November 23, 2026
Submitted electronically via www.regulations.gov (Docket No. CMS-2026-3037)

The Honorable Mehmet Oz, MD, MBA
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

Re: Request for Information (RFI): Medicare Part D Reasonable and Relevant Pharmacy Contracting Standards; File Code CMS-4217-NC, 91 FR 60568 (Sept. 24, 2026)

Dear Administrator Oz:

I. Introduction

FMI – The Food Industry Association ("FMI") respectfully submits these comments in response to the Centers for Medicare & Medicaid Services ("CMS") Request for Information titled "Medicare Part D Reasonable and Relevant Pharmacy Contracting Standards," File Code CMS-4217-NC (the "RFI").[1] The RFI seeks input to inform CMS's implementation of Section 6223(a) of the Consolidated Appropriations Act, 2026 ("Section 6223"). Subsection (a) amends section 1860D-4(b)(1)(A) of the Social Security Act (the "Act"). That provision has long required Part D plan sponsors to allow any pharmacy that meets their standard terms and conditions to participate as a network pharmacy. As amended, the provision requires those terms to be "reasonable and relevant" for plan years beginning on or after January 1, 2029, according to standards established by the Secretary.[2] The Secretary must establish those standards no later than the first Monday in April 2028.[3] Section 6223 also requires a process for pharmacies to report violations, provides for CMS tracking of non-

[1] Request for Information; Medicare Part D Reasonable and Relevant Pharmacy Contracting Standards, 91 Fed. Reg. 60568 (Sept. 24, 2026) [*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] Consolidated Appropriations Act, 2026, Pub. L. No. 119-75, div. J, § 6223(a), 140 Stat. 173, 664–65 (2026) (amending 42 U.S.C. § 1395w-104(b)(1)(A)), https://www.govinfo.gov/content/pkg/PLAW-119publ75/pdf/PLAW-119publ75.pdf; *see also* Pharmacy Benefit Manager Reform Act of 2025, H.R. 4317, 119th Cong. § 2(a) (as introduced July 10, 2025) (predecessor bill containing language identical to Section 6223(a)), https://www.congress.gov/bill/119th-congress/house-bill/4317/text; RFI, *supra* note 1, at 60568.

[3] RFI, *supra* note 1, at 60568.

affiliated "essential retail pharmacies," and routes enforcement through CMS's existing sanctions authority.[4]

To assist CMS's implementation of Section 6223, FMI offers input drawn from the experience of pharmacies directly impacted by the disparity in contracting between pharmacy benefit managers ("PBMs") and pharmacies in Part D. FMI's feedback and recommendations are organized to track the RFI's lettered sections (A through H), as the RFI requests, followed by a section responding to the RFI's question about overlap with section 1860D-12(h) of the Act.[5] In brief, FMI urges CMS to: (1) define "reasonable" reimbursement by reference to a pharmacy's ability to sustain its operations, measured against objective acquisition-cost benchmarks plus a dispensing fee that independently covers the cost of dispensing, and define "relevant" by reference to the purpose of Section 6223 (assuring pharmacy access and choice for Medicare beneficiaries), so that a term is relevant only when it reflects the drug dispensed, the services provided, or beneficiary access, and so that a pharmacy's ownership or affiliation is never a relevant basis for a term; (2) require reimbursement terms to be transparent and predictable at the point of sale, with any effective-rate reconciliation permitted only to increase payment against a reasonable guarantee and subject to clearly defined safeguards, or, if CMS cannot effectively regulate it, deemed not reasonable and relevant; (3) require complete disclosure of all financial terms at the time of contracting, minimum review periods, and affirmative (not deemed) acceptance of material changes; (4) prohibit terms that discriminate in favor of PBM-affiliated pharmacies, including network-design terms that are not tied to objective, pharmacy-level criteria; (5) require quality and performance measures to be relevant to the pharmacy's actual patient population and validated; (6) establish audit standards that separate clerical error from fraud, waste, and abuse and that provide meaningful due process; and (7) establish a timely, accessible process for pharmacies to submit allegations that contract terms violate the standards and obtain adjudication, with protection against retaliation and meaningful corrective action.

II. Background

As the food industry association, FMI works with and on behalf of the entire industry (from grocery companies that operate retail pharmacies across the United States, to producers that supply food and other products) to advance safer and more efficient consumer supply chains for both food and pharmaceuticals. In total, FMI member companies operate more than 45,000 grocery stores, and FMI's retail members operate more than 12,000 supermarket pharmacies located inside those stores in communities nationwide, from major metropolitan centers to small and rural towns.

Section 6223 matters acutely to FMI's members because the standard terms and conditions CMS ultimately deems "reasonable and relevant" will set the baseline contracting rules for every Part D network pharmacy in the country, including supermarket pharmacies. FMI's 2025 State of Pharmacy in Supermarkets survey (the "2025 Supermarket Survey") documented substantial member

[4] Pub. L. No. 119-75, div. J, § 6223(c), 140 Stat. at 667–69 (adding 42 U.S.C. § 1395w-104(b)(1)(F) and authorizing the Secretary to impose "civil monetary penalties or other intermediate sanctions" for violations of the reasonable-and-relevant standards); *see also* H.R. 4317, *supra* note 2, § 2(c) (predecessor bill containing similar enforcement provisions).

[5] RFI, *supra* note 1, at 60569 (asking respondents to "clearly identify which section(s) of this RFI they are responding to").

concerns about PBM practices, pharmacy profitability, and pharmacy closures: 74 percent of responding companies rated their pharmacy business not very or not at all profitable, and roughly 70 percent had closed pharmacies in the prior two years.[6] The survey gathered responses from 24 supermarket companies representing almost 14,000 stores and almost 8,500 pharmacies. Respondent counts vary by question, and, unless otherwise specified, the results describe members' pharmacy businesses overall, not Part D alone.[7] To cut costs over the prior 12 months, 74 percent of respondents reduced hours at one or more of their pharmacies and 56 percent reduced staffing at one or more pharmacies, and members reported eliminating or scaling back services such as free home delivery, unit-dose packaging, and weekend hours, reductions that, as one member put it, "resulted in less patient accessibility to vaccinations."[8] FMI's 2026 Part D survey (the "2026 Part D Survey") adds Part D-specific data.[9] The responding companies together operate more than 2,300 supermarket pharmacies, range from 10 to 49 pharmacies to 500 or more, and place from 5 to 70 percent of their pharmacies in rural areas. About half contract with PBMs only directly, and about half contract both directly and through a pharmacy services administrative organization ("PSAO").

Since 2019, more than 7,000 pharmacies have closed nationwide, and those closures fall hardest on rural, low-income, and underserved communities.[10] A peer-reviewed study found that 29.4

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[6] FMI, The State of Supermarket Pharmacy (Fact Sheet), https://www.fmi.org/industry-topics/fact-sheet/the-state-of-supermarket-pharmacy (95% of FMI members with pharmacies report a very negative PBM impact; 74% of pharmacy businesses are not very or not at all profitable; 74% were less profitable in 2025; 91% of pharmacies filled more prescriptions over the past 12 months; 35% report pharmacies at risk of closing within two years; 70% closed pharmacies in the past two years); *see also* Letter from Peter Matz, Dir., Food, Pharmacy & Health Policy, FMI – The Food Indus. Ass'n, to Mehmet Oz, Adm'r, Ctrs. for Medicare & Medicaid Servs. 2 n.1 (July 20, 2026) (re: Request for Information: Pharmacy Benefit Manager Compensation and Data Collection, File Code CMS-4218-NC, 91 Fed. Reg. 36776 (June 18, 2026)) [hereinafter FMI July 2026 Comments]. The underlying survey results are reported in Food Indus. Ass'n, State of Pharmacy in Supermarkets 2025, at slides 6–7, 9, 11–12, 16 (prelim. rep., May 1, 2025) (unpublished survey presentation) (on file with FMI) [*hereinafter* FMI 2025 Survey Report], and Food Indus. Ass'n, State of Pharmacy in Supermarkets 2025, at 2–6 (presentation to CMS, July 29, 2025) (on file with FMI) [*hereinafter* FMI CMS Presentation].

[7] FMI 2025 Survey Report, *supra* note 6, at slide 2 (survey distributed to FMI members Mar. 4, 2025, with responses collected through Mar. 28, 2025, from 24 supermarket companies representing almost 14,000 stores, almost 8,500 pharmacies, and almost 8,400 retailer-operated pharmacies).

[8] *Id.* at slides 17–19 (open-ended member responses on services cut to reduce costs); *see also* FMI CMS Presentation, *supra* note 6, at 7–8.

[9] See FMI, Supermarket Pharmacy Experience Survey: Medicare Part D Contract Terms (Nov. 2026) (unpublished member survey; responses on file with FMI) [hereinafter FMI 2026 Part D Survey]. Responses are confidential and are reported only in de-identified, aggregate form, and no figure is specific to a PBM or plan. Unless otherwise noted, figures describe calendar year 2025 Medicare Part D experience and are based on the companies answering each question, so respondent counts vary by question.

[10] NFP, Pharmacy Deserts: Why They Matter for Your Clients and What You Can Do About It (Aug. 6, 2025), https://www.nfp.com/insights/pharmacy-deserts-impact-and-action-steps/ ("Since 2019, over 7,000 pharmacies have closed in the U.S."); Michael Murphy & Jennifer Rodis, *The Growing Crisis of Pharmacy Deserts*, Ohio State Univ. Coll. of Pharmacy: PolicyRx (Apr. 28, 2025), https://pharmacy.osu.edu/news/growing-crisis-pharmacy-deserts (last visited Oct. 13, 2026) ("Between 2010 and 2021, over 29% of pharmacies across the country closed, exacerbating pharmacy deserts, particularly in low-income, rural and underserved communities."); *see also* Guadamuz et al., *infra* note 11 (closure risk higher in predominantly Black and Latinx neighborhoods).

percent of retail pharmacies operating between 2010 and 2020 had closed by 2021.[11] Those closures have patient consequences: in a national cohort of 3.1 million adults aged 50 and older, pharmacy closures were associated with an immediate decline in adherence to statins and oral anticoagulants that persisted for 12 months.[12] Pharmacists are among the most accessible health care providers, and that role becomes more important as the Medicare population grows with the aging of the Baby Boom generation and as patients face prescriber shortages. A closure removes not only prescriptions but also vaccinations, testing, and counseling in communities where other care is harder to reach. In the 2026 Part D Survey, nearly all of the companies that answered reported that some of their pharmacies, from 2 to 15 percent, are the only pharmacy in the community or the nearest by a meaningful distance; those shares represent more than 60 pharmacies among the responding companies alone.[13] Supermarket pharmacies sit inside stores that anchor food access, so a closure removes medications, vaccinations, and counseling from the place where many families already shop for groceries.[14] Supermarket pharmacies also operate differently from other pharmacy models. Their staffing follows store hours, they share space and some overhead with the store but must still cover their own costs, their volume skews toward routine maintenance medications, and they deliver counseling, immunizations, and other clinical services in person.[15] In the 2025 Supermarket Survey, every responding company offered vaccinations, 68 percent offered delivery, 55 percent offered point-of-care testing, and 46 percent each offered collaborative practice agreement services and medication synchronization; on average, respondents reported that 79.3 percent of their stores could support all immunizations. Prescriptions nonetheless remain the economic core of the business, accounting for 87 percent of pharmacy revenue, and 91 percent of respondents filled more prescriptions over the prior 12 months, an average increase of 5 percent.[16] The supermarket pharmacy model is high-volume and low-margin, and it has already absorbed years of retroactive direct and indirect remuneration ("DIR") fee clawbacks, below-cost reimbursement, and audit- and quality-measure-driven

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[11] Jenny S. Guadamuz et al., More US Pharmacies Closed Than Opened in 2018–21; Independent Pharmacies, Those in Black, Latinx Communities Most at Risk, 43 Health Affs. 1703, 1703–11 (2024), https://doi.org/10.1377/hlthaff.2024.00192 (29.4% of 88,930 retail pharmacies operating 2010–20 had closed by 2021).

[12] Dima M. Qato et al., *Association Between Pharmacy Closures and Adherence to Cardiovascular Medications Among Older US Adults*, 2 JAMA Network Open e192606 (2019), https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2730785 (national cohort of 3.1 million adults aged 50 or older; adherence decline persisted over 12 months).

[13] FMI 2026 Part D Survey, *supra* note 9 (pharmacies that are the only pharmacy in the community or the nearest by a meaningful distance); *see also* Ass'n of Am. Med. Colls., The Complexities of Physician Supply and Demand: Projections From 2021 to 2036, at vi, viii, 42 (Mar. 2024) (prepared by GlobalData Plc.) (projecting a shortage of between 13,500 and 86,000 physicians by 2036 and growth of 34.1 percent in the population aged 65 and older from 2021 to 2036, and noting "the growing importance of the Medicare program in future years because an increasing proportion of patient care will be provided to Medicare enrollees"), https://www.aamc.org/workforceprojections and https://www.aamc.org/media/75236/download.

[14] FMI July 2026 Comments, *supra* note 6, at 3; *see also* Murphy & Rodis, *supra* note 10 (explaining that residents who lose a local pharmacy "face significant barriers to obtaining critical medications, vaccinations and pharmacist-led care," and that these harms are "disproportionately felt in more socially vulnerable areas, such as underserved, rural, and racial and ethnic minority communities").

[15] FMI July 2026 Comments, *supra* note 6, at 11.

[16] FMI 2025 Survey Report, *supra* note 6, at slides 4–5, 9–10; *see also* FMI CMS Presentation, *supra* note 6, at 4.

penalties.[17] Much of the public commentary on this RFI will likely focus on independent and long-term care pharmacies; FMI writes to ensure that the standards CMS adopts also reflect the operating reality of grocery-embedded pharmacy.

The contracting environment in which these terms are set is highly concentrated. Each of the three largest PBMs shares common ownership with a major insurer and with mail-order pharmacies that compete directly with the network pharmacies whose terms the PBM sets.[18] In practice, pharmacies have no real choice but to accept the terms offered, because rejecting a single large Part D plan can mean losing a substantial share of a pharmacy's Medicare patients.[19] It is against this backdrop that the "any willing pharmacy" guarantee has been undermined in practice: PBMs can nominally "offer" open participation while setting terms that no pharmacy can sustainably accept.[20]

Drug Channels estimates that Caremark, Express Scripts, and Optum Rx together processed 80 percent of all equivalent prescription claims in 2025, a share consistent with prior years that Drug Channels describes as "extraordinarily high" and "remarkably stable."[21] The FTC has likewise found that the three largest PBMs reimbursed their affiliated pharmacies at higher rates than unaffiliated pharmacies.[22] Section 6223 gives CMS the tools to close that reimbursement gap.

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[17] *See generally* Frier Levitt, LLC, Pharmacy Benefit Manager Exposé: How PBMs Adversely Impact Cancer Care While Profiting at the Expense of Patients, Providers, Employers, and Taxpayers 22–28, 47–52, 75–80 (Feb. 2022) (commissioned by the Cmty. Oncology All.) [*hereinafter* PBM Exposé], https://www.frierlevitt.com/articles/pharmacy-benefit-manager-expose-how-pbms-adversely-impact-cancer-care-while-profiting-at-the-expense-of-patients-providers-employers-and-taxpayers/.

[18] Fed. Trade Comm'n, Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies (Interim Staff Report, July 2024), https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf [*hereinafter* FTC Interim Report]; *see also* Press Release, Fed. Trade Comm'n, FTC Releases Interim Staff Report on Prescription Drug Middlemen (July 9, 2024), https://www.ftc.gov/news-events/news/press-releases/2024/07/ftc-releases-interim-staff-report-prescription-drug-middlemen (top three PBMs processed nearly 80% of approximately 6.6 billion prescriptions in 2023).

[19] PBM Exposé, *supra* note 17, at 8–9, 11; *see also* 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., *infra* note 25, at 2 (written statement of Hugh Chancy, PharmD) ("[O]ur contracts with PBMs are take-it-or-leave-it. This is especially the case in Medicare Part D.").

[20] PBM Exposé, *supra* note 17, at 47 (describing below-cost reimbursement offered in "one-sided, take-it-or-leave-it agreements" that allow PBMs to nominally comply with any willing provider requirements while effectively excluding pharmacies).

[21] Adam J. Fein, *The Top Pharmacy Benefit Managers of 2025: Market Share and Key Industry Developments*, Drug Channels (Mar. 30, 2026), https://www.drugchannels.net/2026/03/the-top-pharmacy-benefit-managers-of.html (last visited Oct. 13, 2026) ("For 2025, 80% of all equivalent prescription claims were processed by three companies . . . ."); *see also* Adam J. Fein, *The Top Pharmacy Benefit Managers of 2024: Market Share and Key Industry Developments*, Drug Channels (Mar. 31, 2025), https://www.drugchannels.net/2025/03/the-top-pharmacy-benefit-managers-of.html (about 80% of equivalent prescription claims in 2024).

[22] 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), https://www.ftc.gov/system/files/ftc_gov/pdf/PBM-6b-Second-Interim-Staff-Report.pdf; *see also* Press Release, Fed. Trade Comm'n, FTC Releases Second Interim Staff Report on Prescription Drug Middlemen (Jan. 14, 2025), https://www.ftc.gov/news-events/news/press-releases/2025/01/ftc-releases-second-interim-staff-report-prescription-drug-middlemen.

Congress enacted Section 6223 on a substantial record of these practices. At a May 2023 House Oversight hearing, an independent pharmacy owner testified that his pharmacy "cannot negotiate any aspect of [its] contracts" with PBMs and that "[i]t is just take it or leave it."[23] The Committee's July 2024 staff report found that PBMs share patient data across affiliates to steer patients to PBM-owned pharmacies and use their market position to lower reimbursement paid to competing, non-affiliated pharmacies, and that DIR fees tied to opaque performance ratings fall hardest on independent and specialty pharmacies.[24] In February 2025, a former president of the National Community Pharmacists Association told the House Energy and Commerce Health Subcommittee that PBM contracts are "take-it-or-leave-it," "especially . . . in Medicare Part D," and expressly endorsed a reasonable and relevant contract requirement.[25] And in May 2025, a pharmacist testified before the Senate Judiciary Committee that a PBM reimbursed $10.33 for a medication that cost his pharmacy $728.35.[26]

Section 6223 is among the reforms FMI, alongside its Coalition for PBM Reform partners, helped secure, and FMI has publicly committed to working with CMS to define and enforce the reasonable and relevant standard.[27]

III. Responses to the RFI's Specific Topics

FMI's responses follow the order of the RFI. Each response appears below the corresponding "CMS seeks information on" topic. Where responses rely on survey data, they draw on two FMI member surveys described in Part II: the 2025 Supermarket Survey, whose results generally describe members' pharmacy businesses across all payers, and the 2026 Part D Survey, whose results are specific to Part D.

