PBMs and Prescription Drug Distribution: An Economic Consideration of Criticisms Levied Against Pharmacy Benefit Managers

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EXECUTIVE SUMMARY

Policymakers, payors, and patients are concerned about increasing healthcare costs and the role that expenditures on prescription drugs may play in that increase. This study focuses on the role of pharmacy benefit managers (PBMs) in the healthcare industry and investigates various claims that PBMs are somehow causing—directly or indirectly—increases in the cost of prescription drugs.

A PBM is a service provider that administers the pharmacy benefit portion of health care benefit plans for plan sponsors, which include health insurers, employers of all sizes, labor unions, and government programs. Most prescription drugs are delivered to patients through pharmacy benefit plans. Patients with insurance (plan members) do not pay the full cost of drugs covered by their plan when they fill prescriptions. Instead, pharmacy benefit plan sponsors typically bear the majority of the cost of prescription drugs and seek to develop pharmacy benefit plans to ensure members have cost-effective access to appropriate drugs.

PBMs perform many functions for plan sponsors in the course of managing prescription benefit plans. Given that the overwhelming majority of Americans with health insurance are served by a PBM in some capacity, PBMs play an important role in containing prescription drug costs and thus overall health care costs. The benefits of containing drug costs is not limited to plan sponsors. Members also are expected to benefit if the plan sponsor saves money because insurance premiums and/or out-of-pocket costs are expected to be lower.

This report analyzes concerns that have been raised by commentators (including the Federal Trade Commission (FTC)) that PBMs contribute to the increasing costs of prescription drugs rather than helping to contain these costs. The conclusions of PBM critics, however, are often not based on a systematic study of the available data, and, at times, appear to mistakenly attribute the decisions of plan sponsors to the PBMs. Our report does not rely on anecdotes, case studies of individual drugs, or selected complaints from individuals but instead conducts a systematic study of data on prescriptions, rebates, PBM conduct, and the state of the pharmacy industry to evaluate common criticisms of the PBM industry. Much of the data we analyze was submitted to the FTC by Caremark, Express Scripts, and Optum Rx in response to FTC's requests during its Section 6(b) study of PBMs. We also consider prior studies of the PBM industry.

Among our findings, we show that various claims of critics are inconsistent with the empirical evidence. Specifically, we find the following: (i) PBM profit margins have not been increasing over time and are small relative to the total cost of prescription drugs to plan sponsors and their members; (ii) overall PBM pass-through of rebates from manufacturers to plan sponsors is very high – around 98% of all rebates and fees received by the three largest PBMs in recent years were passed through to plan sponsors; (iii) the average retail pharmacy spread retained by PBMs is low (below 2%); (iv) critics' suggestion that the PBMs' negotiation and retention of rebates can lead to higher, not lower, rates of growth in the list prices of drugs is not consistent with economic theory and is unsupported by data; and (v) the rate of growth in the net prices paid by

plan sponsors and members for branded drugs with rebates is lower, not higher, than the rate of growth in net prices for branded drugs without rebates.

Our principal findings, which are in broad accord with what prior academic and industry studies have found, are as follows:

- Pharmacy benefit plan sponsors often choose to use PBMs to perform a variety of services. These services include performing administrative functions (such as prescription claims processing), engaging in formulary development, and negotiating with branded drug manufacturers and pharmacies to lower the cost of prescription drugs for plan sponsors and their members. PBMs offer flexible service arrangements for plan sponsors, so that plan sponsors can choose which services to procure from the PBM and which to perform themselves. Moreover, for each service provided by the PBM, the PBM typically offers a range of options from which the plan sponsor can choose. Thus, plan sponsors, often with the advice of third-party benefit design consultants, choose which services to obtain from PBMs and choose the features of the prescription drug benefit plan that they offer to their members. When a plan sponsor chooses to outsource services to a PBM, the plan sponsor does so with the expectation that it will benefit from the PBM's lower costs of negotiating with drug manufacturers and pharmacies (compared to individual negotiations), the PBM's aggregation of volume from multiple plan sponsors that allows it to negotiate for better rates from drug manufacturers and pharmacies, and/or the PBM's expertise in designing formularies and administering plan benefits.

- Plan sponsors may use various mechanisms to compensate their PBM for the pharmacy benefit management services the PBM performs. The compensation structure is negotiated between the plan sponsor and PBM, and different plan sponsors may prefer different combinations of payment mechanisms. Typical compensation mechanisms include administrative fees (which may be applied per member, per month and/or per processed claim), retained rebates (*i.e.*, the portion of manufacturer rebates and fees that PBMs are allowed to keep), retail spread (*i.e.*, the portion of plan sponsors' payments for drugs that the PBMs keep), and dispensing profits on PBM-affiliated pharmacies. Different plan sponsors use different combinations of mechanisms to compensate their PBMs, and it is not necessarily meaningful to focus on one particular component of PBM revenue in isolation since it is the sum of payments that matter to the plan sponsor and PBM. One plan sponsor may contract to pay a low (or even negative) amount for one component while another plan sponsor contracts to pay a high amount for that same component; even so, holding costs the same, the total amount the two plan sponsors pay to the PBM across all components of revenue may be the same.

- The claim that PBMs' use of formularies and pharmacy networks has worsened the outcomes for plan sponsors and their members by limiting choice is unfounded. PBMs provide tools for plan sponsors to contain prescription drug costs, including

through the use of formularies, utilization management protocols, and pharmacy networks. Plan sponsors, however, ultimately decide which of these tools to use. Moreover, when designing formularies, plan sponsors and PBMs take into account clinical considerations to ensure that members have access to necessary treatments. Formularies, utilization management tools, and pharmacy networks that may not include all available medication options or pharmacies are designed to incentivize drug manufacturers and pharmacies to offer discounts in exchange for being included (or preferred) in the formulary or pharmacy network. Such "selective contracting" is common in the healthcare industry and has been shown to lead to lower health care costs. The use of formularies, utilization management, and pharmacy networks is effective at shifting demand to lower cost options, such as by shifting demand from more expensive branded drugs to less expensive generic drugs and shifting prescriptions from more expensive pharmacies to less expensive pharmacies. By providing incentives for drug manufacturers and pharmacies to offer discounts and providing incentives to members to choose lower cost options, PBMs reduce drug costs for both plan sponsors and members.

- Far from being a source of increased costs, PBMs help to lower the cost of prescription drugs. Studies of the industry by academics and government agencies demonstrate that PBMs generate substantial value by reducing prescription drug costs. Plan sponsors capture a large fraction of the value created by PBMs in part because PBMs compete for the business of plan sponsors. A variety of characteristics of the PBM industry allow plan sponsors to foster and thereby benefit from competition for the services provided by PBMs. These characteristics include: (i) the heterogeneous nature of PBM contracts across plan sponsors makes it less likely that PBMs can tacitly collude; (ii) the highly detailed Request for Proposal (RFP) process through which a plan sponsor selects a PBM for a multi-year contract, typically lasting one to five years, provides incentives for PBMs to compete aggressively on price and value; (iii) the sophisticated nature of plan sponsors and the consultants with whom they work facilitates their choice of a PBM that provides the desired services (bearing in mind the plan sponsors' preferences) at the lowest total cost; (iv) the ability of some plan sponsors to self-supply some or all of the services offered by PBMs provides additional competitive discipline on PBMs; and (v) the existence and viability of smaller PBMs provides additional competitive discipline on larger PBMs. Data from a variety of sources support the conclusion that the three largest PBMs compete not only with each other but also with other PBMs and with self-supply.

- The claim that PBMs do not benefit plan sponsors because PBMs sometimes do not pass through all of the cost savings they negotiate from drug manufacturers and/or retail pharmacies is unsupported by the data. The fact that pass-through of manufacturer rebates is sometimes less than 100% does not remove the PBM's incentive to lower the plan sponsors' costs of prescription drugs. Competition to

provide PBM services and the fact that plan sponsors are sophisticated buyers reinforce these incentives.

- Claims that PBMs have an incentive to harm efficient independent pharmacies and that, in fact, independent pharmacies are being driven out of business by PBMs are unfounded. PBMs form pharmacy networks to provide benefits to plan sponsors and members. Independent pharmacies, *i.e.*, retail pharmacies that are not part of a pharmacy chain and are not affiliated with a PBM, have been and remain important components of PBMs' pharmacy networks. As service providers to plan sponsors, PBMs do not have an incentive to reduce the viability of efficient independent pharmacies or cause a reduction in pharmacy competition. Instead, because PBMs' incentives are generally aligned with those of plan sponsors—both desire to reduce the cost of pharmacy benefit programs while still ensuring access to necessary treatments—PBMs foster competition among all types of retail pharmacies, including independent pharmacies, which enables PBMs to negotiate lower reimbursement rates paid to all pharmacies for dispensing drugs. One would expect lower cost or higher quality pharmacies to win preferred positions in pharmacy networks regardless of their status as independent or chain pharmacies, or PBM-affiliated or non-affiliated pharmacies. That this may come at the expense of higher cost or lower quality pharmacies is not a harm to competition but rather a natural outcome of competition. Nevertheless, independent pharmacies have long complained that by developing pharmacy networks for plan sponsors and imposing conditions for participation in those networks, the survival of efficient independent pharmacies has been threatened, which has harmed pharmacy competition, plan sponsors, and plan sponsors' members.

    - We examine whether the data are consistent with the claims of independent pharmacies and find that: (i) PBMs pay independent pharmacies higher reimbursement rates than non-affiliated chain pharmacies; (ii) the number of independent pharmacy locations has not declined over time relative to the number of chain pharmacy locations; (iii) the number of non-specialty prescriptions filled at independent pharmacies has grown over time, and there has been only a small decline over time in independent pharmacies' share of non-specialty prescriptions dispensed; and (iv) the available data indicate that independent pharmacy profitability has not declined over time.

    - We also examine the claim that PBMs have an incentive to favor their own affiliated pharmacies over non-affiliated pharmacies. To be clear, because of the benefits of vertical integration, a PBM-affiliated pharmacy could be lower cost than non-affiliated pharmacies and thus could secure a spot on the PBM's pharmacy network and be preferred by plan sponsors and members. Such inclusion of affiliated pharmacies on a PBM's network when they are more efficient is not anti-competitive and does not harm competition, however, even if it makes it more difficult for inefficient competitors to win business. We find that

the data on prescriptions filled are not consistent with claims of critics that PBMs are trying to eliminate non-affiliated retail pharmacies in favor of their own affiliated pharmacies; and the data on prescriptions filled are not consistent with claims that PBMs are trying to eliminate non-affiliated specialty pharmacies in favor of their own specialty pharmacies.

- The FTC staff issued two interim reports on the PBM industry but neither report contains a systematic study of the available data and information. Even in the somewhat broader, second interim report, the FTC staff analyzed only 51 specialty generic drugs constituting less than 2% of total drug expenditures. In that analysis, the FTC staff estimates that the PBMs' reimbursement rates to affiliated pharmacies are far above the estimated acquisition cost of the drugs (measured by NADAC) and that the estimated reimbursement markup over acquisition cost is higher for affiliated pharmacies than non-affiliated pharmacies; the FTC staff concludes that legislative action may be warranted. Our analysis demonstrates, however, that the interim reports fail to provide a reasonable basis for policymakers to understand how PBM practices affect overall drug costs and whether PBM practices create problems that policymakers could or should attempt to solve.
    - The FTC staff's analysis ignores 98% of drug expenditures and fails to demonstrate that the costs and markups on the small subset of drugs analyzed are representative of all drugs. Without such a demonstration, the FTC staff's interim reports cannot reliably support any conclusion about the impact of PBM pricing on overall drug costs paid by plan sponsors and members.
    - We examine the data systematically and find that the subset of specialty generic drugs chosen by the FTC staff are not representative of all drugs: even if one accepts the FTC staff's methodology for calculating reimbursement markups, we find that the markups on the drugs the FTC staff analyze are extreme outliers compared to drugs that make up the vast majority of drug purchases. We examine all of the drugs purchased by affiliated pharmacies and find that the average reimbursement markup is negative, *i.e.*, reimbursement is below acquisition cost as measured by NADAC.
    - Contrary to the FTC staff's finding that the reimbursement markup for the subset of drugs is higher at affiliated pharmacies than at non-affiliated pharmacies, we find that, when one analyzes all drugs purchased, the reimbursement markup is lower at affiliated pharmacies than at non-affiliated pharmacies. Using our available data and our methodology, we find that the cost to plan sponsors and members of the overall basket of drugs purchased is about the same whether the basket is purchased at affiliated or non-affiliated pharmacies. This shows that the FTC's suggestion that overall drug expenditures could be significantly reduced if all drugs were purchased at non-affiliated pharmacies instead of at affiliated pharmacies is wrong.

Claims that PBMs have contributed to rising costs for prescription drugs are not supported by the evidence. There is substantial evidence that PBMs have reduced the cost of prescription drugs for plan sponsors and their members, and, although PBMs are paid for their services, PBM operating margins are a small component (less than five percent) of the cost of prescription drugs. To put PBM margins into perspective, under the extreme assumption that PBMs earned zero operating margin but continued to offer the same services at the same level of quality, the cost of prescription drugs to plan sponsors and members would go down by less than $5 for every $100 spent by plan sponsors and members.

PBMs play an important role in reducing prescription drug costs for their plan sponsor clients by negotiating prices with drug manufacturers and pharmacies and providing services that facilitate plan sponsors' efforts to design drug benefit programs that encourage members and prescribers to choose low-cost treatment options that accord with plan sponsors' health objectives for their members. Given the effectiveness of PBMs, it is unsurprising that drug manufacturers and pharmacies, which would benefit from charging higher prices to plan sponsors and members in the absence of PBMs, complain about PBMs. Perhaps these complaints are the best confirmation of the results of this study: PBMs lower drug costs for plan sponsors and their members.

When considering the possibility of regulation of the PBM industry, policymakers should consider whether the incentives of PBM critics are aligned with the interests of plan sponsors and consumers. Some critics may stand to gain if PBMs' ability to reduce drug costs is restricted. Policymakers should consider the quantitative results presented in this report as well as results from the many studies that have found that several actual and proposed interventions into the PBM industry have—or would have—increased health care costs for consumers.

We intend to continue to study the PBM industry and may update this report further when and if relevant data or topics, including comments on this report, arise.[2]

[2] The results in this report update and replace any results that have been reported previously. This version of the report updates the original version released in October 2024.

I. PBMs FACILITATE PRESCRIPTION DRUG COST SAVINGS FOR PLAN SPONSORS AND MEMBERS

1. Most Americans do not pay the list price for their prescription drugs, regardless of whether they make their purchases at a chain pharmacy, an independent pharmacy, or a mail-order pharmacy. Rather, most prescription drug purchases are paid for in part through health insurance plans that offer a prescription drug benefit plan. Consumers may purchase health insurance privately, such as on insurance exchanges, or it may be provided by an employer (in which the employee might have choices regarding what insurance plan to purchase) or provided by the government (such as Medicare). In many cases, a pharmacy benefit manager (PBM) assists in managing all or part of a health insurance plan that relates to prescription drug coverage. PBM clients include employers, health insurance plans, labor unions, government programs, and other groups. We refer to PBM clients as "clients" or "plan sponsors" and plan beneficiaries as "members" in this report.

2. PBMs perform a host of services for their clients, some of which involve administrative functions such as prescription claims processing while others involve services such as formulary development and negotiating with branded drug manufacturers and pharmacies to help lower the cost of prescription drugs for plan sponsors and their members.[3] PBMs thus play a role in helping plan sponsors provide affordable prescription drug benefits to members.

A. PLAN SPONSORS USE PHARMACY BENEFIT MANAGEMENT SERVICES BECAUSE DOING SO OFFERS IMPORTANT ECONOMIC ADVANTAGES

3. The services performed by PBMs can be (and in some cases are) performed by plan sponsors. Because PBMs have developed efficient, lower-cost methods of providing those services, however, plan sponsors overwhelmingly hire PBMs to reduce the overall costs of offering prescription drug benefits and increase the quality of those benefits compared to what those costs and quality would be if the plan sponsors self-supplied those services. This is similar to what occurs with many third-party service providers across the economy that are able to

[3] *See*, *e.g.*, PCMA, "Finding the Formula for Drug Savings: The Role of Pharmacy Benefit Managers in the Health Care System," 2023, available at https://www.pcmanet.org/wp-content/uploads/2017/09/PBM-Basics-Slide-Deck_012717.pdf, slides 3, 8, and 20; Adam J. Fein, *The 2024 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers* (Drug Channels Institute: 2024) (hereinafter, "Fein Report (2024)"), pp. 146-147.

provide services to firms at lower costs or higher quality relative to firms' self-supplying those services.[4]

4. The plan sponsors' outsourcing of services to PBMs has several significant advantages likely to benefit plan sponsors and, ultimately, their members.[5] First, if every plan sponsor had to negotiate individually with hundreds of drug manufacturers and tens of thousands of pharmacies, the aggregate costs of the negotiations for the plan sponsors (as well as for the manufacturers and pharmacies) would be substantially higher than those incurred by PBMs. Ultimately, even if individual plan sponsors were able to obtain rates as favorable as those obtained by PBMs, these higher negotiating costs would be expected to be passed on to consumers in the form of higher premiums, higher drug costs, higher out-of-pocket costs, and higher dispensing costs, which would make prescription drugs less affordable and less accessible.[6]

5. Second, PBMs typically negotiate with drug manufacturers to secure price concessions and with pharmacies or pharmacy associations to reduce drug fulfillment costs. By aggregating volume over multiple plan sponsors and specializing in the bargaining process, PBMs can negotiate larger discounts from drug manufacturers and pharmacies than individual plan sponsors would be able to negotiate.[7] This is because a PBM negotiating on behalf of multiple plan sponsors can achieve a larger impact on demand than individual plan sponsors can on their own. The importance of scale in negotiating selective contracts has been well documented in

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4 *See*, *e.g.*, Hal R. Varian, *Intermediate Microeconomics: A Modern Approach*, 8th ed. (New York, London: W. W. Norton & Company, 2009), p. 349 ("As technology changes, what is typically inside the firm changes. Forty years ago, firms managed many services themselves. Now they tend to outsource as much as possible. Food service, photocopying service, and janitorial services are often provided by external organizations that specialize in such activities. Such specialization often allows these companies to provide higher quality and less expensive services to the organizations that use their services.").

5 Luke Froeb and Mikhael Shor, "Formularies, Rebates, and the Economics of PBM Bargaining: The Often-Misunderstood Role of PBMs in Pharmaceutical Pricing," Vanderbilt Owen Graduate School of Management (2023) (hereinafter, "Froeb and Shor (2023)"), p. 4.

6 *Id.,* pp. 4, 58.

7 *Id.*, p. 4.

other parts of the healthcare sector, where researchers have shown that larger insurers are able to secure lower prices from hospitals and healthcare providers, which reduces healthcare costs.[8] Drug manufacturers and pharmacies would be expected to be more willing to offer larger price concessions when negotiating with a large entity serving many plan sponsors than when negotiating with the same plan sponsors individually.[9]

6. Third, PBMs use their expert knowledge and experience to develop multiple "template" formularies of covered drugs across many therapeutic categories. PBMs assemble and utilize expert Pharmacy and Therapeutics (P&T) committees when designing their template formulary options, as well as more customized formularies, to ensure the formularies are comprehensive enough to offer clinically appropriate drugs to members. Plan sponsors can choose from the template formulary options developed by PBMs, work with the PBM to create custom versions of a template formulary, or create their own formularies. The plan sponsor, sometimes with assistance from the PBM to model different scenarios, also decides how to structure its plan benefits to encourage plan members to select lower-cost drugs when substitutes are available, thus reducing plan sponsor costs of providing drug benefits. Some plan sponsors lack the expertise or resources to monitor drug developments, review clinical safety and efficacy research on drugs, and evaluate "drug pipelines."[10] They contract with PBMs to reduce costs and obtain access to PBMs' experience and advice in formulary and plan design. Once again, it can be more efficient for a PBM—which is a specialist serving many plan sponsors—to devote substantial resources to these tasks than for every individual plan sponsor to do so on its own behalf.[11] For example, it would likely be cost prohibitive for a small business to hire multiple medical experts to handle these tasks.

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8 *See*, *e.g.*, Eric Barrette, Gautam Gowrisankaran, and Robert Town, "Countervailing Market Power and Hospital Competition," *The Review of Economics and Statistics* 104, no. 6 (2022): 1351-1360. *See also*, Erin E. Trish and Bradley J. Herring, "How Do Health Insurer Market Concentration and Bargaining Power with Hospitals Affect Health Insurance Premiums?," *Journal of Health Economics* 42 (2015): 104-114.

9 Froeb and Shor (2023), p. 4.

10 *Id.*

11 For similar reasons, plan sponsors also commonly engage expert consultants to negotiate on their behalf with PBMs.

7. Fourth, there are significant costs involved in administering pharmacy benefits, including (i) the administration of rebates, which itself involves assessing qualifications, managing invoicing, handling collections, resolving disputes, and completing audits; and (ii) the administration of pharmacy networks, which requires implementing specialized IT systems to process and adjudicate claims from plan members across potentially tens of thousands of pharmacies, protecting plan sponsors against fraud/waste/abuse, handling billing and reimbursement issues, conducting audits, and resolving any disputes. It can be less costly and more efficient for a plan sponsor to contract with a PBM for the provision of these services and systems than for a plan sponsor to perform similar functions on its own.[12]

8. Thus, PBMs play a valuable role in prescription drug cost containment by negotiating discounts off list prices with drug manufacturers and pharmacies for their plan sponsor clients and providing services that facilitate plan sponsors' efforts to design drug benefit programs that encourage members to choose low-cost treatment options that align with the plan sponsors' health objectives for their members. The vast majority of plan sponsors surveyed report they are satisfied with their PBM services and recognize the value they bring in reducing drug costs for their plans and members.[13] Given the effectiveness of PBMs, it is unsurprising that drug manufacturers and pharmacies, which would benefit from charging higher prices to plan sponsors and members in the absence of PBMs, expend substantial resources lobbying against PBMs.[14] Nevertheless, their criticisms should be evaluated carefully.

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12 Matthew Fiedler, Loren Adler, and Richard G. Frank, "A brief look at current debates about pharmacy benefit managers," Brookings Institution, September 7, 2023, available at https://www.brookings.edu/articles/a-brief-look-at-current-debates-about-pharmacy-benefit-managers/ (accessed June 11, 2024).

13 *See*, *e.g.*, PCMA, "The Value of PBMs," available at https://www.pcmanet.org/value-of-pbms (accessed June 11, 2024); *See also*, Dan Judy and Jon McHenry, "Key Findings from Survey of Benefit Managers," North Star Opinion Research, June 15, 2020, available at https://www.pcmanet.org/wp-content/uploads/2020/06/FINAL-Benefit-Manager-Survey-Memo-.pdf (describing the results and methodology of a survey that concluded the vast majority (93%) of respondents are satisfied with their PBM.).

14 We understand that many drug manufacturers use PBMs when providing their prescription drug benefit programs to their employees.

B. PBMs PROVIDE VALUE-ADDED SERVICES TO PLAN SPONSORS TO HELP MANAGE PLAN SPONSORS' PHARMACY BENEFIT PROGRAMS

9. PBMs offer a menu of services and drug plan options to plan sponsors.[15] This enables plan sponsors to choose services and design a drug benefit plan that best meets their requirements and preferences. Key services offered by PBMs include:

- Prescription claims processing: PBMs have developed specialized claims processing systems that instantly process prescription drug claims at the point of service from retail, mail-order, and specialty pharmacies within the PBMs' pharmacy networks.

- Formulary development and management services: A formulary is a list of drugs that are covered under a health plan. Plan sponsors typically design their plans such that members pay less for drugs that are included or preferred on the plan sponsor's formulary compared to drugs not included or not preferred on the formulary. Plan sponsors may build their own formulary, use one of the many template formularies offered by their PBM, or may choose to create a custom formulary using one of these templates as a starting point.

    - When designing formulary options, PBMs (or plan sponsors when they design formularies themselves) rely on P&T committees, comprising independent experts such as pharmacists and physicians from various specialties.[16] P&T

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15 Lawton Robert Burns, *The Healthcare Value Chain: Demystifying the Role of GPOs and PBMs*, 1st ed. (Palgrave Macmillan, 2022) (hereinafter, "Burns (2022)"), pp. 381-382.

16 For example, CVS Caremark's P&T Committee consists of 20 physicians (spanning specialties from allergy and cardiology to pediatrics and medical ethics) and three pharmacists (including hospital and geriatric), with Express Scripts' National P&T Committee consisting of 14 physicians and two pharmacists, and Optum Rx's P&T Committee consisting of 10 physicians and two pharmacists. CVS Caremark, "Formulary Development and Management at CVS Caremark," 2024, available at https://www.caremark.com/portal/asset/FormDevMgmt.pdf ; Express Scripts, "Formulary Development at Express Scripts," April 2022, available at https://d17f9hu9hnb3ar.cloudfront.net/s3fs-public/2022-04/Formulary Development_April 2022.pdf; Optum Rx, "Smart formulary management," 2022, available at https://cdn-aem.optum.com/content/dam/optum4/resources/pdf/opt4750208_211027_interactive_whitepaper_formularymanagement_final.pdf. Some plan sponsors, such as health insurers, may also use their own P&T committees to perform a similar function.

committees evaluate drugs based on scientific evidence and clinical standards to determine which drugs within a therapeutic class used to treat the same health condition are clinically interchangeable and to provide clinical guidelines for formulary design. The P&T committee's clinical guidelines determine which types of drugs, for clinical and safety reasons, must be included on the formulary, which must not be included, and which may be included.[17] The PBM's P&T committee neither has access to, nor does it consider, financial factors such as rebates, discounts, or net costs of drugs when making these clinical assessments.[18]

- Plan sponsors often choose to segment formularies into tiers, with drugs in each tier having different levels of member costs (such as different co-pays or deductible requirements, the levels of which are determined by the plan sponsor). Plan sponsors use formularies (and tiers within formularies) to design benefit plans that provide incentives to their members to choose lower-cost options, where clinically appropriate, which reduces the cost of prescription drugs for the

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17 PBMs follow P&T committee guidance for both their template and custom formularies. In some cases, plan sponsors may have their own P&T committees that guide creation of their own formularies or customized formularies with the PBM. *See* Froeb and Shor (2023), p. 7.

18 CVS Caremark, "Formulary Development and Management at CVS Caremark," 2024, available at https://www.caremark.com/portal/asset/FormDevMgmt.pdf, p. 2 ("P&T Committee reviews medications from a purely clinical perspective without consideration of information on rebates, negotiated discounts, or net costs."); Express Scripts, "Formulary Development at Express Scripts," April 2022, available at https://d17f9hu9hnb3ar.cloudfront.net/s3fs-public/2022-04/Formulary Development_April 2022.pdf ("The Committee does not have access to, nor does it consider, any information regarding Express Scripts' rebates/negotiated discounts, or the net cost of the drug after application of all discounts. The Committee does not use price, in any way, to make formulary placement decisions."); "Priced Out of a Lifesaving Drug: Getting Answers on the Rising Cost of Insulin," Before the United States House of Representatives, Energy & Commerce Subcommittee on Oversight and Investigations (April 10, 2019) (Testimony of Sumit Dutta, M.D., Chief Medical Officer, Optum Rx), available at https://www.congress.gov/116/meeting/house/109299/witnesses/HHRG-116-IF02-Wstate-DuttaS-20190410.pdf, p. 2 ("A drug's cost plays no role in the P&T Committee's clinical review. Cost only becomes relevant after the P&T Committee has identified drugs in a particular therapeutic class that are clinically effective and should be covered.").

plan sponsor and ultimately its members. For example, formularies may encourage generic substitution by placing generic drugs on the lowest-cost tier. This helps explain why generics represent about 91% of all prescriptions.[19] Though PBMs may develop many templates, customization by plan sponsors can result in PBMs administering thousands of different formulary and plan designs for their plan sponsor clients.

- Negotiations with branded drug manufacturers: To facilitate formulary development, PBMs negotiate with branded drug manufacturers to obtain discounts (usually in the form of rebates) on branded drug prices covering practically all formulary configurations that plan sponsor clients may decide to use.
    - Drug manufacturers often condition rebates on favorable placement of their drugs on formularies used by plan sponsors.[20] Manufacturers typically agree to larger discounts for formulary configurations with higher expected volume if adopted by plan sponsors than for formulary configurations with less expected volume.
    - In addition, PBMs attempt to negotiate with manufacturers for price protection, which can moderate the impact of manufacturers' raising list prices above a specified level, thereby helping to protect plan sponsors and their members from manufacturer price increases.
    - Manufacturers may also pay PBMs a "manufacturer administrative fee" for administering the rebate program and performing other services for manufacturers.
    - The discounts and price protection payments offered by a drug manufacturer depend, in large part, on whether the drug faces competition from alternative

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19 U.S. Food and Drug Administration, "Office of Generic Drugs 2022 Annual Report," January 2023, available at https://www.fda.gov/media/165435/download?attachment, p. 1.

20 *See*, *e.g.*, *Sanofi-Aventis U.S., LLC,* v. *Mylan, Inc., and Mylan Specialty, LP*, "Appeal from the United States District Court for the District of Kansas," No. 21-3005, 10th Cir. July 29, 2022, p. 20.

branded or generic drugs. For branded drugs that do not face competition, manufacturers typically offer low or no rebates. But for branded drugs that do face competition, PBMs can use that competition to reduce drug costs for plan sponsor clients and their members.[21] Manufacturers of comparable drugs within the same therapeutic category typically compete for preferred placement on plan sponsor formularies by offering lower net costs via rebates or other discounts, such as price protection, with the expectation that more favorable placement on a particular formulary design will result in increased sales. A firm lowering price to gain sales volume is a standard result of competition.

- Contracts between PBMs and manufacturers typically include a menu of rebate rates for different formulary configurations that help PBMs and plan sponsors analyze the net drug costs of different formulary designs, providing plan sponsors with flexibility in choosing a formulary design. Manufacturers that offer lower net costs than their competitors (including all rebates and price concessions) are more likely to have their drugs chosen for preferred placement on formularies in categories where rival manufacturers compete. PBMs' negotiations with drug manufacturers therefore help plan sponsors reduce the net cost of prescription drugs.[22]

- Development of pharmacy network options and negotiations with pharmacies: PBMs negotiate with pharmacies for discounted drug fulfillment costs. PBMs create a variety of pharmacy networks that plan sponsors can choose from and also create custom networks at the request of plan sponsors. Pharmacy networks may include

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21 With respect to the government plan sponsors, Medicare does not have statutorily defined rebates and allows Part D plans and their PBMs to negotiate with the drug manufacturers. However, Part D plans compensate PBMs by paying an administrative fee (discussed below) and do not permit PBMs to retain rebates. Medicaid, on the other hand, has statutorily defined rebates that ensure that Medicaid pays the lowest price available to any buyer. Fein Report (2024), pp. 294-298.

22 *See, e.g.*, Congressional Budget Office, "Prescription Drug Pricing in the Private Sector," January 2007, available at https://www.cbo.gov/sites/default/files/110th-congress-2007-2008/reports/01-03-prescriptiondrug.pdf (hereinafter "CBO Paper (2007)"), pp. 10-12.

retail, mail-order, and specialty pharmacies.[23] In developing pharmacy networks, plan sponsors typically require PBMs to provide quality control functions to ensure pharmacy safety and integrity in compliance with all laws and plan sponsor contracts by, *e.g.*, verifying that pharmacies are in good standing and have the proper credentials in place and conducting periodic investigations to guard plan sponsors against fraud, waste, and abuse.[24] Pharmacy networks can range from open networks that include practically every pharmacy in the country to managed networks that include a smaller number of lower-priced pharmacies with sufficient geographic coverage to serve the plan sponsors' members. For managed networks, PBMs may negotiate with pharmacies to obtain discounts in exchange for being included or

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[23] A retail pharmacy is a store where members go to get their prescriptions filled and pick up in person. Retail pharmacies generally also sell non-prescription items. Mail-order pharmacies are pharmacies where members place orders for prescriptions by phone or online, and prescriptions are delivered to the member's home via mail. Specialty pharmacies are pharmacies that focus on dispensing specialty drugs, which are typically delivered by mail (although Caremark provides the option for members to have the prescription delivered to a local CVS retail outlet for pickup).

There is no standard definition of specialty drugs. Specialty drugs may be designated by government, plan sponsors, health plans, manufacturers, or others. (Fein Report (2024), p. 23.) For example, the Center for Medicare & Medicaid Services (CMS) "uses an exclusively cost-based definition of specialty drugs for the Medicare Part D program. A drug that exceeds the CMS-specified, dollar-per-month [cost] may be placed on a Medicare Part D plan's specialty tier." (*Id*., p. 24.) For 2021, "the minimum specialty tier eligibility threshold for Part D plans was a negotiated price of $670" for a "one-month supply at an in-network retail pharmacy." (*Id.*, p. 24.) Although specialty pharmacies dispense specialty drugs, retail pharmacies and mail-order pharmacies may also dispense certain specialty drugs.

[24] Medicaid requires audits to detect fraud, waste, and abuse and such audits do identify such practices. For example, according to CMS's Medicaid.gov, "Medicaid Program Integrity: A Shared and Urgent Responsibility," available at https://www.medicaid.gov/about-us/messages/entry/51805 (accessed June 11, 2024), "CMS conducts State Program Integrity Reviews to assess the effectiveness of the state's program integrity efforts, including its compliance with federal statutory and regulatory requirements. The reviews also assist in identifying effective state program integrity activities and sharing best practices with other states." PBMs also conduct audits for non-government plan sponsors, who similarly demand these services from PBMs to protect against fraud, waste, and abuse.

having a favored position in various pharmacy network designs.[25] Because plan sponsors may give plan members financial incentives to choose less expensive, in-network or preferred pharmacies, pharmacies that offer lower drug fulfillment costs are more likely to achieve a higher sales volume; this helps plan sponsors save money.[26] As research co-authored by two economists who are currently staff members of the Bureau of Economics at the FTC and a professor at Ohio State University concluded in a study published in 2020, "the cost savings associated with selective contracting [*i.e.*, limited networks] may be substantial" and laws that require PBMs and plan sponsors to use open networks (*e.g.*, any-willing-provider laws) "reduc[e] competition by inhibiting the ability of insurers to move demand across competing pharmacies."[27] Plan sponsors can choose pharmacy network options that best fit their budget and needs (*e.g.*, sufficient geographic coverage for the plan's members). PBMs may manage thousands of different network designs as they attempt to meet plan sponsors' needs.[28]

- Drug utilization management: PBMs may offer their clients a variety of utilization management services that plan sponsors may choose to ensure that safe, cost-effective, and appropriate drugs are dispensed to their members in compliance with laws and regulations.[29] These services help plan sponsors mitigate fraud, waste, and abuse, which can otherwise substantially increase unnecessary drug spending. Many

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25 As discussed further below, pharmacy networks must also meet the requirements of any relevant state or federal laws.

