify the accreditors they recognize. Where accreditation appears, it is an undefined credentialing criterion or a state-law obligation to report loss of accreditation "if required to be accredited."[184] Each PBM is left to decide which credentials count. The model term recognizes any one nationally recognized, independent third-party specialty pharmacy accreditor (see Section II.E).

E. **Transparent, objective and enforceable standards:** CMS asks *"Criteria CMS should consider to ensure standards are transparent, objective, and enforceable."*

Standards that are not enforced do not change contracts. Before the Consolidated Appropriations Act, 2026, the reasonable-and-relevant requirement had been in the regulations since 2005, yet a 2024 Freedom of Information Act request for CMS compliance and enforcement actions under the flow-down rule since January 1, 2014 returned no responsive records, and CMS told one pharmacy group that the noninterference clause barred even an investigation of below-cost rates.

Core Criteria

A broadly accessible complaint process. The statute requires CMS to establish, by January 1, 2029, a process through which a pharmacy may submit an allegation that a sponsor

violated the standards, using a standardized template and a certification of accuracy.[185] CMS should (i) let a pharmacy file through its PSAO, counsel, or association, with the pharmacy's certification; (ii) treat one submission as covering every violation in a contract, with supplementation as facts develop, since the statute allows one allegation per contract per plan year plus additional allegations when the contract is modified;[186] (iii) acknowledge each submission with a tracking number within ten (10) business days; and (iv) reserve the frivolous-filer bar for routine, bad-faith filings, as the statute provides. The complaint process should incorporate a confidential reporting channel for below-acquisition cost claims, separate from the formal allegation process, so that pharmacies can be comfortable in sharing confidential cost data without publicly alerting a PBM to their complaints.

No contractual bar on sharing terms with CMS. A sponsor may not prohibit or limit a pharmacy's ability to submit documents to the Secretary, and must itself produce contract offers and related correspondence on request.[187] CMS should state that any confidentiality, non-disparagement, or arbitration-secrecy clause is void to the extent it restricts disclosure to CMS, OIG, DOJ, state regulators, or Congress, and that enforcing such a clause against a pharmacy is coercion under subclause (VIII).[188]

Objective tests. Each standard should be verifiable from documents: whether reimbursement met the benchmark-based floor; whether a dispensing fee was at least the cost to dispense; whether an amendment was signed and delivered ninety days in advance with a redline; whether an adverse action rested on concentration or comparison. Tests of this kind can be applied by CMS, an arbitrator, or a court without CMS setting rates.

Required contract terms. The standards should be deemed incorporated into every sponsor, PBM, and pharmacy contract through 42 C.F.R. § 423.505(i)(3)(iii)–(iv), and CMS should require an express compliance clause enforceable by the pharmacy (Model Term 3(f)). That makes private enforcement through Section 5 of the model terms available and reduces the number of disputes CMS must decide itself.

Real anti-retaliation. The statute bars sponsors from retaliating against, coercing, or interfering with a pharmacy that submits an allegation, and a violation is separately subject to penalties.[189] CMS should define retaliation to include termination, non-renewal, rate or fee reductions, new audits, network-tier changes, and changes to the pharmacy's commercial or Medicaid terms (see Section X.A), and should presume retaliation when such an action follows a submission within twelve (12) months unless the sponsor shows by clear and convincing evidence an independent basis.

A stated commitment to penalties and sanctions, with published results. CMS must publish a biennial report on its enforcement and oversight of the pharmacy access requirements.[190] NASP asks CMS to report annually, not biennially; to include allegations received, investigations opened and closed, time to resolution, and outcomes by standard; and to name each sponsor and PBM against which a compliance action, penalty, or sanction was imposed, since imposed sanctions are public.

Clear Expectations, Reasonable Timelines, and Proportionate Enforcement

NASP agrees that the framework should encourage compliance first. CMS already uses graduated compliance actions (notice of noncompliance, warning letter, and corrective action plan), weighing the nature of the conduct, culpability, enrollee harm, and history.

Stage	Recommended Standard
Acknowledgment	Within ten (10) business days of submission.
Sponsor response	Sponsor produces contract offers, correspondence, and claim data within thirty (30) days of CMS request.
Determination	Within ninety (90) days of a complete submission; expedited determination within fifteen (15) days where a pending termination, suspension, or recoupment threatens enrollee access.
Corrective action	For isolated, inadvertent, first-time violations: notice of noncompliance and thirty (30) days to cure, including repayment to the pharmacy, consistent with the 30-day corrective-action opportunity in 42 C.F.R. § 423.509(c).
Material or repeated violations	Warning letter or corrective action plan, plus civil money penalties; compliance actions count toward the points that may bar new Part D applications under 42 C.F.R. § 423.503.
Intentional violations, patterns, or retaliation	No cure period; penalties at or near the maximum, calculated per enrollee; intermediate sanctions (suspension of enrollment, payment, or communications) under 42 C.F.R. § 423.750(a); and, where warranted, non-renewal or termination under 42 C.F.R. § 423.509(a)(4)(xiii).

Liability should follow responsibility. Beginning with plan year 2029, each sponsor's contract must require its PBM to reimburse the sponsor for penalties paid for violations tied to responsibilities delegated to the PBM.

Meaningful Remedies

Meaningful Relief. A penalty paid to the Treasury does not restore a pharmacy paid below cost or wrongly terminated. The statute does not give CMS a separate restitution authority, but CMS controls the conditions for closing a corrective action plan and lifting an intermediate sanction, which remain in effect "until CMS is satisfied that the deficiencies . . . have been corrected and are not likely to recur."[191] CMS should require, as a condition of correction, that the sponsor (i) cease the noncompliant term; (ii) reprocess or repay affected claims with interest; (iii) reverse recoupments and offsets; (iv) reinstate a wrongly terminated or suspended pharmacy; and (v) offer compliant terms to every similarly situated pharmacy, not only the complainant.

Penalties large enough to deter. Under the authorities Section 6223 incorporates, CMS may impose up to $25,000 (as adjusted for inflation) per determination and, where enrollees are or are likely to be adversely affected, up to $25,000 (as adjusted) per affected enrollee, plus up to $10,000 (as adjusted) for each week a deficiency remains uncorrected after notice.[192] Below-cost reimbursement and steering affect every enrollee who must change pharmacies or wait for therapy, so CMS should calculate penalties per affected enrollee and treat each affected pharmacy contract as a separate determination.

The continuing penalty in the current regulations accrues weekly and is capped at $10,000 (as adjusted) per week. That is small relative to the revenue a single noncompliant term can generate across a national network. NASP therefore recommends that CMS (i) begin the continuing penalty from the date of CMS's notice and apply it to each uncorrected determination; (ii) set standard minimum penalties and aggravating-factor amounts so that the expected penalty exceeds the economic benefit of noncompliance; and (iii) require, as a model contract term, that amounts owed to a pharmacy accrue interest compounding daily from the date of underpayment

until paid. NASP also asks CMS to support legislation authorizing a daily penalty for reasonable-and-relevant violations.

F. **Implementation timing:** CMS asks *"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;"*

The Statutory Timeline is Workable if CMS Finalizes Early and Requires Early Contract Offers

The existing timeline in the statute requires that plan sponsors submit bids to CMS "[n]ot later than the first Monday in June," which is June 5, 2028. 42 C.F.R. § 423.265(b)(1). They must make standard contracts available "no later than September 15 of each year for contracts effective January 1 of the following year." *Id.* § 423.505(b)(18)(i). Beneficiaries then choose plans, and the pharmacy networks that come with them, during the annual election period from October 15 through December 7. *Id.* § 423.38(b)(3). Based on that calendar, final standards in April 2028 leave plan sponsors about nine weeks to price them into bids and about five months to issue compliant contracts to pharmacies. However, a pharmacy that first sees its 2029 Part D network participation terms on September 15 has about one month before beneficiaries begin choosing their plans on October 15, and only two weeks if CMS adopts the October 1 network-status notice it proposed for 2026. From an operational perspective, that timeframe provides no realistic opportunity for pharmacies to review the terms, select their networks, and negotiate if they so choose. Therefore, it is incumbent on plan sponsors and their PBMs to begin preparing compliant terms now, to the best of their abilities, rather than waiting for the final rule.

NASP believes it is important that CMS accounts for and proactively engages with industry stakeholders early and often about each operational step between April 3, 2028 and January 1, 2029, including:

i. bid pricing, because standards that set reimbursement floors and dispensing fee requirements change plan costs that actuaries must build into June bids;

ii. contract revision, because PBMs must rewrite standard contracts;

iii. claims systems, because new reimbursement terms must be programmed and tested before the first 2029 claim;

iv. pharmacy and PSAO review, because independent pharmacies often contract through PSAOs that must review terms for thousands of pharmacies at once, *see* Medicare Prescription Drug Benefit Manual, § 50.8.1, and every pharmacy needs complete information to decide whether to participate;

v. network finalization, because network status must be settled before beneficiaries compare plans in October; and

vi. specialty classification under the new "similarly situated" criteria.

In line with the above, NASP also asks CMS to take three steps:

1. *First*, for the first compliant cycle, CMS should require plan sponsors to make complete 2029 standard contracts available by July 1, 2028, which gives pharmacies the 90-day

review period NASP supports, *see* Section VII.C, before network status must be settled for the October election period.

2. *Second*, the standards should apply to every contract in effect on or after January 1, 2029, including multi-year and evergreen agreements signed earlier, with no phase-in. Every contract with a first tier, downstream, or related entity already must "specify that first tier, downstream, and related entities must comply with all applicable Federal laws, regulations, and CMS instructions," 42 C.F.R. § 423.505(i)(3)(iv). Without this rule a PBM could lock pharmacies into multi-year agreements in 2027 and 2028 to avoid the new standards.
3. *Third*, the final rule should confirm that the 2029 standards do not create a safe harbor for earlier terms. The statute applies the new standards to plan years beginning on or after January 1, 2029, *see* 42 U.S.C. § 1395w-104(b)(1)(A)(ii)(I), but the reasonable and relevant requirement itself has applied since 2005, *see* 42 C.F.R. § 423.505(b)(18). The final rule should state that the 2029 standards add specificity to that existing obligation and do not validate the terms that came before them.