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[23] The Role of Pharmacy Benefit Managers in Prescription Drug Markets, Part I: Self-Interest or Health Care?: Hearing Before the H. Comm. on Oversight & Accountability, 118th Cong. 9 (May 23, 2023) (statement of Kevin J. Duane, PharmD, Owner, Panama Pharmacy), https://www.congress.gov/118/meeting/house/116002/documents/HHRG-118-GO00-Transcript-20230523.pdf; *see also* H. Comm. on Oversight & Accountability, *infra* note 24, at 11 (quoting Duane testimony that his pharmacy "cannot negotiate any aspect of [their] contracts").

[24] H. Comm. on Oversight & Accountability, 118th Cong., The Role of Pharmacy Benefit Managers in Prescription Drug Markets 4, 13 (Staff Report, July 2024), https://oversight.house.gov/wp-content/uploads/2024/07/PBM-Report-FINAL-with-Redactions.pdf.

[25] 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. 2 (Feb. 26, 2025) (written statement of Hugh Chancy, PharmD), https://www.congress.gov/119/meeting/house/117934/witnesses/HHRG-119-IF14-Wstate-ChancyRPhH-20250226.pdf ("[O]ur contracts with PBMs are take-it-or-leave-it. This is especially the case in Medicare Part D.").

[26] PBM Power Play: Examining Competition Issues in the Prescription Drug Supply Chain: Hearing Before the S. Comm. on the Judiciary, 119th Cong. 2 (May 13, 2025) (written testimony of Randy P. McDonough, PharmD, President, Am. Pharmacists Ass'n), https://www.judiciary.senate.gov/download/06/30/2026/2025-05-13_-testimony_-mcdonoughpdf.

[27] FMI Praises Approval of Funding Package with Historic PBM Reforms, Mass Mkt. Retailers (Feb. 3, 2026), https://massmarketretailers.com/fmi-praises-approval-of-funding-package-with-historic-pbm-reforms (quoting FMI Chief Public Policy Officer Jennifer Hatcher: FMI members "look forward to working with CMS to define and enforce 'reasonable and relevant' PBM contract terms"); *see also* Press Release, Nat'l Cmty. Pharmacists Ass'n, Pharmacist and Pharmacy Organizations Commend 2026 Spending Bill with Important PBM Provisions, Urge Passage (Jan. 21, 2026), https://ncpa.org/newsroom/news-releases/2026/01/21/pharmacist-and-pharmacy-organizations-commend-2026-spending-bill (joint statement of NCPA, NACDS, FMI, NASP, NGA, and APhA).

A. Pharmacy Reimbursement and Dispensing Fees

CMS seeks information about whether pharmacy reimbursement and dispensing fees paid by Part D sponsors to network pharmacies sufficiently cover the ingredient and operational costs of those pharmacies.[28]

> **CMS seeks information on:** *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.*

FMI Response. Part D reimbursement frequently fails to cover the combined cost of acquiring and dispensing a drug, and on a meaningful share of claims fails to cover acquisition cost alone. The 2025 Supermarket Survey illustrates the scale of the problem. On average, respondents reported that 25 percent of their prescriptions, representing 50 percent of prescription dollars, were reimbursed below cost, including 34 percent of brand-name prescriptions (59 percent of brand dollars) and 16 percent of generic prescriptions (8 percent of generic dollars). These are mean reported shares across all payers, not Medicare Part D alone. Drug acquisition costs were the cost increase with the greatest effect on profitability, with 55 percent of respondents reporting a major impact.[29] The 2026 Part D Survey, which asked specifically about 2025 Part D claims, confirms the problem. On average, responding companies reported that 21 percent of their Part D claims were paid below ingredient acquisition cost alone (14 percent of generic and 49 percent of brand claims) and that 66 percent were paid below acquisition cost plus the cost to dispense (59 percent of generic and 70 percent of brand claims). Every company that reported the second measure placed at least half of its Part D claims below it, and companies identified GLP-1s, oral anticoagulants, insulins, and other high-cost brands as principal drivers. Because prescriptions account for 87 percent of supermarket pharmacy revenue, claims paid below cost of this kind threaten the viability of the pharmacy itself.[30]

The benchmarks PBMs use compound the problem. PBM-set maximum allowable cost ("MAC") rates "need not have any relationship to a drug's market clearing acquisition cost," and PBMs treat MAC lists as proprietary.[31] By contrast, the National Average Drug Acquisition Cost ("NADAC") survey is a transparent, publicly available benchmark derived from pharmacy invoice data, and members prefer it: in the 2025 Supermarket Survey, 77 percent of respondents said other pricing models were more aligned with fair reimbursement, and NADAC-plus was the most frequently

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[28] RFI, *supra* note 1, at 60569.

[29] FMI 2025 Survey Report, *supra* note 6, at slides 8, 14 (mean share of prescriptions, by count and by dollar value, reimbursed under cost).

[30] FMI 2026 Part D Survey, *supra* note 9 (mean shares; below acquisition cost; below acquisition cost plus cost to dispense, ranging from 50 to 79 percent). Companies measured acquisition cost differently (most that described their measure used invoice cost; one used cost net of all rebates and discounts), and some measured payment after subsequent adjustments rather than at the point of sale.

[31] PBM Exposé, *supra* note 17, at 70.

selected alternative.[32] Yet every company that answered the 2026 Part D Survey reported that PBM MAC lists and discounts off average wholesale price ("AWP") appear in its Part D contracts, while most reported NADAC.[33] For brand-name drugs, acquisition cost generally tracks wholesale acquisition cost ("WAC"), which is defined by statute, and CMS already uses WAC as a standardized proxy for pharmacy acquisition cost[34] in setting the standard default refund amount under the Medicare Drug Price Negotiation Program.[35] In light of this evidence, FMI recommends that CMS favor transparent, independently verifiable acquisition-cost benchmarks, such as NADAC for generic drugs and WAC for brand-name drugs where appropriate, with a disclosed and appealable alternative where the benchmark is unavailable or does not reasonably reflect acquisition cost. That alternative should be a safeguard for pharmacies, not a source of PBM discretion. A PBM should be permitted to move a claim off the primary benchmark only under objective criteria stated in the contract in advance, should identify the alternative benchmark that will apply, and should not be permitted to switch benchmarks selectively when doing so lowers reimbursement; the pharmacy should be able to appeal both the switch and the resulting rate.

Use of a benchmark alone, however, should not establish that reimbursement is reasonable; the standards should also address payment adequacy, timely updates, drug availability, and effective appeal rights. Where reimbursement relies on an opaque, PBM-controlled benchmark such as MAC, the sponsor should be required to disclose its basis and demonstrate that it reasonably reflects acquisition cost (see the MAC response below). NADAC has its own limitations, but it is the most viable transparent benchmark currently available. It is far preferable to the untenable position PBMs have taken to establish acquisition cost: compelled disclosure of pharmacy-specific acquisition costs. As discussed below, that approach would conflict with the confidentiality obligations that govern pharmacies' purchasing terms with their suppliers and would place competitively sensitive information in the hands of competitors.

A transparent acquisition-cost benchmark paired with a dispensing fee that covers the reasonable cost of dispensing (a "NADAC-plus" approach, with the disclosed, objective alternative described above where NADAC is unavailable or does not reasonably reflect acquisition cost) would address most of the reimbursement concerns FMI's members face, and CMS can adopt it without first constructing a new benchmark of its own. To serve that role, however, the benchmark should be refined in several respects. *First*, NADAC should be updated more frequently so that it tracks market

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[32] FMI 2025 Survey Report, *supra* note 6, at slide 21 (respondents could select more than one model).

[33] FMI 2026 Part D Survey, *supra* note 9.

[34] Ctrs. for Medicare & Medicaid Servs., *Medicare Drug Price Negotiation Program: Final Guidance, Implementation of Sections 1191–1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price in 2026 and 2027* § 40.4.1 (Oct. 2024), https://www.cms.gov/files/document/medicare-drug-price-negotiation-final-guidance-ipay-2027-and-manufacturer-effectuation-mfp-2026-2027.pdf (using wholesale acquisition cost, as published in pricing compendia on the date of service, as a "reasonable proxy for the dispensing entity's acquisition cost" in calculating the standard default refund amount, equal to (WAC − MFP) × quantity dispensed).

[35] Ctrs. for Medicare & Medicaid Servs., *Medicare Transaction Facilitator: Pharmacies and Other Dispensing Entities Frequently Asked Questions*, https://www.cms.gov/files/document/medicare-transaction-facilitator-pharmacies-other-dispensing-entities-frequently-asked-questions.pdf (explaining that manufacturers may provide refunds at the standard default refund amount, "which is the difference between Wholesale Acquisition Cost (WAC) and MFP," based on WAC as published on the Part D claim's date of service).

price changes. *Second*, CMS should establish guardrails ensuring that the acquisition costs pharmacies report into the benchmark are calculated consistently across all reporting pharmacies; state experience with NADAC-based reimbursement shows that inconsistent submissions undermine a benchmark's reliability. *Third*, acquisition cost should be measured on a fully loaded basis (including distribution and handling fees, carrying and capital costs, and taxes) rather than a dead-net invoice price, because the net invoice price does not reflect what it costs to get a product onto the pharmacy's shelf. *Fourth*, CMS should recognize that survey-based benchmarks, including NADAC and alternatives such as Predictive Acquisition Cost ("PAC"), can understate attainable acquisition cost because they do not account for cross-subsidization in purchasing: a purchaser that accepts higher generic prices in exchange for lower brand prices, and another that does the reverse, each contribute their lowest prices to the benchmark, producing a composite that no single pharmacy can actually achieve. Any benchmark, and any reimbursement formula built on it (for example, NADAC plus a percentage or fixed amount), should be designed to account for that effect. *Fifth*, CMS should recognize that a single national average can shift with changes in who reports into it. Pharmacies with different purchasing volumes report into the same NADAC survey, and when a large purchaser first entered the survey in 2024, its lower invoice costs moved the national average down.[36] CMS should therefore monitor whether changes in survey participation, such as the entry of a large purchaser, move the benchmark away from the acquisition costs that most pharmacies can attain, and adjust the survey methodology if they do.

A transparent, benchmark-based methodology would also reduce reliance on "lesser of" logic, which PBMs have expanded to include an ever-growing set of comparators, each of which can only lower reimbursement. Whatever benchmark is used, it must be objective and independent of the PBM: the reasonableness of reimbursement cannot be left to a PBM's own determination, because a PBM has no incentive to produce a fair evaluation of what a competing pharmacy should be paid. At a minimum, a benchmark-based rate should not fall below the drug's NADAC (or the disclosed, objective alternative where NADAC is unavailable or does not reasonably reflect acquisition cost) plus a dispensing fee that covers the reasonable cost of dispensing.

> **CMS seeks information on:** *The feasibility and utility of network pharmacies sharing their actual acquisition costs with Part D plan sponsors, either directly or via wholesalers, and whether that transparency would be a sufficient alternative to benchmarks.*

FMI Response. Compelled disclosure of pharmacy-specific acquisition costs is not a workable method of establishing acquisition cost, and CMS should not permit it. Two problems are dispositive. *First*, pharmacies' purchasing terms with wholesalers and manufacturers are confidential: every company that answered the 2026 Part D Survey, together operating more than

[36] *See* Michael Murphy & Jennifer Rodis, *Shedding Light on NADAC: How Pricing Power Influences Pharmacy Reimbursement*, Ohio State Univ. Coll. of Pharmacy: PolicyRx (June 26, 2025), https://pharmacy.osu.edu/news/shedding-light-nadac-how-pricing-power-influences-pharmacy-reimbursement (last visited Nov. 8, 2026) (explaining that in 2024, when a large chain pharmacy participated in the NADAC survey for the first time, its significantly lower acquisition costs reduced the national average, and that the episode "highlighted some chains' immense leverage in negotiating prices with wholesalers, an advantage not shared by independent or smaller pharmacies"); *see also* FTC Interim Report, *supra* note 18, at 39 n.198 (observing that "small, independent pharmacies generally pay more than large chain and mail order pharmacies for the same drugs").

1,800 pharmacies, reported that its purchasing terms are subject to confidentiality obligations, so a disclosure mandate would force a pharmacy to choose between breaching those agreements and leaving the network.[37] *Second*, disclosure would effectively hand competitively sensitive information to a direct competitor, because each of the three largest PBMs owns pharmacies that compete with the pharmacies whose costs it would review; all responding companies expressed concern about such disclosure. Disclosure is also impractical, for four further reasons. A pharmacy's net cost cannot be reported reliably at the point of dispensing: true net cost depends on off-invoice discounts, rebates, and purchasing terms that are not known at the point of sale, and only a small minority of responding companies said they could state a single net acquisition cost for each Part D claim at the time of dispensing.[38] Invoice cost is also not full cost, because a historical purchase price misses price changes between purchase and claim, inventory carrying costs, damaged or expired product, and the warehousing, distribution, and transportation costs of pharmacies that self-distribute; pharmacies also often buy the same drug from several sources at different costs, particularly during shortages, so no single invoice price represents what the pharmacy paid for the drug dispensed on a given claim; and members further report that acquisition-cost provisions now appearing in PBM contracts lack any objective starting point and that the PBM-defined "acquisition cost" often bears little relationship to what the pharmacy actually paid. Cost-based reimbursement would also penalize efficient purchasing: under a published benchmark, a pharmacy that negotiates a better price keeps the benefit, but under cost-based reimbursement every dollar saved returns as lower reimbursement in the next rate cycle. Routing the data through wholesalers would not solve these problems: pharmacies buy through primary and secondary wholesalers and direct manufacturer arrangements, no wholesaler invoice captures self-distribution costs, and the data would still likely reach a PBM that owns competing pharmacies. Finally, reporting would be a heavy, recurring burden, because costs are volatile and inventory positions change constantly, and payment tied to reported costs would likely depend on verification and later reconciliation, delaying cash flow on top of the float pharmacies already carry under the maximum fair price ("MFP") refund process.

Acquisition-cost-based contracting in one line of business also exposes a pharmacy across every line of business, because a PBM that learns a pharmacy's acquisition costs through Part D can use that information when contracting in commercial and other segments, including segments still priced off AWP, where that insight could support deeper reimbursement cuts. Allowing PBMs to review pharmacies' purchasing data and to determine acquisition cost unilaterally would move PBMs toward functioning as de facto purchasing organizations for the pharmacies with which they compete. CMS should deem any term requiring disclosure of pharmacy-specific acquisition costs as a condition of network participation not reasonable and relevant, and should instead rely on transparent benchmarks developed by a neutral third party, such as NADAC where appropriate, and alternatives that avoid compelled disclosure of pharmacy-specific confidential acquisition costs. This is consistent with the position FMI took in the record on Section 6224 of the Consolidated Appropriations Act, 2026 ("Section 6224").[39]

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[37] FMI July 2026 Comments, *supra* note 6, at 13–14.

[38] FMI 2026 Part D Survey, *supra* note 9.

[39] FMI July 2026 Comments, *supra* note 6, at 13 (contractual mandates to disclose confidential acquisition data are "neither reasonable nor relevant").

CMS seeks information on: *The frequency of plan updates to MAC pricing lists, communication regarding such updates, related dispute resolution mechanisms, and industry standards or common practices for establishing MAC prices.*

FMI Response. FMI believes that a benchmark-based reimbursement floor, applied to each claim at adjudication, would make MAC pricing unnecessary. If CMS nonetheless permits MAC, FMI recommends that MAC operate only above that floor, and offers the following additional background, recommendations, and member experience.

MAC lists are prepared exclusively by PBMs and, except where state law requires it, are not disclosed to network pharmacies.[40] PBMs also maintain separate MAC lists for payers and for network pharmacies, enabling the PBM to bill a plan sponsor one rate while paying the pharmacy a lower rate.[41] Recognizing the need for MAC standards, many states have required that a drug be generally available for purchase and rated as therapeutically equivalent before it is placed on a MAC list, and have established appeal rights.[42] Those state laws generally do not reach Part D plans because of Part D's express preemption provision, discussed below, but they show that the protections FMI recommends are workable.

Building on those approaches, FMI recommends that a reasonable and relevant MAC term: (i) identify the source and methodology used to set MAC; (ii) update MAC at least every seven days and promptly after a documented market price change in either direction, with each change and its effective date disclosed to pharmacies before it applies to claims; (iii) provide a timely appeal process that the pharmacy itself may initiate and, if successful, a retroactive adjustment for all of the appealing pharmacy's affected claims for that drug, not only the appealed claim, and for all pharmacies that received reimbursement at the same amount as the appealing pharmacy, without requiring the pharmacy to submit invoices or other purchase prices covered by confidentiality agreements; (iv) require that any denial be explained in writing on a claim-specific basis, stating how the claim was priced, the source of the MAC rate applied, and a national drug code available to the pharmacy at or below that rate from a wholesaler to which the pharmacy has access, with a defined path to further review by a decision-maker independent of the PBM; and (v) prohibit placing drugs on a MAC list that are not readily available for purchase. Item (iv) builds on requirements already in force in many states, which require a PBM that denies a MAC appeal to state the reason for the denial and to identify the national drug code of a drug the pharmacy can purchase at or below the MAC rate, in some states together with the wholesaler from which it is available, and at least one national PBM already provides that information in its denial responses

[40] PBM Exposé, *supra* note 17, at 70; *see, e.g.*, Tex. Ins. Code Ann. §§ 1369.354(c)–(d), .356 (West 2026) (requiring PBMs to disclose to contracted pharmacies the sources of MAC pricing data and to provide a process to access the applicable MAC list).