26 CBO Paper (2007), p. 12.

27 Daniel Hosken, David Schmidt, and Matthew C. Weinberg, "Any Willing Provider and Negotiated Retail Pharmaceutical Prices," *Journal of Industrial Economics* 68, no.1 (2020): 1-39 at 1-2. These results are consistent with other research. *See*, *e.g.*, Amanda Starc and Ashley Swanson, "Preferred Pharmacy Networks and Drug Costs," *American Economic Journal: Economic Policy* 13, no. 3 (2021): 406-446.

28 U.S. Federal Trade Commission Office of Policy Planning, "Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies -- Interim Staff Report," July 2024, available at https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf (hereinafter, "FTC First Interim Report (2024)"), p. 11.

29 Fein Report (2024), pp. 158-159.

plan sponsors design or operate utilization management programs themselves. Common utilization management services, where allowed by laws and regulations, include:

- Drug utilization review is performed by PBMs each time a member uses their insurance to pay for a prescription to alert pharmacies and doctors of potential health or safety issues, such as drug interactions, incorrect dosages, drug disease contraindications, drug duplications, and potential drug misuse.
- Prior authorization (PA) is the process by which a physician must submit information to show medical necessity before the plan sponsor will agree to cover the drug.
- Quantity limits are used to limit the number of doses of a drug that are covered, "either per-prescription or per-unit of time (*e.g.*, monthly),"[30] where appropriate.
- Step therapy programs require the use of less expensive therapeutic alternatives, such as generics, over-the-counter, or other branded drugs, before the plan sponsor will agree to cover more expensive therapeutic alternatives.
- Therapeutic interchange programs encourage plan members to use preferred drugs and requires prior physician authorization before a pharmacist can substitute one brand name drug for another.

- Operating mail-order pharmacies: Mail-order pharmacies, some of which are owned by or affiliated with PBMs,[31] send prescription drugs directly to a member's home. These pharmacies typically dispense refills of maintenance drugs—medications taken

30 *Id.*, p. 158.

31 When we refer to affiliated pharmacies, we mean pharmacies that are owned by a PBM or pharmacies where both the pharmacy and PBM are owned by the same corporate parent.

on a recurring basis to treat chronic illnesses—often on a 90-day supply basis.[32] Mail-order pharmacies have helped lower dispensing costs relative to conventional pharmacies.[33] These cost savings may be driven by factors such as lower overhead costs, centralized processing, and dispensing of long-term medications. Mail-order pharmacies also may eliminate a member's costs and inconvenience associated with traveling to a brick-and-mortar pharmacy, which may help encourage better compliance with the prescription drug plan developed by the member's physician.[34] Patients with limited mobility may particularly benefit from the option of using mail-order services.

- Operating specialty pharmacies: Specialty pharmacies, some of which are owned by or affiliated with PBMs, typically focus on the dispensing of specialty drugs, sometimes with associated patient services. These specialty drugs often have special handling or storage requirements and may be used to treat members undergoing intensive therapies for chronic, complex illnesses such as cancer, rheumatoid arthritis, multiple sclerosis, and HIV. Dispensing specialty drugs can require a pharmacy to provide a higher level of service to members including (i) educating members about the administration of, and adherence to, the prescribed treatment; (ii) consulting with members regarding side-effect management; and/or (iii) facilitating the monitoring of members by their physicians.

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32 In contrast to maintenance medications, acute-care drugs are prescribed for a single course to address a short-term medical condition. Such drugs are typically dispensed by a local retail pharmacy.

33 *See*, *e.g.*, CBO Paper (2007), pp. 3-4, 12-13.

34 Burns (2022), pp. 440-441. *See also*, *e.g.*, Elena V. Fernandez, Jennifer A. McDaniel, and Norman V. Carroll, "Examination of the Link Between Medication Adherence and Use of Mail-Order Pharmacies in Chronic Disease States," *Journal of Managed Care & Specialty Pharmacy* 22, no. 11 (2016): 1247-59 at 1248.

C. PBMs WORK WITH PLAN SPONSORS AND THEIR CONSULTANTS TO DESIGN AND IMPLEMENT A PHARMACY BENEFIT PROGRAM TO MEET THE SPONSORS' REQUIREMENTS

10. Plan sponsors choose which services to outsource to the PBM and which not to outsource. For each service provided by the PBM, the PBM typically offers a range of options from which the plan sponsor can choose. Plan sponsors often work with benefit design consultants or purchasing coalitions, as we discuss in more detail below, to choose the features of the prescription drug benefit plan that they will offer to their members, making tradeoffs between plan features, costs, and the level of coverage for members.[35] Many plan sponsors offer their members multiple drug benefit plans, allowing members to choose the plan that best fits their needs. For example, an employer may offer members a high-deductible plan option with a lower premium and higher member cost share, which may be more attractive to healthier members, and a plan with a higher premium and lower member cost share, which may be favored by less healthy members.

11. The features that plan sponsors consider in designing drug benefit plan options include the types of drugs covered by the plan, whether to use a formulary (and, if so, the type of formulary to employ), whether to use a utilization management program (and, if so, the specifics of the program), the level of cost sharing between the plan and its members, the composition and type of the pharmacy network, and the incentives offered to members for using in-network or preferred pharmacies.[36] Plan sponsors are solely responsible for benefit design decisions. The PBM offers plan design options, helps plan sponsors model different options, and supports the plan sponsor's chosen design. As a result, PBMs help administer thousands of unique plan designs.

12. The level of interaction between plan sponsors and PBMs varies. Health insurance plan sponsors generally contract with PBMs directly, though some may also self-supply some of the

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35 Burns (2022), pp. 374-375, 383. Purchasing coalitions such as Aon Rx Coalition and Willis Towers Watson Rx Collaborative provide plan design services as well. *See* Aon, "Aon Rx Coalition," available at https://www.aon.com/human-capital-consulting/rx-coalition/default.jsp (accessed June 11, 2024); WTW, "Rx Collaborative," available at https://www.wtwco.com/en-us/solutions/services/rx-collaborative (accessed June 19, 2024).

36 Burns (2022), pp. 382-386, 388-392.

PBM services such as formulary development and customer services. Smaller employers may obtain PBM services through their health insurance plan, while larger employers may contract directly with a PBM.[37] Employer plan sponsors of any size may also work with PBMs via purchasing coalitions of employers. These coalitions negotiate with the PBMs on behalf of their employer members, leveraging the size of their clients' collective membership to obtain favorable terms and reduce negotiation costs for these employers.[38]

13. A plan sponsor that negotiates directly with PBMs typically chooses a PBM through a competitive bidding process. Plan sponsors can use specialized drug benefit consultants when choosing a PBM or join in coalitions with other plan sponsors to negotiate on their behalf with the PBMs.[39] Such consultancies and coalitions assist plan sponsors with the bidding process by soliciting bids from the PBMs, comparing the PBM bidders' prices, services, and pharmacy networks, and presenting the options to the plan sponsors, which then choose the PBM and

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37 Burns (2022), pp. 370-373.

38 Examples of purchasing consortia include Aon Rx Coalition (includes more than 300 employers with a collective drug spend of at least $1.8 billion annually) (Aon, "Aon Rx Coalition," available at https://www.aon.com/human-capital-consulting/rx-coalition/default.jsp (accessed June 11, 2024)); Willis Towers Watson Rx Collaborative (includes more than 428 employers with a collective drug spend of $7 billion) (WTW, "Rx Collaborative," available at https://www.wtwco.com/en-us/solutions/services/rx-collaborative (accessed June 19, 2024)); Health Action Council (represents around 230 employers) (Health Action Council, "Members," available at https://healthactioncouncil.org/who-we-are/members/ (accessed June 11, 2024)); and Health Transformation Alliance (represents 60+ of America's largest employers who have self-insured employer health plans) (Health Transformation Alliance, available at https://www.htahealth.com/ (accessed June 11, 2024)).

39 Pharmaceutical Strategies Group, "2022 Trends in Drug Benefit Design Report," June 2022, available at https://www.psgconsults.com/benefitdesignreport2022, p. 19. For example, Employers Health has more than 350 plan sponsors with combined annual drug spending of 3.5 billion, the "Aon Rx Coalition" has more than 300 employers with combined annual drug spending of $1.8 billion, and RxBenefits states "With nearly 3M member lives and $3B in annual pharmacy spend under management, RxBenefits is able to extend to our clients the negotiating power of a Fortune 10 company to secure the best available rates and rebates from the industry's leading PBMs." Employers Health, "Pharmacy Benefit Management," available at https://www.employershealthco.com/pbm (accessed June 12, 2024); Aon, "Aon Rx Coalition," available at https://www.aon.com/human-capital-consulting/rx-coalition/default.jsp (accessed June 11, 2024); RxBenefits, "About RxBenefits," available at https://www.rxbenefits.com/about-us/about-rxbenefits/ (accessed June 12, 2024).

services desired. These consultancies and coalitions also can handle contract negotiations with the PBMs, conduct financial oversight and monitoring of PBMs, and conduct audits of rebate payments or other contract terms with PBMs to ensure compliance.[40] PBM contracts with plan sponsors typically last between one and five years, and then plan sponsors may put their business out for competitive bid. Many plan sponsors also negotiate "market check" provisions in their PBM contracts at specified intervals to ensure that the plan sponsors benefit from better terms offered by their current PBM and/or other competing PBMs during the term of the contract.[41] Plan sponsors may switch PBMs if they are not satisfied with their PBM's performance or if they receive a better offer from another PBM for one or more services. (PBM competition to serve plan sponsors is discussed in more detail in Section IV below.)

D. PBMs NEGOTIATE WITH BRANDED DRUG MANUFACTURERS TO HELP PLAN SPONSORS LOWER BRANDED DRUG COSTS

14. PBMs can reduce plan sponsor drug costs by creating or customizing formularies that plan sponsors may use to provide incentives for members to choose less-expensive drugs. PBMs also contribute to lower drug costs by negotiating with manufacturers to obtain discounts and other price concessions (*e.g.*, price protection). We first describe drug formularies and their

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40 Aon, "Health Plans Consulting," available https://www.aon.com/human-capital-consulting/health-plans (accessed August 29, 2024); Apex Benefits, "Pharmacy Benefits Consulting," available at https://apexbg.com/what-we-do/kinetiq-health/pharmacy-benefits-consulting/ (accessed June 12, 2024); Exude, "Pharmacy Consulting," available at https://www.exudeinc.com/solutions/employee-benefits/exuderx/ (accessed August 29, 2024); Hall Render Advisory Services, "Pharmacy, 340B and Pharmacy Benefits Consulting," available at https://hallrenderas.com/service/pharmacy-340b-and-pharmacy-benefits-consulting/ (accessed August 29, 2024); Mercer, "Pharmacy Solutions," available at https://www.mercer.com/en-us/solutions/health-and-benefits/specialty-solutions/pharmacy-solutions-mercerrx/ (accessed August 29, 2024); Milliman, "Pharmacy Benefits Consulting," available at https://www.milliman.com/en/services/pharmacy-benefits-consulting (accessed July 2, 2024); Pharmaceutical Strategies Group, "Pharmacy Benefits Consulting," available at https://www.psgconsults.com/solutions/pharmacy-consulting/ (accessed August 29, 2024).

41 *United States* v. *CVS Health Corp.*, 407 F. Supp. 3d 45, 57 (D.D.C. 2019) ("PBM customers have ways of ensuring that they receive the best deal the market can offer. Clients, for example, 'demand market checks, which means, even if you have a 3-year contract, ... during the contract[,] ... that PBM client will have the right to take the business back out for a market check.'").

incentive structure and then discuss how formularies impact negotiations with drug manufacturers.

15. Formularies are lists of drugs that are covered under a drug benefit plan. Drugs not included on a formulary may require a member to pay more for the drug. Excluded drugs typically have less expensive, therapeutically equivalent alternatives that are available on the formulary, so encouraging members to use these alternatives saves the plan and its members money without compromising care. Alternatively, plan sponsors may decide to include practically all drugs on a formulary without exclusions, which is likely to result in higher costs to the plan and its members as there will be greater utilization of more expensive drugs that have less expensive therapeutic alternatives available.

16. As discussed above, plan sponsors may adopt a formulary with different tiers to incentivize their members to use lower-cost alternatives. Plan sponsors may prefer a benefit plan such that members have a "lower copayment or coinsurance rate" for drugs on a preferred tier than for drugs on a non-preferred tier.[42] For example, members may have a zero-dollar copay for a generic drug that is placed on the first tier but a $25 copay for a therapeutically comparable branded version of the drug on the second tier. Furthermore, plan sponsors may decide to establish and implement utilization management programs for drugs in higher (less preferred) tiers, such as step therapy. This structure incentivizes members to work with their physicians to have drugs prescribed that have a lower cost for the plan sponsor and member, where clinical alternatives are available.[43]

17. Plan sponsors choose from many different formulary structures. Figure 1 illustrates potential benefit design structures for formularies with multiple tiers, ranging from two-tier to six-tier designs.[44] For example, a common design places generic drugs on the lowest tier with the lowest co-pay for plan members. This design encourages the use of generic drugs where

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42 Congressional Budget Office, "Prescription Drugs: Spending, Use, and Prices," January 2022, available at https://www.cbo.gov/system/files/2022-01/57050-Rx-Spending.pdf (hereinafter, "CBO Report (2022)"), p. 7. *See also,* Burns (2022), p. 390.

43 Fein Report (2024), p. 158. *See also,* Burns (2022), p. 382.

44 Fein Report (2024), p. 191.

available and has contributed to a substantial increase in the use of generics, which comprise about 91% of all prescriptions.[45]

18. With multiple possible formulary configurations, drug manufacturers can offer different rebate rates relating to how much volume a given formulary configuration would be expected to deliver to them. For example, "for a drug class with three competitive therapeutic alternatives, a manufacturer may offer the largest rebate for a formulary where its drug is the only one in the class with preferred status, a smaller rebate … where two of the three alternatives have preferred status, and no rebate if all three drugs are preferred."[46] By negotiating a range of different rates conditional on how the manufacturer's drug is treated in formularies chosen by plan sponsors, PBMs enable plan sponsors to evaluate each formulary design option, whether it is to cover one, two, or all three competing drugs in a particular category. To aid in formulary choice, PBMs analyze the net costs of the various manufacturers' contracted rates and create a variety of template formularies for plan sponsors to adopt or use as a potential starting point in designing their own formularies. In creating templates, PBMs undertake extensive modeling of different formulary combinations and drug placement options to evaluate which configurations would help plan sponsors generate the lowest net costs on average conditional on different formulary breadth preferences.

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45 U.S. Food and Drug Administration, "Office of Generic Drugs 2022 Annual Report," January 2023, available at https://www.fda.gov/media/165435/download?attachment, p. 1.

46 Froeb and Shor (2023), p. 7.

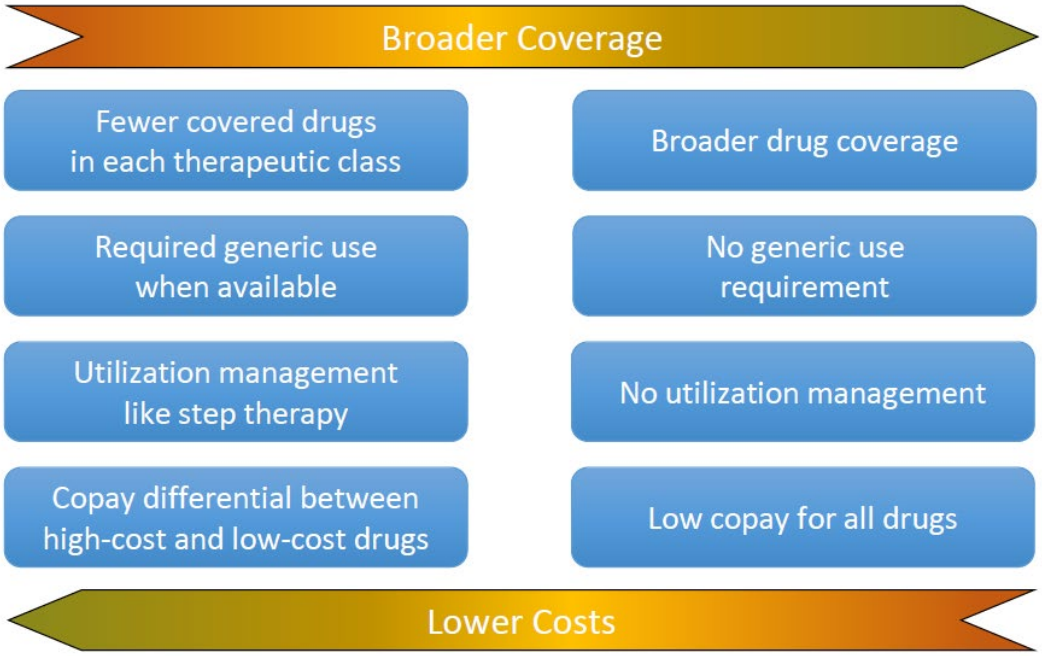
Figure 1: Common Drug Formulary Designs[47]

Tier	Two-Tier Design	Three-Tier Design	Four-Tier Design	Five-Tier Design	Six-Tier Design
First	Generic	Generic	Generic	Generic	Generic
Second	Brand	Preferred Brand	Preferred Brand	Preferred Brand	Preferred Brand
Third		Nonpreferred Brand	Nonpreferred Brand	Nonpreferred Brand	Nonpreferred Brand
Fourth			Specialty	Preferred Specialty	Preferred Specialty
Fifth				Non-Preferred Specialty	Non-Preferred Specialty
Sixth					Lifestyle

19. Plan sponsors balance the breadth of coverage against the costs of each formulary option for the plan and its members. The plan sponsor can choose whether its benefit plan will cover all drugs or a subset within each therapeutic category, provide incentives for generic use (where available) or not, implement utilization management or not, and charge different copays on certain drugs versus others. Generally, plan designs with greater restrictions have lower costs for the plan and its members, which help improve overall affordability for members.

47 Fein Report (2024), Exhibit 113, p. 191. Lifestyle drug is a term that may be applied "to any drug intended or used for a problem that falls into the border zone between the medical and social definitions of health" and/or drugs "intended to treat diseases that result from a person's lifestyle choices." (Joel Lexchin, "Lifestyle drugs: issues for debate," *Canadian Medical Association Journal* 164, no. 10 (2001): 1449-1451.)

Figure 2: Tradeoff Between Prescription Drug Coverage and Costs[48]



20. The total rebates paid by a manufacturer depends on the distribution of drugs utilized across the formulary configurations chosen by plan sponsors. When clinically appropriate alternatives are available, as determined by the PBM's P&T Committee, plan sponsors are more likely to include lower-priced drugs on their formularies and in preferred formulary positions. Because plans typically incentivize their members to choose preferred or on-formulary drugs where these competitive alternatives exist, manufacturers offering lower net costs (after accounting for all rebates, price concessions, and other discounts) can expect higher sales volumes.[49] Thus, the PBM negotiations with manufacturers are very similar to those that occur throughout other parts of the healthcare sector—and, indeed, the economy as a whole—with lower net prices resulting in higher volumes.

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48 Froeb and Shor (2023), p. 9.

49 *See*, *e.g.*, CBO Report (2022), p. 7. The ability to shift utilization to alternative, lower cost drugs depends on the ability of patients to safely switch from a current medication to a therapeutic alternative. The more patients are able to safely switch, the more competition a given drug faces.

21. A manufacturer's overall net price for a drug after all rebates and other payments depends in part on the amount of competition for formulary placement from therapeutic alternatives to that drug. Branded drug manufacturers tend to offer low or no rebates on drugs for which there is little or no competition. By contrast, branded drug manufacturers tend to offer larger rebates and other concessions on drugs that face substantial competition from therapeutic alternatives.[50] In practice, rebates are negotiated on only a small percentage of covered drugs.[51]

E. PBMs NEGOTIATE WITH RETAIL PHARMACIES TO LOWER THE FULFILLMENT COST OF DRUGS FOR PLAN SPONSORS

22. PBMs offer plan sponsors a variety of pharmacy network options that plan sponsors can choose as part of their drug benefit plan design or enable plan sponsors to design a custom network. Plan sponsors can structure benefit plans so that plan members pay different amounts for prescriptions depending on whether they use a pharmacy that is "in-network" or "preferred" and thus can incentivize members to use lower-priced, in-network pharmacies when available and permitted by law.[52] Similar to the way in which formularies foster competition among drug manufacturers, pharmacy networks can foster competition among pharmacies, which can obtain increased volume by offering discounts to gain membership in the pharmacy network.

23. PBMs offer—and plan sponsors can choose from—different types of pharmacy networks:

- In an "open" pharmacy network, a member's copay typically does not vary by pharmacy for the same drug, and the network includes any pharmacy that contracts with the PBM to be part of the network (which is typically almost all pharmacies in the country). Since there is no financial incentive for a member to favor one pharmacy over another, pharmacies in an open network do not expect to gain incremental sales from offering discounts to the PBM.

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50 *See*, *e.g.*, *Id*.

51 *See*, *e.g.*, Government Accountability Office, "Medicare Part D: CMS Should Monitor Effects of Rebates on Drug Coverage and Spending," Testimony Before the Subcommittee on Health, Committee on Energy and Commerce, House of Representatives (September 19, 2023) (Statement of John E. Dicken, Director, Health Care), available at https://www.gao.gov/assets/gao-23-107056.pdf, p. 3.

52 Burns (2022), pp. 437, 444, 499.

- In a "preferred" pharmacy network, in-network pharmacies are designated as preferred or non-preferred; members can fill their prescription at any pharmacy in the network, but their copay is lower if the prescription is dispensed by a preferred pharmacy rather than a non-preferred pharmacy. Thus, preferred pharmacies can expect higher volumes and are willing to accept a lower compensation in exchange. This preferred network design helps plan sponsors save money through the use of these incentives, where permitted by law.[53] Preferred networks may vary in size depending on the plan sponsor's budget and need to provide sufficient coverage for members.

- Finally, in a "limited" pharmacy network, certain pharmacies may be excluded from the network and prescriptions filled at excluded pharmacies are not covered by the plan unless the plan sponsor grants an exception. This type of network gives members an incentive to use lower-cost, in-network pharmacies; pharmacies can expect to gain increased volume by being included in such networks and may therefore be willing to agree to deeper discounts in exchange for inclusion. As with preferred networks, limited networks can be customized by plan sponsors, where permitted by law, and can vary in size depending on the plan sponsor's budget and needs, including network adequacy.

24. Negotiations between PBMs and pharmacies determine the total compensation rate that the pharmacy receives for prescriptions filled under each of the pharmacy networks in which the pharmacy is included. Pharmacy compensation usually includes a payment for the cost of drugs dispensed plus a dispensing fee.[54]

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53 Drug Channels, "Straight From the FTC: Why Any Willing Provider Laws Hike Costs," March 14, 2014, available at https://web.archive.org/web/20231210065034/https://www.drugchannels.net/2014/03/straight-from-ftc-why-any-willing.html (accessed June 12, 2024) ("More than 30 states have passed Any Willing Provider (AWP) or Freedom of Choice (FOC) laws. They require payers to open their networks to any provider willing to accept the terms of a given plan. Many of these laws are specifically directed at pharmacy services.").

54 The PBM pays the pharmacy the total compensation agreed to less the member co-pay which the pharmacy receives from the member upon filling the prescription. Burns (2022), pp. 378-379.

25. Large retail pharmacy chains—including chains of grocers, general merchandisers, and club stores that offer pharmacies inside their stores—typically negotiate directly with PBMs.[55] Smaller, independent pharmacies typically participate in Pharmacy Service Administrative Organizations (PSAOs) that negotiate with PBMs for their pharmacy members.[56] Some PSAOs have several thousand independent pharmacy members and are larger than many retail pharmacy chains.[57]

26. The establishment of pharmacy networks also allows PBMs to perform several other functions that improve the efficiency of the dispensing process and enhance member care. First, a PBM typically uses an electronic communication system to link to network pharmacies, allowing for real-time, efficient processing of a member's prescriptions and eliminating the need for paper claims and retrospective adjudication.[58] Electronic communication also permits the pharmacist to verify the member's eligibility, whether the drug is covered by the member's insurance, and the amount of copayment and/or coinsurance the member is required to pay.[59] Second, the PBM, which may be the only entity with a comprehensive prescription medication history of the member, can perform a drug utilization review to alert the pharmacist to any potentially harmful drug interactions.[60] Third, by investigating and auditing prescription claims

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55 Fein Report (2024), p. 179.

56 Health Evaluations (commissioned by PCMA), "Pharmacy Services Administrative Organizations (PSAOs) and Their Little-Known Connections to Independent Pharmacies," 2021, available at https://www.pcmanet.org/wp-content/uploads/2021/01/PSAO-Report_Health-Evaluations-1.pdf, p. 8 ("In 2019, about 83% of independent pharmacies reported using a PSAO.").

57 For example, Health Mart Atlas, a large PSAO in the U.S., has more than 6,800 community pharmacies within its network. (Health Mart Atlas, available at https://www.healthmartatlas.com/home (accessed June 13, 2024).) In comparison, Rite Aid operates "more than 1,700 retail pharmacy locations across 16 states." (Rite Aid, "Our Story," available at https://news.riteaid.com/about-us/history/default.aspx (accessed June 13, 2024).) Similarly, Kroger has 1,195 pharmacy locations. (Kroger, "Pharmacy Locations," available at https://www.kroger.com/stores/pharmacy (accessed June 13, 2024).)

58 Fein Report (2024), p. 177. *See also,* Burns (2022), pp. 418, 435-436.

59 Fein Report (2024), pp. 177-178. *See also*, Burns (2022), pp. 438-439.

60 Burns (2022), p. 608, citing a 2016 version of the Visante study (Visante, "The Return on Investment (ROI) on PBM Services," November 2016, available at

for errors and irregularities, PBMs can better attempt to detect or prevent fraud, waste, and abuse, and to confirm that contracted pharmacies are operating in compliance with state and federal laws and regulations.[61]

https://www.pcmanet.org/wp-content/uploads/2016/11/ROI-on-PBM-Services-FINAL.pdf), which indicates PBMs were estimated to prevent 1 billion medication errors over the course of 10 years. Burns (2022) discusses how the adjudication of prescription claims involves checking for drug interactions and links this to automation of prescription claims processing. Burns (2022), pp. 378, 442, and 457.

[61] Fein Report (2024), p. 178; Health Evaluations (commissioned by PCMA), "Pharmacy Audits: An Important Tool for Fighting Fraud, Waste, and Abuse and Protecting Patients," White Paper, January 2023, available at https://www.pcmanet.org/wp-content/uploads/2023/01/PBM-Pharmacy-Audit-White-Paper-1.pdf, p. 6.

II. PLAN SPONSORS COMPENSATE PBMS FOR THEIR SERVICES USING SEVERAL MECHANISMS OF THE PLAN SPONSORS' CHOOSING

27. To understand how plan sponsors pay PBMs for their services (either directly or indirectly), it is useful to understand how drugs are distributed to members and how payments for the drugs are made. In the pharmaceutical distribution chain, a drug manufacturer typically sells its drug to wholesalers who distribute the drug to retail pharmacies.[62] In turn, the retail pharmacies sell the drug to the members to whom the drug has been prescribed. Plan sponsors and the PBMs that plan sponsors use to administer their prescription benefit programs do not participate in the distribution of drugs (except insofar as the PBM operates its own pharmacies).[63]

28. A PBM typically receives the rebates and other price concessions negotiated with the branded drug manufacturer for prescriptions filled by the PBM's clients' members. The PBM, in turn, typically passes through most or all of the rebates it receives from the manufacturer to the plan sponsor and its members. For branded drugs that face little or no competition from other manufacturers—and for generic drugs—manufacturers typically do not pay rebates.

29. Plan sponsors determine how rebates are distributed.[64] Plan sponsors may choose to allocate some or all of the rebates to members at the point-of-sale as one means of reducing out-

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62 In this chain, the drug manufacturer sets the price that it charges the wholesaler typically equal to the list price, wholesale acquisition cost (WAC), less a discount. (WAC is the reference price typically used when manufacturers sell to wholesalers. AWP is the reference price typically used when plan sponsors pay PBMs and when PBMs reimburse pharmacies. Fein Report (2024), pp. 271-72.) The wholesaler then sets the price charged to the retail pharmacy, typically equal to the price it pays the drug manufacturer plus a small markup. Some larger pharmacies have their own drug distribution systems and thus do not use wholesalers for all drugs.

63 PBMs only take title and participate in the physical distribution of drugs to members when dispensing them through their own affiliated pharmacies, which are at the retail level of the drug distribution chain.

64 The plan sponsors ability to allocate rebates may be limited by law. Under some state laws, for example, point-of-sale rebates may be required for some plans (*e.g.*, Affordable Care Act exchange plans) or for certain drugs. Although point-of-sale rebates are not required for all plan types, PBMs nonetheless recommend that plan sponsors consider using point-of-sale rebates or discounts to reduce out-of-pocket costs for members. *See, e.g.*, Optum Rx, "Quality, access and affordability," 2023, available at

of-pocket costs for the members who purchase the rebated drugs via a smaller copay or coinsurance payment at the point of sale. Alternatively, the plan sponsor may specify that the PBM transfers all of the rebates to the plan sponsor, which it can use as it sees fit (*e.g.*, to reduce premiums or out-of-pocket costs for members). In other cases, the plan sponsor will allow the PBM to retain a small, negotiated percentage of the rebate payments as part of the compensation for the PBM's services. PBM rebate retention is often 0%, however, meaning that 100% of the rebates that PBMs receive from manufacturers are transferred to the plan sponsor. (See Section V below.)

30. As discussed above, PBMs also commonly negotiate with pharmacies to determine plan sponsors' compensation to pharmacies for the drugs dispensed to the plan sponsors' members. After the pharmacy dispenses the drug to a plan's member, the PBM typically pays the pharmacy an amount pursuant to the contractual terms negotiated with the pharmacy for the PBM pharmacy network used by that plan. The amount paid to the pharmacy is generally based on the drug manufacturer's average wholesale price (AWP) for the drug less a discount, plus a dispensing fee. In turn, the plan sponsor reimburses the PBM for the payment made to the pharmacy based on the terms agreed to by the PBM and the plan sponsor.[65] The price the plan sponsor pays the PBM can differ from the price the PBM pays the pharmacy, either positively or negatively. When the plan sponsor pays the PBM something different from what the PBM pays the pharmacy, the difference—known as the "retail spread"—is a source of revenue or loss to the PBM.

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https://www.optum.com/content/dam/optum4/resources/pdf/orx4750208_221114_interactive_formulary_management_white_paper_final.pdf; UnitedHealth Group, "Successful Prescription Drug Discount Program Expands to Benefit More Consumers at Point-of-sale," March 12, 2019, available at https://www.unitedhealthgroup.com/newsroom/2019/2019-03-12-prescription-drug-program-expands-to-benefit-consumers-point-of-sale.html (accessed July 2, 2024).

[65] From an economic standpoint, it is immaterial whether the plan sponsor pays the pharmacy directly or the PBM handles the payment to the pharmacy and is reimbursed by the plan sponsor. The amount the pharmacy receives is pursuant to the contract that the PBM negotiated for its plan sponsors with the pharmacy. If one thinks of the plan sponsor as paying the pharmacy, the "retail spread," if any, can be viewed as a fee paid by the plan sponsor to the PBM for its services.

31. A PBM may have multiple sources of revenue from a plan sponsor but will not necessarily earn revenue from all of these sources in relation to its work on behalf of each plan sponsor.[66] Instead, the total revenue as well as the components of the revenue a PBM receives from a given plan sponsor depend on the details of the PBM's contract with that plan sponsor. One plan sponsor may contract to pay a low (or even negative) amount for one component while another plan sponsor contracts to pay a high amount for that same component; even so, holding costs the same, the total amount the two plan sponsors pay to the PBM across all components of revenue may be the same. For example, a PBM contract with a client that provides for the PBM to retain a portion of rebates but no retail spread may provide the same total revenue for the PBM as a contract that passes through 100% of the rebates and has a positive retail spread. Stated another way, a PBM can earn the same total revenue from a client through different sources and levels of payments. During the RFP process, plan sponsors (and their consultants, when used) calculate the all-in expected costs for each PBM bid in deciding which PBM to hire, factoring in the plan sponsors' possible preferences over the different payment mechanisms.

32. The mechanisms a plan sponsor may use to compensate PBMs for the services they provide include:

- Per-claim fees: These are per-claim administrative fees that a plan sponsor may pay a PBM.

- Per-member, per-month fee: The plan sponsor may pay the PBM a fixed administrative fee per member, per month.

- Retail spread: As discussed above, this is the difference, if any, between the drug reimbursement that a PBM receives from the plan sponsor and the drug reimbursement that a PBM pays to a pharmacy. A retail spread may be positive (profit) or negative (loss) for the PBM. Plan sponsors may employ "spread pricing" where there is a non-zero retail spread or "no-spread pricing,"[67] under which plan sponsors pay PBMs the same amount that the PBM pays to the pharmacy. Plan sponsors and PBMs routinely use both approaches (or even a hybrid of the two),

66 Fein Report (2024), pp. 183-189.

67 This form of pricing is sometimes referred to as "pass-through pricing."

though surveys show a majority of employers have opted for no-spread pricing arrangements with PBMs.[68]

- Retained rebates and fees: This is the amount of the manufacturer rebates and other payments (*e.g.*, price protection) that a PBM receives from drug manufacturers (based on the utilization of the manufacturers' drugs by a given plan sponsor's members) that the plan sponsor agrees to allow the PBM to retain as payment for its services. PBMs also charge some manufacturers a "manufacturer administrative fee" for administering the rebate program and performing other services for the manufacturers; plan sponsors may negotiate with PBMs for passthrough of those fees as well. In many cases, plan sponsors negotiate to receive 100% of rebates and fees, which means the PBM retains none of the rebates and fees.