X. Related Issues and Legal Authority

A. **Part D rates tied to commercial rates:** CMS asks *"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: Whether any guarantee covers both Part D and commercial reimbursement; Whether and how MAC prices, dispensing fees, or other reimbursement parameters are managed so that overpayments relative to the guarantee on one line of business offset underpayments on the other; Whether such arrangements could result in higher Part D negotiated prices than would be paid under a standalone Part D guarantee, and what the implications for CMS subsidy calculations, enrollee cost sharing, and Part D bids would be; The prevalence of contract provisions that tie Part D reimbursement rates to commercial reimbursement rates, and any variances across pharmacy types; The frequency and magnitude of end-of-year reconciliation payments arising from aggregate guarantee constructs, and whether such reconciliation payments are allocated differently across Part D and commercial lines of business and, if so, how;"*

NASP members have reported "blended" rate guarantees, in which effective rates are calculated as an average across both commercial and Part D networks, and this is a loophole that CMS should close. CMS defines the "negotiated price" for Part D drugs as "the lowest possible reimbursement such network entity will receive, in total, for a particular drug." 42 C.F.R. § 423.100. CMS adopted the singular term to make clear that a negotiated price is set for each covered Part D drug. Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs, 87 Fed. Reg. 27704 (May 9, 2022). A blended guarantee reconciled across lines of business at year end undermines that design. It can also raise Part D negotiated prices above what a standalone guarantee would produce, which affects subsidies, cost sharing, and bids, as CMS itself notes. 91 Fed. Reg. 60568 (§ II.A).

Congress already bars standard terms from requiring pharmacies to accept insurance risk as a condition of participation. Social Security Act § 1860D-4(b)(1)(E), 42 U.S.C. § 1395w-104(b)(1)(E); 42 C.F.R. § 423.120(a)(8)(ii). The same reasoning applies to conditions imposed from outside Part D.

NASP therefore asks CMS to adopt standards that require that Part D reimbursement and any guarantee be set and reconciled on a Part D-only basis; prohibit offsetting Part D payments against commercial results; bar sponsors and their PBMs from conditioning Part D participation or terms on a pharmacy's acceptance of, or participation under, any non-Part D network terms, see 91 Fed. Reg. 60568 (§ II.B); and require that Part D terms be available as a standalone contract, even where a multi-line agreement is also offered, *see id.*

However, separation alone is not enough. A PBM that has promised a client an aggregate guarantee could meet the guarantee by cutting commercial reimbursement to recover what it can no longer offset in Part D. CMS itself asks whether rates are managed "so that overpayments relative to the guarantee on one line of business offset underpayments on the other." *Id.* (§ II.A). The standards should therefore also provide that a reduction in a pharmacy's non-Part D reimbursement or terms made in response to the pharmacy's Part D participation, or to the sponsor's compliance with these standards, is a condition on Part D participation that is not reasonable and relevant; extend the statute's anti-retaliation and anti-coercion protections, which now bar sponsors from retaliating against a pharmacy for submitting allegations, to retaliation through changes in non-Part D terms, see Social Security Act § 1860D-4(b)(1)(F)(i)(VIII), 42 U.S.C. § 1395w-104(b)(1)(F)(i)(VIII); require sponsors to disclose to CMS any guarantee that spans Part D and other lines of business and how reconciliation payments are allocated among them, so CMS can detect offsets, see 91 Fed. Reg. 60568 (§ II.A).

Section 6223 applies "[n]otwithstanding any other provision of law." Social Security Act § 1860D-4(b)(1)(A)(ii)(I), 42 U.S.C. § 1395w-104(b)(1)(A)(ii)(I). These standards therefore fall within the Secretary's authority, even though CMS has previously said that sponsors and pharmacies "remain free to negotiate any such arrangements they wish." 87 Fed. Reg. 27704.

B. **Overlap with Section 6224 PBM reforms:** CMS asks *"How implementation of standards for reasonable and relevant pharmacy contract provisions in section 1860D-4(b)(1)(A)(ii)(II) of the Act is likely to overlap with implementation of the PBM disclosure requirements and remuneration restrictions set forth under section 1860D-12(h) of the Act, and recommendations for how CMS should take such overlap into account when developing the standards for reasonable and relevant pharmacy contract provisions."*

The two provisions are complementary and should be implemented together. Section 6224 governs what PBMs may earn and must report; its rule of construction leaves pharmacy payment rules untouched, so it does not make any pharmacy term reasonable.[193] Section 6223 does that work, and CMS has asked how the two interact.[194] NASP recommends that CMS (1) use Section 6224 reports, including reimbursement by dispensing channel, affiliate share and cost ranges by drug, and benefit designs that encourage use of affiliates, to monitor ownership parity under Section II;[195] (2) apply one ownership-, control-, and agency-based definition of "affiliate" across both provisions, as Section 6223 already does for essential retail pharmacies, without treating limited-distribution or restricted-network participation as affiliation;[196] and (3) adopt one

definition of "specialty pharmacy" and require that the "specialty drug" definitions PBMs disclose under Section 6224 apply consistently in pharmacy contracts. NASP incorporates its July 20, 2026 comments by reference.[197]

C. **Performance measures:** CMS asks *"How such measures are incorporated into network pharmacy contracts;"*

Between 2016 and 2023, pay-for-performance ("PFP") programs were a common feature of PBM network contracts. Each PBM had its own performance networks, and within those networks, their own quality measures to determine pharmacy performance. Most performance networks focused on patient adherence to prescribed medications. Pharmacies received a performance score based on the medication-taking behavior of their patients. No PBM measured adherence in the same way as the next PBM. And many PBMs incorporated other non-adherence metrics to judge pharmacy performance as well.

Following CMS's change in the definition of "negotiated price," these PFP programs became obsolete because they no longer offered Part D plan sponsors the same economic value they did prior to the rule change. At their height, however, these PFPs were highly controversial among participating pharmacies. No performance-based program drew more scrutiny and pharmacy challenges than Caremark's Performance Network Program ("PNP"). Pharmacies have successfully challenged the PNP on multiple fronts including, as relevant here, whether Caremark's quality measures were transparent and accurately captured pharmacy performance.

In July of 2024, the Southern District of New York confirmed an arbitration award finding that Caremark "knew [it] could not develop criteria that [would] consistently and fairly measure adherence." *Caremark, LLC v. New York Cancer & Blood Specialists*, 740 F. Supp. 3d. 340, 346 (S.D.N.Y. 2024). The arbitration award further concluded that Caremark "understood that there was nothing [the arbitration's Claimant] NYCBS could do to improve its adherence score" but never informed NYCBS of this material fact."

Dozens of other claimant pharmacies challenged Caremark's specialty adherence metrics as well. *See Caremark, LLC v. Allied Health Services, Inc., et al.*, 23-cv-1994-PHX-JJT, Dkt. No. 54 (D. Ariz. Dec. 8, 2023) (complaint and petition seeking to compel over twenty (20) pharmacies to submit their complaints about the PNP to specific arbitral venue). While CMS has historically refused to interfere with the contracts between Part D plan sponsors, first tier, and downstream entities, the fallout around Caremark's PNP underscores the need for: (a) rules requiring PBMs to ensure the terms of network participation are fair and transparent; (b) a required, standard term in all Part D pharmacy agreements incorporating the "reasonable and relevant" standard as an enforceable contractual term, enabling pharmacies to hold PBMs accountable for failing to meet this requirement (see supra Section 9.D model term 3(f); and (c) protections barring PBMs from retaliating against providers that seek relief from violations of those requirements.

CMS has clear authority to adopt the standards NASP recommends, including standards that reach reimbursement terms. Section 6223 provides that, "[n]otwithstanding any other provision of law," contract terms "shall be reasonable and relevant according to standards established by the Secretary," and directs CMS to examine whether reimbursement and dispensing fees cover pharmacies' costs in setting them.[198] A "notwithstanding" clause signals that the provision overrides conflicting law.[199] Even before Section 6223, CMS explained that the

noninterference clause "does not prohibit us from establishing or clarifying regulatory requirements to implement the any willing pharmacy requirement."[200] That clause bars interference in negotiations and the institution of "a price structure"; a cost floor and process standards do neither. [201] A federal court has confirmed an arbitration award holding that the clause did not displace the obligation to offer reasonable and relevant terms.[202] Congress also gave CMS civil money penalty and sanction authority to enforce the standards.[203]

Conclusion

In summary, NASP urges CMS to establish clear, meaningful, and enforceable "reasonable and relevant" contracting standards that recognize specialty pharmacy through a single nationally recognized, independent third-party specialty pharmacy accreditation; ensure equitable network access regardless of pharmacy ownership or affiliation; require drug-specific reimbursement that adequately accounts for objective drug acquisition costs, specialty dispensing costs, the provision of specialized patient care services, and a reasonable margin; and establish meaningful transparency requirements, due process protections, enforcement mechanisms, and effective remedies for noncompliance.

NASP appreciates the opportunity to provide these comments and recommendations and stands ready to serve as a resource to CMS throughout the rulemaking process. We welcome the opportunity to meet with CMS, provide additional information and perspective, and address any questions as the agency develops regulations to implement Congress's mandate to establish "reasonable and relevant" terms and conditions pursuant to Section 6223 of the Consolidated Appropriations Act, 2026.

NASP looks forward to working collaboratively with CMS to ensure that these standards reflect the complexities of specialty pharmacy practice, support the sustainability of specialty pharmacy services, and, most importantly, protect beneficiary access to the medications and specialized care they need.

Sincerely,



Sheila M. Arquette, R.Ph.
President and Chief Executive Officer
National Association of Specialty Pharmacy

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[1] Request for Information; Medicare Part D Reasonable and Relevant Pharmacy Contracting Standards, 91 Fed. Reg. 60568 (Sept. 24, 2026) (CMS-4217-NC; RIN 0938-AW08) [hereinafter RFI], https://www.federalregister.gov/documents/2026/09/24/2026-19535/request-for-information-medicare-part-d-reasonable-and-relevant-pharmacy-contracting-standards.

[2] See Nat'l Ass'n of Specialty Pharmacy, About NASP, https://naspnet.org/about (describing NASP as a 501(c)(6) non-profit trade organization and the only national association representing all stakeholders in the specialty pharmacy industry, and stating its mission); The National Association of Specialty Pharmacy Abstract Program (2018), https://www.tandfonline.com/doi/full/10.1080/21556660.2018.1521036 (stating that the association was founded in 2013).

[3] See Press Release, The National Association of Specialty Pharmacy (NASP) Welcomes Four New Board Members at its Record-Breaking 2025 Annual Meeting & Expo, GlobeNewswire (Sept. 16, 2025), https://www.globenewswire.com/news-release/2025/09/16/3151115/0/en/The-National-Association-of-Specialty-Pharmacy-NASP-Welcomes-Four-New-Board-Members-at-its-Record-Breaking-2025-Annual-Meeting-Expo.html (stating that NASP has more than 3,500 members); see also Nat'l Ass'n of Specialty Pharmacy, FAQ, https://naspnet.org/faq (listing categories of NASP members).