[41] PBM Exposé, *supra* note 17, at 73–74.

[42] *See, e.g.*, Tex. Ins. Code Ann. §§ 1369.353, .357 (West 2026); N.Y. Pub. Health Law § 280-a(1)(d), (4) (McKinney 2026); N.J. Stat. Ann. § 17B:27F-4 (West 2026); PBM Exposé, *supra* note 17, at 73–75.

where state law requires it.[43] CMS should also audit PBMs to ensure that such MAC adjustments are made for all pharmacies, because PBMs seldom provide such adjustments even where state law requires them. Member experience confirms the need for these protections. Nearly all companies responding to the 2026 Part D Survey reported that MAC rates are lowered faster than they are raised after market price changes, all that answered reported encountering drugs on MAC lists that could not be purchased at or below the MAC rate (several said often), and most reported obsolete or unavailable generics on MAC lists at least sometimes. Appeals rarely succeed: nearly all companies that reported a success rate said fewer than 5 percent of their 2025 Part D MAC appeals were granted, and none reported more than about 11 percent. When an appeal is denied, several companies said the PBM never identifies a product available to them at the MAC price, and members report receiving boilerplate denials, such as a statement that the claim was "paid within market analysis," that do not explain how the claim was priced. None of the companies answering reported that granted appeals are usually applied retroactively to its other affected claims (several said never).[44]

> **CMS seeks information on:** *The use of "lesser of" pricing methodologies, including the use of usual and customary (U&C) pricing and how U&C is defined.*

FMI Response. "Lesser of" logic is not inherently unreasonable, but it becomes so when a PBM treats as the pharmacy's U&C price a price that the pharmacy does not set or does not offer to the general public, or when "lesser of" logic is combined with post-adjudication clawbacks that reduce payment below the "lesser of" amount actually adjudicated. FMI does not ask CMS to exclude from U&C the cash prices a pharmacy itself sets and offers to the general public, including discount prices available to any cash customer. CMS should instead require that U&C be defined consistently with the pharmacy's own usual and customary cash price to the general public and should clarify two narrower points. *First*, a price made available through a third-party discount card program, such as GoodRx, is not the pharmacy's U&C price. The pharmacy does not set that price as its own cash charge: the card price is a PBM-negotiated network rate that the card program makes available to its users, and the pharmacy's agreements generally establish guardrails rather than the specific price, so the resulting price reflects the terms of the card program and its PBM partners

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[43] See, e.g., Ky. Rev. Stat. Ann. § 304.17A-162 (2026) (reason for denial and the national drug code of a drug product and "source where it may be purchased from a licensed wholesaler" at or below the maximum allowable cost), https://apps.legislature.ky.gov/law/statutes/statute.aspx?id=45114; Md. Code Ann., Ins. § 15-1628.1 (2026) (reason for denial, national drug code, name of the wholesale distributor, and "the mathematical calculation used to determine the maximum allowable cost"), https://mgaleg.maryland.gov/mgawebsite/Laws/StatuteText?archived=False&article=gin&enactments=False&section=15-1628.1; Minn. Stat. § 62W.08(c)(3) (2026), https://www.revisor.mn.gov/statutes/2026/2026-10-20%2010:50:30+00:00/cite/62W.08/pdf; Neb. Rev. Stat. § 44-4608(3)(c) (2026), https://nebraskalegislature.gov/laws/statutes.php?statute=44-4608; Utah Code Ann. § 31A-46-303 (2026) (reason for denial, national drug code, and "the specific basis upon which the pharmacy benefit manager can show that the drug is available for purchase at or below the maximum allowable cost"), https://le.utah.gov/xcode/Title31A/Chapter46/C31A-46-S303_2026050620260506.pdf; Optum Rx, MAC Appeal Submission Guide, https://business.optum.com/en/support/professionalrx-resources/appeals-submission-guide.html (last visited Nov. 18, 2026) (denial responses include alternate or reference national drug code information "where applicable and required by law").

[44] FMI 2026 Part D Survey, *supra* note 9.

rather than the pharmacy's own charge to the general public.[45] Congress drew the same line in the Medicare prescription drug discount card program that preceded Part D, which required that enrollees be charged no more than "the lower of the price based on negotiated prices or the usual and customary price," treating the card's negotiated price and the pharmacy's U&C price as distinct.[46] *Second*, a price available only to members of a bona fide, fee-based pharmacy membership program, which pharmacies increasingly offer to compete with membership models operated by large retail and online competitors, is not the pharmacy's U&C price. That clarification should apply only where membership requires a meaningful fee and confers benefits beyond the price itself, and not where enrollment is a nominal step that in practice makes the program price available to every cash customer. Most companies responding to the 2026 Part D Survey reported that they do not offer loyalty, discount-club, membership, or promotional cash prices on prescriptions at all,[47] which underscores that the clarification FMI seeks is narrow and would not shelter pharmacy-set prices offered to the public. For the avoidance of doubt, a pharmacy's U&C price should be determined by reference to that dispensing pharmacy's own generally available cash price for the drug, and a price the dispensing pharmacy does not set, such as a price advertised by another pharmacy or a price made available through a third-party discount card program, should not establish or reduce that pharmacy's U&C price.

> **CMS seeks information on:** *Costs considered within the scope of dispensing fees, whether dispensing fees sufficiently cover those costs, and whether dispensing fees should be required to cover the cost of dispensing irrespective of ingredient-cost reimbursement.*

FMI Response. Dispensing fees in Part D are, in FMI members' experience, well below the actual cost of dispensing. A dispensing fee should account for pharmacist and technician salaries and benefits, licensure and accreditation fees, dispensing and adherence software, supplies, packaging, delivery, and facility overhead such as rent and utilities.[48] The fee should also factor in costs that FMI members say are routinely omitted from dispensing-fee discussions today: labor, vials and labels, refrigeration and other storage requirements, mandatory patient counseling, and

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[45] *See* Anna Hung & Sean Dickson, *A Primer on Prescription Drug Pricing Benchmarks in the United States*, 31 J. Managed Care & Specialty Pharmacy 1326, tbl. 1 (2025), https://doi.org/10.18553/jmcp.2025.31.12.1326 [hereinafter Hung & Dickson] (identifying U&C as "[s]et by pharmacy") (explaining in the discussion of U&C that U&C "is not used when a patient uses a discount card, such as GoodRx," because "a PBM has typically negotiated a payment amount to the pharmacy on behalf of the discount card program"); GoodRx, What's the Deal With GoodRx? FAQs From Pharmacy Staff (updated May 27, 2021), https://www.goodrx.com/corporate/business/faqs-from-pharmacy-professionals (last visited Nov. 18, 2026) (stating that GoodRx "partners with PBMs to display the contracted price at each pharmacy," whereas for "pharmacy-specific savings programs (e.g., $4 generic medications) . . . the prices are set by the pharmacies").

[46] Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, § 101(a)(2), 117 Stat. 2066 (2003) (adding Social Security Act § 1860D-31(h)(8), 42 U.S.C. § 1395w-141(h)(8)), https://www.govinfo.gov/content/pkg/PLAW-108publ173/html/PLAW-108publ173.htm; see also 42 C.F.R. § 403.806(d)(7) (2025) (requiring endorsed sponsors to "[g]uarantee that network and mail order pharmacies provide the lower of the negotiated price or usual and customary price when a covered discount card drug for a negotiated price is available at the point of sale"), https://www.govinfo.gov/content/pkg/CFR-2025-title42-vol2/pdf/CFR-2025-title42-vol2-sec403-806.pdf. The program applied to drugs dispensed through December 31, 2005, subject to a transition period, see 42 U.S.C. § 1395w-141(a)(2)(C); its provisions ended by their own terms and remain codified.

[47] FMI 2026 Part D Survey, *supra* note 9.

[48] *See* PBM Exposé, *supra* note 17, at 47, 55.

compliance with Risk Evaluation and Mitigation Strategy ("REMS") requirements. Labor, in this context, should also include the labor needed to return unclaimed prescriptions to stock, reverse the claim within the required timeframe, and reprocess the claim if the patient later returns; being made whole on acquisition cost alone, with a nominal dispensing fee, leaves pharmacies underwater on these claims.

FMI also strongly recommends that CMS require the dispensing fee to cover the above reasonable costs of dispensing independent of ingredient-cost reimbursement. Permitting a PBM to justify a nominal dispensing fee by pointing to a purported ingredient-cost margin invites precisely the cross-subsidy that opaque MAC and effective-rate methodologies make impossible to verify. CMS could benchmark the reasonable cost of dispensing using an approach modeled on the cost-of-dispensing surveys that state Medicaid programs use to set dispensing fees.

The reasonable cost of dispensing also varies with the work a prescription requires, and a single national figure drawn from the lowest-cost, highest-volume channel would understate what it costs a supermarket or community pharmacy to dispense. State Medicaid programs already account for cost variation: although most set a single statewide professional dispensing fee, some vary the fee by prescription volume or other criteria so that the fee tracks surveyed costs. CMS's own Part D guidance likewise permits sponsors to vary dispensing fees, for example for rural or long-term care pharmacies, so long as similarly situated pharmacies are offered the same standard terms. CMS should therefore require that any variation in the dispensing-fee standard be based on the work involved in dispensing, with the same criteria applied to every pharmacy that performs comparable work, supported by standardized definitions of the costs of dispensing, a comprehensive independent cost study every few years, reasonable allocation of shared overhead, and protection of confidential cost data. Such variation should operate only to ensure that each pharmacy's dispensing fee covers its reasonable costs; it should not become a basis for paying supermarket or community pharmacies less than the costs they actually incur, or for setting the standard by reference to PBM-affiliated mail-order operations.[49] CMS should also consider whether pharmacies that are the only pharmacy in a community warrant an enhanced dispensing fee, addressing the ongoing "pharmacy desert" problem.

The standard should also permit complexity modifiers that add to the base fee for prescriptions that require materially more pharmacist time or handling, such as compounded prescriptions,

[49] *See* Myers and Stauffer LC, Survey of the Average Cost of Dispensing a Medicaid Prescription in the State of Nebraska (May 2025), https://dhhs.ne.gov/Documents/NE%202024%20COD%20Report.pdf (reporting that 32 states apply a single statewide professional dispensing fee, eight tier the fee by annual pharmacy prescription volume, and seven use other criteria); Ohio State Plan Amendment No. 23-0033 (approved by CMS Dec. 20, 2023; effective Jan. 1, 2024), https://www.medicaid.gov/sites/default/files/2024-01/OH-23-0033.pdf (professional dispensing fees ranging from $15.47 for pharmacies filling less than 49,999 prescriptions per year to $8.30 for pharmacies filling 100,000 or more); Colorado State Plan Amendment No. 25-0038 (approved Feb. 2026; effective Apr. 1, 2026), https://www.medicaid.gov/medicaid/spa/downloads/CO-25-0038.pdf (fees tiered by annual prescription volume for all pharmacies other than government and rural pharmacies); Ctrs. for Medicare & Medicaid Servs., Medicare Prescription Drug Benefit Manual ch. 5, § 20.7 (Rev. 14, Sept. 30, 2011) (permitting sponsors to vary dispensing fees, for example for rural or long-term care pharmacies, provided similarly situated pharmacies are offered the same standard terms); *see also* FMI July 2026 Comments, *supra* note 6, at 11; W. Va. Code § 33-51-14 (2026), https://code.wvlegislature.gov/33-51-14 (directing a biennial study of the cost to dispense outpatient prescription drugs).

which require added pharmacist time, ingredients, equipment, and compliance work to prepare; drugs with special storage, handling, or monitoring requirements, which can require additional packaging, delivery, and clinical support; and drugs subject to prior authorization. Any such modifier should attach to the drug dispensed and the work it requires, not to a pharmacy designation, and should be available on the same criteria to any pharmacy that performs comparable work, so that it cannot become a basis for limiting which network pharmacies may dispense a drug. And a reasonable dispensing fee should not be limited to cost recovery: it should include a reasonable margin that allows pharmacies to sustain their operations and reinvest in staff, services, and access over time, consistent with the sustainability factor FMI proposes in Section III.B.

Dispensing fees should also be indexed annually (for example, to the Consumer Price Index, as some state Medicaid statutes require, or to an appropriate Producer Price Index) so that they do not erode in real terms over time; members report, for example, that vaccine administration fees have not increased since pharmacies began administering vaccines. A dispensing fee paid at the point of sale should not be recouped to meet an aggregate or "dispensing fee effective rate" target (a construct under which a PBM pays one dispensing fee at the point of sale and later claws a portion back to a contractual target), and any dispensing-fee guarantee should operate only as a floor, consistent with the effective-rate approach described below.[50]

The 2026 Part D Survey quantifies the gap between the typical Part D dispensing fee and pharmacies' actual costs to dispense. Most responding companies reported that their typical Part D dispensing fee at the point of sale is more than $0 but less than $1, and the highest fee in any reporting company's contracts ranged from $0.05 to roughly $9.50, while the companies that track their cost to dispense reported $8.50 to $15.50 per prescription, an average of about $11.50. Those costs are in line with the professional dispensing fees that state Medicaid programs set through cost-of-dispensing surveys, which in at least one state exceed $15 per prescription for lower-volume pharmacies, and are far above the fees most Part D contracts pay. Several companies reported that a PBM had paid a dispensing fee at the point of sale and later recouped part of it to meet a dispensing-fee effective rate.[51]

> **CMS seeks information on:** *The extent to which negotiated prices reported on pharmacy claim responses reflect a pharmacy's final reimbursement versus an aggregate guarantee such as a generic effective rate (GER) or brand effective rate (BER) reconciled after the point of sale, the magnitude of the difference, the frequency and magnitude of end-of-year reconciliation payments, the predictability of final reimbursement at the time of dispensing, and whether remittance advice includes sufficient claim-level detail.*

FMI Response. Effective-rate guarantees are among the most consequential issues in the RFI for FMI's members, and they are pervasive: every company responding to the 2026 Part D Survey reported a generic effective rate in its Part D contracts, nearly all reported a brand effective rate,

[50] PBM Exposé, *supra* note 17, at 76.

[51] FMI 2026 Part D Survey, *supra* note 9 (cost to dispense excludes ingredient cost and was generally derived from internal cost accounting; one company that supplied only a state Medicaid cost-of-dispensing reference is excluded).

more than half reported a dispensing-fee effective rate, and nearly all of the companies that could estimate it said that at least a quarter of their Part D revenue is subject to aggregate guarantees.[52] The concern is not effective-rate contracting as such, but systematic underpayment that is reconciled or recouped long after the point of sale, and often long after the plan year has closed. Although CMS's Contract Year 2023 rule required pharmacy price concessions to be reflected in the negotiated price at the point of sale beginning in 2024,[53] effective-rate guarantees reconciled after the fact remain a mechanism by which the claim-level amount a pharmacy sees is not the amount it ultimately keeps. GER and BER constructs are assessed retrospectively and on a network-wide basis, which is "tantamount to giving PBMs unbridled discretion as to how they will pay a given pharmacy," and pharmacies have in some instances learned of effective-rate reconciliations only when PBMs began withholding payments to offset alleged overpayments.[54] Because they operate after the fact and across a network, effective rates also allow PBMs to circumvent MAC appeal rights.[55] CMS has two paths. It can set enforceable standards for how effective-rate agreements are defined, measured, reconciled, and paid, as described below. Or, if it concludes that it cannot effectively regulate effective-rate reconciliation to that degree, it can deem effective-rate reconciliation not reasonable and relevant, as discussed at the end of this response.

Claim-level prices versus final reimbursement. The amount on the claim response is frequently not the amount the pharmacy keeps. None of the companies answering the 2026 Part D Survey said the claim-level amount predicts final Part D reimbursement very well; most said it does so only somewhat, and the rest said poorly or not at all. One member reported that a PBM manages reimbursement throughout the year to hit its year-end target, so the claim-level price reflects the PBM's projected position against the guarantee rather than the value of the claim.[56]

End-of-year reconciliation payments. Reconciliation is irregular, delayed, and often contested. Most companies have received at least one true-up payment, but only a small minority receive one in most years, some have never received one, and several of those that were paid had to request or dispute the payment. Where no payment was made, companies said the PBM reported that the target was met, that they cannot verify the PBM's calculation, or that a dispute was pending. Companies reported that final reconciliation occurs from about two to twelve months after dispensing. Reconciliation does not run only in the pharmacy's favor: some companies reported that the PBM owed them on net in the most recent period, but others reported that net payments have run in both directions depending on the PBM, so that those pharmacies have paid PBMs, or had amounts withheld, under at least one contract. Most companies reported that a PBM or PSAO

[52] FMI 2026 Part D Survey, *supra* note 9.

[53] *See* 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) (codified at 42 C.F.R. pt. 423), https://www.govinfo.gov/content/pkg/FR-2022-05-09/pdf/2022-09375.pdf; *see also* Ctrs. for Medicare & Medicaid Servs., HPMS Memorandum, Application of Pharmacy Price Concessions to the Negotiated Price at the Point of Sale Beginning January 1, 2024 (Nov. 6, 2023), https://www.cms.gov/files/document/pharmacypriceconcessionshpmsmemonovember2023final508g.pdf.

[54] PBM Exposé, *supra* note 17, at 75–76.

[55] *Id.* at 76, 78.

[56] FMI 2026 Part D Survey, *supra* note 9.

had recovered a reconciliation shortfall by deducting it from later payments, and nearly half had disputed a reconciliation, most often over netting or offsets, which claims, pharmacies, or periods were counted, the calculation method, or whether a drug was a brand or a generic.[57]

Predictability of final reimbursement at the time of dispensing. Because final payment depends on an aggregate calculation completed months later, pharmacies cannot reliably budget for it. Only one company said it can reliably estimate and accrue for reconciliation amounts before the PBM reports them; the others can do so only partly or not at all. Tracking reconciliations consumes substantial resources: several companies reported dedicating the equivalent of one or more full-time employees to the task, another reported 800 to more than 1,000 hours a year, and others reported from 30 to several hundred hours, while PBMs devote comparable resources, with no apparent benefit to beneficiaries or reduction in drug costs.[58] In the meantime, the PBM uses the pharmacy's cash flow as an interest-free loan that the pharmacy must cover while meeting payroll and other operating expenses.