- Other customized compensation mechanisms: Plan sponsors can customize other compensation mechanisms. For example, in some cases, plan sponsors may use the PBM's mail-order or specialty pharmacy networks and compensate the PBM for dispensing prescription drugs to plan members.

33. Plan sponsors can use one or more of these mechanisms to compensate the PBM for the various pharmacy benefit management services the PBM performs. The plan sponsor can decide the combination of payment mechanisms to employ depending on its own preferences and requirements. Each item is typically negotiated and memorialized in a contract between the plan sponsor and PBM. Different plan sponsors may prefer different combinations of payment mechanisms depending on their willingness to bear risks or their cash flow priorities.

34. It is not necessarily meaningful to focus on one particular component of revenue in isolation since it is the sum of payments that matter to the PBM and the plan sponsor. But we discuss two components that some critics have focused on: spread pricing and retained rebates.

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[68] For example, a "2020 survey of 50 large employers found that 36% used spread pricing." Fein Report (2024), p. 467 citing *Pharmacy Benefit Management: Takeaways from Our Latest Proprietary PBM Survey*, J.P. Morgan, June 24, 2020, p. 31. A Drug Channels Institute analysis of PBMI/PSG reports found that 28% and 34% of employers in 2022 and 2023, respectively, utilized spread pricing in their PBM contracts. Fein Report (2024), Exhibit 110, p. 184.

35. Several considerations affect whether a plan sponsor chooses spread pricing or no-spread pricing. For example, spread pricing and no-spread pricing carry different levels of risk to the plan sponsor. Spread pricing gives the plan sponsor greater certainty as to what the plan sponsor will owe for a particular type of prescription by setting a fixed rate rather than potentially paying a variety of rates over time depending on which pharmacy a member uses (to the extent the PBM negotiates different rates with different pharmacies within a given pharmacy network). With spread pricing, the plan sponsor shifts more of the risk of variation in drug prices across retail pharmacies to the PBM, and the plan sponsor may pay some premium to the PBM for shifting this risk (*i.e.*, the spread price may exceed the expected average amount the PBM pays to pharmacies). This risk may result in negative or positive network spreads for the PBM, while plan sponsors receive greater protection from fluctuations in pharmacy reimbursement. In comparison, under the no-spread approach, the plan sponsor assumes more of the risk of drug price variation across pharmacies. Because the PBM does not have an opportunity to earn a retail spread under the no-spread approach, the plan sponsor may instead compensate the PBM through some combination of rebate retention, client administrative fees, and/or any of the other ways PBMs can be compensated.

36. PBMs do not necessarily make more money under spread pricing compared to the no-spread approach, or vice versa. Likewise, plan sponsors do not necessarily save more money under one arrangement or the other. For example, the negotiated rate for a spread pricing arrangement may be for an amount below what the PBM actually reimburses pharmacies, in which case the plan sponsor saves money with spread pricing compared to no-spread pricing, and the PBM loses money, all else equal.

37. With regard to rebates (setting aside rebates that are passed on to members at the point of sale), plan sponsors may require 100% pass-through of rebates, fees, and other payments (*e.g.*, price protection) by manufacturers, with no retention by the PBM. Alternatively, plan sponsors may allow the PBM to retain some negotiated portion of the rebates. Many plan sponsors require 100% pass-through of rebates. For example, a recent survey showed that the majority of both large and small employers received 100% of rebates.[69]

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[69] Pharmaceutical Strategies Group, "2023 Trends in Drug Benefit Design Report," 2023, available at https://www.psgconsults.com/2023traditionalbdr, p. 54.

38. Some plan sponsors may prefer more certainty about the amount of rebates they will receive and thus may contract with their PBM for a "rebate guarantee," which typically involves the plan sponsor receiving the *greater of* its negotiated rebate share and a fixed dollar amount.[70] Some plan sponsors negotiate to receive rebate guarantees on all branded drugs, even drugs for which the PBM has not negotiated rebates, thereby ensuring that rebate payments are not dependent on utilization of specific drugs. Plan sponsors may prefer this arrangement as it may make for easier financial planning. If the rebates the PBM receives from manufacturer are less than the rebates the PBM guarantees to the plan sponsor, the realized pass-through rate will be more than 100%.

[70] *See* Burns (2022), p. 387.

III. PLAN SPONSORS' CHOICE TO HAVE PBMs IMPLEMENT FORMULARIES AND OTHER UTILIZATION CONTROLS CAN REDUCE THE COST OF PRESCRIPTION DRUG PLANS

39. Some critics have asserted that PBMs' development of formularies and other utilization controls have worsened member outcomes by limiting choice. We describe in this section why these claims are unfounded. As discussed in Section I, although PBMs provide the tools for plan sponsors to implement formularies, plan sponsors make the decision on what formularies are used and how they are implemented, including any utilization controls to contain costs. In addition, when designing formularies, financial considerations cannot override what is deemed clinically necessary by P&T committees. By offering certain formularies (and pharmacy networks) that may not include all available medication options (or pharmacies) to plan sponsors, PBMs can negotiate with drug manufacturers (and pharmacies) for discounts in exchange for plan sponsors delivering higher expected volumes. In this section, we discuss how such "selective contracting" is common in the healthcare industry, and has been shown to lead to lower costs (Section III.A).[71] We also discuss how formularies are an effective tool to shift demand to lower cost options where appropriate (Section III.B). Ultimately, lower drug costs can help increase patient access to affordable medications.

A. LEVERS USED BY PBMS IN NEGOTIATIONS WITH DRUG MANUFACTURERS AND PHARMACIES ARE SIMILAR TO LEVERS USED IN OTHER PARTS OF THE HEALTHCARE INDUSTRY TO REDUCE THE COST OF HEALTH CARE, AND THE FTC HAS SUPPORTED THE USE OF THESE LEVERS

40. When there are several drugs in the same therapeutic class, PBMs can use the threat of plan sponsors' moving sales from one drug to another based on the structure of the formulary that plan sponsors select to create incentives for drug manufacturers to provide rebates and other price concessions. Similarly, PBMs can use the threat of plan sponsors' shifting volume from one pharmacy to another in order to obtain favorable pricing terms from pharmacies. Thus,

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71 In the context of pharmacies, *see*, *e.g.*, Daniel Hosken, David Schmidt, and Matthew C. Weinberg, "Any Willing Provider and Negotiated Retail Pharmaceutical Prices," *Journal of Industrial Economics* 68, no.1 (2020): 1-39; Amanda Starc and Ashley Swanson, "Preferred Pharmacy Networks and Drug Costs," *American Economic Journal: Economic Policy* 13, no. 3 (2021): 406-446.

PBMs can help plan sponsors use the design of a formulary or pharmacy network to reduce drug-related expenditures.

41. Crucial to the ability to obtain discounts from drug manufacturers and pharmacies is the ability of plan sponsors to influence plan members' demand for different products when clinically appropriate. As we explained in Section I, the threat of exclusion from plan sponsors' formularies, or the threat of being placed on a less preferred tier, incentivizes the drug manufacturer to offer discounts on drug prices in exchange for increased expected sales volume.[72] Similarly, the threat of exclusion from plan sponsors' pharmacy networks, or the threat of not being a preferred pharmacy, incentivizes the pharmacy to offer discounts on reimbursement rates and dispensing fees in exchange for increased expected sales volume. By adopting pharmacy benefit design structures that make on-formulary or preferred drugs lower cost to members and offer members lower copayments or coinsurance rates at in-network pharmacies, plan sponsors can incentivize members to choose on-formulary drugs and to fill their prescriptions at in-network pharmacies, which reduces drug costs for the plan sponsor and members.

42. The use of formularies is not restricted to pharmacy benefit programs managed by PBMs. Large private and public employers who manage portions of their own pharmacy benefit programs without the assistance of PBMs also find it beneficial to design and use formularies to obtain lower prices from drug manufacturers. For example, the University of Michigan self-manages a formulary for its over 100,000 plan members;[73] both the Veterans Administration and the Department of Defense use their own formularies in an attempt to lower prices from drug

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[72] Rena M. Conti, *et al.*, "Common Agent or Double Agent? Pharmacy Benefit Managers in the Prescription Drug Market," Working Paper 28866, *National Bureau of Economic Research* (2021): 1-20 at 2. *See also*, Fein Report (2024), p. 150; Froeb and Shor (2023), p. 6.

[73] University of Michigan Human Resources, "2021 Prescription Drug Plan Annual Report," March 15, 2022, available at https://hr.umich.edu/sites/default/files/2021_prescription_drug_plan_annual_report.pdf, p. 6.

manufacturers;[74] and many state Medicaid programs manage their own formularies.[75] These formulary tools are used because they are expected to lower costs.[76]

43. In short, drug formularies and pharmacy networks are examples of "selective contracting," which is the process of negotiating with suppliers over their participation in a network where there are strong incentives for final customers to use suppliers in the network. Selective contracting is widely used in the healthcare industry in the United States because it enables purchasers to negotiate discounts from suppliers by credibly altering final demand for products.[77] In particular, health insurance companies negotiate with hospitals whereby hospitals agree to lower reimbursement rates for services in exchange for being granted "in-network" status.[78] Insurance companies then incentivize their members to choose these lower-priced, in-

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74 David Blumenthal and David Squires, "Drug Price Control: How Some Government Programs Do It," The Commonwealth Fund Blog, May 10, 2016, available at https://www.commonwealthfund.org/blog/2016/drug-price-control-how-some-government-programs-do-it (accessed August 29, 2024).

75 Medicaid programs maintain open formularies but use utilization management tools such as preferred drug lists to contain costs. Rachel Dolan and Marina Tian, "Management and Delivery of the Medicaid Pharmacy Benefit Program," Kaiser Family Foundation, Issue Brief, December 2019, available at https://www.kff.org/medicaid/issue-brief/management-and-delivery-of-the-medicaid-pharmacy-benefit/ (accessed August 30, 2024); Kaiser Family Foundation, "Medicaid's Prescription Drug Benefit: Key Facts," May 1, 2019, available at https://www.kff.org/medicaid/fact-sheet/medicaids-prescription-drug-benefit-key-facts/ (accessed September 1, 2024).

76 For example, the University of Michigan states that "active formulary management" was a factor assisting in the mitigation of cost increases. (University of Michigan Human Resources, "2021 Prescription Drug Plan Annual Report," March 15, 2022, available at https://hr.umich.edu/sites/default/files/2021_prescription_drug_plan_annual_report.pdf, p. 7.) Similarly, the conclusion of the Commonwealth Fund – a health policy think tank – is that the government's use of formularies "clearly result in cheaper drugs for the VA, DOD, Medicaid, and 340B providers." (David Blumenthal and David Squires, "Drug Price Control: How Some Government Programs Do It," The Commonwealth Fund Blog, May 10, 2016, available at https://www.commonwealthfund.org/blog/2016/drug-price-control-how-some-government-programs-do-it (accessed August 29, 2024).)

77 Froeb and Shor (2023), p. 11; David Dranove, "Chapter 10: Health Care Markets, Regulators, and Certifiers," in *Handbook of Health Economics*, Vol 2 (York, UK: Elsevier, 2011) (hereinafter, Dranove (2011)), p. 648.

78 *See*, *e.g.*, Congressional Budget Office, "The Prices That Commercial Health Insurers and Medicare Pay for Hospitals' and Physicians' Services," January 2022, available at

network hospitals by charging lower copayments and/or coinsurance rates for those hospitals relative to out-of-network hospitals.[79] As is the case with PBM-drug manufacturer negotiations, the threat of being placed in an out-of-network or less-preferred tier (where the number of visits from members in that network would be lower) incentivizes hospitals to compete by offering lower prices.[80] The insurance companies similarly negotiate with outpatient providers such as physician networks and outpatient surgery centers for lower reimbursement rates in exchange for in-network status and therefore higher expected member visits due to financial incentives given to members to use in-network facilities.[81]

44. Academic research has found that the selective contracting practices of the healthcare industry have substantially reduced health care expenditures in the U.S.[82] For example, Broek-Altenburg and Atherly (2020) estimated that restricted networks reduced costs by an average of $761 per member, per year, with the reductions coming from inpatient costs ($335), outpatient costs ($159), and drug costs ($241).[83] These cost savings due to selective contracting were "largely a result of price reductions rather than utilization reductions."[84] In other words, Broek-Altenburg and Atherly showed that selective contracting reduced plan costs largely by lowering prices rather than by causing beneficiaries to forego treatments. Similarly, Gruber and McKnight (2016) showed that costs per member declined by 36% on average for the marginal members induced by incentives to switch to a plan with a limited provider network. These

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https://www.cbo.gov/system/files/2022-01/57422-medical-prices.pdf, p. 3. Health insurance PPO networks are an example of such a network.

79 Zirui Song, *et al*., "Out-Of-Network Spending Mostly Declined In Privately Insured Populations With A Few Notable Exceptions From 2008 To 2016," *Health Affairs* 39, no. 6 (2020): 1032-1041 at 1032.

80 *See*, *e.g.*, Congressional Budget Office, "The Prices That Commercial Health Insurers and Medicare Pay for Hospitals' and Physicians' Services," January 2022, available at https://www.cbo.gov/system/files/2022-01/57422-medical-prices.pdf, p. 3.

81 *Id*.

82 Dranove (2011), p. 640 ("With the growth of selective contracting between providers and payers, competition is now associated with lower prices.").

83 Eline M. van den Broek-Altenburg and Adam J. Atherly, "The relation between selective contracting and health care expenditures in private health insurance plans in the United States," *Health Policy* 124 (2020): 174-182 at 174, 177.

84 *Id*., p. 174.

estimated savings arose both from a decrease in price paid per visit and also from shifting of care from more expensive services (specialist care) to less expensive services (primary care).[85]

45. The FTC's enforcement agenda regarding the healthcare industry in the past few decades has been informed by its understanding of the importance of selective contracting in reducing prices for health care services in many markets. For example, consider the FTC's enforcement approach to hospital mergers. The FTC experienced a string of losses in its efforts to challenge hospital mergers in the 1990s. During this period, the FTC's articulation of how competitive harm from the proposed mergers would arise did not closely reflect the reality of competition, which had become premised on selective contracting.[86] Following the FTC's more explicit incorporation of the role selective contracting plays in disciplining prices and how that discipline can be attenuated by mergers (as demonstrated by scholarly work, including the FTC's retrospective analysis of multiple hospital mergers),[87] the Commission has succeeded in many of its litigated healthcare provider merger challenges.[88] Moreover, an FTC explanation of its approach to healthcare provider mergers acknowledges that the ability of insurers to exclude

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85 Jonathan Gruber and Robin McKnight, "Controlling Health Care Costs through Limited Network Insurance Plans: Evidence from Massachusetts State Employees," *American Economic Journal: Economic Policy* 8, no. 2 (May 2016): 219-250 at 220-221.

86 Cory S. Capps, "From Rockford to Joplin and back again: The impact of economics on hospital merger enforcement," *The Antitrust Bulletin* 59, no. 3 (2014): 443-478 at 455-456 ("This is not to say that either the DOJ and FTC or the courts entirely ignored the advent and rapid expansion of negotiations and selective contracting—they did not. However, the competitive analyses did not center on whether or not a particular merger would enhance the merging hospitals' bargaining leverage and thereby facilitate higher pricing"); Cory Capps, *et al.*, "The Continuing Saga of Hospital Merger Enforcement," *Antitrust Law Journal* 82, no. 2 (2019): 441-496 at 442-444.

87 Cory S. Capps, "From Rockford to Joplin and back again: The impact of economics on hospital merger enforcement," *The Antitrust Bulletin* 59, no. 3 (2014): 443-478; Cory Capps, *et al.*, "The Continuing Saga of Hospital Merger Enforcement," *Antitrust Law Journal* 82, no. 2 (2019): 441-496 at 444; Joseph Farrell, *et al.*, "Economics at the FTC: Hospital Mergers, Authorized Generic Drugs, and Consumer Credit Markets," *Review of Industrial Organization* 39, no. 4 (2011): 271-296.

88 *See*, *e.g.*, Bass, Berry, and Sims, "Antitrust Lessons from the FTC's Failed Bid to Halt the Jefferson-Einstein Hospital Merger," March 10, 2021, available at https://www.bassberry.com/news/jefferson-einstein-hospital-merger-antitrust/ (accessed June 11, 2024) ("Before [the Jefferson-Einstein Hospital Merger], the FTC had not lost a challenge to a hospital or provider merger in 20 years.").

healthcare providers from a network, which steers members away from using those higher-priced providers, is important in maintaining competition.[89] Similarly, in its recent Complaint challenging the proposed acquisition by HCA of five hospitals owned by Steward Health Care System, the FTC noted that:[90]

> Insurers can contain costs using a narrow-network plan [*i.e.*, one that excludes one or more hospitals] because in-network hospitals agree to lower rates or less favorable terms with the expectation that they will obtain a greater portion of patient volume than they otherwise would in a broad-network plan. Hospitals will often give rate and other concessions to insurers to exclude a competing hospital—or hospitals—from the insurer's narrow-network health plan.

46. Consistent with recognizing the importance of selective contracting in its enforcement actions, the FTC's public statements have repeatedly acknowledged the procompetitive implications of the ability to exclude suppliers from a network of suppliers. For example, the agency's public advocacy has cautioned against laws that would have the effect of undermining the "effectiveness of selective contracting by health plans, which serve to reduce health care costs and improve overall value in the delivery of health care services."[91]

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89 Julie A. Carlson, *et al.*, "Economics at the FTC: Physician acquisitions, standard essential patents, and accuracy of credit reporting," *Review of Industrial Organization* 43 (2013): 303-326.

90 Complaint, *In the Matter of: HCA Healthcare, Inc., Steward Health Care System, LLC, and Ralph de la Torre, M.D.*, Docket No. 9410, June 2, 2022, available at https://www.ftc.gov/system/files/ftc_gov/pdf/D9410HCAStewardPart3ComplaintPublic.pdf, p. 12; *see also* Complaint, *In the Matter of: John Muir Health and Tenet Healthcare Corporation*, Docket No. 9421, November 17, 2023, available at https://www.ftc.gov/system/files/ftc_gov/pdf/d09421jmhtenetpart3administrativecomplaintpublic.pdf, p. 4 ("A merger involving hospitals that insurers and their enrollees consider substitutes…may substantially lessen competition by increasing the merged entity's incentive and ability to raise prices or reduce quality, because the merger eliminates an available alternative that an insurer could otherwise offer (or threaten to offer) its health-plan members in response to increased prices or a reduction in service.").

91 Federal Trade Commission, "Re: Amendments to the Minnesota Government Data Practices Act Regarding Health Care Contract Data," Letter to The Honorable Joe Hoppe and The Honorable Melissa Hortman, Washington, D.C., June 29, 2013, available at https://www.ftc.gov/system/files/documents/advocacy_documents/ftc-staff-comment-regarding-amendments-minnesota-government-data-practices-act-regarding-health-care/150702minnhealthcare.pdf, p. 1. *See also*, Federal Trade Commission, "Re: Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the

47. Similarly, the Department of Justice (DOJ) and the State of North Carolina sued Atrium Health to prevent it from using contracts that restrict insurers' ability to steer patients towards low-cost (but high-quality) healthcare providers. The DOJ and the State of North Carolina ultimately reached a settlement with Atrium whereby Atrium agreed not to enforce or enter into such contracts. As the DOJ stated, "[s]teering can be one way of fostering competition" and lowering prices.[92]

48. The narrow provider networks and selective contracting that the FTC and DOJ have described as fostering competition and reducing prices are precisely analogous to the narrow formularies or pharmacy networks that PBMs offer in their efforts to lower prescription drug costs for their plan sponsor clients. Regulations—however well-intended—that restrict the use of formularies, pharmacy provider networks, or how discounts are negotiated have often been associated with meaningfully higher overall prescription drug expenditures. Research has shown the effectiveness of formularies, pharmacy networks, and discount negotiations in reducing drug expenditures.

- A recent study finds that restricting the number of tiers that may be in a formulary leads to a marked reduction in rebates. Moreover, the study finds that allowing PBMs to exclude drugs from a formulary leads to higher rebates.[93]

- The non-partisan Medicare Payment Advisory Commission (MedPAC) examined the impact of the Medicare Part D rule that plans must cover (virtually) all drugs in six protected classes. MedPAC concluded that this obligation has meaningfully limited plans' ability to encourage competition between branded drugs. As a result, rebates

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Medicare Prescription Drug Benefit Programs," Letter to the Centers for Medicare & Medicaid Services, March 7, 2014, available at https://www.ftc.gov/system/files/documents/advocacy_documents/federal-trade-commission-staff-comment-centers-medicare-medicaid-services-regarding-proposed-rule/140310cmscomment.pdf.

92 Competitive Impact Statement, *United States of America and the State of North Carolina* v. *The Charlotte-Mecklenburg Hospital Authority, d/b/a Carolinas Healthcare System*, Case No. 3:16-cv-00311-RJC-DCK, December 4, 2018, available at https://www.justice.gov/atr/case-document/file/1117111/dl?inline, pp. 2-3, 6.

93 Kate Ho and Robin S. Lee, "Contracting over Pharmaceutical Formularies and Rebates," Working Paper 32790, *National Bureau of Economic Research* (2024): 1-42.

on these drugs were "significantly lower, often averaging less than 10 percent of gross prices" when the average rebate as a share of gross spending across drug classes was 23%.[94]

- In 2019, the Department of Health and Human Services considered a rule that would limit the ability of PBMs and plan sponsors to negotiate rebates from drug manufacturers. Both the Congressional Budget Office (CBO) and Medicare's Office of the Actuary (OACT) evaluated the expected consequences of this rule on spending by the federal government. The two agencies independently arrived at estimates suggesting that the proposed rule's limits on discount negotiation would lead to increased federal expenditures of close to $200 billion between 2020 and 2029.[95]

- A study by an academic economist, which was supported by the Pharmaceutical Care Management Association (PCMA), considered the implications of laws that would prohibit PBMs from retaining any of the rebate payments they receive. The study finds that such a limitation on the ability of plan sponsors to decide on how best to compensate their PBMs would "significantly change drug pricing and utilization and shift billions of dollars annually from patients and taxpayers to drug manufacturers and retail pharmacy companies."[96]

- Research co-authored by two economists who are staff members of the FTC's Bureau of Economics and a professor at Ohio State University examined the impact of any-willing-provider laws that inhibit the ability of PBMs and plan sponsors to exclude

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94 Medicare Payment Advisory Commission, "Report to the Congress: Medicare and the Health Care Delivery System," June 2023, available at https://www.medpac.gov/wp-content/uploads/2023/06/Jun23_MedPAC_Report_To_Congress_SEC.pdf, p. 69, Table 2-1 at 77.

95 Congressional Budget Office, "Incorporating the Effects of the Proposed Rule on Safe Harbors for Pharmaceutical Rebates in CBO's Budget Projections—Supplemental Material for Updated Budget Projections: 2019 to 2029," May 2019, available at https://www.cbo.gov/system/files/2019-05/55151-SupplementalMaterial.pdf, pp. 3, 7.

96 Casey B. Mulligan, "Ending Pay for PBM Performance: Consequences for Prescription Drug Prices, Utilization, and Government Spending," Working Paper 31667, *National Bureau of Economic Research* (2023): 1-20 at 1, available at http://www.nber.org/papers/w31667.

high-priced pharmacies from their pharmacy networks. The study reported that "the cost savings associated with selective contracting [*i.e.*, limited networks] may be substantial" and found that restricting the ability to form a narrow network raised prices by 4% - 9%.[97] Moreover, it concluded that laws that force PBMs and plan sponsors to use open networks "reduc[e] competition by inhibiting the ability of insurers to move demand across competing pharmacies."[98]

- In a study published in 2021, academic economists considered the impact of preferred pharmacy networks on spending by Medicare Part D drug plans. Consistent with the findings of the paper co-authored by the two FTC economists and the Ohio State University professor, this study concludes that "Medicare Part D plans with preferred pharmacy networks pay lower retail drug prices."[99]

49. These findings are in keeping with other contributions to the economic literature—outside of the healthcare industry—which have shown that restrictions on how firms negotiate vertical contracts often lead to reductions in consumer welfare.[100]

B. FORMULARY DESIGN RESULTS IN INCREASED USAGE OF LOWER COST DRUGS

50. In this section, we discuss how formulary design has increased the usage of lower cost drugs, focusing on Caremark and Optum Rx, where available data allow investigation of formulary design. Specifically, we present examples of how formulary design incentivizes members to use lower-cost generic drugs when generics enter a therapeutic class.[101] Although

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97 Daniel Hosken, David Schmidt, and Matthew C. Weinberg, "Any Willing Provider and Negotiated Retail Pharmaceutical Prices," *Journal of Industrial Economics* 68, no.1 (2020): 1-39 at 1-3.

98 *Id.*, p. 1.

99 Amanda Starc and Ashley Swanson, "Preferred Pharmacy Networks and Drug Costs," *American Economic Journal: Economic Policy* 13, no. 3 (2021): 406-446 at 406.

100 *See*, *e.g.*, the literature surveyed in Francine Lafontaine and Margaret Slade, "Exclusive Contracts and Vertical Restraints: Empirical Evidence and Public Policy," in *Handbook of Antitrust Economics,* ed. Paulo Buccirossi (Cambridge, MA; London, UK: The MIT Press, 2008).

101 In limited instances, it can save costs for a branded drug to continue to be included on a preferred tier on a formulary even if a generic version is available. If a branded drug has

the dataset Express Scripts' produced does not allow for similar analyses, public statements by Express Scripts also indicate that Express Scripts' largest standard formulary includes almost all generic drugs.[102]

51. Table 1 shows examples of formulary changes following generic entry that Caremark implemented for its most commonly used template formulary, which, as described above, clients may use or customize for their own benefits plans.[103] In these examples, when a generic enters, it is placed on a preferred tier "PREF" while the branded drug may be relegated either to a non-formulary tier "N-FORM" (where the drug may still be partially covered by the plan) or to a non-formulary, non-covered tier "NFRM-NCVRD" (where the plan would not cover any cost of the drug). For this analysis, National Drug Codes (NDCs) are grouped at the Generic Product Identifier (GPI) level, which roughly corresponds to the drug/format/strength level for a particular product.[104]

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a lower net cost than a generic drug, then—assuming the objective is to reduce drug costs—it reduces expected costs to keep the branded drug on a preferred tier.

[102] Evernorth, "Driving Drug Savings Through Formularies," available at https://www.evernorth.com/esfacts/key-topics/driving-drug-savings-through-formularies (accessed September 10, 2024) ("Express Scripts' largest standard formulary, the National Preferred Formulary (NPF), includes about 600 brand-name drugs and 99% of all generics.").

[103] Year of generic entry is defined as the first year in which the generic NDC appears in the formulary data.

[104] An NDC, composed of 10-11 digits, is a unique identifier for drugs in the U.S: "The first set of numbers in the NDC identifies the labeler, such as the drug manufacturer, repackager, or distributor. The second set of numbers is the product code, which identifies the specific strength, dosage form … and formulation[.] The third set of numbers is the package code, which identifies package sizes and types." (Drugs.com, "National Drug Codes Explained," June 11, 2024, available at https://www.drugs.com/ndc.html (accessed June 11, 2024).) The GPI, composed of 14 digits, is a "hierarchical therapeutic classification system;" the GPI codes identify drug group, class, subclass, base name, name, form, and strength. (Wolters Kluwer, "Medi-Span Generic Product Identifier (GPI)," available at https://www.wolterskluwer.com/en/solutions/medi-span/about/gpi (accessed June 11, 2024).)

Table 1: Examples of Formulary Design Changes Following Generic Entry: Caremark Standard Control Formulary

			Formulary Position					
NDC	**Drug**	**Type**	**2017**	**2018**	**2019**	**2020**	**2021**	**2022**
00430375414	ESTRACE	BRND	PREF	PREF	N-FORM	N-FORM	N-FORM	N-FORM
00378877035	ESTRADIOL	GNRC		PREF	PREF	PREF	PREF	PREF
54092047602	LIALDA	BRND	PREF	PREF	PREF	NFRM-NCVRD	NFRM-NCVRD	NFRM-NCVRD
68382071119	MESALAMINE DR	GNRC		PREF	PREF	PREF	PREF	PREF
61958070101	TRUVADA	BRND	PREF	PREF	PREF	PREF	PREF	NFRM-NCVRD
00093770456	EMTRICITABINE/TENOFOVIR D	GNRC					PREF	PREF
61958040101	VIREAD	BRND	PREF	PREF	PREF	N-FORM	N-FORM	N-FORM
33342009607	TENOFOVIR DISOPROXIL FUMA	GNRC		PREF	PREF	PREF	PREF	PREF
12496120203	SUBOXONE	BRND	PREF	PREF	PREF	NFRM-NCVRD	NFRM-NCVRD	NFRM-NCVRD
47781035503	BUPRENORPHINE HYDROCHLO	GNRC			PREF	PREF	PREF	PREF
00023586228	TAYTULLA	BRND	N-FORM	N-FORM	N-FORM	NFRM-NCVRD	NFRM-NCVRD	NFRM-NCVRD
70700015285	GEMMILY	GNRC					PREF	PREF
00007337113	COREG CR	BRND	PREF	PREF	N-FORM	N-FORM	NFRM-NCVRD	NFRM-NCVRD
57664066483	CARVEDILOL PHOSPHATE ER	GNRC		PREF	PREF	PREF	PREF	PREF
60793041105	FLECTOR	BRND	N-FORM	N-FORM	N-FORM	N-FORM	N-FORM	N-FORM
59762070702	DICLOFENAC EPOLAMINE	GNRC				PREF	PREF	PREF
64406000602	TECFIDERA	BRND	PREF	PREF	PREF	PREF	NFRM-NCVRD	NFRM-NCVRD
00378039991	DIMETHYL FUMARATE	GNRC					PREF	PREF
00023585318	DELZICOL	BRND	NFRM-NCVRD	NFRM-NCVRD	NFRM-NCVRD	NFRM-NCVRD	NFRM-NCVRD	NFRM-NCVRD
00093590786	MESALAMINE DR	GNRC				PREF	PREF	PREF

Sources: Specs 19-20 and Specs 12-14 of Caremark 6(b) Submission to the FTC.
Notes:
1. Analysis limited to GPIs that have branded and generic drugs and in which generics enter as preferred; examples shown are the overlapping ten generic NDCs with some of the largest number of 30-day prescriptions in Caremark's claims data.
2. A GPI can have multiple branded and generic drugs.
3. Analysis considers Caremark's Standard Control Formulary, which is the most popular formulary by number of plan sponsors across 2017-2022.

52. Table 2 provides examples of formulary changes related to Optum Rx's Premium Standard Formulary. When a generic entered, it was typically placed on a "PREFERRED" tier, and the branded drug was moved from a "PREFERRED" tier to a "NON-PREFERRED" or EXCLUDED" tier, or from a "NON-PREFERRED" tier to an "EXCLUDED" tier in which the drug was no longer covered by the plan or required prior authorization.

Table 2: Examples of Formulary Design Changes Following Generic Entry: Optum Rx Premium Standard Formulary

			Formulary Position					
NDC	Drug	Type	2017	2018	2019	2020	2021	2022
71101468	LYRICA CAP 75MG	Brand	PREFERRED	PREFERRED	PREFERRED	EXCLUDED	EXCLUDED	EXCLUDED
72205001390	PREGABALIN CAP 75MG	Generic				PREFERRED	PREFERRED	PREFERRED
61958070101	TRUVADA TAB 200-300	Brand	PREFERRED	PREFERRED	PREFERRED	PREFERRED	EXCLUDED	EXCLUDED
93770456	EMTR/TENOFOV TAB 200-300	Generic					PREFERRED	PREFERRED
57894015012	ZYTIGA TAB 250MG	Brand	NON-PREFERRED	NON-PREFERRED	NON-PREFERRED	EXCLUDED	EXCLUDED	EXCLUDED
72205003092	ABIRATERONE TAB 250MG	Generic				PREFERRED	PREFERRED	PREFERRED
61958040101	VIREAD TAB 300MG	Brand	PREFERRED	NON-PREFERRED	NON-PREFERRED	NON-PREFERRED	NON-PREFERRED	NON-PREFERRED
33342009607	TENOFOVIR TAB 300MG	Generic		PREFERRED	PREFERRED	PREFERRED	PREFERRED	PREFERRED
10144042760	AMPYRA TAB 10MG	Brand	PREFERRED	PREFERRED	NON-PREFERRED	NON-PREFERRED	NON-PREFERRED	NON-PREFERRED
42571027560	DALFAMPRIDIN TAB 10MG ER	Generic			PREFERRED	PREFERRED	PREFERRED	PREFERRED
64406000602	TECFIDERA CAP 240MG	Brand	PREFERRED	PREFERRED	PREFERRED	PREFERRED	EXCLUDED	EXCLUDED
69238131906	DIMETHYL FUM CAP 240MG DR	Generic					PREFERRED	PREFERRED
59011075204	BUTRANS DIS 20MCG/HR	Brand	NON-PREFERRED	NON-PREFERRED	NON-PREFERRED	EXCLUDED	EXCLUDED	EXCLUDED
69238120502	BUPRENORPHIN DIS 20MCG/HR	Generic				PREFERRED	PREFERRED	PREFERRED
78042405	RITALIN LA CAP 10MG	Brand	NON-PREFERRED	NON-PREFERRED	NON-PREFERRED	EXCLUDED	EXCLUDED	EXCLUDED
70010001201	METHYLPHENID CAP 10MG ER	Generic				PREFERRED	PREFERRED	PREFERRED
61958080201	LETAIRIS TAB 10MG	Brand	PREFERRED	PREFERRED	NON-PREFERRED	EXCLUDED	EXCLUDED	EXCLUDED
378427193	AMBRISENTAN TAB 10MG	Generic			PREFERRED	PREFERRED	PREFERRED	PREFERRED
61958060101	EMTRIVA CAP 200MG	Brand	PREFERRED	PREFERRED	PREFERRED	PREFERRED	NON-PREFERRED	NON-PREFERRED
69097064202	EMTRICITABIN CAP 200MG	Generic					PREFERRED	PREFERRED

Sources: Optum Rx data produced to the FTC.
Notes:
1. "PREFERRED" includes tier 1 and tier 2 drugs.
2. "NON-PREFERRED" includes tier 3 drugs and non-formulary branded drugs.
3. Analysis limited to GPIs that have branded and generic drugs and in which generics enter as preferred; examples shown are the overlapping ten generic NDCs with some of the largest number of 30-day prescriptions in Optum Rx's claims data.