[4] See, e.g., Nat'l Ass'n of Specialty Pharmacy, Comments on CMS-4182-P, at 10 (Jan. 16, 2018) [hereinafter NASP 2018 Comments], https://naspnet.org/wp-content/uploads/2018/01/NASPs-comments-to-Part-D-Proposed-Rule-Final-Version-011618.pdf (urging that any CMS definition of specialty pharmacy focus on "quality and third party independent accreditation"); Letter from Sheila Arquette, President & CEO, NASP, to Adrienne A. Harris, Superintendent, N.Y. Dep't of Fin. Servs. 4 (Oct. 16, 2023) [hereinafter NASP N.Y. Letter], https://naspnet.org/nasps-letter-to-superintendent-adrienne-a-harris-regarding-ny-state-regulations (proposing that a pharmacy be accredited by a nationally recognized independent specialty pharmacy accreditation organization to be recognized as a specialty pharmacy); Letter from Sheila M. Arquette, President & CEO, NASP, to Mehmet Oz, Adm'r, Ctrs. for Medicare & Medicaid Servs. 11–12 (July 20, 2026) (Docket No. CMS-2026-2212, responding to Request for Information, 91 Fed. Reg. 36776 (June 18, 2026) (CMS-4218-NC)) [hereinafter NASP July 20 Letter], https://naspnet.org/nasp-submits-comments-to-cms-on-medicare-part-d-pbm-compensation-and-data-collection-rfi (recommending a single, objective, and externally verifiable accreditation-based definition of specialty pharmacy).

[5] NASP July 20 Letter, supra, at 11–14 (recommending "a single, objective, and externally verifiable definition of 'specialty pharmacy'" and noting that, absent a CMS definition, "each PBM remains free to classify pharmacies as 'specialty' — or to decline to do so — using whatever internal, self-selected criteria it chooses").

[6] See, e.g., Fed. Trade Comm'n, Off. of Pol'y Plan., Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies, Interim Staff Report 48–51 (July 2024) [hereinafter FTC First Interim Report], https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf (§ III.C) (finding that, because the six largest PBMs control over 90 percent of dispensing volume, pharmacies "often have little choice but to contract with the dominant PBMs," which gives those PBMs "enormous leverage over unaffiliated, independent pharmacies," and reporting that numerous independent pharmacies and a large PSAO described being forced into "one-sided, non-negotiable contracts"); Fed. Trade Comm'n, Off. of Pol'y Plan., Specialty Generic Drugs: A Growing Profit Center for Vertically Integrated Pharmacy Benefit Managers, Second Interim Staff Report (Jan. 2025) [hereinafter FTC Second Interim Report], https://www.ftc.gov/system/files/ftc_gov/pdf/PBM-6b-Second-Interim-Staff-Report.pdf (finding that the three largest PBMs reimbursed their affiliated pharmacies at a higher rate than unaffiliated pharmacies on nearly every specialty generic drug examined); U.S. Dep't of Lab., Emp. Benefits Sec. Admin., Improving Transparency Into Pharmacy Benefit Manager Fee Disclosure, 91 Fed. Reg. 4348, 4368 (proposed Jan. 30, 2026) (to be codified at 29 C.F.R. pt. 2550) (explaining that the proposal is intended to address the "reported opacity in the pharmaceutical supply chain" and "remedy the imbalance in bargaining power between self-insured group health plans and large PBMs"); Staff of H. Comm. on Oversight & Accountability, 118th Cong., The Role of Pharmacy Benefit Managers in Prescription Drug Markets 23 (July 2024), https://oversight.house.gov/wp-content/uploads/2024/07/PBM-Report-FINAL-with-Redactions.pdf (concluding that, because of PBM consolidation, community and independent pharmacies "are left with no choice but to contract with PBMs" and that those contracts are opaque and often designed to hurt competing pharmacies); Minority Staff of H. Comm. on Oversight & Reform, 117th Cong., A View from Congress: The Role of Pharmacy Benefit Managers in Pharmaceutical Markets (Dec. 10, 2021), https://oversight.house.gov/wp-content/uploads/2021/12/PBM-Report-12102021.pdf (finding that PBMs use their market leverage to increase profits, steer patients to PBM-owned pharmacies, reimburse unaffiliated pharmacies at low rates, and charge them fees, making it difficult for independent pharmacies to survive).

[7] Restatement (Second) of Contracts § 208 & cmt. d (Am. L. Inst. 1981); Williams v. Walker-Thomas Furniture Co., 350 F.2d 445, 449–50 (D.C. Cir. 1965); Armendariz v. Found. Health Psychcare Servs., Inc., 6 P.3d 669, 690 (Cal. 2000).

[8] Medicare and Medicaid Programs; Contract Year 2026 Policy and Technical Changes, 89 Fed. Reg. 99340, 99383 (proposed Dec. 10, 2024) [hereinafter CY2026 Proposed Rule] (observing that "pharmacies often do not have the ability to meaningfully negotiate with or demand clear information from PBMs and plans regarding contracting terms"), https://www.federalregister.gov/documents/2024/12/10/2024-27939.

[9] 42 U.S.C. § 1395w-112(h)(4)(A) (as added by Consolidated Appropriations Act, 2026, § 6224(a)).

[10] NADAC has particular limitations as a benchmark for specialty drugs because its underlying surveys generally exclude specialty pharmacies and therefore may not reflect their actual acquisition costs. CMS has expressly acknowledged this limitation. See 81 Fed. Reg. 5170, 5313 (Feb. 1, 2016). Accordingly, while NADAC is a

preferable fallback to benchmarks that do not reflect actual acquisition costs, CMS should recognize that NADAC may understate specialty pharmacies' costs.

[11] See Ctrs. for Medicare & Medicaid Servs., Medicaid Covered Outpatient Prescription Drug Reimbursement Information by State (quarter ending Sept. 2026), https://www.medicaid.gov/medicaid-prescription-reimbursement-quarter-ending-sep-2026.pdf (compiling state Medicaid ingredient-cost methodologies, many of which reimburse at NADAC and, where no NADAC exists, at WAC); see, e.g., Miss. Div. of Medicaid, State Plan Amendment 17-0002, Pharmacy Reimbursement (approved 2017), https://medicaid.ms.gov/wp-content/uploads/2017/05/MS-SPA-17-0002-Pharmacy-Reimbursement-Approved.pdf (ingredient cost is the lesser of NADAC or, "when no NADAC is available," WAC plus zero percent, among other benchmarks).

[12] Improving Transparency Into Pharmacy Benefit Manager Fee Disclosure, 91 Fed. Reg. 4348 (proposed Jan. 30, 2026), https://www.federalregister.gov/documents/2026/01/30/2026-01907/improving-transparency-into-pharmacy-benefit-manager-fee-disclosure.

[13] Supported by documents from NASP members.

[14] Nat'l Ass'n of Specialty Pharmacy, Specialty Pharmacy Experience Survey: Medicare Part D Contract Terms (Nov. 2026) [hereinafter NASP Survey].

[15] NASP Survey.

[16] Ctrs. for Medicare & Medicaid Servs., Medicare Prescription Drug Benefit Manual ch. 5, § 50.3 (Rev. 8, Dec. 18, 2009) (as reissued Sept. 20, 2011) [hereinafter Ch. 5], https://www.cms.gov/files/document/chapter-5-benefits-and-beneficiary-protection-v92011.pdf.

[17] Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program, 83 Fed. Reg. 16440, 16598 (Apr. 16, 2018) [hereinafter CY2019 Final Rule], https://www.govinfo.gov/content/pkg/FR-2018-04-16/pdf/2018-07179.pdf.

[18] Supported by documents from NASP members.

[19] 42 U.S.C. § 1395w-104(b)(1)(A)(i), (C)(i).

[20] CY2019 Final Rule, supra, at 16590.

[21] 42 C.F.R. § 423.505(e)(2); see also id. § 423.505(i)(2).

[22] 42 U.S.C. § 1395w-104(b)(1)(F)(i)(III)(bb).

[23] FTC First Interim Report, supra, at 1–2 (the three largest PBMs "now manage nearly 80 percent of all prescriptions filled in the United States").

[24] CY2026 Proposed Rule, supra, at 99383.

[25] NASP Survey.

[26] FTC First Interim Report, supra, at 1–2, 19 (the three largest PBMs "now manage nearly 80 percent of all prescriptions filled in the United States"; their affiliated pharmacies "now account for nearly 70 percent of all specialty drug revenue"; affiliated share of specialty grew "from 54 percent in 2016 to 68 percent in 2023").

[27] Off. of Inspector Gen., U.S. Dep't of Health & Hum. Servs., OEI-BL-24-00240, Impacts of Vertical Integration in Medicare Part D on Sponsors' Drug Costs, Pharmacy Reimbursement, and Enrollee Cost Sharing 1 (May 2026) (Data Snapshot) [hereinafter OIG Data Snapshot], https://www.oig.hhs.gov/documents/evaluation/11668/OEI-BL-24-00240_highlights.pdf ("In 2023, 6 of 11 vertically integrated organizations we identified accounted for about 82 percent of the $275.9 billion in Part D spending that year."); see also Off. of Inspector Gen., U.S. Dep't of Health & Hum. Servs., OEI-BL-24-00240, Impacts of Vertical Integration in Medicare Part D on Sponsors' Drug Costs, Pharmacy Reimbursement, and Enrollee Cost Sharing 2, 4 (May 2026) [hereinafter OIG Report], https://oig.hhs.gov/documents/evaluation/11667/OEI-BL-24-00240.pdf (same finding); U.S. Gov't Accountability Off., GAO-26-107393, Medicare Part D: Payments and Contracts Between Pharmacies and Plan Sponsors That Are Vertically Integrated 6 (Sept. 3, 2026) (publicly released Oct. 5, 2026) [hereinafter GAO Report], https://www.gao.gov/products/gao-26-107393 (eight of the 15 largest Part D plan sponsors in 2023, "accounting for about 70 percent of total Part D enrollment," were vertically integrated with one or more PBMs, mail-order pharmacies, and specialty pharmacies). On November 4, 2026, CVS Health announced that it intends to separate its retail pharmacy business, which includes approximately 9,000 CVS Pharmacy locations, its mail pharmacy, and MinuteClinic, into an independent, publicly traded company, while Aetna, the CVS Caremark PBM, and the CVS Specialty pharmacy business will remain together in CVS Health; the separation is expected to be completed in the first half of 2028. Press Release, CVS Health Corp., CVS Health Announces Intent to Create Two Distinct Leaders in Healthcare (Nov. 4, 2026), https://www.cvshealth.com/news/company-news/cvs-health-announces-intent-to-create-two-distinct-leaders-in-healthcare.html. [Pincites to GAO Report follow the pagination of the printed full-text version at https://files.gao.gov/reports/GAO-26-107393/index.html]

[28] Letter from Chiquita Brooks-LaSure, Adm'r, Ctrs. for Medicare & Medicaid Servs., et al., to Pharmacy Benefit Managers, Medicare Part D Plans, Medicaid Managed Care Plans, and Private Insurance Plans (Dec. 14, 2023), https://www.cms.gov/newsroom/fact-sheets/cms-letter-plans-pharmacy-benefit-managers ("[T]he increasing level of vertical integration that is occurring among plans, PBMs, and their own pharmacies has the potential to result in anticompetitive behavior and place independent pharmacies at a disadvantage.").