Remittance detail. Remittance advice rarely allows a pharmacy to reconcile its payments. Only one company said Part D remittance advice always lets it determine, claim by claim, what it was paid after all adjustments, and many said it rarely or never does; nearly half said adjustments are often netted across claims, plans, or payment periods; a majority reported that reconciliation results arrive at least in some cases only as a summary without claim-level detail, and some that they learned of amounts only when payments were withheld or offset.[59]

Several states already prohibit fees that are not apparent at the time of claim processing, or prohibit reductions to an "effective rate of reimbursement."[60] CMS should also require remittance advice to identify, at the claim level, the ingredient cost, dispensing fee, each fee or adjustment, the basis for the adjustment, and the applicable contract or rate sheet.

Effective-rate agreements are the norm for supermarket pharmacies: all companies responding to the 2026 Part D Survey have them, a generic effective rate appears in all of them and a brand effective rate in nearly all, and every company that contracts only directly with PBMs has them in its direct contracts.[61] Some contracts also include a dispensing-fee effective rate that sets a single aggregate dispensing-fee floor.[62] Administered as intended, an effective-rate agreement can

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[57] FMI 2026 Part D Survey, *supra* note 9.

[58] FMI 2026 Part D Survey, *supra* note 9.

[59] FMI 2026 Part D Survey, *supra* note 9.

[60] *See, e.g.,* Tenn. Code Ann. § 56-7-3115; Ind. Code § 27-1-24.5-19(b)(4); Fla. Stat. § 626.8825(3)(c) (2026) (prohibiting a pharmacy benefit manager from recouping "brand name or generic effective rate adjustments through reconciliation"), https://www.flsenate.gov/Laws/Statutes/2026/626.8825; PBM Exposé, *supra* note 17, at 79.

[61] *See United States ex rel. Behnke v. CVS Caremark Corp.*, No. 2:14-cv-00824, 2025 U.S. Dist. LEXIS 120177, at *11–12 (E.D. Pa. June 25, 2025) (describing GERs as guarantees of "an agreed upon average price for drugs over the course of a year," usually expressed as a percentage off AWP, that operated as "a price floor but not a price ceiling"); Hung & Dickson, *supra* note 45, at 1327 tbl. 1 (identifying the GER as an AWP-based benchmark for generic drugs and the BER as a parallel benchmark for brand-name drugs). *See also* FMI 2026 Part D Survey, *supra* note 9 (effective-rate agreements reported by all responding companies, in direct and PSAO contracts).

[62] *See* PBM Exposé, *supra* note 17, at 76.

benefit pharmacies, because it checks MAC reimbursement that is otherwise a "black box" and difficult to appeal administratively.[63] In practice, however, although nearly all responding companies have both generic and brand effective rates, FMI members report that effective rates have been useful mainly for generics, as an alternative to pursuing MAC appeals, and have been used against pharmacies for brand drugs, where reimbursement already tracks published pricing benchmarks such as wholesale acquisition cost and a guarantee serves little protective function. Members that value effective rates describe the same benefit: a known floor that provides predictability against "an uncapped and unpredictable MAC list reduction." That benefit exists only if the guarantee operates as a floor.[64]

Floor, not ceiling. CMS should require that the amount paid on the claim at adjudication (the "point-of-sale amount") be the minimum reimbursement the pharmacy can rely on, with any permitted subsequent reconciliation governed by fully disclosed, verifiable terms. Since January 1, 2024, the negotiated price at the point of sale has been required to reflect the lowest possible reimbursement a pharmacy will receive, taking into account all pharmacy price concessions; CMS should confirm that effective-rate reconciliation may not reduce payment below that amount. CMS should require effective rate guarantees to operate as minimum payment commitments: if aggregate reimbursement falls below the guaranteed rate, the PBM pays the shortfall, and if it exceeds the guaranteed rate, the pharmacy retains the difference. Effective-rate reconciliation would therefore produce additional payments to the pharmacy, rather than invoices, debits, offsets, or deductions from future remittances. This floor-only approach would distinguish effective-rate reconciliation from legitimate corrections of payment or billing errors, which would remain available. CMS should also guard against sponsors responding to a floor or an upward-only requirement by narrowing their networks or limiting pharmacy participation. The guaranteed rate itself must also be reasonable so that a PBM cannot set it so low that it provides no meaningful protection against underpayment. A point-of-sale floor also does not, by itself, solve inadequate initial payment: a PBM could pay well below the guaranteed rate at the point of sale and make up the difference only months later. The floor must therefore be paired with the reconciliation safeguards described below, including an earlier true-up when underpayment exceeds a defined threshold, prompt payment of undisputed amounts, interest on late payments, and protection against indirect clawbacks. Many guarantees are already written this way: a majority of the companies that answered the 2026 Part D Survey reported that their guarantees operate as a floor only, and most of the others reported that this varies by contract. In practice, however, several reported that net reconciliation payments have run in both directions depending on the PBM. Companies that described what they value in effective-rate arrangements pointed to predictability, accountability, and auditability; none identified a two-way feature as valuable.[65]

Two-way reconciliation. A two-way reconciliation, even with a claim-level floor, would be more complex for PBMs to administer and considerably harder for pharmacies to verify, because every recovery would depend on the same opaque inclusions, exclusions, and netting that generate

[63] *See id.* at 70 (MAC rates "need not have any relationship to a drug's market clearing acquisition cost").

[64] FMI 2026 Part D Survey, *supra* note 9 (member narrative responses).

[65] FMI 2026 Part D Survey, *supra* note 9.

disputes today. Where contracts permit recovery, PBMs already collect shortfalls by offsetting them against later remittances rather than by a transparent invoice the pharmacy can dispute. FMI therefore recommends that effective-rate reconciliation be permitted only to produce additional payments to the pharmacy and never to reduce compensation, with legitimate corrections of payment or billing errors remaining available. If CMS nonetheless permits downward reconciliation, FMI recommends at a minimum that: no reconciliation reduce payment below the lowest point-of-sale amount permitted under Part D requirements; reconciliation occur at least quarterly and be completed within a defined period; the pharmacy receive claim-level supporting data and a calculation it can reproduce; no offsets be permitted across Part D and commercial business, unrelated plans or networks, pharmacy locations, states, or separate guarantees; the pharmacy have a reasonable review period before any debit or withholding, and access to an independent appeal; and no disputed amount be recouped or withheld until the dispute is resolved.

Drug definitions. Disputes frequently turn on whether a drug is a "generic" or a "brand" for purposes of the guarantee. Most PBM contracts define those terms ambiguously and do not tie them to FDA approval status, a recognized drug compendium such as Medi-Span, or another objective source.[66] Biologics and biosimilars may fall outside either category depending on the contract's definitions. None of the companies answering the 2026 Part D Survey reported that its contracts state how biologics, biosimilars, or authorized generics are classified, and a significant sample had disputed how a drug was classified, including claims paid as brand at the point of sale and later reconciled as generic.[67] CMS should require that drug categories subject to any guarantee be defined by reference to an objective, published source, such as the definitions in 42 C.F.R. § 423.4 that Section 6224 already requires PBMs to use when measuring their own pricing guarantees to sponsors[68], and that the contract state expressly how biologics, biosimilars, authorized generics, single-source or limited-competition generics (for example, a generic during its 180-day exclusivity period or one marketed by two or fewer manufacturers), specialty drugs, and other drugs that are not clearly brand or generic are classified and priced. Members report that PBMs apply different brand and generic indicators at reconciliation than they used when adjudicating the claim, and use dispense-as-written ("DAW") codes to move claims into or out of a guarantee to the pharmacy's detriment. CMS should therefore require that a drug's classification be fixed at the point of sale and applied consistently at reconciliation, and that the formula, inclusions, and exclusions used to calculate effective rates be consistent across Part D so that pharmacies can verify them.

Scope and level of measurement. Disputes also arise over which claims, pharmacies, and time periods are counted, including exclusions, carve-ins, and carve-outs, and when a pharmacy that joins a PSAO mid-year enters the calculation. Contracts also differ on whether the guarantee is measured at the claim, pharmacy, state, PSAO, or plan level, and some contracts contain more than

[66] *See* David Calabrese, *Comparing Pharmacy Benefit Managers: Moving Well Beyond the Simple Spreadsheet Analysis*, 1 Am. Health & Drug Benefits 9, 12 tbl. 2 (2008), https://pmc.ncbi.nlm.nih.gov/articles/PMC4115299/ (advising plan sponsors to "[e]nsure mutual understanding of how your PBM defines a generic drug").

[67] FMI 2026 Part D Survey, *supra* note 9.

[68] Pub. L. No. 119-75, div. J, § 6224(a)(1), 140 Stat. at 671–72 (adding 42 U.S.C. § 1395w-112(h)(1)(B)(i)).

one effective rate.[69] Responding companies reported guarantees measured at levels from the individual claim to a PSAO-wide pool, but pooled measurement predominates: a majority reported measurement across the company's pharmacies combined and a majority at the plan or network level, while only a few reported claim-level measurement. Most reported that a single contract contains more than one effective rate.[70] CMS should require each contract to state clearly the level at which each guarantee is measured and reconciled, including the claims, pharmacies, plans, networks, and periods included, all inclusions and exclusions (for example, whether vaccines, claims paid at U&C, and claims adjudicated under discount card programs are excluded), and how amounts are calculated and allocated. CMS should also require that pharmacies receive sufficient information to verify the reconciliation and to identify any offsets between guarantees, including a distinct network or reimbursement identifier on each claim that ties the payment to the contract and rate schedule under which it was priced, with separate identifiers for one-month and extended-supply claims. Members identified several further practices CMS should address. *First,* a nationwide guarantee can penalize a pharmacy for the performance of unrelated pharmacies elsewhere; CMS should require that guarantees be measured at a level the pharmacy can verify, such as the pharmacy, region, or individual network, and should not permit a single guarantee to pool unrelated networks or plans without the pharmacy's affirmative agreement. *Second*, a PBM should not be permitted to include only selected locations of a chain (enough to satisfy CMS access standards) while excluding others to limit its guarantee exposure. *Third*, Part D claims should never be aggregated with claims from other lines of business, as discussed below. *Fourth*, a guarantee met on a percentage basis can still leave a pharmacy underpaid in dollars when shortfalls fall on high-cost drugs and overages fall on low-cost drugs; CMS should require that reconciliation account for dollar impact, not only aggregate percentages.

Reconciliation process. Reconciliation typically occurs after the plan year closes: the PBM proposes a true-up under the agreement, and the pharmacy or PSAO has a prescribed period to accept or dispute it before any payment is made. CMS should require that the PBM deliver claim-level reconciliation data, that the pharmacy (and not only its PSAO) receive a reasonable period to review and dispute the calculation, and that undisputed amounts be paid promptly. Companies reported review windows of 20 to 45 days, and one reported that, although its PBMs are contractually required to provide reconciliation reporting, reports and payments sometimes require repeated requests and follow-ups.[71] Reimbursement under a guarantee should also be reasonably consistent throughout the plan year. Members report contracts under which reimbursement runs well below the guaranteed rate for most of the year and then rises sharply in the final months, or is adjusted as beneficiaries move through benefit phases, so that the annual target is met while the pharmacy absorbs months of underpayment. CMS should require PBMs to provide at least monthly effective-rate reporting, calculated on the same basis the PBM will use at reconciliation, and should prohibit payment patterns that defer a disproportionate share of guaranteed reimbursement to the end of the measurement period. CMS should also limit the float that a guarantee can create by capping

[69] *See* Hung & Dickson, *supra* note 45, at 1328 tbl. 1 n.b (explaining that GERs and BERs "are trued up at the end of a period and do not necessarily represent the amount that is paid to the pharmacy for a given prescription"); PBM Exposé, *supra* note 17, at 75–76.

[70] FMI 2026 Part D Survey, *supra* note 9.

[71] FMI 2026 Part D Survey, *supra* note 9.

how far below the guaranteed rate a PBM may underpay before it must true up, so that crossing that threshold triggers an earlier true-up, and by requiring that reconciliation occur at least quarterly, with undisputed amounts paid within a defined period and with interest on amounts paid late. PBMs should also be barred from recovering amounts paid above a guarantee indirectly, through prior-period adjustments, audits, or offsets that the contract would not otherwise permit.

Sponsor-side and pharmacy-side treatment. A PBM may treat effective rates differently in its contract with the plan sponsor than in its contract with the pharmacy. For example, a PBM could guarantee the plan sponsor an aggregate rate of AWP minus 85 percent on generics while truing up pharmacies at a narrower level that lets it claw back additional amounts, so that pharmacies are ultimately paid less than the sponsor paid.[72] The resulting spread is difficult to detect because it does not arise at the claim level. Effective-rate true-ups also may not appear on prescription drug event ("PDE") data, and may surface only in a sponsor's DIR reporting.[73] CMS should require sponsors to verify, and disclose to CMS, any differences between the effective-rate methodology applied to network pharmacies and the methodology in the sponsor's PBM contract, including drug definitions, level of measurement, inclusions, and exclusions. CMS should also require sponsors to report effective-rate reconciliation amounts at the pharmacy level, so that CMS can identify and address cases in which pharmacy-side methodologies result in materially lower aggregate payment to pharmacies than the sponsor paid. Upward true-ups are reported only as DIR by design: under the CY 2023 rule, the negotiated price on the PDE must reflect the lowest possible reimbursement, and any later payment above that amount is reported as negative DIR after the year closes, so pharmacy-level reconciliation amounts are not visible in PDE data.[74]

State laws that prohibit undisclosed post-adjudication fees, prohibit negative effective-rate adjustments, or require measurement at the claim or pharmacy level are useful models, but they cannot themselves protect Part D claims, because Part D's express preemption provision supersedes state law with respect to Part D plans, and courts have applied it to state laws governing PBM pharmacy networks and reimbursement. Federal standards are the only way to extend comparable protections to Part D.[75]

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[72] *See* Calabrese, *supra* note 66, at 10–11 (describing PBMs "paying their contracted network pharmacies at one rate and then charging their clients a higher rate, pocketing the difference," including by reimbursing pharmacies from one MAC list while charging plan sponsors from another); PBM Exposé, *supra* note 17, at 73–74.

[73] *See* Ctrs. for Medicare & Medicaid Servs., Medicare Part D – Direct and Indirect Remuneration (DIR) (Fact Sheet) (Jan. 19, 2017), https://www.cms.gov/newsroom/fact-sheets/medicare-part-d-direct-indirect-remuneration-dir (explaining that the price reported on the PDE record is the amount paid to the pharmacy at the point of sale, while "[f]ees, payments, or payment adjustments made after the point-of-sale" must be reported to CMS as DIR); Medicare Payment Advisory Comm'n, Generic Drug Pricing Under Part D 5 (Apr. 2024) (preliminary staff presentation), https://www.medpac.gov/wp-content/uploads/2023/10/Generic-prices-Part-D-April-2024-SEC.pdf (noting that ingredient cost and dispensing fee "are available on the prescription drug event data," while post sale pharmacy fees are "reported to CMS but not publicly available").

[74] *See* sources cited *supra* note 53; Medicare Payment Advisory Comm'n, *supra* note 73, at 5 ("As of January 1, 2024, the pharmacy reimbursement at the point of sale (POS) must reflect the lowest possible payment a pharmacy may receive for a given drug, including pharmacy fees."); 87 Fed. Reg. at 27842 (difference between the negotiated price reported on the PDE and a higher final payment to the pharmacy "would need to be reported as negative DIR").

[75] *See* sources cited *supra* note 60; 42 U.S.C. §§ 1395w-26(b)(3), 1395w-112(g); *Pharm. Care Mgmt. Ass'n v. Mulready*, 78 F.4th 1183, 1206 (10th Cir. 2023) (Part D preemption clause is "akin to field preemption"), *cert. denied*, No. 23-1213 (U.S.

Effective rates without oversight. Effective rate guarantees that are not subject to standards and oversight of this kind should not be considered reasonable and relevant. If CMS concludes that it cannot effectively regulate effective-rate reconciliation to that degree, FMI asks CMS to deem effective-rate reconciliation not reasonable and relevant, provided that point-of-sale reimbursement is tied to a transparent, published, non-MAC benchmark, such as NADAC, plus a reasonable dispensing fee, so that eliminating effective rates does not simply return pharmacies to unpredictable MAC pricing. If a pharmacy is paid accurately at the contracted rate, including a reasonable dispensing fee, the justification for an after-the-fact reconciliation regime largely disappears. CMS should also consider whether brand effective rate guarantees serve any legitimate purpose in Part D, where brand reimbursement already tracks published pricing benchmarks.

> **CMS seeks information on:** *The negotiability of aggregate guarantee methodologies and their parameters, and the relative leverage Part D plan sponsors, PBMs, and pharmacies have in negotiations over contract terms and network participation.*

FMI Response. Guarantee terms, thresholds, and reconciliation timelines are largely set by the PBM, and leverage depends heavily on size and contracting mode. In the 2026 Part D Survey, all companies that described guarantee terms as presented on a take-it-or-leave-it basis operate 10 to 199 pharmacies and contract in part through a PSAO; larger companies contracting directly generally reported that some negotiation is possible, and only one described terms as genuinely negotiable. Although most companies reported having negotiated at least one guarantee parameter at some point, none of the companies answering could decline a modified term and remain in the network for the rest of the plan year: several said they could not, all of them PSAO users, and the rest had never tested the point.[76] Because a small number of vertically integrated PBMs control the large majority of prescription volume, and because many pharmacies cannot realistically reject terms given the number of covered lives administered by a single PBM, exclusion from even one network can be financially untenable; pharmacies that challenge reimbursement at the contracting stage risk exclusion, and those that raise concerns after contracting risk termination without cause.[77] Take-it-or-leave-it contracting has left many pharmacies, particularly smaller ones, with no meaningful ability to negotiate or dispute egregious terms.