53. We have also examined the effects over time of generic entry on the preferred tiers of Caremark's most commonly used template formulary. Specifically, once generic entry occurs, we assess whether the generic drug is listed in a preferred tier and whether branded drugs are no longer listed in a preferred tier. We find that generic drugs are quickly placed on a preferred tier while branded drugs disappear from those tiers. We group NDCs at this level because a generic drug is generally approved for a specific formulation (*e.g.*, tablet) and strength (*e.g.*, 10 mg) and a generic manufacturer must obtain a separate approval for additional formulations or strengths; the GPI level includes a drug's formulation and strength when classifying drugs. We assess the generic share of the total number of NDCs that are in a preferred tier for GPIs where generic entry occurs. That is, for each GPI, we calculate the number of generic NDCs that are in a preferred tier divided by the total number of NDCs (generic plus branded) that are on a preferred tier. We also analyze how the generic share changes in each year following generic entry.

54. The results are shown in Table 3. Each row of the table shows the results across all GPIs where there was generic entry in the given year. So, for example, the first row of the table shows GPIs where there was generic entry in 2018. In the first year of generic entry, 89% of the NDCs in a preferred tier for these GPIs were generic drugs. This share increased to 95% in the first

year following generic entry (2019) and to 98% in the second year following generic entry (2020). Similar results are found for other years. This analysis is consistent with the view that formularies quickly move generic drugs to preferred tiers and branded drugs to non-preferred tiers following generic entry.

Table 3: Generic NDCs Share of All NDCs in a Preferred Tier for GPIs that Experienced Generic Entry: Caremark Standard Control Formulary

Year of First Generic Entry	Year of Generic Entry	First Year Following Entry	Second Year Following Entry	Third Year Following Entry	Fourth Year Following Entry
2018	89%	95%	98%	98%	98%
2019	87%	98%	98%	99%	
2020	93%	96%	98%		
2021	92%	97%			
2022	81%				

Sources: Specs 19-20 of Caremark 6(b) Submission to the FTC.
Notes:
1. Analysis limited to GPIs that have branded and generic drugs.
2. Analysis considers Caremark's Standard Control Formulary, which is the most popular formulary by number of plan sponsors across 2017-2022.

55. Table 4 presents the same analysis using data from Optum Rx for one of its standard formularies. Consistent with the results for Caremark, the Optum Rx data also support the view that formularies quickly shift generic drugs to preferred tiers and branded drugs to non-preferred tiers following generic entry.

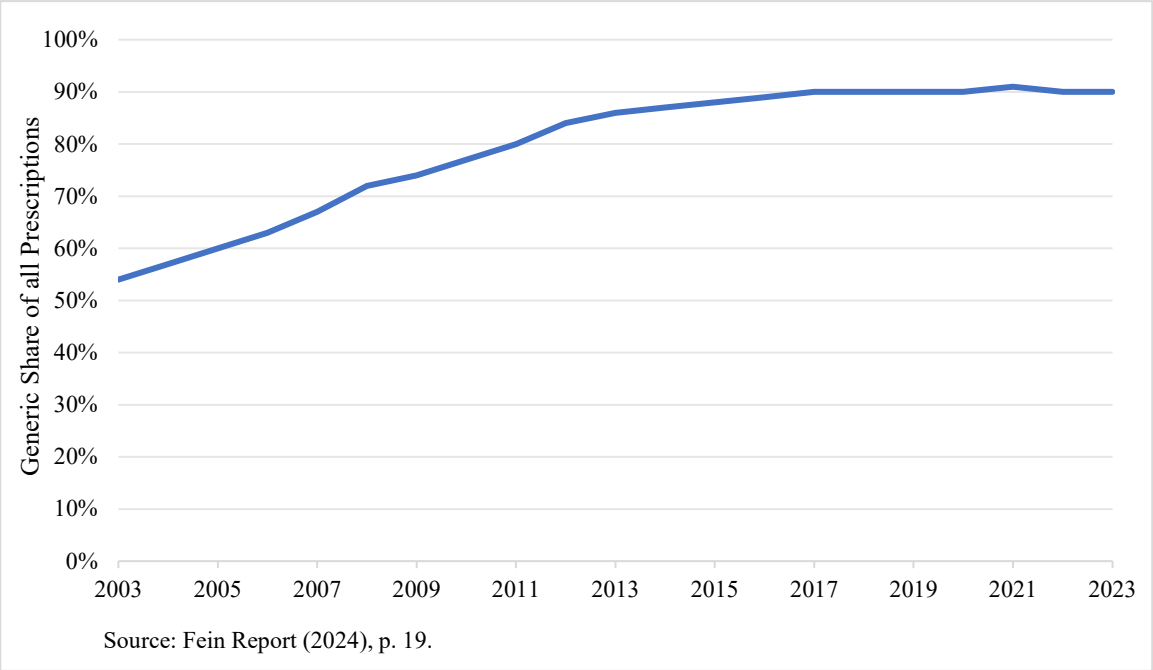
Table 4: Generic NDCs Share of All NDCs in a Preferred Tier for GPIs that Experienced Generic Entry: Optum Rx Premium Standard Formulary

Year of First Generic Entry	Year of Generic Entry	First Year Following Entry	Second Year Following Entry	Third Year Following Entry	Fourth Year Following Entry
2018	97%	98%	99%	99%	99%
2019	96%	99%	99%	99%	
2020	96%	98%	99%		
2021	97%	97%			
2022	93%				

Source: Optum Rx data produced to the FTC.
Notes:
1. "PREFERRED" includes tier 1 and tier 2 drugs.
2. Analysis limited to GPIs that have branded and generic drugs.

56. The increased use of generic drugs is evident in data on total prescriptions. At an aggregate level, the generic dispensing rate (GDR)—the percentage of prescriptions dispensed with a generic drug—increased from 54% in 2003 to about 90% in 2023 (see Figure 3). Although there may be additional reasons for the increased use of generic drugs (such as the expiration of patents over time), the use of formularies by plan sponsors likely have played an important role in encouraging members to use lower cost generic drugs. The increased use of generic drugs has helped contain the increase in prescription costs over time in the U.S.[105]

Figure 3: Generic Dispensing Rate, 2003-2023[106]



Source: Fein Report (2024), p. 19.

105 *See, e.g.*, CBO Report (2022).

106 Fein Report (2024), p. 19. The reported generic share is of all prescriptions (*i.e.*, 30-day and 90-day prescriptions are counted equally) and includes both unbranded generics and branded generics. Branded generics are generic drugs that are sold under a brand name after the patent for the original drug expires. When considering drug spend, generics' share is around 20%. *See*, *for e.g.*, Assistant Secretary for Planning and Evaluation, "Trends in Prescription Drug Spending, 2016-2021," September 2022, available at https://aspe.hhs.gov/sites/default/files/documents/88c547c976e915fc31fe2c6903ac0bc9/sdp-trends-prescription-drug-spending.pdf, pp. 1, 6-7.

IV. PLAN SPONSORS DERIVE SUBSTANTIAL VALUE FROM THE SERVICES PBMS PROVIDE, AND PBMS COMPETE FOR PLAN SPONSORS' BUSINESS

57. As we describe in this section, studies have shown that PBMs provide valuable benefits to plan sponsors, including services that help plan sponsors reduce their spending on prescription drugs. Ultimately, plan members also benefit from plan sponsors' use of PBMs, in significant part by paying less for their prescription drugs, which can improve drug adherence, patient access to affordable medications, and medical outcomes.

58. Plan sponsors capture a large fraction of the value created by PBMs in part because PBMs have to compete with one another to win and retain plan business. Although there are three large PBMs, a variety of characteristics of the PBM industry promote competition and allow plan sponsors to benefit from that competition. These characteristics include: (i) the detailed and tailored nature of PBM contracts, with many negotiated price and non-price terms, which inhibits tacit coordination among PBMs; (ii) the competitive process through which plan sponsors select PBMs; (iii) the sophistication of plan sponsors and the consultants with which they work; (iv) the ability of plan sponsors to self-supply some or all of the services provided by PBMs; and (v) competition from a large number of smaller PBMs, many of which are specialized. Data from a variety of sources support the conclusion that plan sponsors benefit from competition among PBMs.

A. MANY STUDIES SHOW THAT PBMS GENERATE SUBSTANTIAL VALUE FOR PLAN SPONSORS AND MEMBERS

59. Numerous studies, academic articles, and analyses conducted by government agencies demonstrate that PBMs generate substantial value by reducing prescription drug costs. For example:

- The Government Accountability Office ("GAO") found that PBMs helped Medicare Part D plan sponsors reduce their overall expenditures on prescription drugs by negotiating discounts (in the form of rebates) and other price concessions from manufacturers that face competition for their drugs. The GAO estimated that the negotiated savings reduced total drug spending by Medicare Part D plan sponsors by

20% in 2016 and, for the 200 most utilized drugs, the negotiated savings reduced drug spending by Medicare Part D plan sponsors by 36%.[107]

- A forthcoming academic study of the statin market estimated that doing away with PBMs' negotiating of rebates and having drug manufacturers simply set prices would increase plan sponsors' spending on those drugs, ultimately increasing payments to the drug manufacturers by almost 50%.[108] The study's conclusion that PBMs' involvement in negotiating discounts off list prices significantly lowers drug costs for payors is not altered when "[a]ccounting for payments to PBMs."[109]

- A 2019 study by the Congressional Budget Office estimated that a proposed rule essentially prohibiting manufacturers from paying rebates to PBMs would have increased net federal spending on Medicare alone by $170 billion over the 10-year period between 2020 and 2029.[110] Given that total federal spending on Medicare Part

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107 Government Accountability Office, "Medicare Part D: Use of Pharmacy Benefit Managers and Efforts to Manage Drug Expenditures and Utilization," July 15, 2019, available at https://www.gao.gov/assets/gao-19-498.pdf, pp. 18, 21.

108 Josh Feng and Luca Maini, "Demand Inertia and the Hidden Impact of Pharmacy Benefit Managers," *Management Science*, *Articles in Advance* (2024), p. 16 ("The counterfactual results suggest that, relative to the current equilibrium, removing PBMs and imposing a 33% coinsurance would increase payments to drug manufacturers by 47.5%.").

109 *Id*.

110 Congressional Budget Office, "Incorporating the Effects of the Proposed Rule on Safe Harbors for Pharmaceutical Rebates in CBO's Budget Projections—Supplemental Material for Updated Budget Projections: 2019 to 2029," May 2019, available at https://www.cbo.gov/system/files/2019-05/55151-SupplementalMaterial.pdf. Under the proposed rule, manufacturers would no longer enjoy safe harbor protections against kickback statutes for rebates paid to PBMs and plan sponsors. "PBMs could continue to negotiate discounts in return for covering certain medications or giving those medications preferential placement on their formulary…, but the discounts could not take the form of a rebate paid by the manufacturer to the PBM. Rather, all discounts would need to be directed to the pharmacy and reflected in the final price charged to beneficiaries." *Id*, pp. 1-2.

D drugs is expected to be $1.53 trillion in that 10-year time frame,[111] the proposed ban would have raised the cost of prescription drugs paid for by Medicare by 11.1%.

- A recent study by an academic economist ("Mulligan study"), which was sponsored by the PCMA, estimated "the annual value to society of PBM services to be at least $145 billion beyond its resource costs."[112] Moreover, the study concluded that a significant fraction of this value (40%) would be lost if plan sponsors had to self-supply PBM services rather than working with third parties specializing in their provision.[113]

- Another PCMA-sponsored study estimated that PBMs help plan sponsors and their members "save 40-50% on their annual drug– and related medical costs compared to what they would have spent without the PBMs."[114] Though separately derived, these figures closely match those presented in the Mulligan study. As Figure 4 shows, of the 40-50% savings, 30-35 percentage points stem from manufacturer rebates and pharmacy discounts, 5-10 percentage points result from encouraging plan members to buy generics and lowest-cost preferred brands, and 5-10 percentage points result from reducing inappropriate drug usage and improving patient adherence. These estimated

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111 *See* "Operations of the Part D Account of the Supplementary Medical Insurance (SMI) Trust Fund For Calendar Years.xlsx" available in "2024 Expanded and Supplementary Tables and Figures (ZIP)" at CMS.gov, "Trustees Report & Trust Funds," available at https://www.cms.gov/data-research/statistics-trends-and-reports/trustees-report-trust-funds (accessed June 19, 2024).

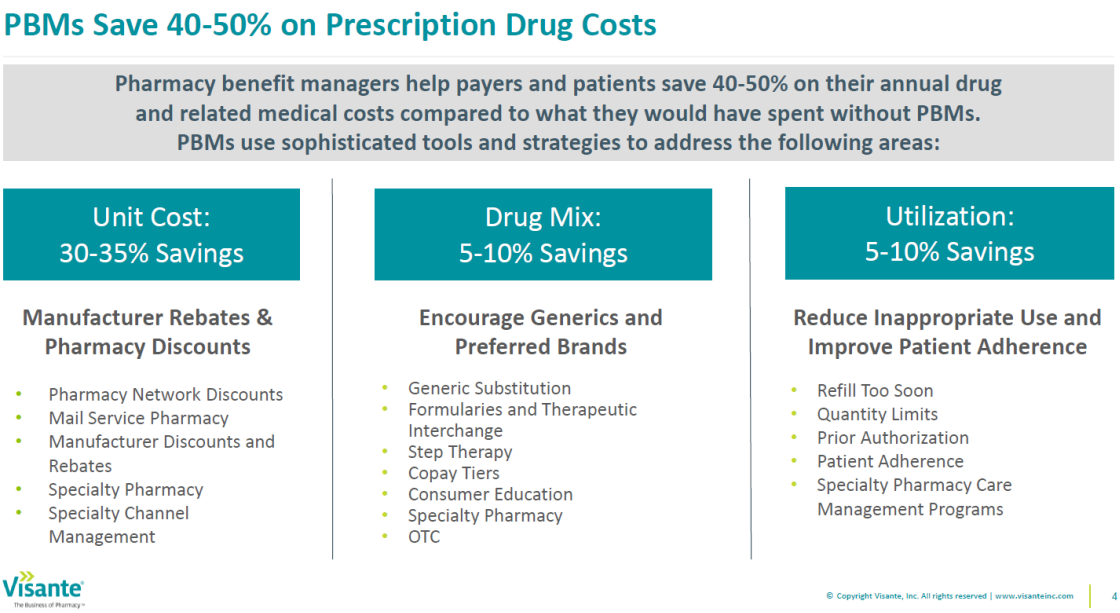
112 Casey B. Mulligan, "The Value of Pharmacy Benefit Management," Working Paper 30231, *National Bureau of Economic Research* (2022): 1-45 at 2, available at https://www.nber.org/papers/w30231. The study broke down the annual gross value created by PBM services as follows: $51 billion from the negotiation of rebates tied to plan design; $16 billion from the promotion of generic drugs; $5 billion from pharmacy rebates; $3 billion from the use of mail-order pharmacies; $40 billion from utilization management and prescription adherence; $47 billion from reducing tax-related distortions; and $6 billion from the promotion of new, efficacious medicines, which speeds drug development. The cumulative value of these services is estimated at $168 billion. Because it costs PBMs $22 billion to provide these services, society as a whole derives $145 billion in benefits. *Id*, p. 4.

113 *Id*., p. 30.

114 Visante, "The Return on Investment (ROI) on PBM Services," February 2020, slide 4.

savings for plan sponsors and members combined translate into roughly $962 per plan member, per year.[115] Plan sponsors were estimated to have received $10 in savings for every $1 spent on PBMs.[116]

Figure 4: Estimates of Prescription Drug Cost Savings Generated by PBMs[117]



60. Thus, studies show that PBMs create substantial value by reducing the cost of drugs, this value exceeds the cost of PBM services, and both plan sponsors and members benefit.

B. PLAN SPONSORS BENEFIT FROM COMPETITION AMONG PBMS

61. There are three large PBMs in the industry, but their combined share varies by PBM function (see discussion below). Notwithstanding the higher combined shares of the three large PBMs in certain PBM functions, it is well recognized that competition among firms can exist even in concentrated industries when certain industry characteristics exist that are conducive to fostering such competition. Such characteristics are present in the PBM industry and, as we

115 *Id.*, slides 4-5.

116 *Id.*, slide 9.

117 *Id.*, slide 4.

discuss in Section V, data show that plan sponsors have taken advantage of them to reduce their drug costs.

62. Several characteristics of the PBM industry facilitate competition, including: (i) the terms of PBM contracts are often detailed and tailored to each plan sponsor with hundreds of negotiated price and non-price terms, making it difficult for competitors both to monitor and to align with each other; (ii) plan sponsors use a request for proposal (RFP) process to select their PBM and focus competition at a point in time; (iii) plan sponsors and their consultants are sophisticated purchasers; (iv) some plan sponsors have the ability to self-supply at least some of the services that PBMs provide; and (v) smaller PBMs have shown an ability to successfully compete for plan sponsors' pharmacy benefit management business. Each of these factors make tacitly coordinated conduct that eliminates competition less likely, all else equal. The FTC has previously acknowledged that coordinated effects in the PBM industry are unlikely due to the multifaceted nature of price competition, the differences in business models among PBM rivals which create different incentives, and the presence of sophisticated buyers and consultants who are able to aggressively promote competition among PBMs.[118] Consistent with these factors and the FTC's prior findings, data indicate that the three largest PBMs compete with each other in RFP processes and are also constrained by plan sponsors' willingness to self-supply or to work with other PBMs.

1. Contracts between PBMs and plan sponsors typically involve many terms and are often customized to the plan sponsor

63. When a product has many features (*e.g.*, a wide variety of price and non-price dimensions) or prices are not observable, it is harder for even a few firms to reduce competition amongst themselves. The reason is that when the product's many features and prices are not transparent to rivals it is difficult for rivals to tacitly coordinate on these features and prices. In its closing statement for the Express Scripts-Medco merger in 2012, the FTC recognized that the fact that PBM contracts are customized with many negotiated price and non-price terms inhibited

118 "Statement of the Federal Trade Commission Concerning the Proposed Acquisition of Medco Health Solutions by Express Scripts, Inc.," April 2, 2012, FTC File No. 111-0210, available at https://www.ftc.gov/sites/default/files/documents/closing_letters/proposed-acquisition-medco-health-solutions-inc.express-scripts-inc./120402expressmedcostatement.pdf, pp. 6-7.

coordination, stating that the "multifaceted and opaque nature of price competition in this market suggests that coordination on price would be difficult. Pricing terms for PBM services are complicated and difficult to compare because each contract includes numerous pricing components, including separate administrative fees, rebate pass-through, discounts, retail and mail-order pricing for branded and generic drugs, plan design, and ancillary services." [119] The evidence shows that the FTC's conclusions continue to apply today.

64. Plan sponsors typically negotiate with PBMs over various contract terms, and the negotiated terms vary across plan sponsors. Contracts between PBMs and plan sponsors involve many terms, such as the breadth of pharmacy networks, the ways in which the PBMs are compensated, and the types of utilization management and other programs that plan sponsors contract with PBMs to implement. Just in terms of how the PBM will be compensated, the contracts typically will contain multiple components, including client administrative fees paid to the PBMs, pharmacy-related reimbursements to the PBMs, and provisions governing the pass-through of manufacturer rebates to plan sponsors (with some clients permitting PBMs to retain some portion of rebates as compensation for their services). Each component in turn typically has several options from which the plan sponsors can choose. Table 5 provides a sense of the complexity of PBM contracts by illustrating the variety of terms that could be included in a plan sponsor's contract with a PBM and the range of options that might be available with each (using terminology employed by one large PBM). See Appendix A for a more detailed description of the contract terms.

119 *Id.*, p. 6.

Table 5: Potential Contract Terms Negotiated Between Plan Sponsors and PBMs[120]

Contract Terms	Contract Subterms	Possible Values
Line of Business	-	for example, Commercial, Medicare Part B, Medicare Part D, Medicaid, Affordable Care Act Exchange
Line of Business Subtype	-	for example, Traditional, Transparent, Combination
Year contract applies to	-	length of contract varies
Admin Fees	Administrative fee type	for example, Paper Per Claim, Mail Per Claim, Specialty Per Claim, Customer Per Claim, Flat Monthly, Per Employee Per Month, Per Member Per Month
	Amount of admin fee payment	Numeric continuous values
	Frequency of claims billing	for example, Weekly, Two Times Per Month, Monthly
	Frequency of admin fee billing	for example, Weekly, Two Times Per Month, Monthly
	Payment terms for claims payments	for example, 2 days, 5 days, 10 days, 15 days, Non-Standard
	Payment terms for admin fee payments	for example, 2 days, 5 days, 10 days, 15 days, Non-Standard
Pharmacy Reimbursement Terms	Brand Discount Rate (Retail/Mail/Specialty)	Numeric continuous values
		Numeric continuous values
		Numeric continuous values
	Generic Discount Rate (Retail/Mail/Specialty)	Numeric continuous values
		Numeric continuous values
		Numeric continuous values
	Non-MAC Discount Rate (Retail/Mail)	Numeric continuous values
		Numeric continuous values
	Brand Dispensing Fee (Retail/Mail)	Numeric continuous values
		Numeric continuous values
	Generic Dispensing Fee (Retail/Mail)	Numeric continuous values
		Numeric continuous values
	Guarantee Type (Retail/Mail)	for example, Brand Effective Rate (BER), Generic Effective Rate (GER), MAC Effective Rate (MER), Overall Effective Discount (OED), Specialty discount rate (SRx), Discount on single-source generic drugs (SSG)
		for example, Brand Effective Rate (BER), Generic Effective Rate (GER), MAC Effective Rate (MER), Overall Effective Discount (OED), Specialty discount rate (SRx)
	Guarantee Rate (Retail/Mail)	Numeric continuous values
		Numeric continuous values
Rebates	Rebate offering type	for example, Split Only, Split with Min Guarantee, Guarantee Only
	Client share of rebates	Numeric continuous values
	Rebate client share payment frequency	for example, 30 Days, 60 Day, 90 Day, 120 Days, 150 Days, 180 Days
	Client share of price protection payment	Numeric continuous values
Miscellaneous Terms	Type of payment	for example, Administrative Allowance, General Credit, Implementation Credit
	Amount of payment	Numeric continuous values
	Metric used for payment	for example, Flat Dollar, Per Member Per Month, Per Net New Employee
	Payment terms	for example, Annually, Contract Term, Quartey, One Time
	Timing of market check	for example, After 12 Months, After 18 Months, After 24 Months, Anytime

120 For this table, we use as examples a subset of the terms employed by one large PBM in its 6(b) Submission to FTC. Other PBMs may use different terms.

65. Contracts may contain many other terms besides those listed in Table 5. For example, a PBM may pay a plan sponsor an allowance or a credit to reduce switching costs when the plan sponsor transitions from another PBM to that PBM. Such terms foster competition among PBMs since plan sponsors are compensated for the costs of moving from one PBM to another. As we discuss in more detail in Section IV.B.3, contracts may also include market check provisions.

66. The existence of so many terms over which PBMs and plan sponsors typically negotiate makes it less likely that PBMs could reach a tacit understanding amongst themselves about these terms. This is particularly the case because PBM contracts are generally confidential. Thus, PBMs would find it difficult to monitor each other. Moreover, there is no evidence of "punishment" phases that the economics literature suggest may be expected in an industry involving tightly coordinated behavior among rivals when monitoring is imperfect and when there may be unobserved changes in demand.[121]

67. Further weighing against the feasibility of coordination is that the three largest PBMs have differentiated business models. For example, Caremark is affiliated with CVS Pharmacy, a large retail pharmacy chain, while Express Scripts is not affiliated with retail pharmacies. Similarly, Optum Rx is part of UnitedHealth Group, which owns and operates more healthcare provider groups than do CVS Health or The Cigna Group, the parent corporations of Caremark and Express Scripts, respectively. Such asymmetries tend to make coordination more difficult.[122]

2. Plan sponsors' use of RFPs increases competition

68. To foster competition among PBMs and to elicit information on what different PBMs can offer, and at what cost, plan sponsors typically utilize highly detailed RFPs that require responses from PBMs.[123] These RFPs identify all of the various dimensions of the working

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121 *See*, *e.g.,* Edward J. Green and Robert H. Porter, "Noncooperative Collusion under Imperfect Price Information," *Econometrica* 52, no. 1 (1984): 87-100.

122 *See*, *e.g.*, Dennis W. Carlton and Jeffrey M. Perloff, *Modern Industrial Organization*, 4th ed. (Pearson, 2004), p. 139.

123 *See*, *e.g.*, Wells Fargo Insurance, "Request for Proposal - Prescription Benefit Management Services, Hampton City Schools," November 15, 2016, available at https://hampton.gov/DocumentCenter/View/14443/Attachment-I---PBM-RFP-

relationship—*e.g.*, compensation, services required, duration—that the plan sponsor cares about, and then ask multiple PBM bidders to enumerate what they can offer in response. RFPs may involve multiple rounds of bidding. Given the degree of complexity, PBMs and plan sponsors may negotiate over their contracts for a long time after the plan sponsor has decided which PBM to use. During these negotiations, there may be back and forth on a multitude of contractual terms until an agreement is reached.[124]

69. Plan sponsors' use of an RFP process, which often results in multi-year contracts (3-year contracts are common), provides incentives for PBMs to compete aggressively on price and value. If a PBM does not make an attractive offer to a plan sponsor, it risks losing that plan sponsor as a customer until the next bidding cycle.

70. Economic research suggests that using a bidding process can encourage competition. Effectively, the RFP process engaged in by plan sponsors is an auction, with different PBMs competing by offering bids that deliver desirable features at lower prices. The plan sponsor selects the PBM that can provide the plan sponsor with the most value.[125] Economic research has shown that, holding all else constant, a buyer benefits more when soliciting confidential bids from possible suppliers than in markets where suppliers post observable prices.[126]

Questinnaire. (50-page RFP requesting information on scores of different points); State of Tennessee Department of Finance and Administration, "Request for Proposals for Pharmacy Benefit Management," June 21, 2023, available at https://www.tn.gov/content/dam/tn/generalservices/documents/cpo/rfp-updates/31786-00174/31786-00174_Release_2_for_posting.pdf (159-page RFP listing requirements for contract, pricing, and other terms, and requesting responses).

124 *See*, *e.g.*, Scott McEachern and Patrick Cambel, "PBM contracts: Understand then optimize," Milliman, August 2020, available at https://us.milliman.com/en/insight/pbm-contracts-understand-then-optimize (accessed August 30, 2024).

125 For more on how procurement processes are analogous to auctions, *see*, *e.g.*, Nathan H. Miller, "Modeling the effects of mergers in procurement," *International Journal of Industrial Organization* 37 (2014): 201-208.

126 Matthew T. Panhans and Charles Taragin, "Consequences of Model Choice in Predicting Horizontal Merger Effects," *International Journal of Industrial Organization* 89, no. 2 (2023): 1-22. In the auction context, *see*, *e.g.*, Paul Klemperer, *Auctions: Theory and Practice* (Princeton University Press, 2004).

3. Plan sponsors and their consultants are sophisticated and knowledgeable purchasers who negotiate contract provisions that protect plan sponsors' interests

71. The use of an RFP process alone does not necessarily guarantee that a buyer will foster competition among suppliers. For example, if the buyer does not possess the sophistication or knowledge to fully exploit the leverage provided by a bidding process, it may not receive the best value. However, those circumstances do not accurately characterize the environment in which PBMs compete.

72. Many PBM customers are large, sophisticated entities like health insurers, labor unions, or large employers that are accustomed to engaging in detailed negotiations and are well acquainted with the details of the prescription drug industry. As indicated above, smaller plan sponsors (in terms of covered lives and claims volume) also commonly band together into cooperatives and coalitions to replicate the scale of larger plan sponsors.[127] Moreover, plan sponsors—large and small alike—have access to the services of consultants that specialize in negotiating with PBMs and using competition between PBMs to get their clients the best outcomes possible given the plan sponsor's preferences.[128] These specialized consultants typically aid in the development of plan sponsors' RFPs and in the evaluation of different PBMs' responses to those RFPs. According to the PSG Benefit Design Report, 73% of PBM customers, including 50% of health plan customers, use a drug benefit consultant for their benefit design.[129] Because benefit design consultants work with plan sponsors to negotiate with PBMs on many

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127 *See* discussion in Section I on purchasing consortia and coalitions that negotiate with the PBMs on behalf of their members, leveraging the size of their clients' collective membership to obtain more favorable terms from the PBM than individual members may be able to obtain on their own.

128 *See*, *e.g.*, "Statement of the Federal Trade Commission Concerning the Proposed Acquisition of Medco Health Solutions by Express Scripts, Inc.," April 2, 2012, FTC File No. 111-0210, available at https://www.ftc.gov/sites/default/files/documents/closing_letters/proposed-acquisition-medco-health-solutions-inc.express-scripts-inc./120402expressmedcostatement.pdf, p. 7 ("In addition, employers routinely retain expert consultants to identify potential bidders, develop detailed solicitations, and evaluate the proposals before settling on a winner.").

129 Pharmaceutical Strategies Group, "2023 Trends in Drug Benefit Design Report," 2023, available at https://www.psgconsults.com/2023traditionalbdr, p. 18.

contracts in any given year, they will have a good understanding of the various elements of PBM contracts.

73. As sophisticated purchasers, plan sponsors negotiate provisions in their multi-year contracts to protect their interests. For example, contracts may include "market check" provisions that, during the term of the PBM contract, allow plan sponsors to compare the terms of their contract to the terms offered by other PBMs. Market checks could include, for example, a comparison of the drug prices the plan sponsor is paying using their current PBM to the prices other PBMs have negotiated for those drugs. If the prevailing terms are better than the contracted rates, the PBM can be required to match those market rates or else the customer could opt to switch to another PBM. Plan sponsors could require market checks on retail, mail-order, or specialty pharmacy discounts, rebate levels, or other terms. Such provisions also constrain a PBM from increasing its fees above market rates during the tenure of the contract.[130] Market check provisions typically run in only one direction: if better rates are available in the marketplace, then the plan sponsor gets the benefit of those better rates; but if rates available in the marketplace are less favorable to the plan sponsor, the PBM would not be entitled to those rates. This characteristic shows how clients are able to leverage PBM competition to extract beneficial contracting terms.

4. Plan sponsors can credibly threaten to self-supply

74. Some plan sponsors can and do self-supply certain PBM services. (See, also, Section IV.B.6.) For example, some health insurers may negotiate their own rebates with pharmaceutical manufacturers or design their own formularies. Such self-supply is not limited to insurers. Other large plan sponsors have expanded into offering PBM services themselves. For example,

130 Caremark, Express Scripts, and Optum Rx internal data show that the vast majority of contracts include market-check provisions. Consultant coalitions representing hundreds of employers and billions of dollars in drug spend, such as Aon and WTW, also tout that their coalition members get market check provisions. *See*, *e.g.*, Aon, "Pharmacy Benefit Consulting," available at https://www.aon.com/en/capabilities/health-and-benefits/pharmacy-benefit-consulting (accessed June 13, 2024); WTW, "Rx Collaborative," available at https://www.wtwco.com/en-us/solutions/services/rx-collaborative (accessed June 19, 2024).

Costco launched Costco Health Solutions, which now also competes for other plan sponsors' business.[131]

75. Fundamentally, if a PBM were to demand an increase in the compensation that it received for its services, some plan sponsors could credibly threaten to reduce or avoid their reliance on PBMs by self-supplying some services.

5. Plan sponsors can credibly threaten to work with smaller PBMs or use multiple suppliers of PBM services

76. Recent estimates suggest there are as many as 73 PBMs that offer services to help plan sponsors manage their prescription drug benefit plans in the United States.[132] Smaller firms offer constraints on larger PBMs, often leveraging technological tools that they argue lend them an edge or offering more attractive terms to differentiate their offerings from larger PBMs.[133] In its closing statement clearing the acquisition of Medco Health Solutions by Express Scripts in 2012, the FTC acknowledged that smaller PBMs offered meaningful competition to the three largest PBMs at the time (Caremark, Express Scripts, and Medco) and that the "high market share of the parties [Express Scripts and Medco] do not accurately reflect the current competitive environment and are not an accurate indicator of the likely effects of the merger on competition and consumers."[134] Specifically, the FTC concluded: [135]

> Smaller standalone PBMs, including but not limited to CatalystRx and SXC, are also winning large employer accounts. Moreover, customers frequently include

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131 Costco Health Solutions, "Discover a PBM with Value, Quality and Integrity: Costco Health Solutions," available at https://costcohealthsolutions.com/pages/TheCostcoDifference.aspx#OurHistory (accessed August 29, 2024).

132 PCMA, "The PBM Marketplace is More Competitive, Not Less," May 8, 2023, available at https://www.pcmanet.org/rx-research-corner/the-pbm-marketplace-is-more-competitive-not-less/05/08/2023/ (accessed June 14, 2024).

133 Denise Myshko and Peter Wehrwein, "Beyond the Big Three," *Modern Healthcare* 32, no. 12 (2022): 16-20 at 17.

134 "Statement of the Federal Trade Commission Concerning the Proposed Acquisition of Medco Health Solutions by Express Scripts, Inc," April 2, 2012, FTC File No. 111-0210, available at https://www.ftc.gov/sites/default/files/documents/closing_letters/proposed-acquisition-medco-health-solutions-inc.express-scripts-inc./120402expressmedcostatement.pdf, p. 2.

135 *Id.*, p. 5.

> these smaller PBMs in bids now and would continue to do so in the future. These smaller PBM competitors have numerous opportunities to expand sales because of the large number of customers that extend RFPs to these firms. There are dozens of formal sales opportunities each year within the Fortune 500 alone (a typical employer issues an RFP every three to five years), and even more informal sales opportunities.
>
> Many of the concerns raised about this merger were based on the assumption that the Big Three enjoy substantial cost advantages over smaller competitors as a result of economies of scale in purchasing inputs and in operating their mail-order pharmacies. In fact, however, after examination of the actual cost data submitted by various PBMs, those cost advantages were not as significant as hypothesized and, for many inputs, may not exist at all. [footnote omitted] Furthermore, many non-Big Three PBMs have made substantial investments in their operations in recent years that have allowed these PBMs to reduce, if not eliminate, their historical cost disadvantage vis-à-vis the Big Three PBMs.