[29] GAO Report, supra, at 4 (lower cost sharing at owned pharmacies "gives beneficiaries a financial incentive to use these pharmacies"), 16 (adjustment amounts "were not available for individual pharmacies"), 18 (for about half of the 20 drugs with the highest payment per 30-day supply, payments "were up to 10 percent higher at owned pharmacies"); OIG Data Snapshot, supra, at 1 (OIG "couldn't account for later payment adjustments to pharmacies," so "the full impacts of vertical integration—particularly on pharmacies—remain unknown"); see also FTC Second Interim Report, supra, at 2, 15 (affiliated pharmacies reimbursed at a higher rate "on nearly every specialty generic drug examined," with a larger disparity on commercial than on Part D claims).

[30] FTC First Interim Report, supra, at 1–2 (FTC study under Section 6(b) of the FTC Act), 25 n.108 (DOJ conditioned the CVS–Aetna merger on divestiture of Aetna's individual Part D prescription drug plan business); Consolidated Appropriations Act, 2026, Pub. L. No. 119-75, § 6224(a), 140 Stat. 173, 670 at 678 (2026) (adding Social Security Act § 1860D-12(h)(6)(A)(v), 42 U.S.C. § 1395w-112(h)(6)(A)(v)) [hereinafter CAA 2026], https://www.govinfo.gov/content/pkg/PLAW-119publ75/pdf/PLAW-119publ75.pdf (permitting disclosure of Section 6224 information "[t]o the Attorney General for the purposes of conducting oversight and enforcement under this title").

[31] Social Security Act § 1860D-4(b)(1)(A)(ii)(I), (III), 42 U.S.C. § 1395w-104(b)(1)(A)(ii)(I), (III).

[32] As used here, "steering" means practices that direct or nudge patients toward particular pharmacies, including a PBM's or plan's affiliated pharmacies, whether by more directly forcing patient choices (for example, redirected prescriptions or mandatory transfers) or by influencing them (for example, through differential cost-sharing or network design). See FTC Second Interim Report, supra, at 2 n.14 (using the term "broadly to include practices that may nudge patients toward making particular pharmacy dispensing choices in addition to practices that more directly force patient choices").

[33] Frier Levitt, LLC, Pharmacy Benefit Manager Exposé: How PBMs Adversely Impact Cancer Care While Profiting at the Expense of Patients, Providers, Employers, and Taxpayers (Community Oncology Alliance, Feb. 2022) [hereinafter Frier Levitt PBM Exposé], https://communityoncology.org/wp-content/uploads/2022/02/COA_FL_PBM_Expose_2-2022.pdf, at 53–54 (prescription trolling "push[es] the burden of performing the initial administrative functions on to" the original provider, "as the first fill is the most expensive claim"); Frier Levitt, Hot Topics in Specialty Pharmacy Law: PBM Prescription Trolling, HUB Arrangements, DIR Fees Update, Opioid and Naloxone Laws, and NADAC Pricing (May 26, 2020) [hereinafter Frier Levitt Hot Topics], https://www.frierlevitt.com/wp-content/uploads/2017/06/Hot-Topics-in-SPRX-Law-Final_PDF.pdf (first fill involves prescriber coordination, prior authorization assistance, patient assistance programs, and patient training).

[34] Frier Levitt PBM Exposé, supra, at 50–51 ("While the PBM is processing the PA, the PBM-owned or affiliated pharmacy surreptitiously communicates to the patient, prescriber, or both, with the goal of having the prescription filled at the PBM-owned or affiliated specialty pharmacy."); Frier Levitt Hot Topics, supra (PBM "transmits information about the claim to its wholly-owned specialty pharmacy"); Staff of H. Comm. on Oversight & Accountability, supra, at 16 (PBMs steer patients by "abusing data received by the PBM to target patients with highly profitable medications").

[35] Frier Levitt PBM Exposé, supra, at 51 (patients report "receiving correspondence from their PBM implying that they must use a pharmacy owned by or affiliated with the PBM," often describing the insurer's "preferred" pharmacy); Nat'l Ass'n of Specialty Pharmacy, Comment Letter to the Fed. Trade Comm'n, FTC-2022-0015-0648, at 6 (May 25, 2022), https://naspnet.org/wp-content/uploads/2022/02/FTC-Comment-Letter-NASP-D0987173.pdf (PBMs "call or send a letter to a patient or prescriber, instructing them to transfer their prescription to the PBM-owned specialty pharmacy, or otherwise risk their drug's coverage").

[36] Frier Levitt PBM Exposé, supra, at 51–53 (PBM "blatantly lied to the patient and pharmacy staff, saying the prescribing physician had authorized the transfer," and describing a lung cancer patient who learned of a purported transfer request only from his oncologist: "Please do not transfer it anywhere else! . . . I did not ask for this."); Cmty. Oncology All., Comment Letter to the Fed. Trade Comm'n on PBM RFI (May 24, 2022), https://assets.mycoa.io/1679078008255_COA_FTC-PBM-RFI_5-24-22.pdf (affiliated pharmacy contacts prescriber "stating (often falsely) that the patient has requested or authorized the transfer").

[37] FTC First Interim Report, supra (reporting NASP and other commenters' accounts that marketing campaigns "employ inaccurate information to coerce patients into switching to affiliated pharmacies").

[38] Frier Levitt PBM Exposé, supra, at 50 (after the provider obtains PA approval, the claim "is subsequently rejected once again by the PBM, this time for the apparent reason that it 'must' be filled at the PBM-owned or affiliated specialty pharmacy"); Cmty. Oncology All., supra ("claim hijacking" occurs when the pharmacy resubmits after obtaining PA and "is told that the prescription has already been filled").
[39] Nat'l Ass'n of Specialty Pharmacy, Comment Letter to the Fed. Trade Comm'n, supra, at 6; Nat'l Ass'n of Specialty Pharmacy, Comment Letter to the Fed. Trade Comm'n re Understanding Competition in Prescription Drug Markets (2017), https://naspnet.org/wp-content/uploads/2017/12/NASP-Understanding-Competition-in-Prescription-Drug-Markets-Entry-and-Supply-Chain-Dynamics.pdf ("while the prescription is 'under review' the PBM owned specialty pharmacy sometimes fills and dispenses the specialty drug"); see also Frier Levitt PBM Exposé, supra, at 51 (PBM-owned pharmacies "have brazenly filled and dispensed the medication in complete absence of having an actual, signed prescription in hand").
[40] Frier Levitt PBM Exposé, supra, at 51 (prescription trolling causes "severe confusion and distress for cancer patients, who are caught in the middle, uncertain of when or from where they will receive their next dose").
[41] Social Security Act § 1860D-12(h)(1)(C)(i)(VIII), 42 U.S.C. § 1395w-112(h)(1)(C)(i)(VIII).
[42] See 42 U.S.C. § 1395w-112(h)(7)(A); RFI, supra (§ II) (requesting comment on overlap with § 1860D-12(h)).
[43] Modernizing Part D and Medicare Advantage To Lower Drug Prices and Reduce Out-of-Pocket Expenses, 83 Fed. Reg. 62152 (proposed Nov. 30, 2018).
[44] FTC Second Interim Report, supra, at 2.
[45] Medicare Program; Medicare Prescription Drug Benefit, 70 Fed. Reg. 4194, 4254 (Jan. 28, 2005), as described in RFI, supra (§ I); see 42 C.F.R. § 423.505(b)(18).
[46] See RFI, supra (§ II.B).
[47] See id. (§ II.F).
[48] Id. (§ II.B).
[49] See id. (§ II.E); 42 C.F.R. § 423.100 (defining "negotiated price").
[50] See RFI, supra (§§ II.B, II.G, II.H).
[51] Patient population should shape the terms a pharmacy receives, including the performance measures used to evaluate it. *See CY2019 Final Rule, supra, at 16598* (requiring terms "reasonable and relevant to the pharmacy practice functions performed by the specific pharmacy's business and service delivery model (including consistently applied terms and conditions held out to promote quality)").
[52] Ch. 5, supra, § 50.3 (drug-by-drug requirements "should only apply to special handling and dispensing that may be required for a particular 'specialty' drug and not to reimbursement or other standard contracting terms and conditions"; "Offering pharmacies unreasonably low reimbursement rates for certain 'specialty' drugs may not be used to subvert the convenient access standards.").
[53] FTC First Interim Report, supra, at 17–18 (no standard definition of a specialty drug; "specialty drug designations can differ significantly across formularies"), 21 ("PBMs are increasing the number of drugs they classify as specialty"); Medicare Program; Implementation of Sections 6219, 6220, and 6224 of the Consolidated Appropriations Act, 2026, 91 Fed. Reg. 66408, 66456 (proposed Oct. 20, 2026) [hereinafter 6224 Proposed Rule], https://www.federalregister.gov/documents/2026/10/20/2026-21420/medicare-program-implementation-of-sections-6219-6220-and-6224-of-the-consolidated-appropriations ("[I]mprecise or non-standardized definitions of terms such as 'brand', 'generic', or 'specialty' may allow PBMs to categorize drug products in ways that maximize their ability to retain revenue via effective rate guarantees.").
[54] CY2019 Final Rule, supra, at 16597–98 (noting complaints that sponsors require "accreditation by multiple accrediting organizations, or additional Part D plan-/PBM-specific credentialing or other network criteria"; finding it "unrealistic to expect pharmacies to obtain multiple accreditation certifications"); GAO Report, supra, at 21 (dispensing fees in the 2023 contracts reviewed "ranged from $0 to $2").
[55] Nat'l Ass'n of Specialty Pharmacy, NASP Definitions of Specialty Pharmacy and Specialty Medications 1, https://naspnet.org/wp-content/uploads/2024/11/NASP-Defintions-Final-2.16.pdf (specialty pharmacies "are accredited as a specialty pharmacy by an independent third party, nationally recognized accreditation organization such as URAC®, the Accreditation Commission for Health Care (ACHC), or the Joint Commission"); Letter from Sheila Arquette, President & CEO, NASP, to Md. Ins. Admin. PBM Workgroup 2–3 (July 13, 2026) [hereinafter NASP Md. Letter], pdf (recommending accreditation "by a single, nationally recognized, independent third-party specialty pharmacy accreditation organization" and eliminating duplicative accreditation, "including accreditation programs [PBMs] own or operate"); NASP N.Y. Letter, supra, at 4 (proposed rule text: "To be recognized as a specialty pharmacy, a pharmacy must be accredited as a specialty pharmacy by a nationally recognized independent specialty pharmacy accreditation organization," with "a single accreditation" as the network condition).