Members also report that some PBMs and PSAOs have sought to change effective-rate guarantees: several companies reported that, since 2023, a PBM or PSAO had proposed to eliminate, narrow, or replace a guarantee, including by introducing a brand effective-rate, by replacing a guarantee with a benchmark-based reimbursement floor, or by reducing reimbursement under an existing guarantee; others reported no such proposal or were unsure.[78] Members report that, as generic effective-rate targets approach pharmacies' actual acquisition costs, the guarantees have become

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June 30, 2025); *Pharm. Care Mgmt. Ass'n v. Rutledge*, 891 F.3d 1109, 1113 (8th Cir. 2018) (state MAC law preempted as applied to Part D plans), *rev'd on other grounds*, 592 U.S. 80 (2020); *cf. Pharm. Care Mgmt. Ass'n v. Wehbi*, 18 F.4th 956, 971 (8th Cir. 2021) (Part D preempts state laws that regulate the same subject matter as a Part D standard).

[76] FMI 2026 Part D Survey, *supra* note 9.

[77] PBM Exposé, *supra* note 17, at 8, 11, 50.

[78] FMI 2026 Part D Survey, *supra* note 9.

harder for PBMs to model, which helps explain the large overpayment and underpayment swings members experience. Until CMS's standards take effect, CMS should treat any mid-contract PBM proposal to narrow or replace an effective-rate guarantee (for example, through new exclusions, a different level of measurement, or a shift to MAC pricing) as a material change subject to the review-period and affirmative-acceptance protections described in Section III.B. This protection is consistent with FMI's request that CMS deem unregulated effective-rate reconciliation not reasonable and relevant: if guarantees are eliminated, it should be by CMS standard, with point-of-sale reimbursement tied to a transparent benchmark, not by unilateral PBM amendment.

> **CMS seeks information on:** *The extent to which a pharmacy's Part D reimbursement rates are set or adjusted in relation to its commercial reimbursement rates, including whether any guarantee covers both Part D and commercial reimbursement.*

FMI Response. CMS should require that Part D reimbursement terms be stated and reconciled on a standalone basis. A single effective-rate target across Part D and commercial lines of business makes it impossible to determine what the pharmacy was actually paid for Part D claims, and permits "overpayments" on one line to offset "underpayments" on the other. Companies operating roughly 40 percent of responding pharmacies reported that at least one of their guarantees is blended across Part D and commercial or other lines of business (and another gave a mixed answer), most of those answering said overpayments on one line offset underpayments on the other, and members report that PBMs can offset concessions in one line of business through fees or terms in another. A federal court has found that one PBM's use of "overall" guarantees that combined Part D and commercial claims allowed Part D overpayments to offset commercial underpayments, so that Part D price reports did not reflect the amounts the PBM actually paid.[79] CMS should prohibit any aggregation of Part D claims with claims from other lines of business for guarantee, fee, or reconciliation purposes.

Within Part D, CMS should require transparent disclosure of the level at which each guarantee is measured and reconciled, with safeguards against inappropriate offsets where one guarantee covers more than one Part D plan or network, as discussed above. Companies operating more than three-quarters of responding pharmacies reported that, where one guarantee covers more than one Part D plan or network, overpayments in one are netted against shortfalls in another.[80]

> **CMS seeks information on:** *Whether CMS should establish reimbursement methodologies or rates as part of the standards for reasonable and relevant pharmacy contract terms.*

FMI Response. FMI recognizes the Part D noninterference clause ("NIC"), which bars CMS from instituting a particular price structure for reimbursement of covered Part D drugs.[81] But CMS has

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[79] FMI 2026 Part D Survey, *supra* note 9; *Behnke*, *supra* note 61, slip op. at 25–26, 100 (E.D. Pa. June 25, 2025), ECF No. 499, *appeal docketed*, No. 25-2820 (3d Cir.).

[80] FMI 2026 Part D Survey, *supra* note 9.

[81] 42 U.S.C. § 1395w-111(i), https://uscode.house.gov/view.xhtml?req=granuleid:USC-prelim-title42-section1395w-111&num=0&edition=prelim; *see also* Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs, 79 Fed. Reg. 1918, 1971 (proposed Jan. 10,

explained that the clause does not prevent it from requiring the inclusion of contract terms necessary to implement the statute.[82] Section 6223 provides that the standards apply "notwithstanding any other provision of law,"[83] and Congress directed CMS to examine whether reimbursement and dispensing fees "sufficiently cover" pharmacies' costs.[84] FMI therefore asks CMS to adopt methodology-based standards, not specific prices, including that: (i) ingredient-cost reimbursement be tied to a transparent, objective benchmark; (ii) dispensing fees independently cover the reasonable cost of dispensing; (iii) reimbursement be predictable at the point of sale, with clearly defined safeguards for any subsequent reconciliation; (iv) reimbursement that fails to cover acquisition and reasonable dispensing costs, or that leaves no reasonable margin to sustain operations, is not reasonable; and (v) non-dispensing clinical services, such as vaccine administration and test-and-treat, be paid separately from dispensing, with vaccine administration fees benchmarked to Medicare Part B.[85]

The NIC presents no obstacle to such standards for several further reasons.

First, Section 6223's "notwithstanding any other provision of law" clause is a deliberate override; the Supreme Court has explained that such a clause signals that the specific directive controls over any conflicting provision.[86] *Second*, Section 6223 is both the more specific and the later-enacted provision, and a specific statute is not submerged by a general one.[87] *Third*, the NIC was enacted "to promote competition" and to prevent government price-fixing,[88] and CMS has proposed to

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2014) (quoting the clause) (proposal not finalized), https://www.federalregister.gov/documents/2014/01/10/2013-31497/medicare-program-contract-year-2015-policy-and-technical-changes-to-the-medicare-advantage-and-the.

[82] *See* 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, 16590 (Apr. 16, 2018) (stating that the noninterference clause "does not prohibit us from establishing or clarifying regulatory requirements to implement the any willing pharmacy requirement"), https://www.federalregister.gov/d/2018-07179.

[83] Pub. L. No. 119-75, *supra* note 2, § 6223(a) (amending 42 U.S.C. § 1395w-104(b)(1)(A)); *see also* RFI, *supra* note 1, at 60568.

[84] RFI, *supra* note 1, at 60569.

[85] *See* 42 U.S.C. § 1395w-104(b)(1)(A); 42 C.F.R. § 423.505(b)(18) (2025); Medicare Prescription Drug Benefit Manual, *supra* note 49, ch. 5, §§ 50.3, 50.8.1; *see also* Ctrs. for Medicare & Medicaid Servs., HPMS Memorandum, Compliance with Any Willing Pharmacy Requirements (Aug. 13, 2015); FMI July 2026 Comments, *supra* note 6, at 12–13; PBM Exposé, *supra* note 17, at 27, 51 (noting CMS's recognition that unreasonably low reimbursement is inconsistent with the federal any willing provider requirement).

[86] *See 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. . . . [T]he Courts of Appeals generally have 'interpreted similar "notwithstanding" language . . . to supersede all other laws . . . .'" (citations omitted)).

[87] *See Morton v. Mancari*, 417 U.S. 535, 550–51 (1974) ("Where there is no clear intention otherwise, a specific statute will not be controlled or nullified by a general one, regardless of the priority of enactment.").

[88] 42 U.S.C. § 1395w-111(i) ("In order to promote competition under this part and in carrying out this part . . . ."); *see 83 Fed. Reg. at 16590* (explaining that, "within the limits of our authority, we also have a duty to implement and enforce other statutory requirements to promote competition," including by "minimizing barriers to entry," and 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"), https://www.federalregister.gov/d/2018-07179; see also 79 Fed. Reg. at 1969, *supra* note 81 (proposed rule) (reading the

interpret its negotiation prong "to pertain to discussions either between prescription drug manufacturers and pharmacies, or between prescription drug manufacturers and Part D sponsors," not to plan-pharmacy contracting.[89] *Fourth*, CMS has repeatedly regulated the structure of pharmacy reimbursement without treating the NIC as a bar: in its Contract Year 2019 rule, CMS explained that the any willing pharmacy requirement is statutory and that the NIC does not prohibit CMS from clarifying requirements to implement it,[90] and its Contract Year 2023 rule required pharmacy price concessions to be included in the negotiated price at the point of sale.[91] A rule that dictates a dollar amount is price-setting; a rule that requires terms to rest on a verifiable, objective benchmark and to permit meaningful, not merely nominal, participation is structural regulation that the NIC does not reach. CMS has long instructed that sponsors must offer reasonable and relevant reimbursement terms.[92]

> **CMS seeks information on:** *The relationship between reimbursement and "pharmacy deserts."*

FMI Response. Below-cost reimbursement can contribute to pharmacy closures and reduced beneficiary access, and contracting practices that divert prescriptions to PBM-affiliated pharmacies can compound those pressures.[93] In the 2025 Supermarket Survey, roughly 70 percent of respondents had closed pharmacies in the prior two years, with closures reported in urban, rural, underserved, and low-income areas.[94] Among respondents that closed pharmacies, not being profitable was the most common primary reason (36 percent), followed by entire-store closures and PBM practices or carve-outs (19 percent each). The survey also documented limited profitability: 74 percent of companies rated their pharmacy business not very or not at all profitable, and only 26 percent reported that most of their pharmacies are profitable. These findings concern members' pharmacy operations overall, not Part D alone.[95] The 2026 Part D Survey shows that the pressure continues. Although all companies that answered reported higher prescription volume in 2025 than in 2024, companies operating nearly 80 percent of responding pharmacies reported lower pharmacy profitability, and more than half reported that some of their pharmacies are at risk of closing in the next two years, with Part D or PBM reimbursement contributing to that risk. One member confirmed it exited the specialty market as a result of below-cost reimbursement.

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clause's opening words to impose "both a duty to act," namely "to promote competition in the private market for Part D drugs," and "a duty to refrain from acting").

[89] 79 Fed. Reg. 29844, 29874–76 (May 2014). Although CMS did not finalize that proposal, it stated that the proposed reading reflects the interpretation under which it has operated the Part D program since before the program began. See 79 Fed. Reg. at 1971, *supra* note 81 (proposing to interpret the negotiation prong "to pertain" to discussions between manufacturers and pharmacies or between manufacturers and Part D sponsors) (proposal not finalized).

[90] 83 Fed. Reg. at 16590, https://www.govinfo.gov/app/details/FR-2018-04-16/2018-07179.

[91] *See* 87 Fed. Reg. at 27840 (stating that such action does not violate the Part D noninterference clause).

[92] 42 C.F.R. § 423.505(b)(18) (2025), https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-B/part-423; *Medicare Prescription Drug Benefit Manual*, *supra* note 49, ch. 5, § 50.3 (sponsors "must offer reasonable and relevant reimbursement terms for all Part D drugs as required by 42 CFR 423.505(b)(18)").

[93] PBM Exposé, *supra* note 17, at 48.

[94] FMI CMS Presentation, *supra* note 6, at 5–6; FMI 2025 Survey Report, *supra* note 6, at slides 11–12.

[95] FMI 2025 Survey Report, *supra* note 6, at slides 13, 29.

B. Current Contracting Practices

> **CMS seeks information on:** *The factors CMS should consider in determining the reasonableness and relevance of contract terms and conditions.*

FMI Response. FMI recommends that CMS evaluate standard terms, individually and collectively, against five objective factors, as applicable to the provision being assessed: (1) Relevance: whether the term bears a rational relationship to the pharmacy's type and service model, the drugs it actually dispenses, and a legitimate Part D purpose (access, safety, quality, or program integrity), consistent with Section 6223's purpose of assuring pharmacy access and choice, with ownership or affiliation never a relevant basis for a term, and, for any performance measure, whether the measure is evidence-based and fits the drugs and patients the pharmacy serves; (2) Sustainability: whether reimbursement is adequate, measured at the claim level rather than across a group of claims, when assessed against verifiable acquisition costs, reasonable dispensing costs, and a reasonable margin, with transparent treatment of fees and adjustments; (3) Transparency and predictability: whether all reimbursement terms are disclosed at the time of offer; whether the minimum payment the pharmacy can rely on is known at the point of sale, with any permitted subsequent reconciliation fully disclosed; whether material changes require advance notice, a reasonable review period, and affirmative acceptance; and whether the contract avoids waivers of substantial legal rights and retroactive non-audit changes; (4) Parity and competitive neutrality: whether similarly situated pharmacies, including PBM-affiliated pharmacies, receive equal rates, terms, and administrative requirements; and (5) Mutuality and due process: whether the contract provides reciprocal notice and termination rights; dispute rights on equal footing with the sponsor's or PBM's self-help remedies (offset, recoupment, payment suspension, and termination); neutral review before termination or significant recoupment; proportionate remedies; access to dispute resolution free of unreasonably short dispute windows or other limits on a pharmacy's ability to raise disputes; and no bar on communicating with CMS. A term that fails an applicable factor is not reasonable and relevant, and a group of terms should be considered unreasonable if their combined effect circumvents these protections. Because sponsors and their PBMs hold the relevant contract and pricing information, the sponsor should bear the burden of demonstrating compliance.

CMS should also expressly prohibit contract provisions, reimbursement methodologies, administrative requirements, network classifications, and related arrangements that have the purpose or practical effect of circumventing the reasonable and relevant standards. Standard terms should not condition Part D network participation on participation in Medicaid or other lines of business. Compliance should be assessed on the totality of the pharmacy's economic and operational obligations, including the cumulative effect of fees, reimbursement adjustments, performance requirements, credentialing conditions, and participation restrictions. A term should not be deemed reasonable and relevant merely because it is uniformly stated, nominally voluntary, or characterized as an alternative contracting arrangement, and CMS should evaluate whether it imposes disproportionate burdens on unaffiliated pharmacies, restricts meaningful network participation, or undermines beneficiary access and choice. The risk is not only that PBMs will violate the standards, but that they will use the standards' own terms to reach the same results: a requirement for transparent acquisition costs can become a demand for proprietary purchasing

information;[96] a reasonable dispensing fee can become a nominal fee justified by claimed ingredient-cost margins; equal network terms can become a standardized contract that only affiliated pharmacies can economically satisfy; quality standards can become financial penalties based on measures the pharmacy cannot control; and claim-level transparency can become an aggregate guarantee with exclusions and delayed reconciliation.

These factors are consistent with the long-recognized principle that any willing pharmacy protections are hollow if a PBM can satisfy them by offering terms designed to be rejected. Pharmacies also need the ability to enforce contract terms short of termination: PBMs can enforce terms privately through offset, recoupment, payment suspension, and termination, while pharmacies generally are limited to arbitration or litigation.[97] As FMI explained in the Section 6224 record, a term is not reasonable merely because the reimbursement it sets covers a pharmacy's invoice cost on the day of dispensing; adequacy must be measured against the pharmacy's ability to sustain its operations and reinvest over time.[98] Member experience confirms the need for factor (5): most companies reported that their Part D contracts include confidentiality terms that restrict sharing contract terms or disputes with CMS, and only one company reported that any dispute is decided by someone independent of the PBM.[99]

> **CMS seeks information on:** *How Part D plan sponsors determine whether pharmacies are "similarly situated," what criteria sponsors use, and how sponsors ensure consistent application.*

FMI Response. In FMI members' experience, the criteria PBMs use to classify pharmacies are not disclosed. CMS clarified in 2005 that terms may vary by geography or pharmacy type provided that all similarly situated pharmacies are offered the same standard terms.[100] CMS should require

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[96] Cf. Fed. Trade Comm'n, Decision and Order as to Respondents Caremark Rx, L.L.C. and Zinc Health Services, LLC § VIII.A, at 9, Docket No. 9437 (proposed July 14, 2026), https://www.ftc.gov/system/files/ftc_gov/pdf/CaremarkandZinc-DecisionandOrder.pdf (requiring Caremark's standard offering to compensate each retail community pharmacy "based upon its actual cost of acquiring prescription drugs plus a dispensing fee so long as" the pharmacy "provides to Respondent on a quarterly basis the data necessary and sufficient to validate its cost of acquiring prescription drugs," and otherwise permitting Caremark to approximate that cost); id. at 5 (limiting "Retail Community Pharmacy" to a pharmacy business with "three or fewer retail store locations"); id. at 4–5 (excluding Medicare from the definitions of "Member" and "Plan Sponsor"); see also Caremark and Zinc Health Services; Analysis of Proposed Agreement Containing Consent Order To Aid Public Comment, 91 Fed. Reg. 50535 (Aug. 5, 2026) (stating that the Commission accepted the consent agreement "subject to final approval"), https://www.federalregister.gov/documents/2026/08/05/2026-15913/caremark-and-zinc-health-services-analysis-of-proposed-agreement-containing-consent-order-to-aid; Express Scripts, Inc., et al.; Analysis of Agreement Containing Consent Order To Aid Public Comment, 91 Fed. Reg. 6640, 6643 (Feb. 12, 2026) [hereinafter ESI Consent Order Analysis], https://www.federalregister.gov/documents/2026/02/12/2026-02844/express-scripts-inc-et-al-analysis-of-agreement-containing-consent-order-to-aid-public-comment (describing the parallel Section VIII standard offering to retail community pharmacies in the Express Scripts proposed order).

[97] PBM Exposé, *supra* note 17, at 28, 39–40, 47.

[98] FMI July 2026 Comments, *supra* note 6, at 12.

[99] FMI 2026 Part D Survey, *supra* note 9.

[100] Medicare Program; Medicare Prescription Drug Benefit, 70 Fed. Reg. 4194, 4254 (Jan. 28, 2005), https://www.federalregister.gov/documents/2005/01/28/05-1321/medicare-program-medicare-prescription-drug-benefit; RFI, *supra* note 1, at 60568.

sponsors to publish the objective criteria (e.g., licensure, dispensing capability, accreditation, hours, and services) used to define each class of similarly situated pharmacies, and should provide that common ownership with the PBM or sponsor is never a permissible basis for classification. Most companies responding to the 2026 Part D Survey reported that PBMs never disclose the criteria used to place their pharmacies in a contract class or tier, and several reported being offered different terms than PBM-affiliated pharmacies with comparable capabilities. One company reported being told that grocery pharmacies are placed in a lower reimbursement tier because they can make up lower reimbursement through PBM-driven store traffic.[101] Reimbursement premised on cross-subsidy from grocery sales is not reasonable or relevant to the pharmacy services being purchased.