77. Recent evidence suggests that the FTC's conclusions in 2012 continue to apply. As discussed by a trade publication in 2022, new entrants to the PBM market continue to try to disrupt the status quo by introducing new technology and business models.[136] Moreover, the new entrants are having success in the marketplace. For example, earlier this year, Tyson Foods switched from one of the three largest PBMs to Rightway, a relatively recent PBM entrant.[137] CapitalRx (another new entrant) recently won some of the PBM services business of Johns Hopkins University that had previously been handled by one of the three largest PBMs.[138] Blue Shield of California announced in 2023 that it would switch to Abarca Health, a small PBM headquartered in Puerto Rico, for prescription claims processing. Blue Shield of California also provides an example of how plan sponsors can use multiple suppliers for different PBM service components: Blue Shield of California uses Abarca for claims processing, Prime Therapeutics

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136 Denise Myshko and Peter Wehrwein, "Beyond the Big Three," *Modern Healthcare* 32, no. 12 (2022): 16-20 at 17.

137 Rightway, "Tyson Foods ditches the traditional PBM model to partner with Rightway," January 24, 2024, available at https://www.rightwayhealthcare.com/blog/tyson-foods-ditches-the-traditional-pbm-model-to-partner-with-rightway (accessed June 14, 2024).

138 Johns Hopkins University, "Transitioning from Express Scripts to Capital Rx," November 16, 2023, available at https://hub.jhu.edu/at-work/2023/11/16/transitioning-from-express-scripts-to-capital-rx/ (accessed June 14, 2024).

for negotiations with drug manufacturers, and Amazon for mail-order pharmacy.[139] These examples of plan sponsors switching from one of the three largest PBMs to a smaller PBM are not isolated examples, as we discuss below in Section IV.B.6. And, as we discuss in Section V, PBM margins have not increased over time, which is consistent with the FTC's conclusions from 2012 continuing to hold. In fact, the three largest PBMs today are not the same as the three largest PBMs in 2012 despite one dissenting FTC Commissioner expressing serious doubt that UnitedHealth (*i.e.*, Optum Rx) would become a "significant competitor" in the marketplace given its small size at the time.[140]

6. Data show that the three largest PBMs compete against each other and also are constrained by smaller rivals as well as plan sponsors' ability to self-supply

78. Win-loss data maintained by PBMs in the ordinary course of business support the conclusion that the three largest PBMs compete not only with each other but also with other PBMs. Furthermore, data on plan sponsors' contracting choices show that they regularly work with smaller PBMs as well as self-supply many of the services provided by the largest PBMs.

a) The largest PBMs compete not only with each other but also with smaller PBMs

79. As described above, plan sponsors frequently use an RFP process to select a PBM supplier and determine the terms of the PBM contractual agreement. We analyze data on RFP competitions where one of the three largest PBMs is the incumbent supplier that is seeking to renew its contract with the plan sponsor. When such a contract nears its conclusion, plan sponsors typically solicit bids not only from their current supplier but also from other PBMs, both large and small. The three PBMs respond to RFPs to renew contracts every three to five

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139 PR Newswire, "Blue Shield of California Unveils First-of-its-Kind Model to Transform Prescription Drug Care; Save up to $500 Million Medications Annually," August 17, 2023, available at https://www.prnewswire.com/news-releases/blue-shield-of-california-unveils-first-of-its-kind-model-to-transform-prescription-drug-care-save-up-to-500-million-on-medications-annually-301903627.html (accessed June 26, 2024).

140 "Dissenting Statement of Commissioner Julie Brill Concerning the Proposed Acquisition of Medco Health Solutions Inc. (MEDCO) by Express Scripts, Inc. (ESI)," April 2, 2012, FTC File No. 111-0210, available at https://www.ftc.gov/sites/default/files/documents/public_statements/dissenting-statement-commissioner-julie-brill/120402medcobrillstatement.pdf, pp. 6-7.

years.[141] Table 6 summarizes the outcome of RFP processes where Caremark, Express Scripts, or Optum Rx was the incumbent PBM between 2020 and 2022, aggregated across the three PBMs.[142]

80. For renewal opportunities where the incumbent PBM lost, Table 6 shows that the plan sponsor turned both to large and small PBMs. For example, about half of the opportunities that one of the three incumbent PBMs lost were to one of the other two largest PBMs and about half were to smaller PBMs.[143] Thus, these data show that the three largest PBMs compete with each other and also with smaller PBMs.

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141 "Statement of the Federal Trade Commission Concerning the Proposed Acquisition of Medco Health Solutions by Express Scripts, Inc," April 2, 2012, FTC File No. 111-0210, available at https://www.ftc.gov/sites/default/files/documents/closing_letters/proposed-acquisition-medco-health-solutions-inc.express-scripts-inc./120402expressmedcostatement.pdf, p. 5.

142 To be conservative, we include in this analysis opportunities associated with either the PBM or its affiliated insurer, to the extent that information is available. For renewals, the incumbent PBM wins about 88% of opportunities on average. The fact that incumbents often win does not necessarily indicate a lack of competition among PBMs for that renewal business. The value offered by an incumbent would be expected to be higher if the incumbent is forced to go through an RFP process with competitors than if the plan sponsor negotiates only with the incumbent and does not consider other alternatives. Moreover, because plan sponsors typically have market check conditions in their contracts, plan sponsors are not locked into contracts and they can benefit from competition among PBMs without having to change suppliers.

143 Our analysis weights each opportunity equally regardless of the size of the opportunity. We are unable to provide an aggregate weighted analysis across PBMs that accounts for opportunity size because there is no common size metric in the data provided by the PBMs that we can use as weights.

Table 6: Competition for Renewal of Existing Customer Relationships for Caremark, Express Scripts, and Optum Rx: Incumbent Win Rates and Share of Losses by PBM, Win-Loss Data for 2020-2022

Renewal Opportunities for Caremark, Express Scripts, and Optum Rx Combined	
Incumbent Renewal Rate	87.8%
Share of Lost Renewal Opportunities Where Winner is Identified	
Winner is one of the other two of the three largest PBMs	47.7%
Winner is a smaller PBM	52.3%

Sources: Caremark, Express Scripts, and Optum Rx win-loss opportunity data.
Notes:
1. Not all PBMs maintain detailed tracking of competing renewal winners.

81. The fact that other PBMs such as Humana, MedImpact, and Prime Therapeutics remain rivals to and win business from Caremark, Express Scripts, and Optum Rx is consistent with the history of the PBM industry, which shows that small PBMs can become significant competitors. For example, in 2012, Optum Rx was small, but today it is one of the three largest PBMs.

b) Plan sponsors contract for a variety of services, some of which they self-supply

82. As described above, the ability of plan sponsors to self-supply some services, as well as the presence of smaller PBMs, allow plan sponsors to foster competition for PBM services. In this section, we examine data on covered lives by PBM and by function to measure how often plan sponsors turn to self-supply or to smaller PBMs for one or more PBM functions.[144]

[144] Using metrics other than covered lives, the relative size of Caremark, Express Scripts, and Optum Rx, may differ from that implied by the Clarivate data. However, all metrics show that smaller PBMs participate. For example, when focusing on claims processed and when including as part of a PBM's share the claims processed for other PBMs, the three largest PBMs' share is roughly 80%. *See*, *e.g.*, Drug Channels, "The Top Pharmacy Benefit Managers of 2023: Market Share and Trends for the Biggest Companies—And What's Ahead," April 9, 2024, available at https://www.drugchannels.net/2024/04/the-top-pharmacy-benefit-managers-of.html (accessed June 26, 2024).

The higher combined share of claims processed for the three largest PBMs in third-party sources reflect the fact that some of the smaller PBMs contract with plan sponsors and

83. The Managed Market Surveyor data from Clarivate, which is referenced in the FTC staff's First Interim Report, provide information on the PBMs used by health insurance plans and the number of patient lives covered by those plans.[145] The Clarivate data also identify the PBM that is used by each health plan to perform various functions defined by Clarivate, or report that the service is self-supplied. The Clarivate-defined functions generally correspond to several of the PBM services we describe above, including claims adjudication, rebate negotiation, retail network management, and formulary management.[146, 147]

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manage the relationship with plan members but sub-contract the claim processing part of their business to larger PBMs. For example, the Fein Report states that Caremark's share includes claims from Centene (parent of Envolve Pharmacy Solutions) and Elevance Health. *Id*. *See also* Fein Report (2024), p. 163.

145 The FTC staff cites analyses based on these data. *See*, *e.g.,* FTC First Interim Report (2024), footnotes 52 and 232 (citing José R. Guardado, "Competition in Commercial PBM Markets and Vertical Integration of Health Insurers with PBMs: 2023 Update," American Medical Association (2023): 1-26). When the aforementioned paper was published, the Managed Market Surveyor data was provided by the Decision Resources Group (DRG). DRG is now known as Clarivate.

146 Based on information from Clarivate, Clarivate defines these functions as follows: Claims Adjudication involves administering and processing pharmacy claims information. Rebate Negotiation involves negotiating with drug manufacturers who typically offer pricing rebates in exchange for formulary placement. Retail Network Management involves maintaining and developing a pharmacy network based on cost and convenience of access for enrollees and performance. Formulary Management is the process of determining which drugs are covered under a plan's formulary as well as each drug's tier and required utilization management criteria. (We note that PBMs' clients can choose which formularies and utilization management criteria to employ.) Clarivate also defines a Benefit Design function (in which it states that the three largest PBMs have a share below 30%), but we understand that the three largest PBMs do not provide Benefit Design services as defined by Clarivate.

147 A limitation of the Clarivate data is that it includes only covered lives whose drug benefit plan is managed by a commercial health insurance plan. Thus, the Clarivate data do not include information on which PBMs are used if the drug benefit is "carved out," *i.e.*, if the plan sponsors choose not to get their drug coverage through an insurance plan and instead buy the management of their drug benefit separately from a PBM. It is estimated that 39% of the commercial covered lives are not captured in the Clarivate data because the data exclude carve-out lives. *See* José R. Guardado, "Competition in Commercial PBM Markets and Vertical Integration of Health Insurers with PBMs: 2023 Update," *American Medical Association* (2023): 1-26 at 4. In addition, the Clarivate data do not reflect whether a PBM subcontracts with another PBM for some of the functions it provides.

84. Table 7 shows PBM shares of covered lives by Clarivate-defined function. We present shares separately for the three largest PBMs (Caremark, Express Scripts, and Optum Rx), for other PBMs, and for health plans as a group if they self-supply the designated PBM function. The three largest PBMs account for a little over half of the covered lives for the claims adjudication and retail network management functions, but only 39% of covered lives for rebate negotiation, and 32% of covered lives for formulary management. Smaller PBMs and state authorities account for around half of covered lives for claims adjudication, rebate negotiation, and retail network management, and account for 28% of covered lives for formulary management. The "Health Plan Managed" share, which represents self-supply by the health plans, is less than 1% of covered lives for claims adjudication, 6% of covered lives for rebate negotiation, zero percent for retail network management, and 40% of covered lives for formulary management.[148]

[148] As noted, Clarivate data do not include carve-out lives where plan sponsors contract directly with PBMs for drug plan management. These plan sponsors are probably less likely to perform formulary management in-house (compared to health insurers). Thus, the share estimates based on Clarivate data may underestimate shares for the three largest PBMs and other smaller PBMs for formulary management functions.

Table 7: Share of Covered Lives: by PBM, by Function, 2023

Share Group	Claims Adjudication		Rebate Negotiation
Three Largest PBMs	**50.6%**	**Three Largest PBMs**	**38.7%**
Caremark	17.8%	Caremark	13.9%
Express Scripts	13.9%	Express Scripts	10.3%
Optum Rx	18.9%	Optum Rx	14.5%
Other PBMs	**48.5%**	**Other PBMs**	**55.4%**
CarelonRx	10.1%	State Managed	26.6%
Envolve Pharmacy Solutions	9.9%	Prime Therapeutics	8.6%
Prime Therapeutics	9.1%	CarelonRx	7.8%
Kaiser Permanente Pharmacy	5.8%	Kaiser Permanente Pharmacy	5.8%
Humana Pharmacy Solutions	4.9%	Humana Pharmacy Solutions	4.8%
MedImpact	1.8%	Scripius	0.5%
Navitus Health Solutions	1.7%	Navitus Health Solutions	0.4%
SS and C Health	1.6%	MedImpact	0.3%
PerformRx	1.1%	Capital Rx	0.2%
Other PBMC	0.6%	Envolve Pharmacy Solutions	0.2%
Other PBM	2.0%	Other PBM	0.2%
Health Plan Managed	**0.8%**	**Health Plan Managed**	**5.9%**

Share Group	Retail Network Management		Formulary Management
Three Largest PBMs	**50.7%**	**Three Largest PBMs**	**32.0%**
Caremark	17.8%	Caremark	9.5%
Express Scripts	13.9%	Express Scripts	7.0%
Optum Rx	19.0%	Optum Rx	15.5%
Other PBMs	**49.3%**	**Other PBMs**	**27.6%**
CarelonRx	10.1%	State Medicaid Formulary	11.0%
Envolve Pharmacy Solutions	9.9%	Prime Therapeutics	7.7%
Prime Therapeutics	9.8%	CarelonRx	7.7%
Kaiser Permanente Pharmacy	5.8%	Intermountain Healthcare	0.5%
Humana Pharmacy Solutions	4.9%	Elixir Pharmacy	0.2%
MedImpact	1.8%	Navitus Health Solutions	0.2%
Navitus Health Solutions	1.7%	Envolve Pharmacy Solutions	0.1%
SS and C Health	1.6%	Capital Rx	0.1%
PerformRx	1.1%	MedImpact	0.0%
State Managed	0.6%	Magellan Rx Management	0.0%
Other PBM	2.0%	Other PBM	0.0%
Health Plan Managed	**0.0%**	**Health Plan Managed**	**40.4%**

Source: Clarivate Managed Market Surveyor Data.

Notes:

1. Caremark and Express Scripts shares are combined with those of their affiliated pharmacy management companies. Optum Rx's share is combined with FutureScripts.
2. Clarivate data include only health insurance lives who also receive their drug benefit through the insurer (*i.e.*, the data exclude "carved-out" lives).

85. In summary, these data indicate that health insurance plans often contract with PBMs other than Caremark, Express Scripts, and Optum Rx for many PBM functions and commonly perform formulary management internally. Smaller PBMs compete with the three largest PBMs, which is consistent with the results observed in the win-loss data, while the health plans themselves frequently self-supply instead of using a PBM for at least one of the PBM functions.

86. Share data from Clarivate also show that concentration among PBMs may not be as high as critics assert after considering that many plan sponsors perform one or more of the PBM services themselves or split their PBM services across multiple PBMs. Table 8 shows the combined national shares of covered lives for the three largest PBMs by function, over time. Between 2018 and 2023, the largest PBMs combined share has decreased for three of the four functions and increased slightly for only one function. These data indicate that the importance of smaller PBMs and self-supply has not diminished overall in recent years, and smaller PBMs and self-supply remain a significant competitive constraint on the largest PBMs.

Table 8: Share of Covered Lives:
Caremark, Express Scripts, and Optum Rx, Combined,
by Function, 2018-2023

CVS-Caremark, Express Scripts and Optum Rx Shares - All Payor Types (2018-2023)

Year	Claims Adjudication	Rebate Negotiation	Retail Network Management	Formulary Management
2018	58.2%	59.1%	58.2%	31.4%
2019	53.5%	51.5%	53.8%	32.7%
2020	55.1%	52.8%	55.2%	31.6%
2021	55.0%	51.9%	55.1%	30.5%
2022	55.3%	52.7%	55.4%	31.8%
2023	50.6%	38.7%	50.7%	32.0%

Source: Clarivate Managed Market Surveyor Data.
Notes:
1. Caremark and Express Scripts shares are combined with those of their affiliated pharmacy management companies. Optum Rx's share is combined with FutureScripts.
2. Clarivate data include only health insurance lives who also receive their drug benefit through the insurer (*i.e.*, the data exclude "carved-out" lives).

87. In summary, data on the number of covered lives by PBM and function confirms that plan sponsors contract not only with the three largest PBMs but also with many smaller PBMs, and that many health insurers self-supply some PBM services.

V. QUANTITATIVE EVIDENCE IS INCONSISTENT WITH CLAIMS BY CRITICS THAT PBMS DO NOT BENEFIT PLAN SPONSORS AND THEIR MEMBERS

88. As described above, PBMs reduce the cost of prescription drugs in several ways, including by negotiating for plan sponsors with (i) branded drug manufacturers to lower prices for branded drugs via rebates and (ii) pharmacies to lower fees for dispensing prescriptions to members. Plan sponsors may choose to pay for the services they receive from PBMs in a variety of ways, where different compensation schemes may reflect plan sponsor preferences. For example, plan sponsors may allow the PBM to retain some fraction of the savings negotiated with drug manufacturers and/or retail pharmacies. Alternatively, plan sponsors may pay the PBM fixed fees for its services and keep all of the negotiated savings. Plan sponsors may also choose a hybrid of these approaches.

89. A structure in which a firm negotiates with suppliers on behalf of its customers and shares in any resulting cost savings is not unusual, especially in healthcare.[149] Yet some critics claim that PBMs do not benefit plan sponsors because PBMs do not pass through all of the negotiated cost savings to plan sponsors. Indeed, some claim that PBMs' incentives are not aligned with those of plan sponsors. These critics appear to be claiming that PBMs act to maximize the rebates they retain rather than to minimize the plan sponsors' costs of prescription drugs.

90. The claim that PBMs are acting in their own interests by maximizing rebates instead of acting in plan sponsors' interest by minimizing drug benefit plan costs would seem more plausible if there were no competition among PBMs to win plan sponsor business or if plan sponsors often lacked the information to reliably compare the value propositions offered by

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149 *See*, *e.g.*, Eugene Schneller, *et al*., *Strategic Management of the Healthcare Supply Chain,* 2nd ed. (Hoboken: John Wiley & Sons, 2023). "Purchasing alliances and consortia exist in other industries but are exceptionally prevalent and pivotal to the healthcare supply chain." (*Id.*, p. 95.) "GPOs are purchasing alliances that negotiate contracts with suppliers on behalf of a group of hospitals or other healthcare providers (referred to as 'members'). A GPO can leverage its large member base to negotiate better contract terms with suppliers. … In exchange for their services, GPOs gain an administrative fee of approximately 3% from the vendors on all contracted purchases. While GPOs have other revenue streams (such as hospital membership fees), the administrative fee represents over 90% of the revenue, as observed by the largest GPOs in the United States." (*Id.*, pp. 109-110.)

different PBMs. Neither story fits the facts. In Section IV, we discussed evidence of competition not only among the three largest PBMs but also with smaller PBMs, which undermines the claims made by critics. We also described how plan sponsors are sophisticated purchasers who have access to specialized consultants and, as such, have the information needed to foster competition among PBMs to obtain favorable contract terms, including on how PBMs would be compensated.

91. In this section, we show that critics' claims that PBMs do not benefit plan sponsors and their members is inconsistent with the quantitative evidence. Specifically, we assess PBM margins, rebate pass-through rates, retail spreads, the relationship between rebates and growth in list prices, and growth in real net drug prices for rebated and non-rebated drugs,[150] and show that the data consistently run contrary to the claims of critics.

92. The claim by critics that plan sponsors and their members do not benefit from the PBMs' negotiations with drug manufacturers and pharmacies because PBMs may share in the savings could be interpreted in several ways. We present data in this section to refute those various interpretations.

- First, if critics are asserting that PBM compensation is, in some sense, too high, we show that examining pass-through rates in isolation is not useful for addressing such a claim. Margins are a better measure of what PBMs are earning, though with some limitations.[151] We show that PBM margins generally have not increased over the last

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150 The three largest PBMs are vertically integrated, *i.e.*, they are each affiliated with a plan sponsor (insurer) and pharmacies (all three own mail-order and specialty pharmacies, while Caremark and Optum Rx also have affiliated retail pharmacies). Because transfer prices are not based on market transactions between independent parties, their use can potentially raise issues of interpretation. Therefore, we prefer results that exclude transactions involving transfer pricing. In our analyses below, when possible, we exclude transactions where transfer prices may be involved.

151 Comparing accounting measures of profitability across firms often raises concerns as different firms may record revenues and costs differently. Gross margins (often called price-cost margins) have their own set of caveats as measures of profitability (Dennis W. Carlton and Jeffrey M. Perloff, *Modern Industrial Organization*, 4th ed. (Pearson, 2004), pp. 246-254.). (More generally, we recognize that to the extent our calculations in this report rely on accounting figures, they have their own sets of caveats.) We analyze gross margins here not to compare margins across different firms but to examine whether those margins show any trend.

several years. Moreover, PBM margins are small relative to the total amount paid by plan sponsors and members for drugs. Thus, even under the extreme assumption that PBMs earned no margin but still provided the same services to plan sponsors, the amount paid by plan sponsors and members for drugs would fall by only a small amount—roughly 5%.

- Second, if critics insist on focusing on pass-through rates in isolation and claim that PBMs use low pass-through rates to enrich themselves rather than benefit plan sponsors, then it is useful to understand that data show that PBM pass-through of manufacturer rebates is on average in excess of 90% of the negotiated savings and, in the most recent two years for which we have data, pass-through is on average close to 100%.

- Third, if the claim is that the difference between what plan sponsors pay PBMs for dispensed drugs and what PBMs pay pharmacies (the "retail spread," which can be another component of PBM compensation), is too high, then it is useful to understand that the retail spread is less than 2% on average.

- Fourth, if the claim is that because PBMs retain a share of manufacturer rebates, they may benefit from list price increases and thus somehow cause list price increases when they negotiate rebates from manufacturers, the data do not support this claim. We find that higher rebate percentages are not correlated with higher list price growth.

- Finally, if the claim is that PBMs' practice of negotiating rebates leads to higher net price growth than would otherwise occur, the evidence contradicts this claim. Data show that overall real net prices for drugs where PBMs may negotiate discounts (*i.e.*, branded drugs that face competition from other manufacturers) have fallen over time while overall real net prices for drugs where PBMs cannot negotiate for discounts (*i.e.*, branded drugs that do not face competition from other manufacturers) have risen.

A. PBMs' OPERATING MARGINS ARE BELOW 5% IN RECENT YEARS AND THUS ARE SMALL RELATIVE TO THE TOTAL COST OF DRUGS TO PLAN SPONSORS AND THEIR MEMBERS

93. Claims that PBMs enrich themselves by retaining an undue portion of the savings they generate from negotiations with branded drug manufacturers and retail pharmacies may really be claims that PBMs are overcompensated for their services. The issue is how best to assess whether PBMs are overcompensated.

94. Critics have focused on individual components of PBM compensation, but this approach makes little economic sense. Contracts between plan sponsors and PBMs differ in the services provided and in their terms, including the compensation terms. Among other things, contracts differ in the percentage of manufacturer rebates that PBMs must pass through to the plan sponsor, in the use of pharmacy network retail spreads, in the use of price guarantees or price protection clauses, and in the use of administrative fees. Plan sponsors that allow PBMs to retain some of the negotiated rebates presumably could use different compensation arrangements if they wanted to; indeed, many plan sponsors require 100% pass-through of rebates. The fact that some plan sponsors do not require 100% pass-through suggests that they prefer a compensation structure that uses part of the negotiated savings to pay the PBM for its services.[152] Critics' focus on the pass-through rate of rebates (or on any individual component of compensation) ignores the fact that the level of pass-through affects only the structure of compensation, and not necessarily the expected level of compensation. A PBM can charge a lower client administrative fee when the plan sponsor allows it to retain 2% of rebates compared to when the plan sponsor requires the PBM to pass through 100% of rebates. It is for this reason that focusing on pass-through rates (or any individual component of PBM compensation) in isolation does not make

[152] The literature on vertical restraints is informative. A survey by leading organizational economics scholars concludes that privately agreed upon "vertical restraints benefit consumers or at least do not harm them... in contrast [the empirical literature] shows that when restraints are mandated by the government, they systematically reduce consumer welfare or at least do not improve it. It appears that when dealers or consumer groups convince the government to 'redress' the unfair treatment that they allege to be suffering, the consequences are higher prices, higher costs, shorter hours of operation, and lower consumption as well as lower upstream profits." (Francine Lafontaine and Margaret Slade, "Exclusive Contracts and Vertical Restraints: Empirical Evidence and Public Policy," in *Handbook of Antitrust Economics,* ed. Paulo Buccirossi (Cambridge, MA; London, UK: The MIT Press, 2008), p. 408.)

economic sense if the actual concern is that PBMs are compensated too highly with plan sponsors not benefitting as a result.

95. If the real criticism is that the PBMs are extracting too much money from their clients and that their ability to do so has been increasing over time, it is more informative to examine PBMs' overall margins than, for example, looking only at retention of rebates. Therefore, we analyze the average operating margins and gross margins for Caremark, Express Scripts, and Optum Rx as a group using data provided by each company (the margins reported include margins earned on the affiliated mail-order and specialty pharmacy businesses of the three PBMs).[153] We find that the PBMs' average operating margin is generally below 5% and has not been increasing over time, and the average gross margin is around 8% and has not been increasing over time.[154]

96. Figure 5 shows the overall operating and gross margins for all services from 2017-2022, averaged across the three PBMs.[155] The PBM's average operating margin decreased from 5.6%

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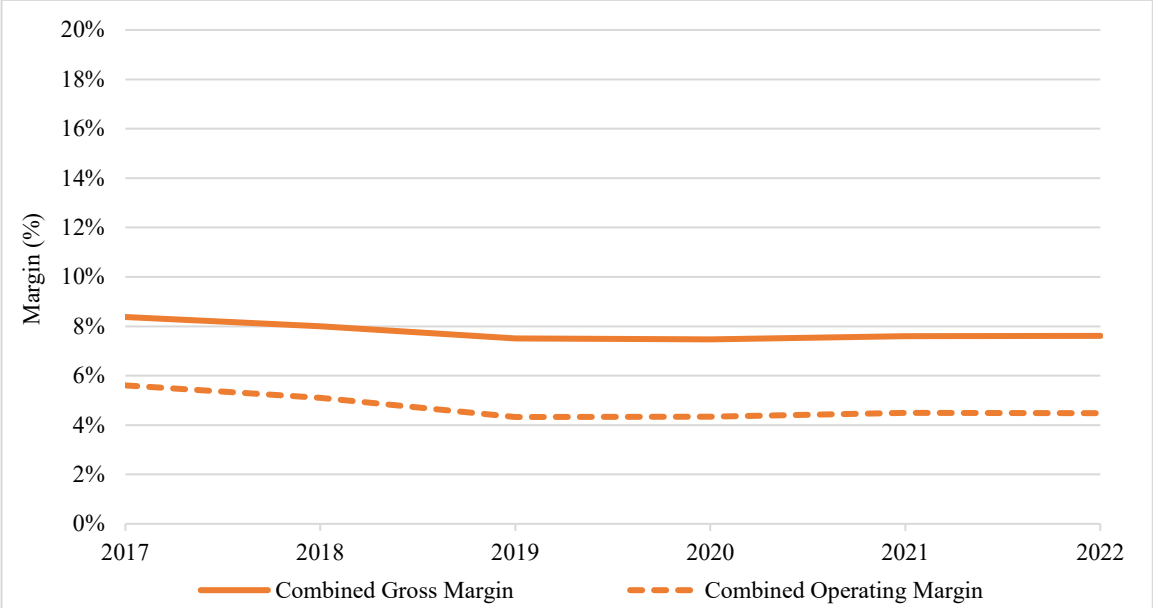
153 We understand that, for Optum, the margin also includes margins earned on Optum's affiliated retail pharmacies, and, for Caremark, the margin excludes margins earned on CVS retail pharmacies.

154 We understand that, in PBM financial accounting, gross margins are calculated as revenues less Costs of Goods Sold ("COGS"). PBM revenues are defined as the sum of payments by plan sponsors net of rebates and other discounts passed through, member co-pays paid to affiliated or non-affiliated pharmacies in the PBM pharmacy network, and other applicable client fees. PBM COGS includes the cost to purchase drugs for affiliated pharmacies net of rebates and other discounts, payments for drugs to non-affiliated pharmacies, member co-pays for non-affiliated pharmacies, and direct costs associated with dispensing drugs from affiliated mail-order and specialty pharmacies. Operating margins are calculated as gross margins less operating costs, which include costs such as labor costs and Sales, General, and Administrative ("SGA") costs. Operating costs typically include fixed costs and potentially additional variable costs.

155 These are weighted average margins, constructed by summing the dollar margins across the three PBMs and dividing by dollar revenues across the three PBMs. Because the operating and gross margins reported include sales to the plan sponsors (insurers) affiliated with each of the three PBMs, the use of transfer prices could potentially raise interpretation issues. To address this potential issue, we remove the transactions affected by transfer pricing for the one PBM for which we can do so. Including these transactions does not have a significant impact on that PBM's margins.

in 2017 to 4.5% in 2022, and their average overall gross margin decreased from 8.4% in 2017 to 7.6% in 2022.

Figure 5: Average Overall Gross Margin and Operating Margin: Caremark, Express Scripts, and Optum Rx Combined



Sources: Caremark internal data, Express Scripts internal data, Optum Rx internal data.
Notes: Aetna is excluded from CVS Caremark gross margins and operating margins.

97. To put these margin figures in context, it may be helpful to consider their magnitude relative to the total amount that plan sponsors and members pay for drugs. If the total amount paid by plan sponsors and members for a drug were $100, PBM operating margins on that $100 would on average be about $5.[156] Even if plan sponsors paid PBMs only enough to cover their operating costs of providing services—that is, under the extreme assumption that PBMs were willing to continue to provide all of the PBM services (*e.g.*, claims processing, pharmacy network negotiations, plan and member customer service, rebate negotiations, and utilization management), mail-order pharmacy services, and specialty pharmacy services that plan sponsors

[156] The accounting margin from the PBMs' financial records closely approximates PBM margins as a percentage of total cost to plan sponsors and members for drugs.

demand at the same level of quality and yet earn zero operating margin—drug costs would be reduced by just 5%.[157]

B. PBMs PASS THROUGH A HIGH AND INCREASING PERCENTAGE OF MANUFACTURER REBATES TO PLAN SPONSORS

98. As discussed above, it does not make economic sense to look at pass-through rates in isolation if one is interested in the question of whether plan sponsors benefit from PBMs' negotiations with manufacturers. Nevertheless, taking at face value the claim that PBMs do not benefit plan sponsors because PBMs do not pass through all of the negotiated cost savings to plan sponsors, it is relevant to understand what percentage of manufacturer rebates is passed through to plan sponsors and what percentage is retained by the PBMs as part of their compensation. In this section, we show that overall PBM pass-through of rebates from manufacturers to plan sponsors is very high, close to 100% in 2020 and 2021, the most recent full years for which we have data.

99. The pass-through rate of manufacturer rebates is defined as the share of the rebates PBMs receive from manufacturers that PBMs pay to plan sponsors. For purposes of this analysis, rebates include not only discounts off of a drug's list price but also administrative fees that are paid by drug manufacturers to PBMs for conducting drug utilization reviews, administering rebates, and managing invoicing and collections, as well as price protection payments, which are additional payments that offset certain list price increases of branded drugs. Pass-through rates are calculated using data provided by Caremark, Express Scripts, and Optum Rx.[158]

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157 One academic study analyzes profits at various points in the drug distribution system and estimates that, for a $100 expenditure on prescription drugs, PBMs earn roughly $2 in after-tax profit while drug manufacturers earn roughly $15 in after-tax profit. (Neeraj Sood, *et al*., "Flow of Money Through the Pharmaceutical Distribution System," University of Southern California, Schaeffer Center White Paper Series, June 6, 2017, available at https://healthpolicy.usc.edu/research/flow-of-money-through-the-pharmaceutical-distribution-system.)

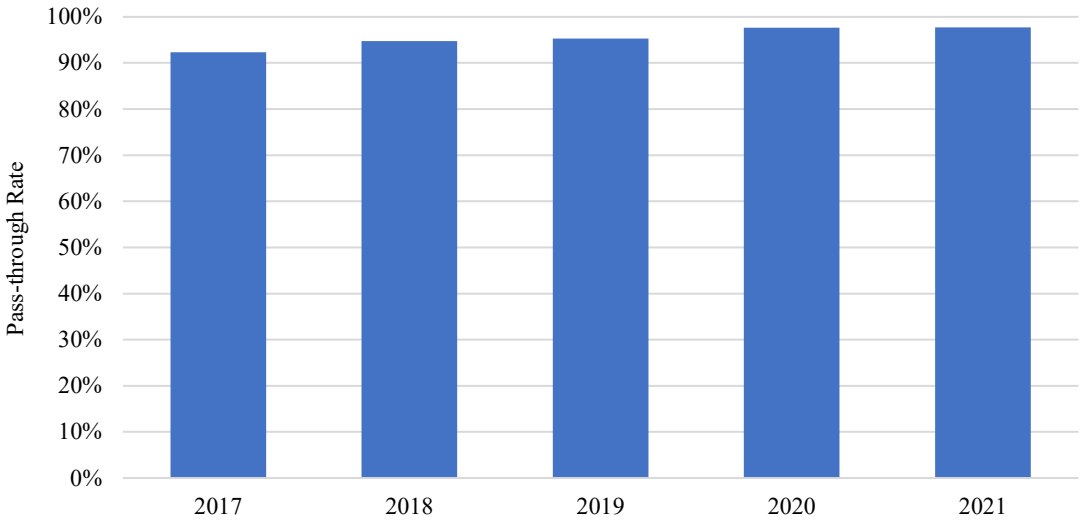
158 For Caremark, we compute pass-through using rebates data for the subset of drugs requested by the FTC for Specifications 12-14. For Express Scripts and Optum Rx, we use data provided by Express Scripts and Optum Rx on all rebated drugs.

100. Figure 6 shows that the average rebate pass-through rate for Caremark, Express Scripts, and Optum Rx has increased over time, rising from 92% in 2017 to 98% in 2021.[159] Thus, Caremark, Express Scripts, and Optum Rx pass through the vast majority of rebates they receive from manufacturers to plan sponsors, and the pass-through rate has increased over time and was close to 100% in 2020 and 2021.[160]

[159] We compute the average rebate pass-through rate as the total rebates passed through by Caremark, Express Scripts, and Optum Rx to their plan sponsors divided by the total rebates received by Caremark, Express Scripts, and Optum Rx from manufacturers.