[56] Brief of the Nat'l Ass'n of Specialty Pharmacy as Amicus Curiae Supporting Petitioners at 4, 8–9, Mulready v. Pharm. Care Mgmt. Ass'n, No. 23-1213 (U.S. June 14, 2024) [hereinafter NASP Amicus Br.], https://www.supremecourt.gov/DocketPDF/23/23-1213/315012/20240614115330645_23-1213%20NASP%20Amicus%20Brief%20Final.pdf ("Traditional retail community pharmacies cannot routinely dispense specialty medications because such medications may be extremely expensive to maintain in inventory, typically require special handling and mandate substantial patient support and education, which only specialty-accredited specialty pharmacies are able to provide."); NASP Md. Letter, supra, at 3 (accreditation standards cover temperature-controlled shipping, standardized patient management, ongoing education, and care-team engagement, with reaccreditation every three years); An Examination of How Reining in PBMs Will Drive Competition and Lower Costs for Patients: Hearing Before the Subcomm. on Health of the H. Comm. on Energy & Com., 119th Cong. 1–2 (Feb. 26, 2025) (written testimony of Sheila Arquette, President & CEO, NASP) [hereinafter NASP Testimony], https://naspnet.org/wp-content/uploads/2025/02/NASP-Testimony-Energy-and-Commerce-Subcmt-Feb-2025.pdf ("Unless accredited as a specialty pharmacy by an independent, nationally recognized, third party accreditation organization, typical retail pharmacies are not designed to provide the intense and time-consuming patient care services that specialty medications require.").

[57] CY2019 Final Rule, supra, at 16596 ("[W]e continue to believe any attempt by us to define specialty pharmacy could prematurely and inappropriately interfere with the marketplace."); see also NASP 2018 Comments, supra, at 10 (CMS "could define specialty pharmacy without prematurely and inappropriately interfering with the marketplace if the definition focuses on quality and third party independent accreditation").

[58] NASP July 20 Letter, supra, at 11–12 (absent a CMS definition, "each PBM remains free to classify pharmacies as 'specialty' — or to decline to do so — using whatever internal, self-selected criteria it chooses"; accreditation "now functions as a de facto industry requirement rather than a voluntary credential"); NASP Md. Letter, supra, at 2 (a definition "reduces manipulation by some PBMs who may use drug prices or other nebulous definitions of patient support to narrow the network").

[59] FTC First Interim Report, supra, at 17 n.79 ("There is, however, no standard definition of a specialty pharmacy, and any pharmacy can self-designate as one. PBMs and health insurers often rely on accreditation organizations to verify the specialty dispensing capabilities of pharmacies.").

[60] CAA 2026, supra, § 6224(a) (adding Social Security Act § 1860D-12(h)(1)(B)(i)(III), 42 U.S.C. § 1395w-112(h)(1)(B)(i)(III)) (PBMs must "define, interpret, and apply, in a fully transparent and consistent manner," terms including "'specialty drug'" when evaluating performance against pricing guarantees).

[61] Ch. 5, supra, § 50.3 (sponsors may restrict a drug to a subset of network pharmacies only where "[t]he FDA has restricted distribution of the drug" or "[a]ppropriate dispensing of the Part D drug requires extraordinary special handling, provider coordination, or patient education that cannot be met by a network pharmacy"); CY2019 Final Rule, supra, at 16597 (CMS "support[s] Part D plan sponsors that want to negotiate an accreditation requirement in exchange for, for example, designating a pharmacy with a special label such as a 'specialty' pharmacy").

[62] CY2019 Final Rule, supra, at 16598 ("[W]e believe it is unrealistic to expect pharmacies to obtain multiple accreditation certifications . . . ."), 16598–99 (sponsors should not limit dispensing of drugs, "including, but not limited to, drugs on the 'specialty/high cost tier,'" to a subset of pharmacies where a network pharmacy is capable and agrees to meet reasonable handling requirements); Ch. 5, supra, § 50.3 (limited access "may not be based solely on the placement of a Part D drug in a specialty or high-cost tier"); NASP Amicus Br., supra, at 12 (PBMs require "multiple and often duplicative accreditations rather than a single accreditation by a national independent specialty accreditor").

[63] Ch. 5, supra, § 50.3 ("Limited Access Drugs and 'Specialty' Pharmacies"). Section 50.3 provides that Part D sponsors may not limit access to certain Part D drugs to "specialty" pharmacies in a manner that contravenes the convenient access protections, may restrict access to a subset of network pharmacies only for enumerated reasons, may not use unreasonably low reimbursement for "specialty" drugs to subvert the convenient access standards, and may not require a network pharmacy to qualify as a "specialty" pharmacy in order to dispense a drug it is capable of dispensing appropriately.

[64] CY2019 Final Rule, supra, at 16591, 16598–99 (explaining that standard terms must be reasonable and relevant to the functions a pharmacy performs, that a pharmacy's ability to dispense one drug does not bear on its ability to dispense another, and that a requirement to dispense from a list of drugs or for particular disease states is not a relevant standard term).

[65] See, e.g., CVS Caremark, 2026 Caremark Provider Manual § 3.04, at 26–27 (2026) [hereinafter Caremark Provider Manual], https://www.caremark.com/content/dam/enterprise/caremark/pdfs/pharmacists-and-medical-professionals/2026_caremark_provider_manual.pdf (pharmacy whose specialty claims exceed twenty percent of its

claims in any month "is not considered a Retail Pharmacy," and Caremark reserves the right "to exclude Provider from any retail network(s)" or "to apply unique terms and conditions" to its participation).

[66] See Frier Levitt, Pharmacy Alert: Growing Trend in Aberrant Quantity Audits and Terminations, https://www.frierlevitt.com/articles/pharmacy-alert-growing-trend-in-aberrant-quantity-audits-and-terminations/ (describing a volume provision, a PBM-maintained list of drugs, a 25% threshold, and the absence of any definition of "aberrant quantities"); Frier Levitt, PHARMACY ALERT: Major PBM Terminating Specialty Pharmacies, https://www.frierlevitt.com/articles/pharmacy-alert-major-pbm-terminating-specialty-pharmacies/ (reporting terminations of specialty pharmacies solely because they dispensed a high percentage of specialty drugs); Barclay Damon, Pharmacies on High Alert: Optum Rx's 25 Percent Therapeutic Class Cap Creates Major Legal, Operational, and Competitive Risks, https://www.barclaydamon.com/alerts/pharmacies-on-high-alert-optum-rxs-25-percent-therapeutic-class-cap-creates-major-legal-operational-and-competitive-risks (reproducing a single-therapeutic-class provision).

[67] See Ch. 5, supra, § 50.3 (stating that offering unreasonably low reimbursement for certain "specialty" drugs may not be used to subvert the convenient access standards, and that sponsors must offer reasonable and relevant reimbursement terms for all Part D drugs).

[68] Nat'l Cmty. Pharmacists Ass'n, NCPA Member Survey on the Medicare Drug Price Negotiation Program, Executive Summary (Jan. 27, 2025), https://ncpa.org/sites/default/files/2025-01/1.27.2025-FinalExecSummary.NCPA_.MemberSurvey.pdf (survey of 8,000 pharmacy owners and managers conducted Jan. 14–24, 2025); see also Pharmacy Times, NCPA to CMS: A Third of Independent Pharmacies Won't Carry Drugs in the Negotiated Price Program (Jan. 28, 2025), https://pharmacytimes.com/view/ncpa-to-cms-a-third-of-independent-pharmacies-won-t-carry-drugs-in-the-negotiated-price-program-and-60-percent-more-are-considering-dropping-out (reporting that 40.8 percent of independent pharmacists were paid below the National Average Drug Acquisition Cost on more than 40 percent of their Part D prescriptions).

[69] See, e.g., Caremark Provider Manual, supra, § 3.02.03, at 22 (prohibiting "[d]ispensing aberrant quantities of a Covered Item and/or disparate volume of claims or products within a therapeutic category . . . as measured by number of claims, quantity dispensed and/or dollars," without defining "aberrant" or "disparate," and authorizing termination and "Chargeback of applicable claims" for any breach).

[70] Frier Levitt, Frier Levitt Successfully Reverses PBM Termination for Texas Pharmacy, https://www.frierlevitt.com/?p=41380 (noting that PBMs often flag activity as abnormal by comparing one pharmacy against other similarly situated pharmacies to identify "outlier practices").

[71] See RFI, supra, § II.B (asking about limited or exclusive specialty networks, specialty designations, common ownership, and whether pharmacies meeting the same objective criteria are offered specialty participation on the same terms); Ch. 5, supra, § 50.3 (specialty pharmacies are to supplement network pharmacy access when necessary and not otherwise restrict it).

[72] RFI, supra, § II.B (asking about the extent to which limited or exclusive specialty networks and specialty designations overlap with common ownership between the PBM and the designated specialty pharmacy); Ch. 5, supra, § 50.3.

[73] NASP Survey.

[74] Supported by documents from NASP members.

[75] Supported by documents from NASP members.

[76] NASP Survey.

[77] NASP Survey.

[78] NASP Survey.

[79] NASP Survey.

[80] NASP Survey.

[81] NASP Survey.

[82] 42 U.S.C. § 1395w-112(b)(6); 42 C.F.R. § 423.505(b)(21).

[83] Ga. Code Ann. § 33-64-9(a)(1).

[84] Iowa Code § 510B.8A.

[85] Colo. Rev. Stat. § 25-37-103.5(1)–(2).

[86] Md. Code Ann., Ins. § 15-1628.1.

[87] N.J. Stat. Ann. § 17B:27F-4; 760 Ind. Admin. Code 5-4-2.

[88] Va. Code Ann. § 38.2-3407.15:2.

[89] FTC Second Interim Report, supra, at 2 (the Big 3 PBMs "reimbursed their affiliated pharmacies at a higher rate than unaffiliated pharmacies on nearly every specialty generic drug examined"); see also id. at 15 & Fig. 3 (affiliated pharmacies "almost always reimbursed at higher rates" than unaffiliated pharmacies, with the disparity

larger for commercial than for Medicare Part D prescriptions). The FTC's analytic sample comprised 51 specialty generic drugs and 882 National Drug Codes ("NDCs"), id. at 1, 8–9 (narrowed from 171 drugs and 2,715 NDCs in the Big 3 PBMs' data). The report does not identify individual NDCs: NDC-level data were aggregated to the drug level, id. at 7, and only anonymized, aggregated results are disclosed publicly, id. at 15 n.66. Drug-level results appear in Figure 3 and Appendix A.