> **CMS seeks information on:** *Whether any willing pharmacy terms are offered for preferred networks as well as non-preferred networks; how "similarly situated" is determined for specialty purposes; and the extent to which specialty designations overlap with common ownership between the PBM and the designated pharmacy.*

FMI Response. Preferred and narrow network structures route Part D beneficiaries away from supermarket pharmacies and toward PBM-affiliated or mail-order pharmacies.[102] Network-design tools (restrictive drug designations, accreditation and credentialing requirements unrelated to the drug being dispensed, and lengthy credentialing delays) can also be used to carve drugs out of retail dispensing altogether.[103] Current CMS policy treats standard terms and conditions as a floor and permits sponsors to require additional terms for preferred status, so FMI's recommendation would establish a new protection rather than restate an existing requirement.[104] FMI recommends that CMS require: (i) that preferred-network terms be offered on the same terms to every similarly situated pharmacy willing to accept them, based on published, objective criteria and never on common ownership, so that any pharmacy that meets those criteria and accepts those terms may join the preferred network; (ii) that any designation used to restrict a drug from retail network pharmacies be based on objective, published criteria tied to the handling requirements of the specific drug, and not on common ownership; and (iii) firm deadlines for credentialing decisions. CMS's existing guidance already bars sponsors from requiring a network pharmacy to qualify as a "specialty" pharmacy to dispense a drug it can appropriately dispense, and from using "unreasonably low reimbursement rates for certain 'specialty' drugs" to subvert access; the standards should codify both principles.[105]

FMI further recommends that CMS adopt an objective, functional definition of a specialty pharmacy based on therapy-specific handling, monitoring, patient support, and applicable accreditation; separate pharmacy designation from drug designation and from manufacturer distribution restrictions, giving qualified pharmacies equal access on equivalent terms; preserve local pickup of

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[101] FMI 2026 Part D Survey, *supra* note 9.

[102] *See* PBM Exposé, *supra* note 17, at 29–31, 37–38.

[103] PBM Exposé, *supra* note 17, at 30, 37.

[104] 83 Fed. Reg. at 16596–97.

[105] Medicare Prescription Drug Benefit Manual, *supra* note 49, ch. 5, § 50.3 (sponsors "must offer reasonable and relevant reimbursement terms for all Part D drugs").

specialty drugs where clinically appropriate, without requiring a pharmacy that serves only as a pickup location for a drug dispensed by a qualified specialty pharmacy to meet the dispensing pharmacy's specialty standards, such as accreditation; and require transparency for limited-distribution restrictions, identifying who imposes each restriction (manufacturer, sponsor, or PBM), the affected products, and its scope, duration, and justification. Companies operating roughly 85 percent of responding pharmacies reported being denied or excluded from a Part D preferred network they asked to join, and companies reported that preferred participation typically requires accepting reimbursement about 10 to 300 basis points lower (one reported that preferred and broad-network rates are now at parity); most of those that said below-cost rates vary by network said preferred-network reimbursement is lower.[106]

> **CMS seeks information on:** *The use of provider manuals, policy bulletins, or other communications to modify standard contract terms outside of formal amendment; and the extent to which financial terms are contained in documents other than the executed contract.*

FMI Response. Provider manuals that PBMs may unilaterally amend through policy bulletins or other communications are routinely incorporated by reference into pharmacy contracts and used to impose new obligations and recoupment grounds without negotiation. One national PBM's manual, for example, provides that a pharmacy that submits a claim after the effective date of any manual update has "accepted" the update, which then becomes "part of the Agreement."[107] Courts have enforced such one-sided contracts according to their literal terms, even where the PBM's conduct harmed the pharmacy.[108] CMS should provide that a term affecting reimbursement, audit, recoupment, or termination is not reasonable unless it appears in the executed contract or a rate sheet expressly accepted by the pharmacy, and that a provider manual may not impose new material obligations without the same notice and affirmative-acceptance protections applicable to contract amendments. CMS should also distinguish routine operational updates from discretionary changes, and provide that discretionary mid-year changes to reimbursement take effect no earlier than the next plan year, except as required by law. Most companies responding to the 2026 Part D Survey reported that a provider-manual or policy change imposed a new obligation or recoupment

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[106] FMI 2026 Part D Survey, *supra* note 9.

[107] Optum Rx, *Pharmacy Provider Manual 2026*, at 3 (4th ed., ver. 4.1) [hereinafter Optum Rx Manual], https://business.optum.com/content/dam/noindex-resources/business/support-documents/manuals-guides/optum-rx-pharmacy-provider-manual.pdf.

[108] *See Trone Health Servs., Inc. v. Express Scripts Holding Co.*, 974 F.3d 845, 854–55 (8th Cir. 2020) (affirming dismissal of retail pharmacies' claims challenging the PBM's use of customer information submitted with pharmacy claims to fill refills through its own mail-order pharmacy, because the parties' agreements "give [the PBM] access to the Pharmacies' customer information and do not prevent its use for mail-order service dispensing"), *aff'g* No. 4:18-CV-467 RLW, 2019 WL 1207866, at *4–5 (E.D. Mo. Mar. 14, 2019); PBM Exposé, *supra* note 17, at 45–46; *see also Life Star Pharmacy, Inc. v. Express Scripts, Inc.*, No. 4:23CV186 JAR, 2024 U.S. Dist. LEXIS 36750, at *4–11, 2024 WL 940365 (E.D. Mo. Mar. 4, 2024) (dismissing pharmacy's contract claim premised on Part D any willing pharmacy requirements because the provider manual's bare citation to 42 C.F.R. § 423.505(i) did not incorporate them), *modified on reconsideration*, 2025 U.S. Dist. LEXIS 21551 (E.D. Mo. Feb. 5, 2025).

ground without a formal amendment, some reporting more than ten such changes in two years, and several reported encountering side letters or financial terms outside the executed contract.[109]

> **CMS seeks information on:** *The role and impact of PBMs, pharmacy services administrative organizations ("PSAOs"), and other entities on the Part D pharmacy contracting process.*

FMI Response. Members use materially different PSAO arrangements. More than half of the responding companies contract through a PSAO for part of their Part D business, all of them companies with fewer than 200 pharmacies; some said they use a PSAO because no direct contract was offered or to reach networks they could not join directly, and none reported always seeing material PSAO-negotiated terms before they take effect.[110] PSAOs can be useful, but PBMs have used retroactive contracts with PSAOs to impose effective-rate terms without individual pharmacies' knowledge or consent.[111] Protections CMS should consider include: (a) disclosure of PSAO-negotiated material terms to each participating pharmacy; (b) preservation of each pharmacy's direct contract, appeal, and dispute rights; and (c) pass-through of any effective-rate true-up paid to a PSAO based on each pharmacy's own claims, with claim-level visibility into the calculation.

PSAOs also handle effective-rate agreements very differently. True-up payments made to a PSAO may be passed through to member pharmacies in full, allocated using a pooled formula, or partly retained, and disputes often arise over when a pharmacy joined the PSAO and which claims are counted.[112] Responding PSAO users reported each of these experiences: three reported that true-ups are passed through in full based on their own claims, one that true-ups are allocated using a pooled formula, and four that they cannot see how their PSAO calculated their share.[113]

> **CMS seeks information on:** *Contract provisions that permit sponsors to recoup or suspend payment or terminate a pharmacy contract, the conditions necessary to invoke them, and whether an appeal process exists.*

FMI Response. Termination without cause, payment suspension absent a credible and supported allegation of fraud or another defined ground, and retaliatory or disproportionate suspension or recoupment are not reasonable or relevant terms of network participation. Legitimate recovery of substantiated improper payments should remain available, determined through the audit protections described in Section III.E (claim-level findings, an opportunity to cure, and independent appeal before recoupment). PBMs have terminated pharmacies without cause or on pretextual

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[109] FMI 2026 Part D Survey, *supra* note 9.

[110] FMI 2026 Part D Survey, *supra* note 9.

[111] PBM Exposé, *supra* note 17, at 75; *see generally Reports Show Pharmacy Middlemen Making Big Money In Other States*, The Columbus Dispatch (Mar. 14, 2019), https://www.dispatch.com/story/news/politics/elections/2019/03/14/reports-show-pharmacy-middlemen-making/5712954007/.

[112] *See* PBM Exposé, *supra* note 17, at 75.

[113] FMI 2026 Part D Survey, *supra* note 9.

bases, including after pharmacies raised concerns about reimbursement; have withheld payments to offset alleged overpayments; and have invoked unspecified "fraud, waste, and abuse" concerns to close networks to, and remove, dispensing providers.[114] Publicly available provider manuals show how broad these rights are. The 2026 Optum Rx manual permits the PBM to "immediately terminate or suspend" a pharmacy "pursuant to business needs, Client-specific network design," or for actions that, "in the opinion of Administrator," are "detrimental to the provider network(s)," including any attempt to "steer any client" to "enter into a direct agreement" with the pharmacy and any "communication(s)," including "contact with any third party, including any Client, Plan," that "disparages" the PBM.[115] The same manual bars pharmacies from contacting clients "for disputed issues," imposes penalties of "at a minimum of $5,000 per incident/per day" for disclosing confidential information to a client, permits payment suspension "for an indefinite period of time," and reserves "the exclusive right to create any custom networks, which may exclude" the pharmacy.[116] Other national PBM manuals contain comparable provisions. None of these grounds bears on patient safety or program integrity. In one recent case, a PBM terminated a pharmacy after reviewing 11 claims, relying on a provider-manual clause that made failure to collect copayments a material breach, and then argued that it could defend the termination on any ground, whether or not stated at the time.[117] CMS should require defined grounds for suspension or termination, written notice identifying the specific basis, and independent review before the action takes effect. Exceptions permitting immediate action should be narrowly defined and limited to imminent patient harm supported by evidence, loss of licensure or required registration, exclusion or preclusion that legally bars the sponsor from paying the pharmacy, or a credible allegation of fraud supported by evidence. Termination without cause should not be permitted in a Part D network that must be open to any willing pharmacy. A pharmacy, by contrast, should be able to leave a network on reasonable notice (for example, 90 days) rather than being locked into a multi-year term, because a pharmacy that cannot exit a contract has no practical leverage to negotiate it. In the 2026 Part D Survey, several companies reported that a PBM or plan had terminated, suspended payment to, or threatened to terminate one or more of their pharmacies since 2023; stated bases included termination without cause, "affiliation" with another pharmacy, clerical audit findings, and a plan's determination that patient access was sufficient without the company's pharmacies, which forced patients to change pharmacies mid-year. Every company that answered reported that at least some of its current Part D contracts permit termination without cause.[118]

> **CMS seeks information on:** *Acceptance of standard terms: review time, deemed acceptance or negative consent, completeness of reimbursement information at the time of offer, and mid-contract modifications.*

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[114] PBM Exposé, *supra* note 17, at 30–31, 50, 75–76.

[115] Optum Rx Manual, *supra* note 107, at 126–27.

[116] *Id.* at 108, 113, 128, 133.

[117] *Life Star Pharmacy, Inc. v. Express Scripts, Inc.*, No. 4:23CV186 JAR, 2025 U.S. Dist. LEXIS 53736, at *1–2, *8–9 (E.D. Mo. Mar. 24, 2025) (discovery order; no ruling on the merits).

[118] FMI 2026 Part D Survey, *supra* note 9.

FMI Response. FMI recommends that CMS require: (i) a minimum review period of at least 90 days for new standard terms and at least 60 days for material amendments; (ii) affirmative written acceptance, not deemed acceptance or negative consent, for any change affecting reimbursement, fees, performance measures, audit, or termination; (iii) delivery of every term that affects payment (including all rate sheets and effective-rate or performance terms) at the time of offer; (iv) no mid-year changes to reimbursement methodology other than benchmark-driven MAC updates, in particular, no unilateral mid-year reductions in reimbursement, which CMS can prohibit without setting any rate; and (v) a right to decline a modified term and remain in the network on the existing terms for the remainder of the plan year, with any proposed change open to negotiation for the following plan year. Without that right, notice, review-period, and affirmative-acceptance protections accomplish little, because a pharmacy that declines a change would simply lose its contract. CMS has itself raised minimum review periods, disclosure requirements, and affirmative acceptance as potential standards. Member experience shows why. Most responding companies reported 30 days or less to review material amendments, and more than half reported a change taking effect on 14 days' notice or less, retroactively, or immediately; nearly all reported that a contract or provider manual treats continued claim submission or silence as acceptance of a change, several reported that changes had been applied retroactively, some reported mid-year reimbursement reductions other than routine MAC updates, and none could decline a modified term and remain in the network (several said they could not, and the rest had never tested it). Fewer than half reported that they usually receive all five categories of payment terms (ingredient-cost methodology and MAC basis, dispensing fees, effective-rate targets, performance measures, and fee schedules) when a contract is offered. Most said they need at least 90 days to review and accept new terms each contracting cycle, and none said 30 days.[119]

> **CMS seeks information on:** *Whether a mechanism is provided to resolve disputes, its adequacy, and incentives that foster a level playing field.*

FMI Response. Dispute mechanisms in PBM contracts are typically controlled by the PBM, lack defined timelines, and are limited in scope. FMI recommends that CMS require a clearly outlined, timely dispute process for all payment and contract disputes; an independent decision-maker for disputes not resolved at the first level; defined resolution timeframes; and reporting of dispute volumes and outcomes to CMS. The process should include a dedicated, monitored email address and telephone number rather than reliance on a web portal alone; a tracking number and prompt acknowledgment of each dispute; a written response within 30 calendar days; and no recoupment or withholding of a disputed amount before review is completed, absent credible evidence of fraud or an immediate patient-safety concern. CMS should also require reporting of the number of disputes, response times, outcomes, and how long unresolved disputes remain open. FMI also asks CMS to clarify that whether a given term is "reasonable" or "relevant" may be raised in a contractual dispute between a pharmacy and a sponsor or PBM, and to prioritize CMS enforcement against sponsors that fail to comply with the standards, alongside the statutory allegation process discussed in Section III.H.[120] Because courts have held that the Part D any willing pharmacy

[119] FMI 2026 Part D Survey, *supra* note 9.

[120] *See* PBM Exposé, *supra* note 17, at 28–29, 39–40.

provisions create no private right of action and will not read them into a pharmacy contract that merely cites Part D regulations, CMS should also require standard contracts to incorporate the standards expressly.[121] Companies responding to the 2026 Part D Survey that tracked outcomes reported resolving 3 to 50 percent of their disputes in their favor, and one reported that resource constraints limit its ability to pursue disputes at all.[122]

C. Trends in Contract Terms and Conditions

> **CMS seeks information on:** *Reimbursement methodologies, payments to network pharmacies and payments from pharmacies to sponsors or PBMs (for example, network participation fees), performance-based payment models, and the complexity and transparency of terms.*

FMI Response. The trend over the past decade has been toward greater complexity and greater retrospective control by PBMs. Pharmacy DIR grew from $229 million in 2013 to an estimated $9.1 billion in 2019, and was frequently assessed as a percentage of list price months after dispensing.[123] More recently, in the 2025 Supermarket Survey, respondents reported that fees they characterized as DIR averaged 5 percent of total pharmacy sales over the prior 12 months (ranging from 0 to 25 percent). Because that survey did not define DIR fees or limit responses to Medicare Part D, this figure should not be read as a measure of current Part D DIR.[124] Although point-of-sale reform has changed how those concessions are reported, the underlying economic levers (effective-rate reconciliation, performance-based adjustments, network participation and credentialing fees, transaction fees, and audit-related fees) persist. This is the recapture risk FMI identified in 2022: that PBMs would offset lost DIR revenue through higher credentialing, transaction, and administrative fees.[125] FMI asks CMS to deem as not reasonable any fee charged to a pharmacy as a condition of network participation (including participation, credentialing, portal, and per-claim transaction fees) that does not compensate the PBM for an itemized service that the pharmacy has requested.[126] Nearly all of the companies that answered the fee questions in the 2026 Part D Survey

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[121] *Life Star*, 2024 U.S. Dist. LEXIS 36750, at *5–6, *8–11; *see supra* note 108.

[122] FMI 2026 Part D Survey, *supra* note 9.

[123] *See* Drug Channels Inst., *Pharmacy DIR Fees Hit a Record $9 Billion in 2019—That's 18% of Total Medicare Part D Rebates*, Drug Channels (Feb. 13, 2020), https://www.drugchannels.net/2020/02/pharmacy-dir-fees-hit-record-9-billion.html ("The net value of pharmacy price concessions has grown significantly, from $229 million in 2013 to an estimated $9.1 billion in 2019."; noting that these concessions "are collected from pharmacies after claim adjudication"); *see also* PBM Exposé, *supra* note 17, at 23, 27 (describing DIR fees as a percentage of a drug's list price assessed three to six months after dispensing and "tied to the list price of drugs").

[124] FMI 2025 Survey Report, *supra* note 6, at slide 15; *see also id.* at slide 16 (95% reporting that PBM practices, including "audits, DIR fees, [and] under-reimbursement," have a very negative impact).

[125] Letter from Leslie G. Sarasin, President & CEO, FMI – The Food Indus. Ass'n, to Chiquita Brooks-LaSure, Adm'r, Ctrs. for Medicare & Medicaid Servs. 2, 10 (Mar. 7, 2022) (re: Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs, CMS-4192-P) [*hereinafter* FMI 2022 Comments], https://www.reginfo.gov/public/do/eoDownloadDocument?eodoc=true&documentID=136142 (warning of "the possibility of higher administrative and credentialing fees imposed by PBMs to supplement income lost from pharmacy DIR"; expressing concern that members "will be subjected to enhanced credentialing fees, transactional fees, or other unforeseen fees").