[160] The three PBMs recently created group purchasing organizations (GPOs) to handle rebate negotiations with drug manufacturers for commercial plan sponsors. Caremark formed Zinc GPO in 2020, Express Scripts formed Ascent Health Services GPO in 2019, and Optum Rx formed Emisar Pharma Services GPO in 2021. Drug Channels, "Drug Channels News Roundup, August 2021, OptumRx's New GPO, Pharmacy DIR Fees, State Biosimilar Laws, UM Views, and a Newspaper Delivers," August 25, 2021, available at https://www.drugchannels.net/2021/08/drug-channels-news-roundup-august-2021.html (accessed August 12, 2024). The data the pass-through analysis relies on does not include information on fees (if any) retained by GPOs. We understand the GPOs could not have had a material effect on rebates, if any, for about a year after formation. Thus, the presence of GPOs should not affect our pass-through analysis for Caremark prior to 2021 or for Express Scripts prior to 2020, and it does not impact Optum. We understand that the FTC has asked for additional information from the three PBMs on their GPOs and that the PBMs are in the process of collecting that information.

Figure 6: Average Pass-through Rate of Manufacturer Rebates: Caremark, Express Scripts, and Optum Rx Combined, All Payor Types



Sources: Specs 12-14 of Caremark 6(b) Submission to the FTC; internal Caremark rebate data, internal Express Scripts rebate data; internal Optum Rx rebate data.
Notes: Administrative fees are included for Optum Rx starting in 2019 and for Caremark and Express Scripts for all years.

C. THE AVERAGE RETAIL SPREAD RETAINED BY PBMS IS BELOW 2%

101. As noted above, the difference between prescription payments made by plan sponsors to PBMs and prescription payments made by PBMs to pharmacies is known as the "retail spread." Critics have raised concerns about retail spreads, claiming they reduce transparency for plan sponsors and allow PBMs to increase their profits. The retail spread represents another potential mechanism by which plan sponsors may compensate PBMs, and, as with pass-through of manufacturer rebates, it is a mistake to focus on any one element of PBM compensation in isolation. Nevertheless, we investigate the level of retail spreads in an effort to address criticisms specifically related to this form of PBM compensation.

102. The dollar value of the retail spread will depend on what the PBM negotiates with the plan sponsor and what the PBM negotiates with the pharmacy. We express the retail spread for a prescription as a percentage of the amount paid by plan sponsors. Thus, if the retail spread is 2%, that means that the PBM keeps 2% of the drug and dispensing fees paid by plan sponsors, paying the remaining 98% to the pharmacy. A retail spread of 0% means the plan sponsor pays the same amount that the pharmacy receives, and the PBM retains nothing. A negative retail spread

means the plan sponsor pays less than the amount that the pharmacy receives, and the PBM loses money on that prescription.

103. We compute the average retail spread using pharmacy claims data produced by Caremark, Express Scripts, and Optum Rx to the FTC.[161] The data include claims for all pharmacy types—retail pharmacies, mail-order pharmacies, and specialty pharmacies—for drugs included in the FTC's data request.[162] Figure 7 shows the average retail spread across the three PBMs and across all payor types, expressed as a percentage of the total amount billed by the PBMs to plan sponsors. The average retail spread is around 1.5% from 2017-2021. Thus, pharmacies received 98.5% of the amount that plan sponsors paid PBMs.

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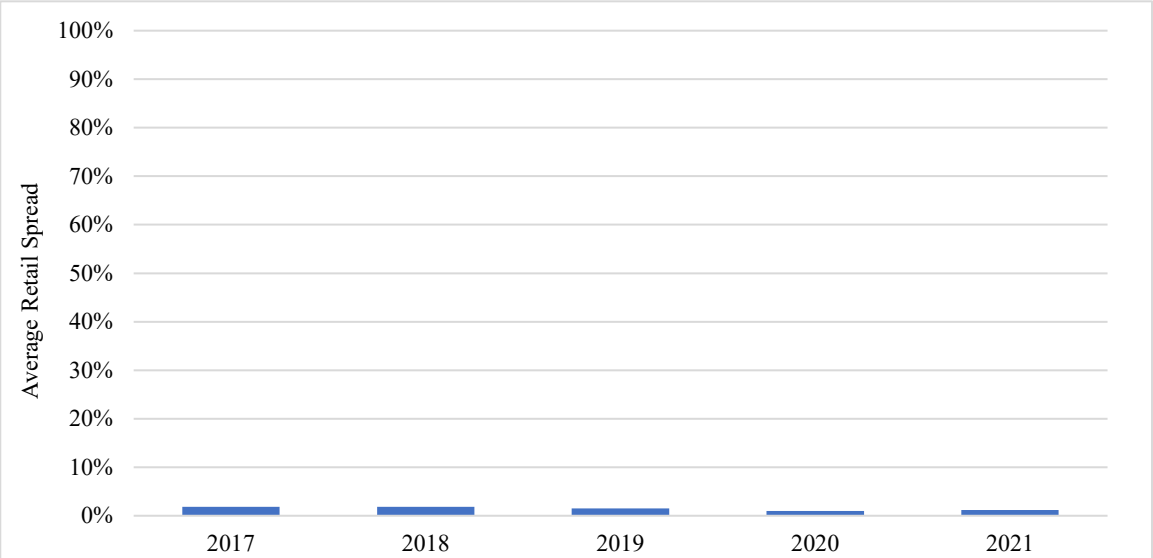
161 Specifically, we use data submitted by the PBMs for the top 100 drugs by dollar sales in each year (Specification 12), the top 100 drugs by unit sales in each year (Specification 13), and specialty drugs and rebated drug products (Specification 14). We calculate the average retail spread for the three PBMs combined by summing dollar spreads across these drugs and across the three PBMs and dividing this by the sum of the amounts billed to plan sponsors across these drugs and across the three PBMs.

162 Where possible in our analyses, we exclude transactions that may be affected by transfer pricing. (*See* note 150.) Thus, for this analysis, we exclude payments to affiliated pharmacies when calculating the retail spread. Prescriptions at a particular pharmacy are designated as occurring at an affiliated pharmacy only when the prescriptions are managed by the PBM that is affiliated with that particular pharmacy. For example, prescriptions at CVS occur at an affiliated pharmacy when the prescriptions are managed by Caremark but not when the prescriptions are managed by Express Scripts or Optum Rx. We are unable to exclude transactions related to the plan sponsor (health insurer) being vertically integrated with a PBM.

Figure 7: Average Retail Spread as a Percentage of Total Amount Billed to Plan Sponsors: Caremark, Express Scripts, and Optum Rx Combined, All Plan Sponsors



Sources: Specs 12-14 of Caremark, Express Scripts, and Optum Rx 6(b) Submissions to the FTC.
Notes: Excludes affiliated pharmacies. Not all PBM data for 2022 is through to December 2022, and thus, 2022 is omitted.

D. PBMs' REBATES FROM BRANDED DRUG MANUFACTURERS ARE NOT ASSOCIATED WITH HIGHER GROWTH RATES IN THE REBATED DRUGS' LIST PRICES

104. Critics have raised concerns that because contracts between plan sponsors and PBMs sometimes allow PBMs to retain a percentage of the rebates negotiated with branded drug manufacturers, PBMs focus only on the size of the rebate that they retain rather than on the net price of the drug paid by plan sponsors. If one assumes that the retention rate—the percentage of rebates that PBMs retain—is set by contract and does not change during the term of the contract, then an increase in the list price would in theory lead to higher retained rebates (in dollar terms) for PBMs. For this reason, critics theorize that PBMs encourage (or do not oppose) list price increases. According to these critics, the end result of rebate negotiations between PBMs and manufacturers is that the growth rate in the list prices of rebated branded drugs is higher than the growth rate in the list prices of non-rebated branded drugs. We show in this section that the data do not support this hypothesis and explain that this finding is not surprising as the claim does not make economic sense. In addition, the claim is inconsistent with the fact that PBMs often obtain price protection terms in agreements with manufacturers.

1. The growth rate of list prices for rebated branded drugs is not higher than the growth rate of list prices for non-rebated branded drugs

105. If the rebate system incentivizes higher increases in list prices by branded drug manufacturers than would otherwise occur, then, all else equal, the rate of increase in list prices over time would be higher for branded drugs that are rebated than for branded drugs that are not rebated. In this section, we compare the growth rate in average list prices of branded drugs that have rebates and branded drugs that do not have rebates and show that list prices of rebated drugs are not systematically increasing at a higher rate than list prices of non-rebated drugs.[163]

106. To compare the growth rate of list prices of rebated branded drugs and non-rebated branded drugs, we proceed as follows. We use AWP for individual drugs from Caremark, Express Scripts, and Optum Rx data to measure the list prices of those drugs. We adjust all prices for inflation using the Bureau of Labor Statistics' (BLS) consumer price index (CPI).[164] Then we construct a real AWP price index across the three PBMs for two groups of drugs: rebated branded and non-rebated branded.[165] Figure 8 shows the real AWP index over time for

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163 We exclude generic drugs from this analysis as they typically do not involve rebates.

164 The CPI is obtained from U.S. Bureau of Labor Statistics, available at https://www.bls.gov/cpi/data.htm (accessed February 5, 2024). The deflated net price in year *t* is calculated as $Net\ price\ in\ year\ t\ /\left(\frac{CPI_t}{CPI_{2018}}\right)$.

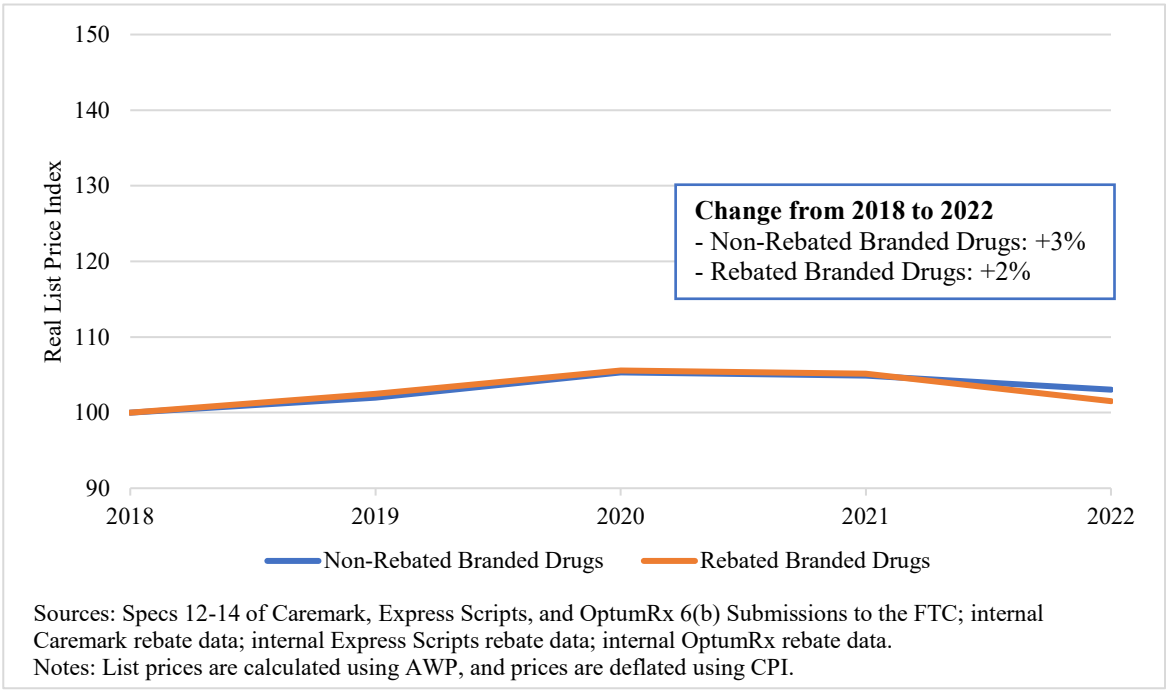
165 For each PBM, we calculate the chained Fisher price index for the AWPs. The Laspeyres price index measures the price change from the base period to the current period using the base-period quantity as the weights. The Paasche price index also measures this price change but uses the current-period quantity as the weights. The Fisher price index is the geometric mean of the Laspeyres price index and the Paasche price index. The formula for the Fisher Price index is below. The left-hand term is the Laspeyres index and the right-hand term is the Paasche index. For NDC *i*, $P_{i,0}$ and $Q_{i,0}$ reflect the price and quantity, respectively, in the base period while $P_{i,1}$ and $Q_{i,1}$ reflect the price and quantity in the current period:

$$\left(\left[\frac{\Sigma_i\ P_{i,1}\ Q_{i,0}}{\Sigma_i\ P_{i,0} Q_{i,0}}\right]\left[\frac{\Sigma_i\ P_{i,1}\ Q_{i,1}}{\Sigma_i\ P_{i,0}\ Q_{i,1}}\right]\right)^{\frac{1}{2}}$$

We construct the Fisher price indexes from 2018 to 2019, 2019 to 2020, 2020 to 2021, and 2021 to 2022, and then use these indexes to measure the price change over the entire period. Constructing the Fisher price indexes in this way accounts for the changing set of drugs available over time due to new drugs entering the market and/or old drugs exiting.

rebated branded drugs and for non-rebated branded drugs, averaged across Caremark, Express Scripts, and Optum Rx. In real terms, the AWP on rebated branded drugs increased by 2% between 2018 and 2022 while the AWP on non-rebated branded drugs increased by 3% during this time.[166] This difference in the growth of average real list prices is contrary to what would be expected if critics were correct that PBMs' negotiation of rebates leads to a higher growth rate in list prices for the rebated drugs.

Figure 8: Indexed Real List Prices of Rebated Branded and Non-Rebated Branded Drugs: Average Across Caremark, Express Scripts, and Optum Rx



Sources: Specs 12-14 of Caremark, Express Scripts, and OptumRx 6(b) Submissions to the FTC; internal Caremark rebate data; internal Express Scripts rebate data; internal OptumRx rebate data.
Notes: List prices are calculated using AWP, and prices are deflated using CPI.

This is a methodology commonly used in the literature (*See*, *e.g.*, Ana Aizcorbe and Nicole Nestoriak, "Price Indexes for Prescription Drugs: A Review of the Issues," in *The Oxford Handbook of the Economics of the Biopharmaceutical Industry*, eds. Patricia M. Danzon and Sean Nicholson (Oxford University Press, 2012): 438-462; J. Rovira, *et al.*, "The role of prices in drug expenditure analysis: An application of price indexes for two therapeutic groups in the Catalan Health Service (1991-1999)," *The European Journal of Health Economics* 2 (2001): 142-149.).

166 Without adjusting for inflation, the AWP on rebated branded drugs increased by 18% between 2018 and 2022, while the AWP on non-rebated branded drugs increased by 20% during this time.

107. A recent Medicare Payment Advisory Commission Report to Congress confirms that the rate of growth in list prices of rebated drugs is not systematically higher than the rate of growth in list prices of non-rebated drugs. That study shows that both list prices and net prices on drugs that can be excluded (*i.e.*, those drugs for which PBMs' can bargain for discounts (rebates)) increased at a lower rate between 2015 and 2021 than the list price of drugs that cannot be excluded (*i.e.*, "mandatory" drugs for which PBMs' have less ability to bargain for discounts (rebates)).[167]

2. Of branded drugs receiving rebates, the growth in the list price is not higher for those drugs with higher rebate percentages

108. Another way to assess the claim that rebates lead to higher list price growth is to analyze whether drugs that have higher rebate percentages also have higher rates of growth in their list price. In this section, we first describe studies that have addressed this question and found no such relationship. We then analyze data from Caremark, Express Scripts, and Optum Rx to assess whether drugs with higher rebate percentages also have higher rates of growth in their list prices. Consistent with the prior studies, we find no such evidence.

a) Studies find no evidence that drugs with higher rebate percentages have a higher rate of growth in their list prices

109. Studies generally find no evidence that higher rebate percentages are associated with higher rates of growth in list prices.[168] For example:

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167 The analysis shows that the list prices and net prices of mandatory drugs increased by 8.0% and 7.5% respectively between 2015 and 2021, while the list prices and net prices for all Part D drugs increased by 7.6% and 4.8% respectively. (Medicare Payment Advisory Commission, "Report to the Congress: Medicare and the Health Care Delivery System," June 2023, available at https://www.medpac.gov/wp-content/uploads/2023/06/Jun23_MedPAC_Report_To_Congress_SEC.pdf, Table 2-2 at 83.)

168 One study found that higher rebates in dollar terms are associated with higher list prices in dollar terms. (Neeraj Sood, *et al*., "The Association Between Drug Rebates and Drug Prices," University of Southern California, Schaeffer Center White Paper Series, February 11, 2020, available at https://healthpolicy.usc.edu/research/the-association-between-drug-rebates-and-list-prices/.) Although the authors of the study claim that this "suggests that rebates do play a role in increasing list prices, and that reducing or eliminating rebates could lower list prices," such a conclusion is not warranted because

- Froeb and Shor (2023) use a study conducted by the actuarial firm Milliman using 2016 data on rebated Medicare Part D drugs to show that drugs with lower rebate percentages had higher rates of growth of list prices than drugs with higher rebate percentages.[169] This pattern is the opposite of what one would expect if higher rebate percentages were associated with higher rates of growth in list prices.

- A study commissioned by the PCMA analyzed list price increases and rebate percentage levels during the 2011-2016 period for the top 200 branded drugs as of 2016. The study found "no correlation between the increasing prices that the drugmakers set on individual drugs and the rebates that they negotiate with PBMs."[170] Figure 9 shows the lack of correlation between list price growth and rebates expressed as a percentage of list price.

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the direction of causation is not clear. *Id*. The study's result could arise because, *e.g.,* list prices increased while net prices increased less because PBMs succeeded in obtaining increased rebates to protect payors. *See* Froeb and Shor (2023), p. 22.

169 Froeb and Shor (2023), p. 27, citing Nicholas J. Johnson, Charles M. Mills, and Matthew Kridgen, "Prescription Drug Rebates and Part D Drug Costs: Analysis of historical Medicare Part D drug prices and manufacturer rebates," Milliman, July 16, 2018, available at https://ahiporg-production.s3.amazonaws.com/documents/AHIP-Part-D-Rebates-20180716.pdf.

170 Visante, "Increasing Prices Set by Drugmakers Not Correlated With Rebates," prepared on behalf of PCMA, June 2017, available at https://www.pcmanet.org/wp-content/uploads/2017/06/Visante-Study-on-Prices-vs.-Rebates-FINAL.pdf, p. 2.

Figure 9: Correlation Between List Price Growth and Average Rebate Percentage Reported by PCMA Study[171]

b) Regression analysis also shows no evidence that higher rebates are associated with a higher rate of growth in list prices of branded drugs

110. To empirically test the relationship between rebates and the rate of growth in list prices of branded drugs, we implement a regression analysis using Caremark, Express Scripts, and Optum Rx data. This regression analysis uses data on rebated drugs to estimate the relationship between list price growth rates from year to year and rebates expressed as a percentage of list price. Specifically, we regress the ratio of AWP in year "t" to AWP in year "t-1" (*i.e.*, the list price in year "t" divided by the list price in year "t-1") on the rebate percentage in year t (*i.e.*, the amount of rebates in year "t" divided by AWP in year "t"). We also include indicator variables for each

171 The Figure is taken from *Id.*, p. 4.

year (2018 through 2022) and indicator variables for drug types (NDCs).[172] Given this specification, the regression coefficient on the rebate percentage measures the relationship between the rebate percentage and the percentage change in list prices. A positive and significant coefficient would imply that higher rebate percentages are correlated with larger percentage increases in list prices of branded drugs.

111. Table 9 reports the regression results and shows there is no statistical evidence that rebate percentages are positively correlated with the rate of growth in list prices. The coefficient on the rebate percentage implies there is a small negative relationship between rebate percentages and list price growth rates.

Table 9: Relationship between Rebate Percentage and Rate of Growth in List Price of Branded Drugs, Caremark, Express Scripts, and Optum Rx Estimated Together

Dependent Variable: AWP_t / AWP_{t-1}

	All PBMs
Rebate as a Percentage of AWP ($Rebate_t / AWP_t$)	-0.010**
Observations	9,274

Sources: Specs 12-14 of Caremark, Express Scripts, and Optum Rx 6(b) Submissions to the FTC; internal Caremark rebate data; internal Express Scripts rebate data; internal Optum Rx rebate data.
Notes:
1. *** $p < 0.01$, ** $p < 0.05$, * $p < 0.1$; Clustered standard errors on NDC are used.
2. The analysis is performed at the NDC/year level using Caremark, Express Scripts, and Optum Rx claims data; Observations are weighted using the number of 30-day prescriptions.
3. The regression includes fixed effects for NDC, year (2018-2022), and PBM.

112. These regression results are consistent with the findings in the studies discussed above that show either no relationship or a negative relationship between rebates and list price growth

[172] The equation for the base specification of this regression is as follows:

$$AWP_t / AWP_{t-1} = \beta_0 + \beta_1 Rebates_t / AWP_t + \beta_2 NDC + \beta_3 Year + \beta_4 PBM + \varepsilon$$

Observations are weighted by volume of 30-day equivalent prescriptions. Standard errors are clustered on NDC.

rates.[173] All of the analyses produce results that are inconsistent with the critics' claims that higher rebates are associated with higher growth in list prices.

3. Critics' claim that PBMs prefer that manufacturers charge high list prices so that PBMs can earn more rebates does not make economic sense

113. We have shown empirically that rebate percentages are not associated with higher rates of growth in list prices. This result is not surprising. The claim that PBMs act to maximize the dollar amount of retained rebates and thus have an incentive to permit—or even encourage—manufacturers to raise list prices rests on the idea that manufacturers set list prices after an agreement on rebate levels (in percentage terms) has been reached. This ignores market realities and the manufacturer's price setting incentives. To illustrate the importance of the fundamental economic forces influencing pricing incentives, we use a highly simplified model. Suppose a manufacturer faces two types of customers: (i) plan members (insured patients), whose prescriptions are paid for by a plan sponsor[174] that engages a PBM to negotiate rebates with the manufacturer;[175] and (ii) uninsured patients, who pay for their prescriptions themselves and lack any ability to negotiate with the manufacturer. The two groups are identifiable, and a profit-maximizing manufacturer would set different prices to the two groups.

114. Because they are individual buyers who do not negotiate with manufacturers, uninsured patients may be most exposed to decisions by manufacturers to raise list prices.[176] The list price

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173 Each observation is weighted by the number of prescriptions for that drug, so that drugs with higher prescription volumes are given a larger weight in determining the regression coefficients. An unweighted version of this analysis produces a negative coefficient that is not statistically significant. That is, without weighting, this analysis shows no statistically significant relationship between rebates and list price growth rates.

174 For simplicity, we ignore the fact that members generally pay a co-pay or co-insurance for their prescriptions.

175 We note that these dynamics would exist whether plan sponsors use PBMs to negotiate with drug manufacturers or negotiate directly with drug manufacturers themselves.

176 In practice, uninsured buyers account for a small share of all drug purchases and many uninsured patients do receive discounts, sometimes in the form of coupons from manufacturers. Burns (2022), p. 406 (coupons and patient assistance programs maintain a small stable share of payments). However, the existence of uninsured patients that pay full list price encourages the drug manufacturer to set a price to them, knowing that it can set other prices to other patients through the use of means-tested coupons and rebates to PBMs.

that such buyers pay would be either the monopoly price for the drug to those buyers or something lower than the monopoly price if the manufacturer faces at least some competition. In contrast, the PBM, negotiating on behalf of plan sponsors (and therefore on behalf of a large number of plan members), is able to negotiate a below-list price for sales to plan members for drugs that face competition if the PBM can credibly threaten that failure to provide discounts will reduce the manufacturer's sales. That is, the PBM is able to negotiate discounts in situations where its plan sponsor clients can incentivize a significant number of their plan members to use lower-cost branded drugs from competing manufacturers. In these situations, the manufacturer receives the discounted price (where the discounted price = list price*(1-rebate percentage)). Viewed this way, the amount of rebate negotiated by the PBM is simply the difference between these two independently determined prices, *i.e.*, the rebate is just the difference between the list price (which the manufacturer chooses to maximize profits on uninsured patients) and the discounted price (which the manufacturer chooses to maximize profits on plan members). Claiming that PBMs' negotiating for discounts would lead manufacturers to raise the list price ignores the role of the list price in maximizing manufacturer profits from sales to uninsured patients.

115. From an economic point of view, the list price and the discounted price are two separate prices that are set by the manufacturer to maximize profits to different populations and the amount of the rebate is just the difference between the two. For example, if the price to an uninsured patient is $10 while that to a plan member (and the plan sponsor) is $6, then the rebate is $4 and the percentage rebate is 40%. If the pool of uninsured patients changes so that the optimal list price rises to $20, there is no necessary reason for the discounted price of $6 to change. In that case, the rebate rises to $14, the percentage rebate rises to $14/$20 or 70%, and the discounted price to the plan member remains at $6.[177] Thus, the criticism that rebates cause manufacturers to raise the list price is economically incorrect because it ignores the manufacturer's profit-maximizing incentives. Of course, if common factors, such as increased popularity of a drug, affect both plan members and uninsured patients, then the list and

[177] This example shows that an increase in the list price caused an increase in the rebate (both in dollar and percentage terms), and not the reverse.

discounted price could move together but it would be improper to characterize that change as one price causing movements in the other.

116. Even if one assumed the criticism were an accurate characterization of the PBM's and manufacturers' incentives, it ignores the role of plan sponsors. The criticism implies not only that PBMs do not act to benefit plan sponsors but also that plan sponsors do not have the ability to remedy this outcome either because they are not aware of the problem or there is not enough competition among PBMs to force a realignment of incentives. As we discuss above in Section IV, plan sponsors (together with their consultants) are sophisticated purchasers who can use competition among PBMs when negotiating PBM contracts. If, as critics contend, retained rebates ultimately harm plan sponsors through higher list prices, then plan sponsors would account for that in their negotiations with PBMs. For example, a plan sponsor could require that the PBM pass through 100% of the rebates negotiated on its behalf in order to retain the plan sponsor's business going forward. Indeed, many plan sponsors do require complete pass-through of rebates. For these plan sponsors, PBMs would not benefit from list price increases and thus the claimed concern would not exist. For a plan sponsor that agrees to less than 100% pass-through with its PBM, the fact that it could have required 100% pass-through and chose not to indicates that the plan sponsor concluded that allowing the PBMs to retain a percentage of rebates is a preferable form of compensation to the PBM than other approaches and will not lead to higher net prices compared to the other approaches.

117. In addition, as discussed above, many rebate contracts between PBMs and drug manufacturers include price protection clauses that require the drug manufacturer to make additional payments if list prices rise above certain levels. Plan sponsors generally contract for those payments to be passed through or retained by the PBM in the same manner that plan sponsors contract for rebates to be passed through or retained by the PBM, to compensate the PBM for its services. Such price protection clauses are inconsistent with claims that PBMs are working against the interests of plan sponsors.

E. OVERALL REAL NET PRICES HAVE FALLEN OVER TIME FOR DRUGS WHERE PBMS CAN FOSTER MANUFACTURER COMPETITION TO NEGOTIATE REBATES

118. If critics are claiming that PBMs' negotiation of rebates has contributed to higher growth rates in the net prices paid by plan sponsors and members than would otherwise be the case, that

claim is unfounded. Data show that the rate of change in real net prices for drugs where the PBMs can negotiate with manufacturers is lower than the rate of change of real net prices where PBMs cannot negotiate.[178] In fact, the real net price for drugs where PBMs can negotiate with manufacturers has fallen (*i.e.*, the growth rate of real net prices is negative) while the real net price for drugs where PBMs cannot negotiate has increased.

119. The ability of PBMs to impact the net price of drugs differs depending on the nature and amount of competition a drug faces. For branded drugs that face competition from other branded manufacturers within a therapeutic class, PBMs can cause manufacturers to compete for placement on formularies through the provision of rebates. For branded drugs that do not face meaningful branded competition, PBMs typically cannot obtain significant rebates for plan sponsors as the manufacturers of these drugs have no or reduced incentives to offer rebates. By comparing how net prices have increased for rebated and non-rebated drugs, we can test whether PBMs' negotiation of rebates is associated with net prices for rebated drugs growing at a higher rate than net prices for non-rebated drugs.

120. We compute the net prices paid by plan sponsors, which reflect the rebates passed on to plan sponsors, using the most disaggregated drug-level data available for Caremark, Express Scripts, and Optum Rx. We also compute the net amount paid by members[179] and an overall net price, which is just the sum of the net prices paid by plan sponsors and members. Assessing the overall net price is important because that is the total price paid for a drug, and it ensures that any change in the division of payment responsibility between plan sponsors and members does not give a false appearance that the net cost of a drug has changed.[180] We adjust all prices for inflation using the Bureau of Labor Statistics' (BLS) consumer price index (CPI). Then, we

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178 We find similar results when analyzing prices without adjusting for inflation.

179 The member payment data are net of POS rebates for Caremark and Optum Rx but not for Express Scripts.

180 If, for example, plan sponsors shifted more of the payment burden onto members, the net price paid by plan sponsors might decline even though the net price paid by plan sponsors and members combined did not.

construct a price index using data across all payors for two groups of drugs: rebated branded and non-rebated branded.[181]

121. Figure 10 shows the average of the indexes for Caremark, Express Scripts, and Optum Rx combined for the overall real net price (the sum of the payments by plan sponsors and members) for rebated branded drugs and non-rebated branded drugs.[182] Between 2018 and 2021, we find that the overall real net price decreased by 5% for rebated branded drugs, while it increased by 4% for non-rebated branded drugs.[183] Thus, while real net prices increased over time for non-rebated branded drugs that do not face meaningful branded competition, real net prices declined over time for rebated branded drugs for which PBMs can foster competition among drug manufacturers.[184]

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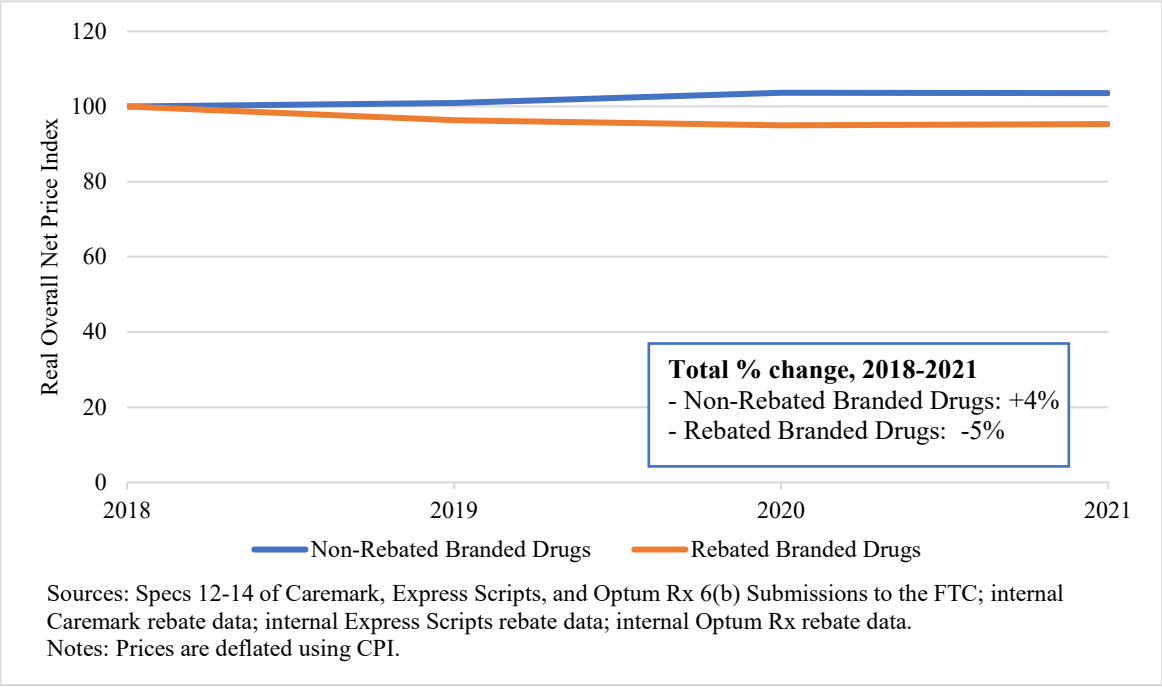
181 For each PBM, we calculate the chained Fisher price index for the net prices paid by plan sponsors, members, and the total (plan sponsors and members) to summarize the trends in these prices for the two categories of drugs.

182 Non-rebated branded drugs contain both branded drugs for which there are no competitors within a therapeutic class and branded drugs that faced competition but for which the PBM was unable to obtain a rebate (*e.g.*, some drugs are in "protected classes" for which multiple competing drugs in the category must be covered).

183 We also find that the real net prices paid by the member (excluding payments by plan sponsors) are decreasing over time for rebated branded drugs but are increasing over time for non-rebated branded drugs.

184 Without adjusting for inflation, the net price on rebated branded drugs increased by 3% between 2018 and 2021, while the net price on non-rebated branded drugs increased by 12% during this time.

Figure 10: Indexed Overall Real Net Prices of Rebated Branded and Non-Rebated Branded Drugs: Average Across Caremark, Express Scripts, and Optum Rx



Sources: Specs 12-14 of Caremark, Express Scripts, and Optum Rx 6(b) Submissions to the FTC; internal Caremark rebate data; internal Express Scripts rebate data; internal Optum Rx rebate data.
Notes: Prices are deflated using CPI.

122. To summarize, data on overall real net prices demonstrate that PBMs' negotiation of rebates does not lead to higher growth in the overall real net prices that the plan sponsor and its members pay. To the contrary, the overall real net price paid by plan sponsors and members for rebated branded drugs decreased over time while the overall real net price paid by plan sponsors and members for non-rebated branded drugs increased over time. This illustrates that the ability of PBMs to achieve cost savings through negotiations with drug manufacturers substantially benefits plan sponsors and their members and helps to explain the wide utilization of PBMs.

VI. PBMs FORM PHARMACY NETWORKS TO PROVIDE BENEFITS TO PLAN SPONSORS AND MEMBERS AND HAVE NOT THREATENED THE VIABILITY OF EFFICIENT INDEPENDENT PHARMACIES

123. As discussed above, PBMs commonly negotiate with pharmacies for the reimbursement rates that the pharmacies receive for filling prescriptions if the pharmacies become part of the plan sponsor's pharmacy network. Prior to discussing claims that critics have made about PBM pharmacy networks, it is useful to define the various types of pharmacies that may be part of PBM pharmacy networks and dispense prescriptions to members.