[90] Caremark, L.L.C. v. N.Y. Cancer & Blood Specialists, 740 F. Supp. 3d 340, ECF No. 70, slip op. at 7 n.2 (S.D.N.Y. July 15, 2024) (denying Caremark's petition to vacate the arbitration award and confirming the award; observing that, under Caremark's Performance Network Rebate program, "once Caremark calculates a provider's score," it "retroactively collects the PNR fees by withholding the provider's reimbursements," and that a score for a January–August period might not result in collection until November, with a witness testifying that Caremark "claws back money" "usually six to nine months [later]").

[91] This net reimbursement was approximately the same reimbursement a pharmacy could expect had it not participated in the PBPA.

[92] 42 C.F.R. § 423.100 (definition of "negotiated price"); Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs, 87 Fed. Reg. 27704 (May 9, 2022) [hereinafter CY2023 Final Rule].

[93] *See* Memorandum from Jennifer R. Shapiro, Dir., Medicare Plan Payment Grp., Ctrs. for Medicare & Medicaid Servs., to All Part D Sponsors, Application of Pharmacy Price Concessions to the Negotiated Price at the Point of Sale Beginning January 1, 2024, at 2 (Nov. 6, 2023), https://www.cms.gov/files/document/pharmacypriceconcessionshpmsmemonovember2023final508g.pdf ("[I]f the payment to a Part D pharmacy may be reduced by up to a certain amount, the maximum possible reduction in payment must be treated as a pharmacy price concession and reflected in the negotiated price available at the POS . . . ."); see also Memorandum from Jennifer R. Shapiro, Dir., Medicare Plan Payment Grp., Ctrs. for Medicare & Medicaid Servs., to All Part D Sponsors, Reminder of Regulatory Requirements for Pharmacy Price Concessions 1 (June 2, 2023), https://www.cms.gov/files/document/pharmacydirreminder508g.pdf (same).

[94] To avoid disclosing competitively sensitive, contract-specific reimbursement terms, every rate, fee, and net rate in this Section is fictionalized. Each fictionalized figure is stated as a range or is calculated from the midpoints of fictionalized ranges. The ranges were selected so that the relationships described in the text, including how each replacement rate or post-2024 rate compares with the corresponding pre-2024 net rate, match the relationships in the underlying contracts. Supported by documents from NASP members (Medicare Part D performance network enrollment forms, plan years 2020–2023, on file with counsel).

[95] *Id.* (regulatory change and program infeasibility provisions).

[96] Supported by documents from NASP members (performance network enrollment form, on file with counsel). Net rate calculated as (1 − base AWP discount) × (1 − DIR fee), applied to ingredient cost. At the midpoint of the fictionalized DIR fee range (12%), a base reimbursement of AWP-8% nets 0.92 × 0.88 = 0.8096, or approximately AWP-19.0%, and a base reimbursement of AWP-10% nets 0.90 × 0.88 = 0.7920, or approximately AWP-20.8%. In the underlying contract, the replacement rate equals the average-performance net rate to the hundredth of a percentage point.

[97] Supported by documents from NASP members (four additional performance network enrollment forms, plan years 2020–2023, on file with counsel). In each, the replacement rate differed from the midpoint net rate by no more than approximately six one-hundredths of a percentage point.

[98] Supported by documents from NASP members (performance network enrollment form, on file with counsel). Using the midpoint of each fictionalized range: 0.83 × 0.965 = 0.8010, or approximately AWP-19.9%. In the underlying contract, the replacement rate was more than half a percentage point deeper than the midpoint net rate.

[99] Supported by documents from NASP members (Medicare Part D retail network enrollment form, plan year 2025, on file with counsel (rates stated as maximums that vary by plan sponsor)).

[100] Calculated from the fictionalized ranges above, using the midpoint of each. At the 2025 brand rate (AWP-23%), a $1,000-AWP brand claim pays $770.00 in ingredient cost, compared with $805.00 at the pre-2024 average-performance net rate (AWP-19.5%), a decline of approximately 4.3%. Across the underlying contracts, the decline on a $1,000-AWP brand claim ranged from roughly 3% to 5%, depending on the pre-2024 network. Performance and bonus payments are excluded.

[101] Supported by documents from NASP members (Medicare network reimbursement exhibit, 2019 (reimbursement rates and DIR fee schedule at an average performance rating), on file with counsel).

[102] Supported by documents from NASP members (Medicare network reimbursement exhibit, 2024 (superseding the 2019 exhibit), on file with counsel).

[103] Calculated from the fictionalized ranges above, using the midpoint of each. $1,000-AWP claim: 2019 net $830.15 ($842.50 + $1.15 − $13.50) versus 2024 net $810.55 ($810.00 + $0.55). $5,000-AWP claim: 2019 net $4,200.15 versus 2024 net $4,050.55. The 2019 figures exclude the separate specialty DIR fee, which would further reduce 2019 net pay where it applies. The underlying exhibits produce the same pattern: a break-even point of a few hundred dollars AWP and a decline that grows with the cost of the drug.
[104] 42 C.F.R. § 423.100 (definition of "dispensing fees").
[105] GAO Report, supra, at 21.
[106] NASP Survey.
[107] NASP Survey.
[108] NASP Survey.
[109] CAA 2026, supra, § 6223(a), 140 Stat. at 664–65 (adding Social Security Act § 1860D-4(b)(1)(A)(ii)(I), (III), 42 U.S.C. § 1395w-104(b)(1)(A)(ii)(I), (III)) ("Notwithstanding any other provision of law, for plan years beginning on or after January 1, 2029, . . . contract terms and conditions offered by such PDP sponsor shall be reasonable and relevant according to standards established by the Secretary"; the RFI "for purposes of establishing the standards" must address "whether pharmacy reimbursement and dispensing fees paid by PDP sponsors to network pharmacies sufficiently cover the ingredient and operational costs of such pharmacies").
[110] Ch. 5, supra, § 50.3 ("In other words, Part D sponsors must offer reasonable and relevant reimbursement terms for all Part D drugs as required by 42 CFR 423.505(b)(18).").
[111] 42 U.S.C. § 1395w-111(i) (Secretary "may not interfere with the negotiations between drug manufacturers and pharmacies and PDP sponsors" and "may not require a particular formulary or institute a price structure for the reimbursement of covered part D drugs").
[112] CAA 2026, supra, § 6224(a) (adding Social Security Act § 1860D-12(h)(4)(A), 42 U.S.C. § 1395w-112(h)(4)(A)) (nothing in Section 6224 prohibits "reimbursement or payment for ingredient costs (including customary, industry-standard discounts directly related to drug acquisition that are retained by pharmacies or wholesalers)"); NASP 2018 Comments, supra, at 3 n.7 (PBMs that own specialty pharmacies "are generally aware of the acquisition cost because their own specialty pharmacy is also purchasing the same drug").
[113] FTC Second Interim Report, supra, at 7 (NADAC is based on "surveys of invoices voluntarily provided . . . primarily by small, independent pharmacies" and "is reported only on selected drugs"), 8 (116 of the 171 specialty generic drugs in the FTC's data were excluded because they had no corresponding NADAC); OIG Report, supra ("[D]rugs that are not available in retail pharmacies, such as specialty drugs, typically do not have NADAC data.").
[114] NASP Testimony, supra, at 3–4 (the CY2023 rule "did not establish any standards or protections to ensure that the negotiated price inclusive of all price concessions that is paid by plans to pharmacies is reasonable to cover a pharmacy's costs"; CMS stated it would consider such safeguards, "[h]owever, nothing was done") (citing CY2023 Final Rule, supra, at 27845); NASP 2018 Comments, supra, at 3–4 (warning that a sponsor could move all concessions to the point of sale "but have a total reimbursement rate below the pharmacy's acquisition cost").
[115] NASP Survey.
[116] NASP Survey.
[117] See, e.g., Caremark Provider Manual, supra, § 6.02.05, at 48 (post-adjudication settlements "include, but are not limited to: . . . Effective rate reconciliation," and a pharmacy's "acceptance of reimbursement for a claim processed for a network where a post-adjudication settlement applies obligates Provider to finalize the post-adjudication settlement").
[118] See, e.g., Caremark Provider Manual, supra, § 3.04, at 27 (a pharmacy "owned by a 340B covered entity and/or whose volume of claims filled using 340B Drug Pricing Program acquired or replenished drugs is the basis for any pharmaceutical manufacturer denying pharmaceutical rebates . . . is not considered a Retail Pharmacy," and may be excluded from retail networks or subjected to "unique terms and conditions").
[119] Caremark LLC v. Allied Health Servs. Inc., No. CV-23-01994-PHX-JJT, Doc. 113, slip op. at 2–3 (D. Ariz. Nov. 22, 2024), https://cases.justia.com/federal/district-courts/arizona/azdce/2:2023cv01994/1346937/113/0.pdf.
[120] Caremark Provider Manual, supra, § 14.07, at 100; see also id. § 14.09, at 100 (current arbitration clause requiring administration by JAMS and arbitration in Scottsdale, Arizona).
[121] Caremark, L.L.C. v. Chickasaw Nation, 43 F.4th 1021 (9th Cir. 2022) (describing a provider manual, amended eight times between 2004 and 2020, under which providers accept amendments by receiving the updated manual and subsequently submitting claims for reimbursement).
[122] See, e.g., Caremark Provider Manual, supra, at 1 (the manual "is incorporated by reference into your Caremark Provider Agreement," and pharmacies must "monitor and comply with all amendments and updates"); id. § 14.07, at 100.
[123] Caremark Provider Manual, supra, § 6.02, at 47; id. § 14.07, at 100.