[126] *See* FMI July 2026 Comments, *supra* note 6, at 8–9.

reported at least one condition-of-participation fee, including per-claim transaction fees of $0.05 to $0.42, technology or portal fees of up to 1 percent of total payment, enrollment fees of $500, recredentialing fees of $150 to $600 per pharmacy, and audit fees of $5 per audit, which one PBM charges even when the audited claims are not discrepant.[127]

Members also report that PBMs are creating new categories of fees and aggregating fees across market segments, so that a fee that does not apply in Part D is recovered elsewhere. CMS should define permissible terms precisely enough that PBMs cannot create new fees or charges through ambiguous contract language.

> **CMS seeks information on:** *Terms offered to pharmacies with multiple lines of business, terms for non-dispensing services, and impacts of the Inflation Reduction Act, including maximum fair prices (MFPs).*

FMI Response. Supermarket pharmacies provide immunizations, medication therapy management, point-of-care testing, and other services alongside dispensing, yet those services are frequently not reflected in Part D contract terms or performance measures. In the 2025 Supermarket Survey, every respondent offered vaccinations and 55 percent offered point-of-care testing, yet 71 percent of respondents that provide point-of-care test-to-treat services reported that none of those services are reimbursable by a PBM or third-party payer, and only 32 percent reported participating in a value-based program.[128] The 2026 Part D Survey shows the same gap in Part D: all responding companies provide immunizations and nearly all provide medication therapy management, yet only one company is paid under its Part D contract for in-person counseling, none of those answering is paid for adherence packaging, and only a minority are paid under the contract for medication therapy management. Members report that non-dispensing work, including statutorily required counseling, prior-authorization and coverage work, REMS compliance, and immunization administration, is often unpaid or paid below cost under Part D contracts, and one company reported that Part D immunization reimbursement is below that of Part B.[129] FMI asks CMS to require that non-dispensing clinical services, such as vaccine administration, test-and-treat, and medication therapy management, be governed by stand-alone service agreements and paid separately from dispensing, with vaccine administration payment benchmarked to Medicare Part B, and that payments for those services never count toward or offset any ingredient-cost or dispensing guarantee.

With respect to MFPs under the Medicare Drug Price Negotiation Program, manufacturers are responsible for effectuating the MFP refund. Sponsor contract terms should not compound the pharmacy's float or loss, for example through reduced dispensing fees on selected or non-selected drugs, delayed payment, or reimbursement less than the MFP plus a reasonable dispensing fee, and CMS should use its authority over manufacturers, including the 14-day prompt MFP payment window and the civil monetary penalties available under section 1197 of the Act, to ensure that

[127] FMI 2026 Part D Survey, *supra* note 9.

[128] FMI 2025 Survey Report, *supra* note 6, at slides 4, 26–27, 30.

[129] FMI 2026 Part D Survey, *supra* note 9.

pharmacies are made whole promptly for the difference between acquisition cost and the MFP.[130] The 2025 Supermarket Survey, fielded before the program took effect, bears out these concerns: 77 percent of respondents anticipated that negotiated pricing would decrease their reimbursement rates, 39 percent were undecided whether to continue stocking the selected drugs and 8 percent were considering not stocking them, 69 percent expected a negative effect on the long-term financial sustainability of their pharmacy operations, and none expected a positive effect. Members' principal concerns were the period during which pharmacies must float the difference between acquisition cost and the MFP and the lack of accountability for timely payment; their recommendations included a required prompt-pay timeframe "for the entirety of the process (From dispensing to manufacturer payment)."[131] Members' 2026 experience confirms these concerns. Nearly all companies reported receiving manufacturer refunds within 35 days of dispensing and one reported waiting 45 to 60 days, so pharmacies float the difference for weeks even when the process works as designed; companies operating roughly 85 percent of responding pharmacies reported that Part D reimbursement on selected drugs left them below acquisition cost for some period, some reported reduced dispensing fees on selected or non-selected drugs, and one reported that a PBM or plan attempted to add contract language allowing it to reconcile MFP claims against other Part D claims.[132] FMI also asks CMS to ensure that Part D contract terms do not shift to pharmacies the covered entity's responsibility for identifying 340B claims, or penalties for failing to do so.

> **CMS seeks information on:** *Trends related to the use of guarantees that utilize a single effective-rate target for both Part D and commercial lines of business.*

FMI Response. FMI refers CMS to its response in Section III.A above and recommends that Part D guarantees be stated and reconciled on a standalone basis.

D. Pharmacy Quality and Performance Measures

> **CMS seeks information on:** *How measures are incorporated into contracts, what measures are used, whether they are applied uniformly or vary by pharmacy type, whether they are validated or risk-adjusted, how often pharmacies receive performance data, and appeal processes.*

FMI Response. Performance-based programs historically have been used less to improve quality than to justify retrospective payment reductions. Providers have been measured on metrics they have no meaningful ability to influence, with no opportunity for upside, using metrics and scoring

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[130] 42 U.S.C. §§ 1320f-2(a)(3), 1320f-6(a) (manufacturer that fails to provide access to the MFP "to pharmacies, mail order services, and other dispensers" is subject to a civil monetary penalty equal to ten times the difference between the price made available and the MFP); Ctrs. for Medicare & Medicaid Servs., *Medicare Drug Price Negotiation Program: Final Guidance, Implementation of Sections 1191–1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price in 2026 and 2027* § 40.4 (Oct. 2024) (requiring manufacturers to transmit MFP refunds within 14 days).

[131] FMI 2025 Survey Report, *supra* note 6, at slides 35, 37, 40–42 (member responses).

[132] FMI 2026 Part D Survey, *supra* note 9.

methodologies that were not approved by CMS.[133] For supermarket pharmacies, measures calibrated to other dispensing models, and adherence measures that do not account for patients who also use mail-order or other channels, can penalize pharmacies for factors outside their control; drug holidays, clinical holds, and generic dispensing rate measures are further examples.[134] An arbitration panel has already found one PBM's specialty adherence metric not "reasonable and relevant" because it treated clinically necessary holds or discontinuation of toxic oncology drugs as nonadherence, and a federal court confirmed the panel's award returning more than $17 million in performance-based fees.[135] FMI recommends that any performance measure be: (i) relevant to the pharmacy's actual patient population and the drugs it dispenses; (ii) developed or endorsed by a recognized measure steward and, where aligned with Star Ratings, appropriately re-specified at the pharmacy level; (iii) risk-adjusted and subject to minimum denominator thresholds; (iv) applied uniformly to affiliated and unaffiliated pharmacies; (v) structured to permit upside only, with no downside financial risk; (vi) reported to pharmacies at least monthly at the patient and claim level; and (vii) subject to a timely appeal process.[136] Performance measures should also recognize the clinical services that supermarket pharmacies deliver alongside dispensing. Pharmacy performance should be incentivized, but failure to meet particular metrics should not result in financial penalties. The reasons some pharmacies struggle with adherence measures can often be attributed to factors outside the pharmacy's control, such as a patient's ability to pay for and receive the medication, and pharmacies operating in underserved communities should not be exposed to penalties that cut into already unsustainable margins. The 2026 Part D Survey shows that the shift to point-of-sale pricing has not resolved these problems. Fewer companies reported net reimbursement reductions from performance programs in 2025 than before 2024, but members report that PBMs moved former DIR value into lower base rates and that upside payments can be unattainable; only a small minority of companies receive patient- or claim-level performance data, and only a few reported an appeal process for performance results. Members also report that adherence measures count patients as nonadherent when they fill through cash or discount-card programs outside the Part D benefit.[137]

E. Auditing Practices

> **CMS seeks information on:** *The frequency and type of audits, transparency of audit and recoupment methodologies, common findings, the extent to which audits identify clerical issues rather than fraud, extrapolation, recoupment for minor errors, corrective action, and due process.*

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[133] PBM Exposé, *supra* note 17, at 23, 26–27.

[134] *See* FMI 2022 Comments, *supra* note 125, at 4–5, 9–10 (explaining that adherence is "unfairly measured in a manner that fails to account for . . . drug vacations and holds for adverse reactions," and that PBMs use "arbitrary metrics like formulary compliance and generic dispense rate, which penalize pharmacies for dispensing drugs as prescribed by a physician"); PBM Exposé, *supra* note 17, at 26–27 (describing how a physician-directed medication "hold" is "wrongly . . . measured by the PBM as a lack of adherence").

[135] *Caremark, L.L.C. v. N.Y. Cancer & Blood Specialists*, 740 F. Supp. 3d 340 (S.D.N.Y. 2024); Mem. & Order at 10–12, *Caremark, L.L.C. v. N.Y. Cancer & Blood Specialists*, No. 23 Civ. 8508 (NRB) (S.D.N.Y. July 15, 2024), ECF No. 70.

[136] *See* PBM Exposé, *supra* note 17, at 28.

[137] FMI 2026 Part D Survey, *supra* note 9.

FMI Response. Audits serve an important role in combating fraud, waste, and abuse, but that function is not served when audits are used to derive additional income from pharmacies that are compliant with state and federal law.[138] PBMs have used abusive audit practices, including demands for thousands of pages of documentation, truncated look-back periods for inventory audits, and provider-manual-based recoupment terms.[139] PBM audit and performance methodologies often penalize clerical and recordkeeping discrepancies, high dispensing volume, and factors beyond a pharmacy's control rather than actual dispensing accuracy.[140] CMS itself has recognized the problem: in 2013 it warned that "the growing practice of post-audit total claim recoupments from pharmacies" for "routine clerical errors" was "distorting Part D payment," but it declined to set uniform audit standards at that time.[141] Supermarket pharmacies have pressed a parallel concern, arguing that PBM performance metrics fail to account for "structural disadvantages inherent in supermarket pharmacy dispensing."[142]

Some states have responded by separating documentation deficiencies from real dispensing errors. Kentucky, for example, bars recoupment for clerical or recordkeeping errors unless there is proof of intent to commit fraud, an actual overpayment to the pharmacy, or "the wrong medication being dispensed to the patient," and requires that each pharmacy be audited "under the same standards and parameters as other similarly situated pharmacies." [143] West Virginia's Pharmacy

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[138] FMI July 2026 Comments, *supra* note 6, at 8–9.

[139] PBM Exposé, *supra* note 17, at 31 (describing PBM demands for "thousands of pages of documentation").

[140] *See* Letter from Joel Kurzman, Dir., State Gov't Affs., Nat'l Cmty. Pharmacists Ass'n, to Pharmacy Benefits Bureau, N.Y. State Dep't of Fin. Servs. 1 (Mar. 9, 2023) (responding to RFI PBM2022-07), https://ncpa.org/sites/default/files/2023-03/pbm2022-07-ncpa-comments-ny-rfi-audits.pdf (stating that PBMs "recoup vast sums of money for nothing more than harmless clerical errors where the correct medication was properly dispensed and no financial harm was incurred"); *What Are the Most Common PBM Audit Triggers in 2026 (And How Do You Avoid Them)?*, NimbleRx, https://www.nimblerx.com/articles/5-common-pbm-audit-triggers-in-2026-and-how-do-you-avoid-them (last visited Oct. 14, 2026) (identifying "unusually high prescription volumes" as a common audit trigger).

[141] Ctrs. for Medicare & Medicaid Servs., Announcement of Calendar Year (CY) 2014 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter 158–60 (Apr. 1, 2013), https://www.cms.gov/medicare/health-plans/medicareadvtgspecratestats/downloads/announcement2014.pdf (finding that sponsors were recouping "100% of prior payment on claims from pharmacies" for "routine clerical errors" rather than incorrect payment amounts, and noting pharmacies' request for "consistent standards across Part D plans regarding all PBM audit practices").

[142] FMI 2022 Comments, *supra* note 125, at 9–10 (arguing that metrics such as generic dispensing rate and formulary compliance "penalize supermarket pharmacies simply for dispensing the product prescribed and over which the pharmacy has no control"); *see also id.* at 2 (criticizing PBM metrics that "fail to accurately measure performance" and "unfairly rank pharmacies against each other despite impactful socio-economic and business model differences"); Peter Matz, *Why the FTC's PBM Industry Study Is a Big Deal for Supermarket Pharmacies*, FMI (June 24, 2022), https://www.fmi.org/blog/view/fmi-blog/2022/06/24/why-the-ftc-s-pbm-industry-study-is-a-big-deal-for-supermarket-pharmacies (identifying "[p]otentially unfair audits of supermarket pharmacies" as a concern raised with policymakers).

[143] Ky. Rev. Stat. Ann. § 304.17A-741(6), (15) (West 2026); *see also* Conn. Gen. Stat. § 38a-479iii(d)(1)(D), (e)(1) (2025) (generally prohibiting extrapolation and barring recoupment for clerical errors absent actual financial harm); Or. State Pharmacy Ass'n, *History of PBM Legislation in Oregon* 1, http://olis.oregonlegislature.gov/liz/2025R1/Downloads/CommitteeMeetingDocument/307181 (describing Oregon's 2013 audit limits "designed to prevent the unfair targeting of minor clerical or administrative errors where no true fraud, patient harm, or financial loss has occurred"); Mont. Code Ann. § 33-2-2005(4), (5), (7) (2025) (prohibiting the use of extrapolation, auditor compensation based on a percentage of the amount recovered, and recoupment based on the

Audit Integrity Act offers another useful model. Among other things, it requires auditors to accept paper or electronic signature logs documenting delivery; prohibits extrapolation unless federal requirements or federal plans require it; excludes dispensing fees from overpayment calculations unless the prescription was a misfill; bars any recoupment or other adjustment for a dispensed product unless the auditor finds fraud or intentional misrepresentation, dispensing in excess of the benefit design, a prescription not filled as ordered, or an actual overpayment; and limits any recovery to the actual financial harm. FMI does not ask CMS to adopt the West Virginia act wholesale, but these provisions show how audit standards can separate documentation issues from real dispensing errors and limit recovery to actual loss.[144]

FMI recommends that CMS adopt standards providing that: (i) recoupment is not permitted for clerical or recordkeeping errors that did not result in financial harm to the plan or enrollee, absent credible and demonstrable evidence of fraud; (ii) extrapolation is prohibited except where a statistically valid methodology is disclosed and there is evidence of a sustained pattern of improper billing; (iii) audits apply the contract terms and law in effect on the date of dispensing; (iv) inventory-reconciliation audits credit all documented lawful purchases and use a reasonable look-back period; (v) audit fees and auditor compensation may not be contingent on recovery amounts or calculated as a percentage of claims; (vi) pharmacies receive reasonable advance notice, limits on audit frequency and claim counts, claim-level findings, an opportunity to cure, and an independent appeal before recoupment; and (vii) PBM-affiliated pharmacies are audited under the same standards and with the same frequency.

These standards should apply to any review of pharmacy claims or records that can result in recoupment, however the PBM labels it, including post-adjudication document or claim reviews that a PBM designates as something other than an audit. One national PBM, for example, describes its daily post-adjudication "Prescription Validation Reviews" as "distinct from and not considered audits," even though it reserves the right to recoup payment for claims it later determines to be discrepant.[145] The 2026 Part D Survey confirms that audits target documentation rather than fraud. Responding companies reported more than 5,300 desk audits and 770 on-site audits in 2025, with one company reporting nearly 7,900 staff hours spent responding. Companies that quantified recoupments reported a combined $1.56 million in 2025 Part D audit recoupments, and every company that quantified it, together operating more than 1,300 pharmacies, reported that 90 to 100 percent of its recoupments arose from clerical or technical findings rather than fraud or patient

timing of drug purchases; subsection (7) added by 2025 Mont. Laws ch. 474 (H.B. 740), § 1, and terminates June 30, 2029), https://mca.legmt.gov/bills/MCA/title_0330/chapter_0020/part_0200/section_0050/0330-0020-0200-0050.html.

[144] *See* W. Va. Code §§ 33-51-2, 33-51-4(a)(6), (10)–(13) (2026), https://code.wvlegislature.gov/33-51-2; https://code.wvlegislature.gov/33-51-4. The act covers any audit of pharmacy records conducted by a PBM or other auditing entity, but it does not apply to investigative audits where fraud or other intentional misconduct is indicated and does not supersede federal audit requirements. *Id.* § 33-51-6, https://code.wvlegislature.gov/33-51-6. Like the other state laws discussed in these comments, it does not govern Part D plans because of Part D's express preemption provision, discussed in Section III.A; FMI cites it as a model for federal standards.

[145] *Cf.* W. Va. Code § 33-51-3 (2026), https://code.wvlegislature.gov/33-51-3 (defining "pharmacy audit" as an audit, conducted by or on behalf of an auditing entity, "of any records of a pharmacy" for drugs dispensed to a covered individual); Optum Rx Manual, *supra* note 107, at 105–06 (Prescription Validation Reviews); *id.* at 108 (reserving right to recoup payments for claims later determined to be discrepant).

harm; the most common findings were refill-too-soon, days'-supply, overbilled-quantity, and DAW-code discrepancies. All companies that answered, together operating more than 1,800 pharmacies, reported full-claim recoupments where the patient received the correct drug, most were never offered a corrective action plan instead of recoupment, more than half never had access to an independent appeal before recoupment, and inventory look-back periods ranged from 12 months to as long as ten years.[146] One company also observed that PBMs should not apply days'-supply standards stricter than those they use for their own mail-order pharmacies.

> **CMS seeks information on:** *Whether and how Part D plan sponsors audit or validate the claim-level pricing and DIR data they receive from PBMs, particularly where the PBM is affiliated with network pharmacies.*

FMI Response. FMI members are not party to sponsor-PBM agreements and cannot determine whether or how sponsors validate PBM-reported data. FMI notes, however, that DIR has historically been reported to CMS by drug rather than by pharmacy, making it impossible to match pharmacy-level deductions with amounts reported to CMS.[147] FMI recommends that CMS require sponsors to validate PBM-reported pricing at the pharmacy (NPI) level and to compare reimbursement to affiliated and unaffiliated pharmacies. Florida's Prescription Drug Reform Act offers a workable model. It requires a PBM, at the time of adjudication, to give the pharmacy remittance information sufficient to identify the reimbursement schedule for the network applicable to the claim and the basis the PBM used to calculate payment, including the network reimbursement ID or plan ID defined in the NCPDP Telecommunication Standard, and it requires that any basis-of-reimbursement information communicated in effective-rate reconciliation be accurate, correspond with the applicable network rate, and be one on which the pharmacy may rely. CMS should require Part D sponsors to ensure that their PBMs report an accurate basis of reimbursement determination on each claim in the same manner, so that sponsors, CMS, and pharmacies can verify how each claim was priced and validate PBM-reported data against it.[148]

F. Limitations

> **CMS seeks information on:** *Part D plan sponsor restrictions or limitations on the dispensing of covered Part D drugs by network pharmacies, including the nature and prevalence of such limitations.*

FMI Response. The most significant dispensing limitation FMI members encounter is steering: mandatory or incentivized use of PBM-affiliated mail-order pharmacies, and claim rejections that redirect prescriptions to affiliated pharmacies. CMS's sub-regulatory manual guidance already

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[146] FMI 2026 Part D Survey, *supra* note 9.