- Pharmacies can be distinguished by how members receive their prescriptions. *Retail pharmacies* are brick-and-mortar store locations that dispense prescriptions that are typically picked up by members. Retail pharmacies typically also sell non-prescription items. *Mail-order pharmacies* deliver prescriptions by mail to members who place orders either by phone or online.

- Retail pharmacies can be further categorized by whether they are *chain pharmacies* or *independent pharmacies*.[185] Chain pharmacies are pharmacies with a large number of retail locations and independent pharmacies are pharmacies where the pharmacy owner owns only one or a small number of locations.[186]

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185 When we use the term chain pharmacy, we mean chain retail pharmacy. When we use the term independent pharmacy, we mean independent retail pharmacy.

186 Definitions of independent pharmacies vary. In its 6(b) order, the FTC defines an independent pharmacy as "any business entity that owns less than four pharmacy locations nationwide, either under a single banner or multiple banners, and any individual pharmacy locations within such business entity." (Federal Trade Commission, *Order to File a Special Report*, FTC Matter No. P221200 (June 6, 2022), p. 12.) Each of the three largest PBMs define independent pharmacies somewhat differently: Express Scripts' data considers 1-15 pharmacies under common ownership and PSAO membership as an independent pharmacy; Optum Rx data considers 1-3 pharmacies under common ownership and PSAO membership as an independent pharmacy; Caremark data considers 1-4 pharmacies under common ownership as independent (without regard to PSAO membership). For our analysis, we use a definition of independent pharmacy that is as close to the FTC definition as the data allow. We use the following approach to designate independent pharmacies: (i) we start with the Caremark designation as the default as that is closest to the FTC definition; (ii) where Caremark information is not available for a particular pharmacy, we use the Optum Rx designation where available;

- Pharmacies can also be distinguished by the types of drugs they typically dispense. Some pharmacies focus on the dispensing of specialty drugs and are called *specialty pharmacies*. Specialty pharmacies typically deliver drugs by mail.[187] Although specialty pharmacies focus on the sale of specialty drugs, they are not the only pharmacies that dispense specialty drugs. Specialty drugs can also be dispensed by retail and mail-order pharmacies.[188]

- Finally, pharmacies can be distinguished by whether they are affiliated with a PBM. In this report, we define *affiliated pharmacies* to include all pharmacies owned by the PBM (or owned by the same corporate parent), including retail, mail-order, and specialty pharmacies.[189, 190]

  - Caremark is affiliated with CVS, a chain pharmacy.[191]

  - Each of the three largest PBMs has an affiliated mail-order pharmacy but there are also mail-order pharmacies that are not affiliated with a PBM.

  - Each of the three largest PBMs has an affiliated specialty pharmacy but there are also specialty pharmacies that are not affiliated with PBMs.

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and (iii) we use the Express Scripts designation where neither Caremark nor Optum Rx information are available.

187 Caremark provides an option for members to have certain specialty drugs delivered to a nearby CVS location for pickup.

188 For our analysis of specialty drugs, we generally do not focus on specialty pharmacies but rather on the dispensing of specialty drugs, no matter what type of pharmacy dispenses them. For some of our analyses, we exclude specialty pharmacies that dispense only specialty drugs as not being relevant to the issues being considered. We note such exclusions when they occur.

189 We use the term "affiliated pharmacy" to refer to any pharmacy owned by the PBM (or its parent company). If we are focusing on a particular type of affiliated pharmacy we will use that type as part of the description, *i.e.*, affiliated retail pharmacy or affiliated mail-order pharmacy.

190 Note that, in our analyses, prescriptions filled at CVS are treated as "affiliated" only if the prescriptions are managed by Caremark.

191 Optum Rx also has a small number of affiliated retail pharmacies.

124. Independent pharmacies, *i.e.*, retail pharmacies that are not part of a pharmacy chain and are not affiliated with a PBM, have long complained that by developing pharmacy networks for plan sponsors and imposing conditions for participation in those networks, PBMs have harmed efficient independent pharmacies, because PBMs' practices either favor large, chain pharmacies over independents or favor affiliated pharmacies over non-affiliated pharmacies, or both. Independent pharmacies or their advocates have claimed for years that PBM practices are causing independent pharmacies to disappear. In 2006, a representative of the Association of Community Pharmacists Congressional Network claimed that, in part due to PBM policies, "patients may soon see their neighborhood pharmacy disappear."[192] In 2011, a representative of the National Community Pharmacists Association argued that a PBM merger "threatens the very existence of community pharmacies."[193] In 2014, the President of a state pharmacy association claimed that PBM negotiating tactics threatened the survival of "'[n]early 600 Oklahoma pharmacies.'"[194]

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192 "With many independents struggling to survive, there is a high probability that patients may soon see their neighborhood pharmacy disappear." (Mike James (VP of Government Affairs for the Association of Community Pharmacists Congressional Network), "Viewpoint: Can independents survive Part D?," Drug Topics, November 20, 2006, available at https://www.drugtopics.com/view/viewpoint-can-independents-survive-part-d (accessed June 24, 2024).)

193 While objecting to the merger of Express Scripts and Medco, the National Community Pharmacists Association ("NCPA"), which lobbies on behalf of independent pharmacies, testified to Congress that: "This entity could single-handedly put pharmacies out of business, reducing competition and choice for consumers. . . . This proposed merger threatens the very existence of community pharmacies and the individualized care that we provide." (National Community Pharmacists Association, Hearing on the Proposed Merger between Express Scripts and Medco, Before the United States Judiciary Committee Subcommittee on Antitrust, Competition Policy and Consumer Rights (December 6, 2011) (Testimony of Sue Sutter, Independent Pharmacist and Member of the National Community Pharmacists Association), available at https://www.judiciary.senate.gov/imo/media/doc/11-12-6SutterTestimony.pdf, pp. 2, 5.)

194 The President of the Oklahoma Pharmacist Association warned that "'[n]early 600 Oklahoma pharmacies are at risk of shutting down'" because "'[t]he pharmacy benefit managers are not willing to negotiate fairly.'" (Drug Topics, "Okla. independents rally against PBMs," March 5, 2014, available at https://www.drugtopics.com/view/okla-independents-rally-against-pbms (accessed June 24, 2024).)

125. Claims that PBMs threaten the existence of independent pharmacies are inconsistent with the economic incentives of PBMs. Because PBMs are interested in fostering competition among suppliers, PBMs do not have an incentive to disadvantage independent pharmacies that are efficient providers of pharmacy services. PBMs compete for plan sponsors' business by meeting plan sponsors' demands and by negotiating with pharmacies to reduce plan sponsors' drug costs. As service providers to plan sponsors, PBMs do not have an incentive to reduce the viability of efficient independent pharmacies or cause a reduction in pharmacy competition. Instead, because PBMs' incentives are aligned with those of plan sponsors—both desire to reduce the cost of pharmacy benefit programs while still ensuring access to necessary treatments—PBMs encourage competition among all types of retail pharmacies, including independent pharmacies, which enables PBMs to negotiate for lower reimbursement rates paid to all pharmacies for dispensing drugs.

126. Fundamentally, independent pharmacies provide a competitive constraint on chain pharmacies, and vice versa. As elsewhere in the economy, however, competition causes demand to shift to more efficient competitors. In the context of pharmacy networks, PBMs or plan sponsors have an incentive to find the most efficient solution and forming pharmacy networks to control costs is rooted in that incentive. One would expect the lower cost or higher quality pharmacies to win preferred positions in pharmacy networks regardless of their status as independent or chain pharmacies, or affiliated or non-affiliated pharmacies. That this may come at the expense of higher cost or lower quality pharmacies is not a harm to competition but rather a natural outcome of competition. Fostering competition among suppliers ultimately benefits consumers even if it makes it more difficult for inefficient competitors to survive.

127. Independent retail pharmacies have argued that PBMs have taken advantage of them because of their small scale compared to chain retail pharmacies. Most independent pharmacies, however, are part of PSAOs that negotiate with PBMs, and, in many cases, these PSAOs represent more pharmacy locations than chain pharmacies.[195] Thus, the idea that independent pharmacies are necessarily disadvantaged in their negotiations with PBMs because of their smaller scale, compared to chain pharmacies, is incorrect.

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[195] *See* note 57 above.

128. Claims that PBMs threaten the existence of independent pharmacies are also contradicted by empirical evidence. In Section VI.A, we examine evidence on whether the survival of independent pharmacies appears to have been threatened by PBMs and conclude that the evidence do not support such a claim. First, data show that PBMs pay independent pharmacies higher reimbursement rates than non-affiliated chain pharmacies. Second, data show that the number of independent pharmacy locations has not declined relative to the number of chain pharmacy locations, *i.e.*, the share of independent pharmacy locations has not declined. Third, PBM data show that the number of prescriptions filled at independent pharmacies has grown over time and there has been only a small decline over time in independent pharmacies' share of prescriptions dispensed by all retail pharmacies. Fourth, the available data indicate that independent pharmacy profitability has not declined. Thus, the evidence consistently runs contrary to the claim that PBM's formation of pharmacy networks and contracting processes have threatened independent pharmacies' survival.

129. Independent pharmacies have also argued that, because PBMs have affiliated pharmacies, PBMs' incentives are not aligned with plan sponsors. Instead, they argue that PBMs have an incentive to favor their own affiliated pharmacies, causing harm to non-affiliated pharmacies, reducing competition among pharmacies, and thereby harming plan sponsors and their members. To be clear, because of the benefits of vertical integration, a PBM-affiliated pharmacy could have a lower quality-adjusted cost than non-affiliated pharmacies and thus could secure a spot on a PBM's pharmacy networks and be preferred by plan sponsors and members. However, the inclusion of affiliated pharmacies on a PBM's network when they are more efficient is not anti-competitive and does not harm competition. Competition from lower-cost suppliers ultimately benefits consumers even if it makes it more difficult for inefficient competitors to survive.

130. In Section VI.B, we analyze whether there is empirical evidence that affiliated pharmacies have grown substantially compared to non-affiliated pharmacies and whether non-affiliated pharmacies appear to have been harmed.[196] Specifically, we make three comparisons:

[196] We also note that although retail and mail-order pharmacies may compete with each other, that competition may be limited to a subset of drugs that patients take on a recurring basis and for which mail delivery is an option. Mail-order sales are, on average, about 13% of non-specialty prescriptions and 13% of non-specialty total payments from Caremark, Express Scripts, and Optum Rx. The data thus indicate that

(i) affiliated mail-order pharmacies versus non-affiliated retail pharmacies;[197] (ii) CVS retail pharmacies versus other retail pharmacies for Caremark; and (iii) sales of specialty drugs at affiliated pharmacies (of all formats) versus non-affiliated pharmacies (of all formats). We find that the data do not support a claim that affiliated pharmacies have grown substantially compared to non-affiliated pharmacies, nor do they suggest that non-affiliated pharmacies have been harmed: (i) prescriptions of non-specialty drugs dispensed at affiliated mail-order pharmacies have not grown at the expense of non-affiliated retail pharmacies, (ii) although Caremark prescriptions of non-specialty drugs dispensed through CVS retail pharmacies have grown at a slightly higher rate than prescriptions dispensed through non-affiliated retail pharmacies, prescriptions dispensed through non-affiliated retail pharmacies still represent the majority of prescriptions dispensed to members of plans managed by Caremark; and (iii) although prescriptions of specialty drugs dispensed through affiliated pharmacies have grown at a slightly higher rate than specialty drugs dispensed through non-affiliated pharmacies, prescriptions of specialty drugs dispensed through non-affiliated pharmacies still represent the majority of prescriptions of specialty drugs dispensed to members of plans managed by the three largest PBMs.

A. EMPIRICAL EVIDENCE IS INCONSISTENT WITH THE CLAIM THAT PBMS HAVE "SQUEEZED" INDEPENDENT RETAIL PHARMACIES OUT OF BUSINESS

131. In this section, we show that empirical evidence is inconsistent with the claim that PBMs have "squeezed" independent retail pharmacies out of business.[198] First, we show that PBMs

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prescriptions filled via mail-order are a minority of all prescriptions. As a result, it is hard to see what incentive the PBMs would have to take actions that would reduce the competitiveness of retail pharmacies. Nevertheless, we assess below whether there is evidence that PBMs have favored mail-order pharmacies over retail pharmacies for prescriptions that can be fulfilled by a mail-order pharmacy, and we find no such evidence.

197 We focus on affiliated mail-order versus non-affiliated retail pharmacies because prescriptions dispensed through non-affiliated mail-order pharmacies are small.

198 For this analysis, we focus on the claim that PBMs harm independent retail pharmacies relative to chain retail pharmacies and thus we exclude mail-order and specialty pharmacies. Correspondingly, where we examine prescription volumes, we include only non-specialty drugs. We discuss mail-order pharmacies in Section VI.B.1 and specialty drugs in Section VI.B.3.

pay independent retail pharmacies higher reimbursement rates than non-affiliated chain retail pharmacies. Second, we show that the number of independent pharmacy locations has not declined relative to the number of chain pharmacy locations. Third, data reported by independent pharmacies show that their profitability increased slightly between 2011 and 2021, and generally has remained stable. Fourth, PBM data show that the number of prescriptions filled at independent retail pharmacies has grown, with only a small decrease in the share of prescriptions dispensed at all retail pharmacies.

1. PBMs pay higher reimbursement rates to independent retail pharmacies than to chain retail pharmacies

132. To the extent that independent pharmacies are claiming they are disadvantaged because of their size relative to chain pharmacies because independent pharmacies receive lower reimbursement rates than chain pharmacies for the same drugs, we show that such a claim is not supported by the data.[199] To assess this claim, one can compare reimbursement rates by a particular PBM to independent pharmacies and chain pharmacies not affiliated with that PBM (which we term non-affiliated chain pharmacies).[200] We exclude affiliated chain pharmacies from this analysis to address any potential issues with transfer prices.[201] Examining data produced by the three largest PBMs to the FTC, we find that reimbursement rates paid to independent pharmacies are generally higher than reimbursement rates paid to non-affiliated chain pharmacies.

133. To compare reimbursement rates paid by Caremark, Express Scripts, and Optum Rx to independent and non-affiliated chain retail pharmacies, we examine data for non-specialty

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199 *See, also*, ¶ 127 above.

200 We define reimbursement as the sum of payments made to the pharmacy by the PBM, the patient, and any secondary insurers. A previous version of this paper defined reimbursement as the payment made by the PBM to the pharmacy. We updated our definition to align with the definition set out in the FTC staff's First Interim Report. *See* FTC First Interim Report (2024), note 199. We understand that FTC staff uses essentially the same methodology in the Second Interim Report.

201 Because of Caremark's affiliation with CVS retail pharmacies, we exclude Caremark prescriptions at CVS but include Express Scripts and Optum Rx prescriptions at CVS. Similarly, we exclude Optum Rx prescriptions at Optum Rx owned retail pharmacies but include Express Scripts and Caremark prescriptions at those pharmacies.

branded and non-specialty generic drugs that have at least 100 prescriptions for each PBM, within a given year, between 2017 and 2022, at both independent and non-affiliated chain retail pharmacies.[202] We then estimate a regression relating the reimbursement rate paid to the pharmacy for a drug (in logarithms) to an indicator variable for chain pharmacy, indicator variables for the type of payor (commercial/Medicare/Medicaid), indicator variables for years (2017 through 2022), indicator variables for NDCs, and indicator variables for each of the three largest PBMs.[203] The coefficient on the chain pharmacy indicator can be used to estimate the percentage difference in average reimbursement rates paid to chain and independent pharmacies, holding constant the year, payor type, PBM, and NDC.[204] As Table 10 indicates, the coefficients are negative for both branded and generic drugs and statistically significant for generic drugs. We find that, relative to independent pharmacies, reimbursement rates paid to chain pharmacies are lower on average by about 11% for generic drugs[205] and that they are not statistically different for branded drugs.

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202 We used data from Specifications 12-14 submitted to the FTC. We focus on non-specialty drugs because the vast majority of the prescriptions dispensed by retail pharmacies are non-specialty drugs. A version of this analysis that includes both specialty and non-specialty drugs produces similar results.

203 The equation for the base specification of this regression is as follows:

$$\text{Ln(Reimbursement)} = \beta_0 + \beta_1 \text{ Non-Affiliated Chain Pharmacy Dummy} + \beta_2 \text{ Year} + \beta_3 \text{ Payor Type} + \beta_4 \text{ PBM} + \beta_5 \text{ NDC} + \varepsilon,$$

where reimbursement is the payment from the PBM to the pharmacy per 30-day equivalent prescription for a given pharmacy type, year, payor type, PBM, and NDC. Observations are weighted by volume of 30-day equivalent prescriptions. Standard errors are clustered on NDC. The regression equation is estimated separately for branded drugs and generic drugs.

204 Each observation is weighted by the number of prescriptions for that drug, so that drugs with higher prescription volumes are given a larger weight in determining the regression coefficients. Unweighted regression results are provided in Appendix B and show similar results. A version of this analysis that does not use payor fixed effects leaves our conclusions unchanged.

205 This value is calculated using the exponentiated value of Column 2 in Table 10. This result implies that reimbursements on generic drugs are 13% higher for independent pharmacies than for chain pharmacies.

Table 10: Comparison of Reimbursement Rates Paid to Retail Pharmacies: Independent Pharmacies and Non-Affiliated Chain Pharmacies, Non-Specialty Branded Drugs and Non-Specialty Generic Drugs, Caremark, Express Scripts, and Optum Rx

Dependent Variable: Log Total Reimbursement (PBM + Member + Secondary Insurer) per 30-Day Equivalent Rx

	Branded	Generic
	(1)	(2)
Non-Affiliated Chain Pharmacy Dummy Coefficient	-0.005	-0.121***
Observations	66,609	646,288

Sources: Specs 12-14 of Caremark, Express Scripts, and Optum Rx 6(b) Submissions to the FTC.
Notes:
1. *** p < 0.01, ** p < 0.05, * p < 0.1; Clustered standard errors on NDC are used.
2. Includes non-specialty NDCs with at least 100 30-day prescriptions for each type of pharmacy, in each year.
3. The regression includes year fixed effects (2017-2022), payor fixed effects (Commercial, Medicare, Medicaid), PBM fixed effects and NDC fixed effects.

2. Data indicate that the independent pharmacy share of all retail pharmacy locations has not declined

134. If PBMs were harming independent retail pharmacies relative to chain retail pharmacies, or if independent retail pharmacies were in a weaker position to negotiate with PBMs compared to chain pharmacies, one might expect that the independent pharmacy share of all retail pharmacy locations would be declining. However, the evidence on pharmacy locations does not support a claim that independent retail pharmacies are being driven out of business: the independent pharmacy share of all retail pharmacy locations has not declined.

a) Third-party data show that the number of independent pharmacies has remained stable or increased and the independent pharmacy share of all retail pharmacy locations has not decreased

135. Data from a third-party source on retail pharmacy locations over time do not support a claim that the number of locations of independent pharmacies has declined in either absolute terms or relative to chains. Instead, the data show that the total number of independent pharmacy locations in the U.S. has been stable or has increased and the independent pharmacy share of locations has not declined over time.

136. Data from the National Council of Prescription Drug Programs ("NCPDP")—a not-for-profit, standards development organization with over 1,500 members in the pharmacy industry[206]—show that the number of independent pharmacy locations *increased* by 9.3% between 2011 and 2021. By contrast, the number of chain pharmacy locations *decreased* by more than 5% during this same period (see Figure 11).[207, 208] Thus, the number of independent pharmacy locations has increased in absolute terms, and independent pharmacies' share of total retail pharmacy locations has risen slightly.

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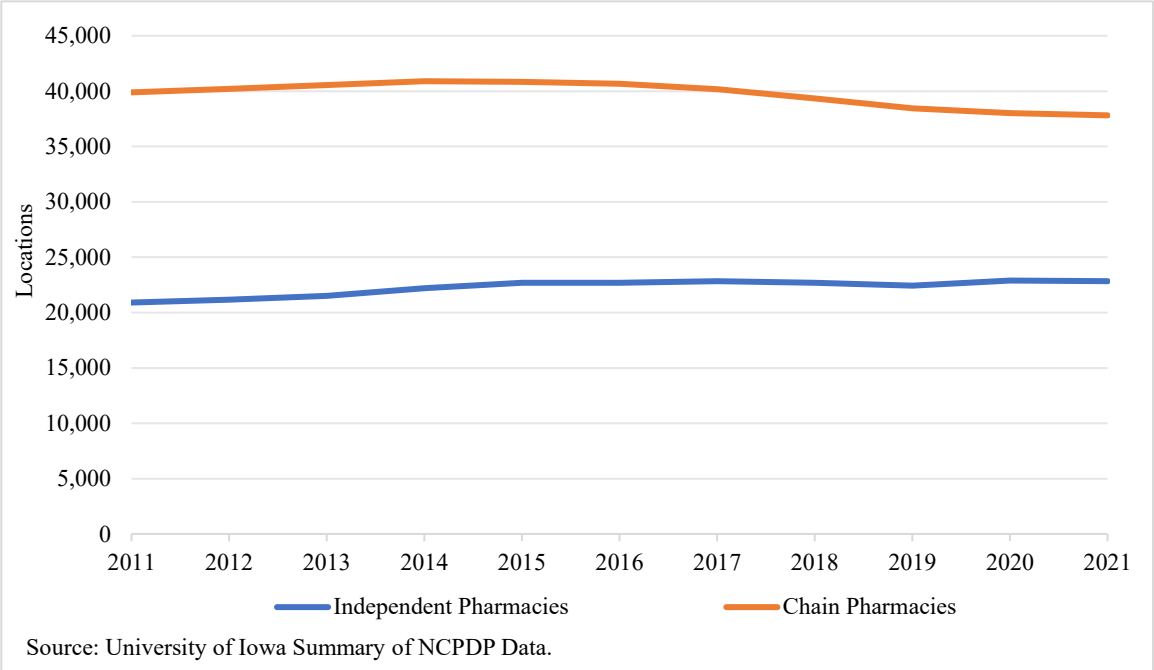
206 National Council for Prescription Drug Programs, "RE: Proposed Rule CMS-4201-P," February 13, 2023, available at https://standards.ncpdp.org/Standards/media/pdf/Correspondence/2023/20230213_To_CMS_CMS_4201_P_NPRM.pdf. NCPDP standards are regularly relied upon by government agencies and third-party payors. For example, the Health Insurance Portability & Accountability Act of 1996 ("HIPAA") required that the U.S. Department of Health & Human Services ("HHS") "establish national standards for electronic transactions to improve the efficiency and effectiveness of the nation's health care system" and, for all retail pharmacy transactions, HHS adopted standards set by the NCPDP. (Centers for Medicare and Medicaid Services, "Adopted Standards and Operating Rules," available at https://www.cms.gov/Regulations-and-Guidance/Administrative-Simplification/HIPAA-ACA/AdoptedStandardsandOperatingRules (accessed August 29, 2024).) Even the FTC's 6(b) PBM study order requests data based on these NCPDP standards.

207 Chain pharmacies include traditional chain pharmacy locations as well as pharmacy locations in supermarkets and mass merchant locations.

208 Independent pharmacies are defined as "those where 1-3 pharmacies are under common ownership." Chain pharmacies are defined as those where "four or more pharmacies [are] under common ownership." (Edmer Lazaro, Fred Ullrich, and Keith J. Mueller, "Update on Rural Independently Owned Pharmacy Closures in the United States, 2003-2021," Brief No. 2022-3, *RUPRI Center for Rural Health Policy Analysis* (2022): 1-8 at 7.)

Figure 11: Number of Retail Pharmacy Locations: Independent Pharmacies and Chain Pharmacies, NCPDP Data



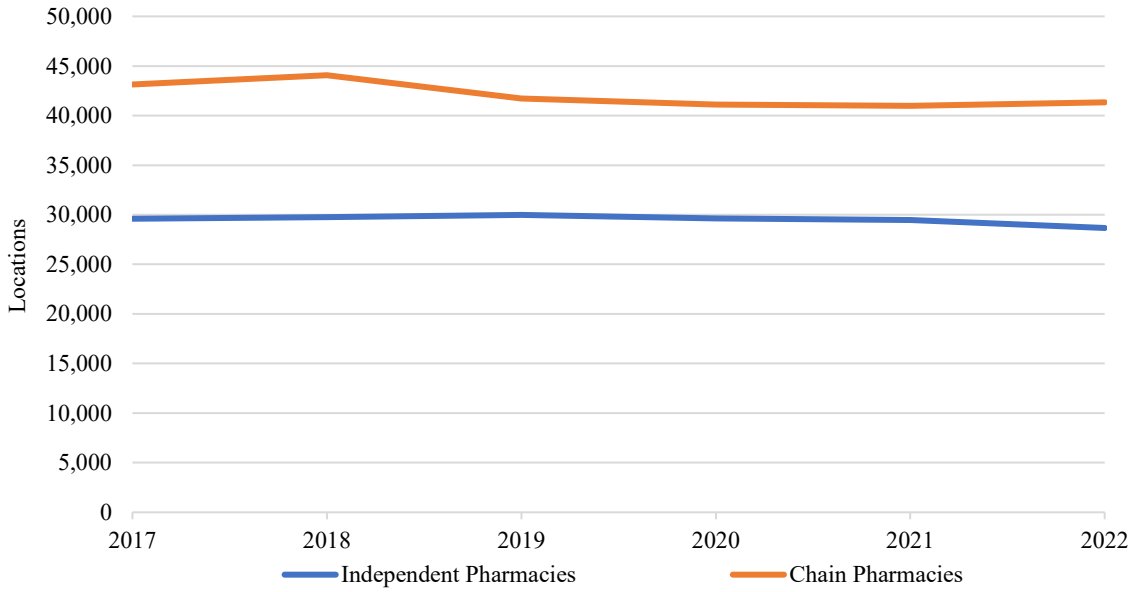
Source: University of Iowa Summary of NCPDP Data.

b) PBM data show that the number and share of pharmacy locations receiving payments from the PBMs has remained stable over time for independent pharmacies

137. We can also use the PBM data recently provided to the FTC to measure whether independent pharmacy locations have declined by examining how many independent and chain pharmacy locations receive payments from PBMs, *i.e.*, how many locations fill prescriptions within the PBMs' networks. Using data from Caremark, Express Scripts, and Optum Rx, we confirm the finding above from third-party data that independent pharmacy locations as a share of total retail pharmacy locations has not declined in recent years. Figure 12 shows the number of independent and chain pharmacy locations receiving payments from the three PBMs between

2017 and 2022.[209] The independent pharmacy share of retail pharmacy locations across the networks of Caremark, Express Scripts, and Optum Rx has remained stable at about 41%.[210]

Figure 12: Number of Retail Pharmacy Locations: Independent Pharmacies and Chain Pharmacies, in the Pharmacy Networks of Caremark, Express Scripts, and Optum Rx



Sources: Specs 12-14 of Caremark, Express Scripts, and Optum Rx 6(b) Submissions to the FTC.
Notes: Excludes specialty drugs.

3. Data indicate that the prescription volumes for non-specialty drugs at independent pharmacies have increased over time

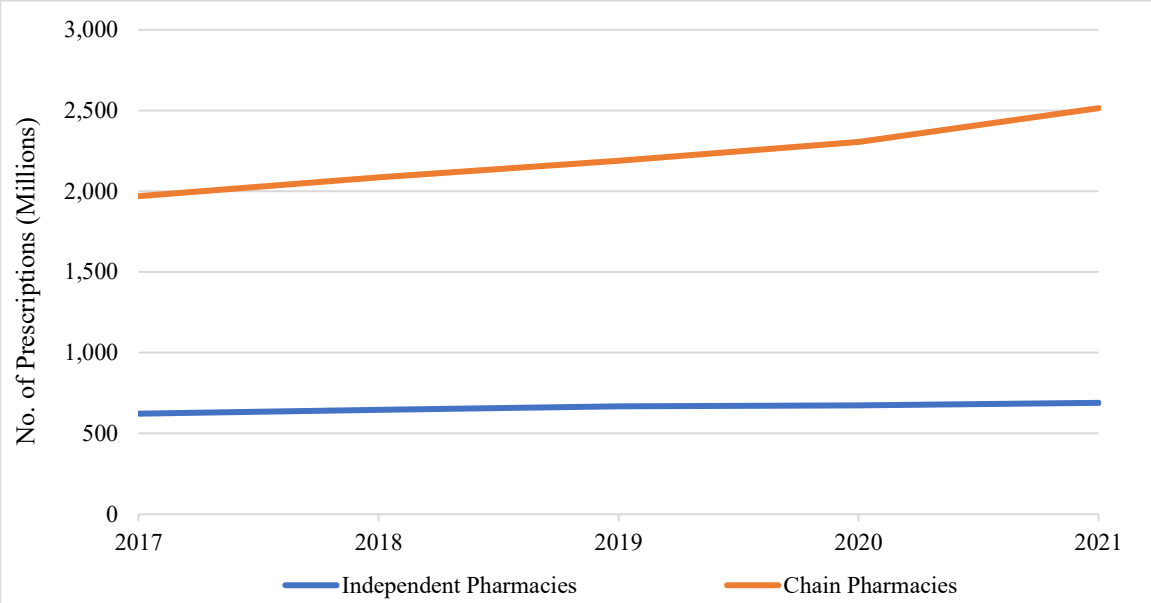
138. Although the number (or share) of locations is one informative measure as to whether independent retail pharmacies have been harmed relative to chain pharmacies, another measure is the number of prescriptions (unit sales) at independent and chain retail pharmacies. This metric addresses the possibility that prescription volumes differ across locations. As with locations data, the data on prescriptions filled do not support the claim that PBMs are driving

209 We exclude mail-order and specialty pharmacies. The number of retail pharmacy locations by type (independent or chain) are obtained from Specifications 12-14 data submitted to the FTC.

210 We include both affiliated and non-affiliated chain pharmacies in our analysis. If affiliated pharmacies are excluded from the analysis, we obtain similar results to those reported in the text.

independent pharmacies out of the retail drug distribution business. Figure 13 shows the number of 30-day prescriptions for non-specialty drugs dispensed by independent and chain pharmacies between 2017 and 2021 across the pharmacy networks of Caremark, Express Scripts, and Optum Rx.[211] The number of 30-day prescriptions increased for both independent pharmacies and chain pharmacies during the 2017 to 2021 period.[212] The independent pharmacy share of prescriptions at retail pharmacies decreased slightly from 24% in 2017 to 22% in 2021.

Figure 13: Number of 30-Day Prescriptions for Non-Specialty Drugs at Retail Pharmacies: Independent Pharmacies and Chain Pharmacies, Across the Pharmacy Networks of Caremark, Express Scripts, and Optum Rx



Sources: Specs 12-14 of Caremark, Express Scripts, and Optum Rx 6(b) Submissions to the FTC.
Notes: Not all PBM data runs through December 2022, and thus 2022 data is omitted.

211 We focus on non-specialty drugs as these represent the vast majority of prescriptions filled by retail pharmacies. Information on non-specialty prescriptions by pharmacy type (independent or chain) is obtained from Specifications 12-14 data submitted to the FTC. We analyze specialty drugs separately later in this section.

212 We include both affiliated and non-affiliated chain pharmacies in our analysis. If affiliated pharmacies are excluded from the analysis, we obtain similar results to those reported in the text.

139. Given that total prescriptions are increasing at both independent and chain pharmacies, these results do not support claims that independent pharmacies' existence is threatened by an absolute loss of prescription volumes.

4. Data indicate that independent pharmacy profitability has not declined

140. Given that the number of independent pharmacies has remained relatively stable, or increased slightly, relative to chain pharmacies, if PBMs have harmed independent pharmacy viability, independent pharmacy profits should have declined relative to chain pharmacy profits. The data, however, refutes that claim and, if anything, shows that the opposite is true.

141. One standard indicator of profitability is gross margin, which equals revenues minus costs of goods sold, divided by revenue.[213] Data from the National Community Pharmacists Association indicates that the average gross margin of its member independent pharmacies has been stable at around 23% since 2011 (see Figure 14).[214] In contrast, publicly available information indicates gross margins for two large chain pharmacies have decreased over time (see Figure 15).[215] Specifically, Walgreens' gross margin decreased from 28% in 2011 to 19% in 2023; and Rite Aid's gross margin decreased from 26% in 2011 to 20% in 2023.

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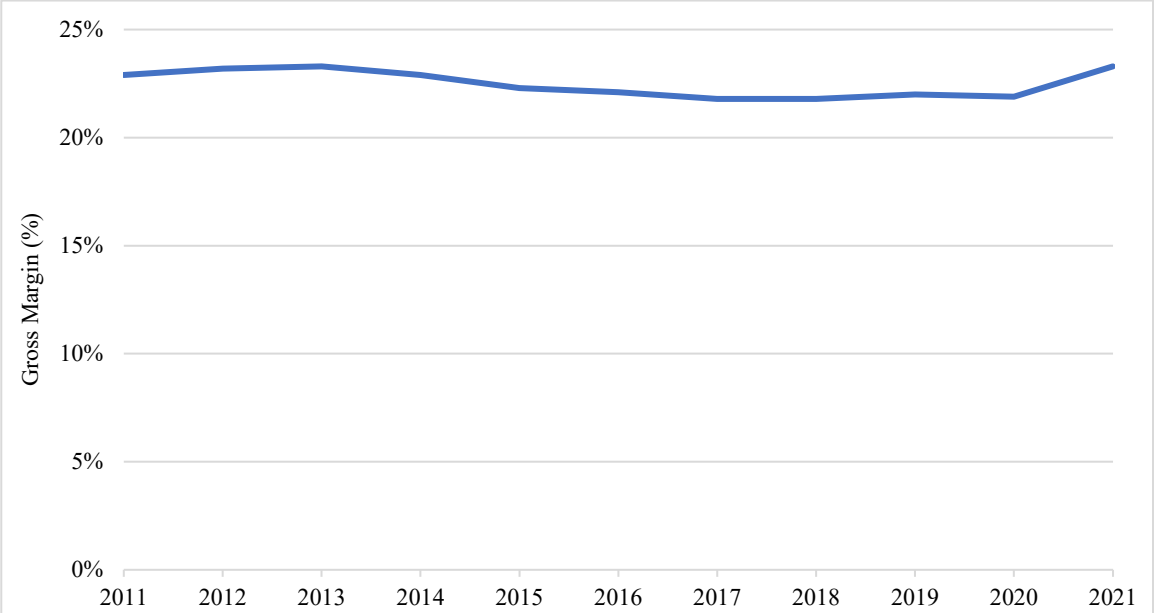
213 We analyze gross margins here not to compare margins across different firms but to examine whether those margins show any trend. (*See* note 151.)