[124] See Restatement (Second) of Contracts § 24 (1981) (defining an offer as a manifestation of willingness to enter into a bargain so made as to justify another in understanding that assent is invited and will conclude it); id. § 50(1) (defining acceptance as a manifestation of assent to the terms of the offer made in the manner invited or required by the offer); id. § 69(1) (silence or inaction operates as acceptance only in limited circumstances); id. § 89 (modification of a contract not fully performed is binding only in limited circumstances, including where it is fair and equitable in view of circumstances not anticipated when the contract was made).
[125] See, e.g., 15 U.S.C. § 1635(a) and 12 C.F.R. § 1026.23 (three-business-day right to rescind certain consumer credit transactions secured by the consumer's principal dwelling); 16 C.F.R. pt. 429 (Federal Trade Commission's Cooling-Off Rule, giving consumers three business days to cancel certain door-to-door sales); 16 C.F.R. § 436.2 (Franchise Rule, requiring delivery of the franchise disclosure document at least fourteen calendar days before a prospective franchisee signs a binding agreement or pays any consideration, and delivery of the final form of agreement at least seven calendar days before signing where the franchisor has unilaterally and materially altered its terms); 29 U.S.C. § 626(f)(1)(E)–(G) (requiring that a release of age discrimination claims advise the employee in writing to consult an attorney, allow at least twenty-one days to consider it (forty-five days in a group program), and allow seven days to revoke).
[126] 42 C.F.R. § 423.505(b)(18) (requiring sponsors to make standard contracts available upon request no later than September 15 of each year for contracts effective the following January 1); S.B. 271, 153d Gen. Assemb. (Del. 2026) (signed Sept. 8, 2026) (barring a PBM from amending a pharmacy contract without at least 60 days' notice); see Frier Levitt, Delaware Enacts SB 271: New PBM Audit Limits, Expanded Pharmacy Appeal Rights, and Anti-Retaliation Protections (Nov. 3, 2026), https://www.frierlevitt.com/articles/delaware-sb-271-pbm-audit-pharmacy-appeal-protections/.
[127] RFI, supra, § II.A (asking about the impacts of post-adjudication adjustments on net reimbursement and the predictability of final reimbursement at the time of dispensing); see also CY2023 Final Rule, supra (requiring that pharmacy price concessions be reflected in the negotiated price at the point of sale beginning in 2024).
[128] RFI, supra, § II.A (asking about aggregate guarantees such as generic and brand effective rates reconciled after the point of sale, the difference between claim-level negotiated prices and end-of-year effective rates, and whether claim-level reimbursement is meaningfully predictive of what a pharmacy actually receives); RFI, supra, § II.B (asking about financial terms contained in documents other than the executed contract).
[129] See Healthcare Brew, Pharmacies, PBMs at odds over proposed change to Part D contracting rule (Feb. 28, 2025), https://www.healthcare-brew.com/stories/2025/02/28/pharmacies-pbms-proposed-change-part-d-contracting-rule (reporting that pharmacies cannot terminate Part D contracts without cause without giving notice that can exceed a year, while PBMs may terminate without cause).
[130] CY2026 Proposed Rule, supra (proposing to require Part D sponsors to notify network pharmacies by October 1 of the plans in which they will participate the following year, and to allow pharmacies to terminate network contracts without cause after the same notice period the sponsor is allowed). CMS did not finalize either proposal in the final rule published April 15, 2025. See Nat'l Cmty. Pharmacists Ass'n, NCPA publishes member summary of Medicare Part D final rule (Apr. 14, 2025), https://ncpa.org/newsroom/qam/2025/04/14/ncpa-publishes-member-summary-medicare-part-d-final-rule.
[131] See CY2019 Final Rule, supra, at 16590 (noting that Part D enrollees increasingly need access to specialty drugs); Ch. 5, supra, § 50.3; see generally Frier Levitt, Harini Bupathi Discusses the Far-Reaching Impact of PBM Network Terminations with Drug Topics (Oct. 19, 2026), https://www.frierlevitt.com/news/harini-bupathi-pbm-network-terminations-drug-topics/.
[132] See, e.g., Caremark Provider Manual, supra, § 6.10, at 51–52 (Caremark "may immediately suspend, pending further investigation, the participation status (which may include temporary payment withholding . . .)" of a pharmacy if it "has reason to believe" the pharmacy has engaged in activity that, among other things, "alters the dispensing patterns of the Provider sufficiently to indicate potential fraud, waste, or abuse").
[133] See, e.g., Minn. Stat. § 62W.09 (providing that clerical or record-keeping errors, such as typographical errors, may not be treated as fraud); Frier Levitt, Frier Levitt Helps Reduce PBM Audit by $705k for New York-Based Pharmacy, https://www.frierlevitt.com/?p=5521 (describing a PBM that refused to consider a pharmacy's purchases because of a minor clerical error, producing a recoupment above $700,000).
[134] See supra Section II.F (explaining why concentration-based penalties are not reasonable and relevant for specialty pharmacies, and proposing a categorical prohibition on concentration-based restrictions and penalties).
[135] Frier Levitt, result reversing a plan-initiated network termination of commonly owned New Jersey pharmacies, https://www.frierlevitt.com/?p=35374; Jesse C. Dresser, Adino "A.J." Barbarito & Kamron A. Sharif, Pharmacy Alert: Oscar Health Suspends PrEP-Dispensing 340B Contract Pharmacies in South Florida, Including Those

Unlinked to Alleged Fraud, https://www.frierlevitt.com/articles/oscar-health-prep-340b-pharmacy-suspensions/ (describing a commercial plan suspension, not a Part D action).
[136] See 42 C.F.R. § 422.111(e) (requiring Medicare Advantage organizations to make a good faith effort to give written notice of a provider termination at least 30 calendar days before the effective date to enrollees who regularly see the provider); 42 C.F.R. § 423.120(a) (Part D convenient access standards).
[137] NASP Survey.
[138] See, e.g., S.B. 271, 153d Gen. Assemb. (Del. 2026) (signed Sept. 8, 2026) (no audit more often than once every 12 months; wholesale invoice audits limited to verification of purchased inventory specific to the claims paid); 215 Ill. Comp. Stat. 5/513b7 (24-month audit period; no more than 100 prescriptions per audit and 200 in any 12-month period; 14 business days' notice and a list of the prescriptions to be audited); Minn. Stat. § 62W.09 (24-month audit period; 14 days' notice before an on-site audit); Frier Levitt, Delaware Enacts SB 271: New PBM Audit Limits, Expanded Pharmacy Appeal Rights, and Anti-Retaliation Protections (Nov. 3, 2026), https://www.frierlevitt.com/articles/delaware-sb-271-pbm-audit-pharmacy-appeal-protections/; Frier Levitt, Pennsylvania Fair Audit Law Protects Pharmacies Against Unfair and Aggressive Audit Practices, https://www.frierlevitt.com/?p=43404 (describing Pennsylvania's notice requirement and its limit of 250 prescriptions in a 24-month period).
[139] See, e.g., Caremark Provider Manual, supra, § 3.02.06, at 23 (reserving "the right to charge back the entire claim amount" for a dispensing error); id. § 4.07, at 34 ("Incorrect submission of any ingredient(s) may result in Chargeback of the entire claim."); id. § 8.01.03, at 55 (right to "recoup one hundred percent (100%) of the amount for the claims in question" if a telephonic Part D auditor is denied access to information).
[140] NASP Survey.
[141] Frier Levitt, Part 1 of 4: Abusive PBM Audit Practices (Invoice Reconciliation Audit), https://www.frierlevitt.com/articles/service/pharmacylaw/abusive-pbm-audit-practices-part-1-of-4-invoice-reconciliation-audit/ (describing a PBM that disclosed only after repeated inquiries that it needed confirmation that a wholesaler held a valid distributor license, after it had already withheld funds to offset the claimed shortages); see also Del. Code Ann. tit. 18, ch. 33A, subch. I (requiring that a preliminary audit report contain claim-level information for any discrepancy and an estimated recovery amount).
[142] Minn. Stat. § 62W.09 (providing that an auditing company or agent may not receive payment based on a percentage of the amount recovered, subject to a limited exception where the plan sponsor's contract states the percentage and no agent's commission depends on amounts recouped); Del. Code Ann. tit. 18, ch. 33A, subch. I (providing that a commission to an agent or employee of the entity conducting the audit may not be based, directly or indirectly, on amounts recouped).
[143] See, e.g., Caremark Provider Manual, supra, § 8.05, at 59 (in an aggregate purchase invoice review, "Caremark will not consider purchases occurring outside of thirty (30) days prior to the selected date range" absent a bulk-purchase notice given within twenty-one days and acknowledged by Caremark, and failure to timely provide all requested documentation subjects "one hundred percent (100%) of the amount for the paid claims audited" to chargeback).
[144] Frier Levitt, Frier Levitt Helps Reduce PBM Audit by $705k for New York-Based Pharmacy, https://www.frierlevitt.com/?p=5521; Frier Levitt, Pharmacy Alert: Growing Trend in Invoice Reconciliation Audits, https://www.frierlevitt.com/articles/pharmacy-alert-growing-trend-in-invoice-reconciliation-audit/ (reporting that PBMs declined to accept documents concerning pharmacy-to-pharmacy transfers and demanded additional documents); Frier Levitt, Frier Levitt Successfully Reverses 100% of Audit Findings for Texas Pharmacy, https://www.frierlevitt.com/?p=40619 (reporting that PBMs refused purchase records from certain wholesalers and purchase records outside the audit period).
[145] Frier Levitt, Pharmacy Alert: Growing Trend in Invoice Reconciliation Audits, https://www.frierlevitt.com/articles/pharmacy-alert-growing-trend-in-invoice-reconciliation-audit/; Frier Levitt, Frier Levitt Successfully Reverses 100% of Audit Findings for Texas Pharmacy, https://www.frierlevitt.com/results/frier-levitt-successfully-reverses-100-of-audit-findings-for-texas-pharmacy-2/ (noting that purchases from a wholesaler one PBM treats as unauthorized may be accepted entirely by another).
[146] See Frier Levitt, Delaware Enacts SB 271: New PBM Audit Limits, Expanded Pharmacy Appeal Rights, and Anti-Retaliation Protections (Nov. 3, 2026), https://www.frierlevitt.com/articles/delaware-sb-271-pbm-audit-pharmacy-appeal-protections/ (describing escalation of denied reimbursement appeals to the Insurance Commissioner).
[147] See Minn. Stat. § 62W.09 (a pharmacy must be allowed at least 45 days after receiving a preliminary audit report to provide documentation addressing any discrepancy); Del. Code Ann. tit. 18, ch. 33A, subch. I (same).