[147] PBM Exposé, *supra* note 17, at 23.

[148] Fla. Stat. § 626.8825(3)(a)–(b) (2026), https://www.flsenate.gov/Laws/Statutes/2026/626.8825; *see also id.* § 626.8825(3)(g) (requiring Electronic Remittance Advice to contain claim-level payment adjustments with detail sufficient for the pharmacy to reconcile debits and credits). Florida's requirements govern state-regulated pharmacy benefits plans and programs and, because of Part D's express preemption provision discussed in Section III.A, do not reach Part D plans; FMI cites them as a model for federal standards.

prohibits "[s]teering of physicians or beneficiaries to a sponsor's and/or PBM's own mail order Pharmacy," yet PBMs have used claims data to move prescriptions to affiliated pharmacies, for example by rejecting a claim for prior authorization and then rejecting it again because it "must" be filled at an affiliated pharmacy.[149] Restrictive drug designations and carve-outs can produce the same result. Vertical integration extends this concern to the drugs themselves: each of the three largest PBMs is now affiliated with a private-label business that markets biosimilars, those PBMs have preferred the affiliated products on their commercial formularies while excluding most competing biosimilars, and the Federal Trade Commission has challenged formulary practices of the same PBMs and their affiliated group purchasing organizations. Although that preference has so far appeared mainly in commercial formularies, the same incentives exist in Part D, and a network pharmacy cannot dispense a biosimilar that the formulary excludes.[150] FMI asks CMS to provide that a term restricting a network pharmacy from dispensing a covered drug (or day supply) that an affiliated pharmacy is permitted to dispense is not reasonable or relevant unless justified by objective, drug-specific handling or safety requirements that the pharmacy does not meet, and to require that Part D sponsors cover biosimilars of the same reference product on equal terms, whether marketed by a PBM-affiliated or an unaffiliated labeler. All companies that answered the 2026 Part D Survey, together operating more than 1,300 pharmacies, reported retail day-supply limits (for example, 90-day supplies available only through mail order) and cost sharing that is lower only at PBM-affiliated or preferred pharmacies, and companies operating roughly 85 percent of responding pharmacies reported claim rejections that redirect prescriptions to PBM-affiliated pharmacies. Members shared rejection messages stating, for example, that a maintenance medication "must fill at mail order" after a set number of retail fills, or that the pharmacy is "not contracted in [the] 90 day retail network," which forces a patient either to make three trips for what would otherwise be one fill or to obtain a new prescription for mail delivery.[151] Provider manuals also restrict the delivery services many supermarket pharmacies offer: one national PBM's manual bars network retail pharmacies from delivering prescriptions by mail or through third-party delivery

[149] Ctrs. for Medicare & Medicaid Servs., *Medicare Prescription Drug Benefit Manual* ch. 6, § 30.2.2.3 (Rev. 18, Jan. 15, 2016); *see also* PBM Exposé, *supra* note 17, at 40 (describing claim rejections that redirect prescriptions to PBM-affiliated pharmacies).

[150] *See* Drug Channels Inst., The Big Three PBMs' 2026 Formulary Exclusions: MFP, Private Label Biosimilars, and Direct-to-Patient Threats for PBMs, Drug Channels (Jan. 22, 2026), https://www.drugchannels.net/2026/01/the-big-three-pbms-2026-formulary.html (reporting that the largest PBMs' formularies favor biosimilars marketed by private-label subsidiaries of their parent companies: Cordavis (CVS Health), Nuvaila (UnitedHealth Group), and Quallent Pharmaceuticals (Cigna)); Stanton R. Mehr, Will the Emerging Private-Label Market Access Channel Help or Hinder Biosimilar Market Access?, 31 J. Managed Care & Specialty Pharmacy 824 (2025), https://doi.org/10.18553/jmcp.2025.31.8.824 (describing CVS Health's April 2024 exclusion of Humira in favor of biosimilars that included private-label versions distributed by its Cordavis subsidiary); ESI Consent Order Analysis, *supra* note 96, at 6641–42 (describing the FTC's 2024 administrative complaint against the three largest PBMs and their affiliated group purchasing organizations, and a proposed order requiring Express Scripts to cease discriminating against low-list-price versions of a drug on its standard formularies). *But see* Tyler Novotny & Bryce Platt, The Private Label Biosimilar Paradox in Medicare Part D, Drug Channels (Sept. 1, 2026), https://www.drugchannels.net/2026/09/the-private-label-biosimilar-paradox-in.html (reporting that PBM-affiliated private-label ustekinumab biosimilars have so far been largely absent from Part D formularies, which the authors attribute to manufacturer discount obligations under the redesigned Part D benefit).

[151] FMI 2026 Part D Survey, *supra* note 9.

services such as DoorDash or Uber without the PBM's advance written approval.[152] CMS guidance already requires a sponsor that offers extended supplies through mail order to make an extended-supply addendum available to retail pharmacies on request and to ensure reasonable access to the same benefit at retail; the standards should make that requirement enforceable.[153]

G. Current Regulations and Guidance

> **CMS seeks information on:** *Areas in current regulations or Part D program guidance related to contracting that may require clarification or additional specificity.*

FMI Response. FMI recommends that CMS: (i) amend 42 C.F.R. § 423.505(b)(18) to incorporate the objective factors and specific standards described above, rather than leaving "reasonable and relevant" undefined, and supersede Manual guidance under which CMS "does not generally involve itself in determining whether standard contracting terms and conditions are 'reasonable and relevant'" and "generally does not opine on" compensation terms[154];[155] (ii) amend 42 C.F.R. § 423.120(a)(8) to clarify that preferred-network terms must be offered to all similarly situated pharmacies based on objective, published criteria, and that any pharmacy that meets those criteria and accepts those terms may participate in the preferred network; (iii) codify the Manual's anti-steering guidance in regulation and extend it to the use of pharmacy claims data; (iv) strengthen the prompt-pay requirements at 42 C.F.R. § 423.520 so that post-adjudication recoupment cannot be used to circumvent them; (v) clarify that sponsors are responsible for the compliance of their PBMs and other first tier, downstream, and related entities with these standards; and (vi) strengthen network adequacy requirements so that sponsors cannot satisfy access standards while excluding willing pharmacies.

H. Implementation of Standards

> **CMS seeks information on:** *Operational timelines, compliance documentation, contracting practices not captured in the RFI, model terms, and criteria to ensure that standards are transparent, objective, and enforceable.*

FMI Response. Because the standards apply for plan years beginning on or after January 1, 2029, CMS should require sponsors to issue compliant standard terms to all pharmacies early enough in the 2029 contracting cycle to allow for meaningful pharmacy review. Until then, existing 42 C.F.R. § 423.505(b)(18) authority requiring reasonable and relevant terms and conditions should form the basis for relief from the issues discussed. To document compliance from 2029 onward, CMS should require sponsors to submit annually their standard pharmacy contract templates, rate sheets, provider manuals, and similarly situated classification criteria, together with an attestation and

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[152] Optum Rx Manual, *supra* note 107, at 113–14, 124.

[153] Medicare Prescription Drug Benefit Manual, *supra* note 49, ch. 5, § 50.10.

[154] Medicare Prescription Drug Benefit Manual, *supra* note 49, ch. 5, § 50.5.3 (long-term care contracting); *see also id.* § 50.8.1 (describing such questions as "generally best left between the parties").

[155] RFI, *supra* note 1, at 60568 ("CMS has not established additional requirements for what constitutes reasonable and relevant terms and conditions.").

pharmacy-level reimbursement data.[156] CMS should also establish an accessible process through which pharmacies may submit allegations that contract terms fail to meet the standards and obtain timely adjudication. The process should include clear submission requirements, reasonable evidentiary burdens, defined review timelines, written determinations, appropriate protection of sensitive information, and meaningful corrective action. Members identified the features that would make that process usable: a simple, secure submission process; the ability to raise systemic issues spanning multiple claims, contracts, or locations; participation through an authorized representative; visibility into the status of an allegation; independent review; enforceable deadlines; and protection against retaliation or network exclusion.[157] CMS should implement and enforce Section 6223's protections against retaliation for submitting allegations or supporting information, and should clarify how the CMS process interacts with contractual appeal and arbitration provisions so that those provisions do not obstruct access to CMS review. Consistent with the anti-circumvention principle described in Section III.B, CMS's oversight and enforcement should evaluate the practical and cumulative effect of a sponsor's terms, not only whether each term appears compliant on its face. This statutory reporting right is the enforcement centerpiece of Section 6223.[158] Because supermarket pharmacies are, as a rule, not affiliated with a PBM, FMI also asks CMS to ensure that the essential retail pharmacy designation and the violation-reporting process are structured to capture supermarket pharmacies and to protect reporting pharmacies against retaliation. During standards development, CMS should also establish a targeted mechanism outside the public docket, consistent with applicable law, for receiving legitimately confidential commercial information that stakeholders may be uncomfortable providing publicly because of concerns about competitive harm or retaliation. As model frameworks, CMS can draw on state laws addressing MAC transparency and appeals, prohibition of post-adjudication fees, below-cost reimbursement, and affiliate reimbursement parity.[159]

CMS should also anticipate, and build its record to answer, the objections the PBM industry is likely to raise. The Pharmaceutical Care Management Association ("PCMA") has warned that "overly

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[156] *See* RFI, *supra* note 1, at 60569 n.1 (noting that sponsors and their first tier, downstream, and related entities must make available documentation of terms offered to pharmacies) (citing 42 C.F.R. § 423.505(e)(2), (i)(2)).

[157] FMI 2026 Part D Survey, *supra* note 9.

[158] Pub. L. No. 119-75, *supra* note 2, § 6223(c)(1), 140 Stat. at 667–69 (adding Social Security Act § 1860D-4(b)(1)(F), 42 U.S.C. § 1395w-104(b)(1)(F)), https://www.govinfo.gov/content/pkg/PLAW-119publ75/pdf/PLAW-119publ75.pdf; *id.* § 1860D-4(b)(1)(F)(i)(I) (requiring the Secretary, "[n]ot later than January 1, 2029," to "establish a process through which a pharmacy may submit to the Secretary an allegation of a violation by a PDP sponsor . . . of the standards for reasonable and relevant contract terms and conditions"); *id.* § 1860D-4(b)(1)(F)(i)(III)(bb) (sponsor "shall not prohibit or otherwise limit the ability of a pharmacy to submit such documents or materials to the Secretary"); *id.* § 1860D-4(b)(1)(F)(i)(IV) (standardized template with certification); *id.* § 1860D-4(b)(1)(F)(i)(VI) ("Allegations submitted under this clause shall be exempt from disclosure under section 552 of title 5, United States Code."); *id.* § 1860D-4(b)(1)(F)(i)(VII) (process does not limit "the ability of a pharmacy to pursue other legal actions or remedies"); *id.* § 1860D-4(b)(1)(F)(i)(VIII) (sponsor shall not "retaliate against a pharmacy for submitting any allegations" or "coerce, intimidate, threaten, or interfere with the ability of a pharmacy to submit any such allegations"); *id.* § 1860D-4(b)(1)(F)(ii)–(iii) (investigation "as determined appropriate by the Secretary"; civil monetary penalties or intermediate sanctions for violations of the standards or of clause (i)(VIII)).

[159] *See, e.g.*, Tenn. Code Ann. § 56-7-3115 (2026) (post-adjudication fees); Ind. Code § 27-1-24.5-19(b)(3)–(5) (2026); N.J. Stat. Ann. § 17B:27F-4 (West 2026) (MAC appeals); Va. Code Ann. § 38.2-3467(A)(3) (2026) (affiliate reimbursement parity); PBM Exposé, *supra* note 17, at 51–52, 79.

broad [any willing pharmacy] rules can undermine benefits for patients and taxpayers."[160] But comparisons of relative reimbursement between pharmacy types say nothing about whether reimbursement to any pharmacy (chain, supermarket, or independent) covers acquisition and dispensing costs, which is the question Congress directed CMS to examine. Nor does a standard requiring an objective, verifiable benchmark and a sustainable dispensing fee institute a "price structure"; it regulates how terms are constructed, not the price. Importantly, the 2029 implementation date is eminently achievable and should not be delayed.

I. Overlap with Section 1860D-12(h) PBM Requirements

The RFI also asks how these standards will overlap with the PBM disclosure requirements and remuneration restrictions under section 1860D-12(h) of the Act.[161] FMI addressed section 1860D-12(h) in its July 2026 comments.[162] FMI recommends that CMS coordinate the two rulemakings so that: (i) the reimbursement data PBMs must report under section 1860D-12(h)(1)(C) is used to monitor compliance with the reasonable and relevant standards, including affiliate reimbursement parity; this includes average pharmacy reimbursement broken out by dispensing channel and cost comparisons between affiliated and unaffiliated network pharmacies;[163] (ii) any fee a PBM or its affiliate collects from a network pharmacy that does not qualify as a bona fide service fee under section 1860D-12(h)(7)(B), and so is already restricted by section 1860D-12(h)(1)(A), is also deemed not reasonable and relevant for network-participation purposes under section 1860D-4(b)(1)(A)(ii);[164] (iii) the price-guarantee transparency requirements CMS has proposed for sponsor-facing guarantees at 42 C.F.R. § 423.2812 (drug categories defined consistently with Part D definitions, NDC-level lists of the drugs in each category and of excluded drugs, claims, and price concessions, and a WAC-based equivalent for any guarantee based on another benchmark) also apply to pharmacy-facing effective-rate guarantees, a topic CMS has said it may address in future rulemaking;[165] and (iv) "affiliate," "pharmacy benefit manager," and related terms are given the

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[160] Pharm. Care Mgmt. Ass'n, *Inside PBM Reform: Major Changes Impacting Medicare Present Opportunities to Improve Affordability for America's Seniors*, PCMA Blog (May 11, 2026), https://www.pcmanet.org/pcma-blog/inside-pbm-reform-major-changes-impacting-medicare-present-opportunities-to-improve-affordability-for-americas-seniors/ (stating that PCMA will emphasize to CMS "that overly broad AWP rules can undermine benefits for . . . .").

[161] RFI, *supra* note 1, at 60569, https://www.federalregister.gov/d/2026-19535.

[162] *See* FMI July 2026 Comments, *supra* note 6.

[163] Pub. L. No. 119-75, *supra* note 2, § 6224(a)(1), 140 Stat. at 673 (adding Social Security Act § 1860D-12(h)(1)(C)(i)(I)(ii), (II)(bb)–(cc)) (requiring an annual report of "the average pharmacy reimbursement amount paid by the plan for the drug in the aggregate and disaggregated by dispensing channel," and, for PBMs with affiliated pharmacies, cost ranges for drugs dispensed by "pharmacies that are not an affiliate" and by "pharmacies that are an affiliate" of the PBM), https://www.govinfo.gov/content/pkg/PLAW-119publ75/pdf/PLAW-119publ75.pdf.

[164] *Id.* (adding § 1860D-12(h)(1)(A)(i), (iv), (h)(7)(B)) (PBM and affiliates "shall not derive any remuneration . . . from any such entity or individual other than bona fide service fees"; remuneration arrangements with "pharmacies" are subject to fair market value review; a bona fide service fee must be "a flat dollar amount" reflecting fair market value for "a bona fide, itemized service actually performed"); *but see id.* (adding § 1860D-12(h)(4)) (subsection is not to be construed as "prohibiting flat dispensing fees" or "modifying regulatory requirements . . . related to pharmacy payment, reimbursement, or dispensing fees"),

[165] Medicare Program; Implementation of Sections 6219, 6220, and 6224 of the Consolidated Appropriations Act, 2026, 91 Fed. Reg. 66408, 66456–57, 66484–85 (proposed Oct. 20, 2026) (CMS-4214-P) (proposed 42 C.F.R. § 423.2812) (noting that CMS "considered whether the requirements discussed in this section of the proposed rule should apply to effective rate guarantees between PBMs and pharmacies" but "may address this topic in future rulemaking"),

meanings in section 1860D-12(h)(7) for both provisions, as Congress already did for the essential retail pharmacy provisions of section 6223(b).[166]

IV. Conclusion

FMI appreciates the opportunity to comment and shares CMS's interest in effective, administrable standards under Section 6223. In summary, FMI respectfully urges CMS to adopt standards that make reimbursement sustainable, transparent, and predictable at the point of sale, with appropriate safeguards for any subsequent reconciliation; ensure that all financial terms are disclosed and affirmatively accepted; prohibit terms that favor PBM-affiliated pharmacies; require relevant, validated performance measures; and establish fair, transparent audit and dispute processes. Doing so will give effect to Congress's directive that any willing pharmacy be able to participate on reasonable and relevant terms, and will help preserve access to the supermarket pharmacies on which so many Medicare beneficiaries rely.

FMI would welcome the opportunity to provide additional information and stands ready to assist CMS as it develops these standards. If you have any questions or wish to discuss the topic in greater detail, please do not hesitate to contact me at pmatz@fmi.org or (202) 452-8444.

Sincerely,



Peter Matz
Director, Food, Pharmacy & Health Policy

https://www.federalregister.gov/documents/2026/10/20/2026-21420/medicare-program-implementation-of-sections-6219-6220-and-6224-of-the-consolidated-appropriations.

[166] *Id.* (adding § 1860D-12(h)(7)(A), (C)); *id.* § 6223(b) (adding Social Security Act § 1860D-42(e)(4), which gives "affiliate" and "pharmacy benefit manager" "the meaning given those terms in section 1860D-12(h)(7)")