[148] Caremark Provider Manual, supra, § 2.01, at 12; see also id. § 14.05.01, at 99 (termination remedies extending to "pharmacies found to have a direct or indirect relationship with Provider or its affiliates based upon common officers, directors, Pharmacists-in-Charge/responsible pharmacist, managing employees, current/former employees, owners (direct or indirect)").
[149] See Dresser, Barbarito & Sharif, Pharmacy Alert: Oscar Health Suspends PrEP-Dispensing 340B Contract Pharmacies in South Florida, Including Those Unlinked to Alleged Fraud, https://www.frierlevitt.com/articles/oscar-health-prep-340b-pharmacy-suspensions/ (describing a commercial plan suspension, not a Part D action, of pharmacies that shared two characteristics, many of which had no apparent connection to the alleged wrongdoing).
[150] See, e.g., Caremark Provider Manual, supra, § 14.09, at 100 (JAMS arbitration in Scottsdale, Arizona); id. § 14.09.03, at 101 ("disputes with a Provider are limited to a single NCPDP number per arbitration"); id. § 14.09.04, at 102 (parties "shall not disclose the existence, content, or results of any dispute or arbitration hereunder without the prior written consent of both parties," while Caremark "may notify any of its Plan Sponsor clients of any pending arbitration or the results thereof"); id. § 14.09.05, at 102 (award has no "precedential impact on any other proceeding").
[151] Caremark Provider Manual, supra, § 14.09.01, at 101 ("Absent a showing of compelling need, no such documents are required to be produced from backup servers, tapes, or other media," and "[d]iscovery shall be limited to the Provider initiating the dispute and no other Provider").
[152] See, e.g., Mount Sinai Hospital, et al. v. CVS Health Corp., et al., No. 1:26-cv-4143 (S.D.N.Y. filed May 18, 2026).
[153] 42 C.F.R. § 423.505(b)(18).
[154] Ch. 5, supra, § 50.3.
[155] 42 C.F.R. § 423.505(i)(3)(iii)–(iv).
[156] Ch. 5, supra, § 50.5.3.
[157] 42 U.S.C. § 1395w-104(b)(1)(F)(i)(VII).
[158] Ch. 5, supra, § 50.8.1.
[159] Ch. 5, supra, § 50.3.
[160] 42 U.S.C. § 1395w-104(b)(1)(F)(iii).
[161] Social Security Act § 1860D-12(h)(4)(A), 42 U.S.C. § 1395w-112(h)(4)(A); Social Security Act § 1860D-12(b)(6), 42 U.S.C. § 1395w-112(b)(6).
[162] GAO Report, supra, at 21.
[163] Decision and Order as to Respondents Express Scripts, Inc., Evernorth Health, Inc., Medco Health Services, Inc., and Ascent Health Services LLC § VIII.B, at 8, In re Caremark Rx, LLC, FTC Docket No. 9437 (proposed Feb. 4, 2026), https://www.ftc.gov/system/files/ftc_gov/pdf/d09437caremarkproporder-esiresps.pdf.
[164] See, e.g., Ind. Code § 27-1-24.5-19(b)(4); Tenn. Code Ann. § 56-7-3115.
[165] Social Security Act § 1860D-12(h)(1)(B), 42 U.S.C. § 1395w-112(h)(1)(B).
[166] Frier Levitt PBM Exposé, supra, § 13.
[167] See, e.g., Caremark Provider Manual, supra, § 14.07, at 100.
[168] Caremark, L.L.C. v. Chickasaw Nation, 43 F.4th 1021 (9th Cir. 2022); see also August 2023 forum change on eight days' notice; S.B. 271, 153d Gen. Assemb. (Del. 2026) (60 days' notice for amendments).
[169] CY2026 Proposed Rule, supra.
[170] 42 C.F.R. § 423.505(i)(3)(iii)–(iv).
[171] Life Star Pharmacy v. Express Scripts, 2024 U.S. Dist. LEXIS 36750, at *6 (E.D. Mo. 2024).
[172] See, e.g., 215 Ill. Comp. Stat. 5/513b7; Minn. Stat. § 62W.09; S.B. 271, 153d Gen. Assemb. (Del. 2026).
[173] See, e.g., Minn. Stat. § 62W.09; Del. Code Ann. tit. 18, ch. 33A (45 days to respond).
[174] 42 C.F.R. § 422.111(e) (30-day enrollee notice of provider terminations in Medicare Advantage); id. § 423.120(a)(8)(i) (any willing pharmacy obligation).
[175] Social Security Act § 1860D-12(b)(7), 42 U.S.C. § 1395w-112(b)(7) (applying Social Security Act § 1862(o), 42 U.S.C. § 1395y(o)).
[176] 42 C.F.R. § 423.4.
[177] See, e.g., Caremark Provider Manual, supra, § 14.09.03, at 101.
[178] COA, Comment Letter on Proposed Rule, Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs (CMS-4192-P), 87 Fed. Reg. 1842 (Jan. 12, 2022).
[179] See, e.g., Caremark Provider Manual, supra, § 14.09.04, at 102.
[180] Social Security Act § 1860D-4(b)(1)(F)(i)(III)(bb), 42 U.S.C. § 1395w-104(b)(1)(F)(i)(III)(bb).

[181] See, e.g., Caremark Provider Manual, supra, § 3.04, at 26–27 (defining "Retail Pharmacy" in part by reference to the share of a pharmacy's claims that are for specialty drugs); Express Scripts, Network Provider Manual: Operations/Federal Regulatory Handbook § 11, at 132–33 (rev. Apr. 2026) (defining "Retail Provider" to exclude specialty providers without defining them).
[182] Prime Therapeutics, Provider Manual for Participating Network Providers § 5, at 40 (2025) ("Specialty terms and conditions include criteria related to clinical interventions and programming, care coordination, specialty pharmacy accreditation, specialty providers, clinical reporting and member experience reporting . . . .").
[183] MedImpact Healthcare Sys., Inc., MedCare Pharmacy Networks Policies and Procedures Manual, Maryland Addendum § 34, at 181–82 (Nov. 1, 2024) (referring to "a requirement that a specialty pharmacy obtain national certification to be considered a specialty pharmacy in a MedImpact network").
[184] See, e.g., Express Scripts, Network Provider Manual: State Regulatory Handbook, supra, Louisiana Addendum § 6, at 59; CVS Caremark, 2020 Caremark Provider Manual: Federal and State Laws and Regulations, Louisiana § 75, at 113 (eff. May 1, 2020).
[185] Social Security Act § 1860D-4(b)(1)(F)(i)(I), (IV).
[186] Id. § 1860D-4(b)(1)(F)(i)(II).
[187] Id. § 1860D-4(b)(1)(F)(i)(III).
[188] See, e.g., Caremark Provider Manual, supra, § 13.03, at 94 (defining "Confidential Caremark Information" to include "reimbursement rates and terms" and "the Provider Agreement, the Provider Manual, network enrollment forms and other addenda," and barring disclosure "to any third party, including a Plan Sponsor," without Caremark's consent "unless otherwise permitted by applicable Law"); cf. id. § 13.02, at 94 (non-disparagement clause does not "prohibit Provider from communicating with elected officials or a government agency").
[189] Social Security Act § 1860D-4(b)(1)(F)(i)(VIII), (iii)(I); id. § 1857(g)(1)(K).
[190] Social Security Act § 1860D-42(f), 42 U.S.C. § 1395w-152(f) (added by CAA 2026, § 6223(e)) (report may not disclose identifiable information unless otherwise publicly available, or trade secrets).
[191] 42 C.F.R. § 423.750(a); see id. § 423.505(n).
[192] 42 C.F.R. § 423.760(b)(1), (2), (4); Social Security Act §§ 1857(g)(3), 1860D-12(b)(3)(E). The inflation-adjusted maximums in the HHS adjustment table reviewed for this draft were $48,833 per determination or per enrollee and $19,535 per week (45 C.F.R. § 102.3, 2024 adjustment).
[193] 42 U.S.C. § 1395w-112(h)(4) (as added by CAA 2026 § 6224) (nothing in Section 6224 shall be construed as "modifying regulatory requirements or sub-regulatory program instruction or guidance related to pharmacy payment, reimbursement, or dispensing fees"); 6224 Proposed Rule, supra, at 66453 (rule of construction "does not create a blanket exemption" for payments to PBM-affiliated pharmacies).
[194] 6224 Proposed Rule, supra, at 66454 (soliciting comment on "the implications that this rule of construction and the limitations on payment to affiliated pharmacies may have on the codification and enforcement of the standards for reasonable and relevant terms and conditions for pharmacy contracts," including "pricing transparency and reimbursement in pharmacy contracts").
[195] 42 U.S.C. § 1395w-112(h)(1)(C)(i)(I)(cc), (ii); (II)(aa)–(cc); (VIII) (as added by CAA 2026 § 6224) (requiring reports of claims and average reimbursement "by dispensing channel," the percentage of each drug dispensed by affiliated pharmacies, interquartile cost ranges at affiliated and non-affiliated network pharmacies, and "[a]n explanation of any benefit design parameters . . . that encourage plan enrollees to fill prescriptions at pharmacies that are an affiliate").
[196] CAA 2026, supra, § 6223(b) (adding 42 U.S.C. § 1395w-152(e)(4)) (adopting the § 1860D-12(h)(7) definitions of "affiliate" and "pharmacy benefit manager"); 42 U.S.C. § 1395w-112(h)(7)(A); NASP July 20 Letter, supra, at 4–5 (affiliate status should turn on "actual ownership, control, or agency — and never based on network participation status alone"; limited distribution network participation "Must Not Be Treated as an Affiliate Relationship").
[197] NASP July 20 Letter, supra, at 2–3 (summary of recommendations, including an accreditation-based definition of specialty pharmacy, an ownership- and control-based definition of affiliate, and data "sufficient to detect discriminatory reimbursement, network-tier placement, or product-mix steering based on ownership status"), 11–14 (recommending "a single, objective, and externally verifiable definition of 'specialty pharmacy'").
[198] CAA 2026, supra, § 6223(a), 140 Stat. at 664–65 (adding 42 U.S.C. § 1395w-104(b)(1)(A)(ii)(I)–(III)).
[199] Cisneros v. Alpine Ridge Grp., 508 U.S. 10, 18 (1993) ("[T]he use of such a 'notwithstanding' clause clearly signals the drafter's intention that the provisions of the 'notwithstanding' section override conflicting provisions of any other section.").
[200] CY2019 Final Rule, supra, at 16590 (also stating that "CMS has always interpreted the any willing pharmacy requirement to require Part D sponsors to offer reasonable and relevant contract terms and conditions to minimize barriers to pharmacy network participation").

[201] 42 U.S.C. § 1395w-111(i)(1)–(2).
[202] N.Y. Cancer & Blood Specialists, 740 F. Supp. 3d 340, ECF No. 70, slip op. at 35–39 (declining to vacate under the manifest-disregard standard; noting CMS's statement that the clause does not prevent it from "requir[ing] the inclusion of terms and conditions in agreements when necessary to implement requirements under the Act" (quoting 79 Fed. Reg. 1918, 1971 (proposed Jan. 10, 2014)), and that CMS "retains the ultimate authority to review those terms, investigate complaints, and enforce the relevant requirements"). https
[203] CAA 2026, supra, § 6223(c), 140 Stat. at 667–69 (adding 42 U.S.C. § 1395w-104(b)(1)(F)(iii)) (authorizing "civil monetary penalties or other intermediate sanctions").