214 Gross margins are at the store level and include pharmacy and non-pharmacy product margins.

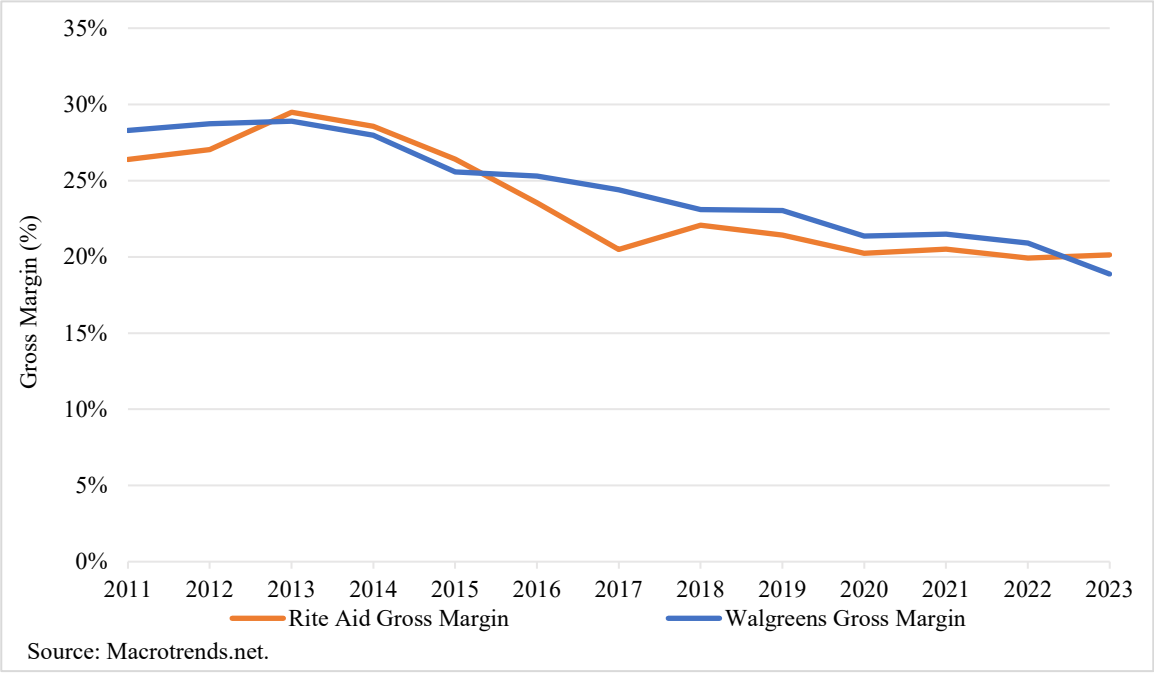
215 Information on margins at CVS retail pharmacies is not included because publicly available margins also include margins related to CVS Health—which include Aetna after 2019—and thus are not comparable to the margins of Rite Aid and Walgreens. For the years prior to 2019, the data for CVS show margins are lower than those shown for Rite Aid and Walgreens and decline over time.

Figure 14: Average Gross Margins for Independent Pharmacies, NCPA Data, 2011-2021



Sources: NCPA Digests (2016-2022). NCPA stopped publishing the data after 2021.

Figure 15: Gross Margins for Selected Chain Pharmacies, 2011 – 2023



Source: Macrotrends.net.

142. Thus, based on one commonly used indicator of profitability, the profitability of independent pharmacies has remained stable over an 11-year period, while the profitability of chain pharmacies has decreased. These patterns are inconsistent with the claim that PBM conduct has lowered the profitability of independent pharmacies relative to chain pharmacies.

B. PRESCRIPTIONS FILLED BY MEMBERS OF PLANS MANAGED BY THE THREE LARGEST PBMS AT NON-AFFILIATED PHARMACIES HAVE NOT DECLINED SUBSTANTIALLY RELATIVE TO THOSE FILLED AT AFFILIATED PHARMACIES

143. Affiliations between PBMs and pharmacies take two forms. First, the three largest PBMs are each affiliated with mail-order and specialty pharmacies that compete with retail pharmacies (both independents and chains) for certain drugs. Second, Caremark is affiliated with CVS, a retail pharmacy chain that competes with independent pharmacies and other retail pharmacy chains. Independent pharmacies have claimed that, because of these affiliations, PBMs' incentives are not aligned with those of plan sponsors. In particular, critics claim that PBMs will inefficiently direct prescriptions to be dispensed at their affiliated pharmacies, causing harm to non-affiliated pharmacies, which reduces competition among pharmacies and harms plan sponsors and plan members.

144. Any practice that may shift prescriptions to affiliated pharmacies may, of course, reflect efficiencies from vertical integration or the fact that PBM mail-order operations have lower costs of operation than retail pharmacies. If plan sponsors decide to adopt plan designs that prefer lower cost or higher quality pharmacies, affiliated pharmacies' lower costs or higher quality may cause them to gain share compared to higher-cost or lower-quality non-affiliated retail pharmacies, but this outcome does not harm competition, plan sponsors, or plan members. To the contrary, this would be a pro-competitive outcome.

145. We examine the number of prescriptions filled at non-affiliated pharmacies and affiliated pharmacies to look for evidence that non-affiliated pharmacies are becoming less prominent in drug distribution.[216] We do not find evidence to support the claim that non-affiliated pharmacies are being excluded from the distribution of drugs. Instead, for non-specialty drugs we find: the

[216] Because the reimbursement rate to affiliated pharmacies is a transfer price within a vertically integrated company and therefore may potentially raise transfer pricing issues, we do not examine reimbursement rates.

number of prescriptions through non-affiliated retail pharmacies has grown, and the share of prescriptions at non-affiliated retail pharmacies has been stable. For non-specialty drug prescriptions processed by Caremark we find: the number of prescriptions through non-affiliated retail pharmacies has grown, and, although the share of prescriptions through non-affiliated retail pharmacies relative to CVS pharmacies has declined slightly over time, non-affiliated pharmacies still account for the majority of prescriptions processed by Caremark. For specialty drugs, we find: the number of prescriptions through non-affiliated pharmacies has grown over time, and non-affiliated pharmacies' share of prescriptions of specialty drugs has only slightly declined, with the majority of sales being through non-affiliated pharmacies. These results are not consistent with non-affiliated pharmacies having their existence as dispensers of non-specialty drugs or specialty drugs threatened by PBMs.

1. Data indicate that prescriptions dispensed through non-affiliated retail pharmacies have not declined relative to PBM-affiliated mail-order pharmacies

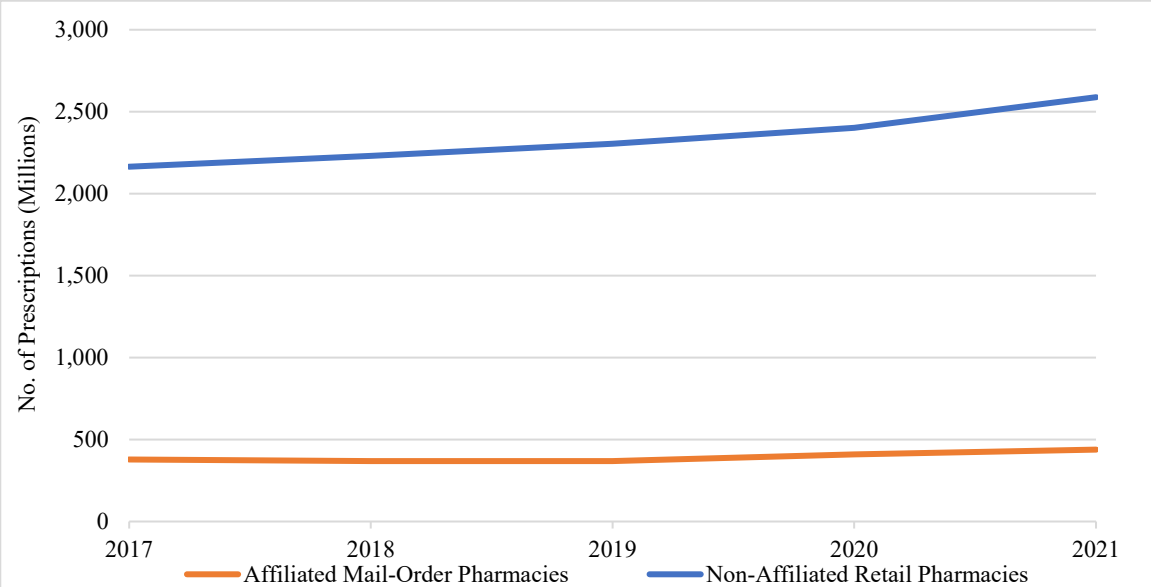
146. We first assess whether there is evidence that PBMs' mail-order pharmacies are growing at the expense of non-affiliated retail pharmacies. We find that PBM-affiliated mail-order pharmacies' share of prescription volume is small and has been stable over time, indicating that non-affiliated retail pharmacies, in aggregate, are not losing share to PBM-affiliated mail-order pharmacies.

147. Figure 16 shows the number of 30-day prescriptions of non-specialty drugs dispensed by non-affiliated retail pharmacies and by PBM-affiliated mail-order pharmacies, across the pharmacy networks of Caremark, Express Scripts, and Optum Rx between 2017 and 2021.[217] The Figure shows that the number of prescriptions dispensed through both non-affiliated retail pharmacies and PBM-affiliated mail-order pharmacies has increased. Moreover, the non-affiliated retail pharmacy share of prescriptions is substantial, around 85%, and has remained steady over time. Thus, the data provided by the three largest PBMs do not support the claim

[217] We exclude specialty drugs in this analysis because most prescriptions at retail pharmacies are for non-specialty drugs. If we include specialty drugs in the analysis, the results are similar. We discuss specialty drugs in Section VI.B.3.

that non-affiliated retail pharmacies have been declining relative to PBM-affiliated mail-order pharmacies in the distribution of non-specialty drugs.

Figure 16: Number of 30-Day Prescriptions for Non-Specialty Drugs: Non-Affiliated Retail Pharmacies and Affiliated Mail-Order Pharmacies, Across the Pharmacy Networks of Caremark, Express Scripts, and Optum Rx



Sources: Specs 12-14 of Caremark, Express Scripts, and Optum Rx 6(b) Submissions to the FTC.
Notes: Not all PBM data runs through December 2022, and thus 2022 data is omitted.

2. Caremark data show that prescriptions dispensed at non-CVS retail pharmacies have increased over time and constitute the majority of all retail prescriptions for plan members covered by Caremark's pharmacy networks

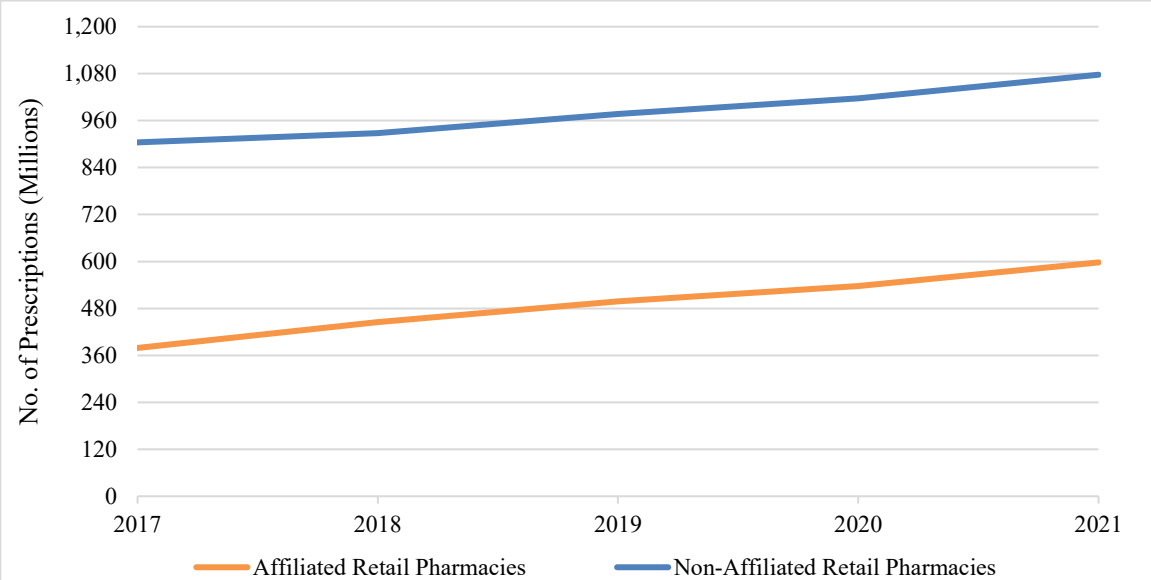
148. Using data on prescriptions dispensed for members of plans managed by Caremark, we analyze whether there is evidence that Caremark-affiliated CVS retail pharmacy is growing at the expense of non-affiliated retail pharmacies.[218] Figure 17 shows the number of 30-day prescriptions of non-specialty drugs processed by Caremark dispensed by non-affiliated pharmacies and by CVS between 2017 and 2021.[219] Although the non-affiliated pharmacy share

[218] In Section VI.A above, we assessed whether PBMs favored chain pharmacies over independent pharmacies. In this section, we evaluate whether Caremark, which has CVS as its affiliated retail pharmacy, favors CVS over other retail pharmacies.

[219] We exclude 2022 data because data are only complete through June 2022. As with the mail-order versus non-affiliated pharmacy comparison, we exclude specialty drugs in this

has declined by about 6 percentage points (from 70% in 2017 to 64% in 2021), Figure 17 shows that the number of prescriptions at non-affiliated retail pharmacies has increased substantially and that non-affiliated pharmacies still account for nearly two-thirds of prescriptions filled in Caremark's retail pharmacy networks. Thus, non-affiliated pharmacies still represent an important dispensing outlet for Caremark. These facts are not consistent with the claim that Caremark is trying to eliminate non-affiliated retail pharmacies.

Figure 17: Number of 30-Day Prescriptions for Non-Specialty Drugs at Retail Pharmacies: Non-Affiliated Retail Pharmacies and CVS, in Caremark's Network



Sources: Specs 12-14 of Caremark 6(b) Submission to the FTC.
Notes: Excludes affiliated infusion and affiliated long-term care pharmacies.

analysis because non-specialty drugs constitute the vast majority of prescriptions dispensed by retail pharmacies. Including specialty drugs in the analysis does not change the conclusions.

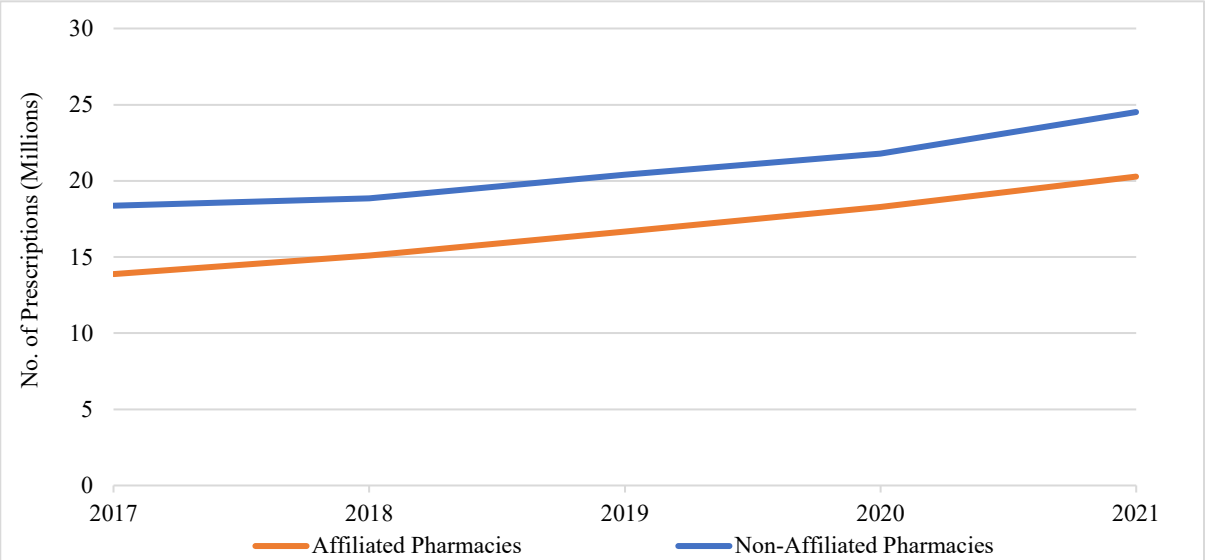
3. Non-affiliated pharmacies' role in dispensing specialty drugs is not vanishing and non-affiliated pharmacies continue to fill more than half of specialty drug prescriptions

149. Critics have claimed that PBMs have shifted dispensing of specialty drugs to affiliated pharmacies at the expense of non-affiliated pharmacies.[220] As discussed above, specialty drugs can be dispensed at specialty pharmacies or at retail or mail-order pharmacies. Thus, for this analysis, we analyze the trends in dispensing of specialty drugs by affiliated pharmacies and non-affiliated pharmacies, no matter the format of the pharmacy. The issue we address here is whether there has been a substantial decline over time in non-affiliated pharmacies' dispensing of specialty drugs relative to affiliated pharmacies' dispensing of specialty drugs.

150. Figure 18 shows the number of 30-day specialty prescriptions dispensed by non-affiliated and affiliated pharmacies, between 2017 and 2021, across the pharmacy networks of Caremark, Express Scripts, and Optum Rx. The number of prescriptions increased substantially over time for both the non-affiliated and affiliated pharmacies. The non-affiliated pharmacy share of specialty drug prescriptions is more than 50%, and has declined only slightly from 57% in 2017 to 55% in 2021. Thus, for the three PBMs, the number of prescriptions of specialty drugs at non-affiliated pharmacies increased substantially over time and non-affiliated pharmacies continue to provide more than half of all specialty drug prescriptions, even if the non-affiliated pharmacy share of specialty drug prescriptions decreased slightly over time. This result is inconsistent with the claim that PBMs have harmed non-affiliated pharmacies leading to a vanishing share of specialty drugs dispensed.

[220] As discussed above, there is no one definition of what constitutes a specialty drug. For this analysis, we designate a drug as specialty for an individual PBM based on that PBM's own designation.

Figure 18: Number of 30-Day Prescriptions for Specialty Drugs: Non-Affiliated Pharmacies and Affiliated Pharmacies, Across the Pharmacy Networks of Caremark, Express Scripts, and Optum Rx



Sources: Specs 12-14 of Caremark, Express Scripts, and Optum Rx 6(b) Submissions to the FTC.
Notes: Not all PBM data runs through December 2022, and thus 2022 data is omitted.

VII. THE FTC STAFF'S INTERIM PBM REPORTS ARE BASED ON A SMALL, NON-REPRESENTATIVE SAMPLE OF DRUGS AND REACH CONCLUSIONS THAT DO NOT HOLD WHEN ANALYZING ALL DRUGS

151. In its Second Interim Report issued on January 14, 2025, the FTC staff presents analyses of a subset of specialty generic drugs and concludes:[221]

> [L]egislative reforms may be warranted. FTC staff is encouraged to see bipartisan interest in Congress and among the states in addressing PBM practices, and we stand ready to provide assistance to policymakers as needed.

Neither the analyses of two specialty generic drugs in the FTC staff's First Interim Report, nor the analyses of additional specialty generic drugs in the Second Interim Report provide a reasonable basis for policymakers to understand how PBM practices affect overall drug costs and whether PBM practices create problems that policymakers could or should attempt to solve. Specifically, the FTC staff's most recent analysis ignores more than 98% of drug expenditures and fails to show that the 2% of expenditures on which it focuses are representative of drug expenditures overall.

152. The First Interim Report discusses two specialty generic drugs for which the FTC staff estimate that (i) reimbursement rates to pharmacies (both affiliated and non-affiliated) far exceed estimated acquisition costs as measured by NADAC; and (ii) reimbursement rates to PBM-affiliated pharmacies are higher than reimbursement rates to non-affiliated pharmacies.[222, 223] The implication is that the PBMs are increasing the costs of these drugs and steering prescriptions to their affiliated pharmacies to enrich themselves through higher revenue and profit at their affiliated pharmacies. The First Interim Report speculates without any empirical support that these two drugs might be emblematic of the PBMs' treatment of other drugs as well,

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221 U.S. Federal Trade Commission, "Specialty Generic Drugs: A Growing Profit Center for Vertically Integrated Pharmacy Benefit Managers -- Second Interim Staff Report," January 2025, available at https://www.ftc.gov/system/files/ftc_gov/pdf/PBM-6b-Second-Interim-Staff-Report.pdf (hereinafter, "FTC Second Interim Report (2025)"), p. 30.

222 NADAC is a third-party data source that gathers information on drug acquisition costs from pharmacies, primarily independent pharmacies. FTC Second Interim Report (2025), p. 7.

223 FTC First Interim Report (2024), Figure 11.

suggesting a widespread, systematic problem whereby the PBMs are earning unjustified profits on all drugs and plan sponsors and patients are paying too much.

153. The Second Interim Report examines the "markup" on a broader subset of specialty generic drugs (51 drugs instead of two), where the markup is defined as the ratio of the reimbursement rate paid to the pharmacy and the estimated acquisition cost as measured by NADAC.[224] The FTC staff estimates that, for many of the 51 specialty generic drugs selected, the PBMs' reimbursement rates to pharmacies (both affiliated and non-affiliated) are far above (*e.g.*, more than 100% above) the NADAC acquisition cost of the drugs and the markup over the NADAC acquisition cost is higher for PBM-affiliated pharmacies than for non-affiliated pharmacies.[225] The FTC staff also claims that the PBMs may be steering sales of specialty drugs with high markups to their own affiliated pharmacies and estimates that a small number of specialty generic drugs account for a large and growing share of PBM-affiliated pharmacy revenue and profit (as measured by the FTC staff's calculation of PBM-affiliated pharmacy operating income). In this section, we examine the FTC staff's analyses and conclusions.

- In Section VII.A, we consider whether the FTC staff's analysis of an expanded list of drugs in the Second Interim Report provides a reasonable basis for conclusions about PBM pricing in general and its impact on overall drug costs. We find that the FTC staff's analysis still focuses on a tiny subset of all drugs (less than 2% of total expenditures), fails to provide any analysis of drugs that account for the vast majority (98%) of total expenditures for drugs dispensed through agreements with PBMs, and fails to demonstrate that the specialty generic drugs analyzed are representative of all drugs or even any other category of drugs. Thus, we find that the FTC staff's analyses do not support any conclusions about the impact of PBM pricing on overall drug costs paid by plan sponsors and members.
- In Section VII.B, we demonstrate that the FTC staff's findings regarding only 51 specialty generic drugs are not generalizable. We discuss how the FTC staff's "markups" are not useful for understanding the profitability of PBM-affiliated pharmacies because

224 The reimbursement rate and NADAC acquisition cost are both measured per 30-day equivalent prescription.

225 FTC Second Interim Report (2025), Figure 1.

specialty generics are such a small, non-representative slice of total drug expenditure and the FTC staff's markup calculation ignores operating costs (see Section VII.B.1).[226] Then we show that the overall margins earned by the PBMs and by the specialty pharmacies affiliated with the PBMs are much lower than would be suggested by the FTC staff's markup calculations on specialty generic drugs, indicating that those specialty generic markups are not representative of markups across all drugs (see Section VII.B.2). Finally, we use the FTC staff's markup methodology to demonstrate that markups for the 51 specialty generics do not accurately represent markups overall: using the FTC staff's methodology where NADAC is a proxy for acquisition costs and operating costs are ignored, we find that the FTC staff's analysis focused on a subset of drugs that have markups at affiliated pharmacies that are extreme outliers; a comprehensive analysis by FTC staff would have shown markups on all drugs sold at affiliated pharmacies are *negative* in aggregate. Thus, even if, as the FTC staff reports, reimbursements for the examined specialty generics at affiliated pharmacies are $7.3 billion above NADAC, reimbursements for all drugs at affiliated pharmacies (including those examined by the FTC) are $15.9 billion *below* NADAC (see Section VII.B.3). All of our analyses in this section show that one cannot reliably conclude anything about overall drug costs or overall profitability of PBMs or PBM-affiliated pharmacies from an analysis of only a subset of specialty generic drugs.

- In Section VII.C, we examine the FTC staff's finding that the reimbursement markup for specialty generics is higher for affiliated pharmacies than non-affiliated pharmacies. Again, the FTC staff's findings are not generalizable beyond the subset of drugs examined: we find that the reimbursement markup is lower for affiliated pharmacies than non-affiliated pharmacies when calculated over all drugs sold at affiliated and non-affiliated pharmacies. Using our available data and our methodology, we reach the general conclusion that plan sponsors and members would pay about the same amount whether they purchased the overall basket of drugs at affiliated pharmacies or at non-

[226] The FTC staff's markup calculations may also be flawed in cases where NADAC does not reflect true acquisition costs, which may be higher or lower.

affiliated pharmacies.[227, 228] That is, any suggestion that overall drug expenditures would be substantially lower—and the FTC staff indicate that the lowering is on the order of 1000%—if all drugs were purchased at non-affiliated pharmacies instead of at affiliated pharmacies is simply wrong.

- Finally, in Section VII.D, we examine the FTC staff's claims that the PBMs are steering sales of drugs to their affiliated pharmacies, with the implication that non-affiliated pharmacies' survival is threatened. Data on overall drug sales do not support such an implication. Sales of overall drugs and specialty drugs at non-affiliated pharmacies have increased substantially over time and non-affiliated pharmacies still account for the majority of overall drug sales.

A. THE 51 SPECIALTY GENERICS ANALYZED BY THE FTC STAFF ACCOUNT FOR ONLY A SMALL PERCENTAGE OF OVERALL SPENDING ON PRESCRIPTION DRUGS

154. In conducting its study of the PBM industry, the FTC staff's stated concern is about high drug prices and whether PBMs are responsible for high drug prices. However, when studying reimbursements made by PBMs to pharmacies (the measure of "price" on which the FTC staff focuses), the FTC staff studies only a small number of specialty generic drugs out of the thousands of drugs purchased by plan sponsors and members.[229]

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227 We understand that the data we have are more likely to exclude out-of-network prescriptions for non-affiliated pharmacies compared to affiliated pharmacies. Since out-of-network pharmacies are likely to have higher prices than in-network pharmacies, this will likely bias upward our calculations of prices at affiliated pharmacies compared to non-affiliated pharmacies.

228 The FTC staff report suggests that PBMs are responsible for high drug prices, and so we focus on overall prices for all payors (commercial, Medicare, and Medicaid), while the FTC staff reports results for commercial and Medicare payors separately. Where relevant, we indicate in subsequent footnotes whether the results we report for all plan sponsors combined lead to the same general conclusions if we examine commercial and Medicare plan sponsors separately.

229 As acknowledged by the FTC staff, the analysis still does not consider all 171 specialty generic drugs for which at least one of the three PBMs reported a prescription but rather a subset of those 171 drugs; drugs were excluded from the FTC staff's analysis primarily because the FTC staff's measure of acquisition cost, NADAC, is not available for those drugs. FTC Second Interim Report (2025), p. 8. The FTC staff reports that the 51 drugs

155. Specialty generics comprise just one category of drugs purchased by plan sponsors and members. Drugs purchased also include specialty branded drugs, non-specialty generic drugs, and non-specialty branded drugs. For a study of a subset of specialty generic drugs to be informative as to whether PBMs are contributing generally to high drug prices or earning excessive profits, these specialty generics would have to represent a significant fraction of spending or be representative of other drugs purchased. The FTC staff's report does not indicate the relative importance of this subset of specialty generics to overall drug spending nor whether its findings for these drugs are representative of other drugs.

156. In fact, the 51 specialty generic drugs represent only a small percentage—less than 2%—of drug sales, whether measured by payments, reimbursements, or prescription volume. Table 11 shows the relative size of different categories of drugs in terms of payments made by plan sponsors and members (which reflect overall spending on prescription drugs), reimbursements to pharmacies (which is the metric on which the FTC staff focuses), and the number of 30-day equivalent prescriptions.[230] We provide this information for all types of plan sponsors combined.

157. Table 11 also shows, across all pharmacies (both affiliated and non-affiliated), the share of each metric accounted for by the specialty generic drugs studied by the FTC staff in the Second Interim Report. The 51 specialty generic drugs analyzed by the FTC staff ("FTC

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used in its study represent 91% of prescriptions dispensed for specialty generics and 67% of reimbursements of specialty generics during the time period studied. *Id*, p. 9.

230 The FTC staff's analysis focuses on reimbursements to pharmacies rather than on what plan sponsors and members pay for prescriptions. The combined amount paid by plan sponsors and members ("total payments") is the relevant metric for measuring drug expenditures as it reflects the overall cost of prescriptions for plan sponsors and their members;reimbursements to pharmacies do not necessarily capture all expenditures by plan sponsors and their members. Moreover, reimbursement rates to PBM-affiliated pharmacies involve transfer prices that are not based on market transactions between independent parties and that can potentially raise issues of interpretation; payments by plan sponsors and members, in contrast, are based on market transactions between independent parties and reflect actual expenditures. We note that total payments by plan sponsors and members are gross payments before rebates, as we are not able to allocate formulary rebates by affiliated versus non-affiliated pharmacies for all PBMs. However, when we do a version of the analysis for the PBM for which we can allocate rebates, the results are similar to Table 11, with the specialty generic drugs analyzed by the FTC staff representing a small fraction of spending by plan sponsors and payors.

Specialty Generic Drugs") represent a small fraction of spending or volume for the three PBMs across all payors: 1.8% of payments by plan sponsors and members, 1.7% of reimbursements, and 0.3% of prescription volume.[231]

[231] To identify the NDCs associated with the 51 FTC specialty generic drugs in the PBM data, we matched the drug names provided in the FTC staff's Second Interim Report to drug names in the PBMs' Specs 12-14 data. We note that brand, generic, specialty and non-specialty designations may differ between the PBMs based on how they or their clients identify drugs in the ordinary course of business. In this report, we have identified drug designations based on information provided by each PBM. In a few cases, an NDC associated with the FTC's 51 drugs may not be designated as a specialty generic in a particular PBM's data. In such a case, to focus on specialty generic drugs as defined by each PBM and to be consistent with how we have assigned drug types elsewhere, we have not included that NDC as one of the FTC's 51 specialty generic drugs for that PBM. If we include these NDCs (*i.e.*, if we include all NDCs associated with the drug names identified in the FTC staff's Second Interim Report across PBMs no matter how each PBM categorizes the NDC) it would not meaningfully impact the results.

Table 11: Payments and Volume of Prescriptions by Drug Type at All Pharmacies (2017-2022)[232]

Drug Type	Share
Gross Plan Sponsor + Member Payment	
FTC Specialty Generic Drugs	1.8%
Other Specialty Generic	0.4%
Specialty Branded	47.5%
Non-Specialty Generic	11.4%
Non-Specialty Branded	39.0%
Reimbursement	
FTC Specialty Generic Drugs	1.7%
Other Specialty Generic	0.4%
Specialty Branded	47.7%
Non-Specialty Generic	10.8%
Non-Specialty Branded	39.5%
No. of 30-Day Prescriptions	
FTC Specialty Generic Drugs	0.3%
Other Specialty Generic	0.0%
Specialty Branded	0.9%
Non-Specialty Generic	88.5%
Non-Specialty Branded	10.4%

Sources: Specs 12-14 of Caremark, Express Scripts, and Optum Rx 6(b) Submissions to the FTC.

[232] Values might not add to 100% due to rounding. Other specialty generic drugs constitute 0.01% of 30-day prescriptions.

158. Even if one focuses on specialty drugs[233]—which are typically sold at specialty pharmacies—Table 11 also shows that the category of specialty generic drugs accounts for less than 5% of all specialty drug payments.[234]

159. Thus, the FTC staff's analysis in its Second Interim Report—although broader than the analysis in its First Interim Report where it only analyzed two drugs—excludes drugs that account for over 98% of drug payments by plan sponsors and members, over 98% of reimbursements to pharmacies, and over 99.5% of 30-day equivalent prescriptions. The FTC staff's report does not even attempt to show that its findings regarding markups for its small subset of drugs apply to all drugs or even to all specialty drugs. Nor does the report explain why an analysis of such a limited subset of drugs would potentially be representative or informative

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233 We remind the reader of some subtleties in terminology. There is no precise definition of "specialty" drug. Drugs referred to as specialty drugs are typically expensive compared to other drugs, may require special professional care or detailed instructions and assistance from professionals to administer, may have limited distribution as designated by the pharmaceutical manufacturer, may require additional patient services such as monitoring of side effects and dynamic adjustments of dosing, and often treat chronic conditions that require additional patient services. These drugs may be sold at retail pharmacies, at pharmacies called specialty pharmacies (which typically focus on dispensing specialty drugs and offering extra services related to the administration of those drugs), or at mail-order pharmacies. We follow the usage of this term by the FTC staff or, if that is not possible, use the classification that the PBMs use to classify a drug as specialty or non-specialty. The classification can differ among PBMs. Specialty drugs can be branded or generic, and non-specialty drugs can be branded or generic.

A sale at a "PBM-affiliated pharmacy," as used by both the FTC staff and us, means the claim for the drug is processed by a particular PBM and dispensed by a pharmacy owned by that same PBM or a related entity. For example, a Caremark member's prescription filled at a Caremark mail-order pharmacy or at a CVS retail pharmacy is a sale at a PBM-affiliated pharmacy, but an Express Scripts member's prescription filled at a Caremark mail-order pharmacy or at CVS is not.

For more information on limited distribution drugs, *see* Ashley Wong, "Limited Distribution Drugs: A Guide to Networks and Specialty Pharmacies," GoodRx, September 12, 2023, available at https://www.goodrx.com/drugs/medication-basics/limited-distribution-drugs (accessed April 19, 2025).

234 Specialty generics in total account for 2.1% of payments and specialty branded account for 47.5% of payments, so specialty generics are less than 5% of all specialty drugs. (2.1% ÷ (2.1% + 47.5%) = 4.3%.)

as to the broader market basket of drugs purchased. As we describe in the next section, the evidence demonstrates it is not.

B. ANALYSIS OF MARGINS AND MARKUPS SHOW THAT THE FTC STAFF'S ESTIMATED MARKUPS FOR ITS SMALL SUBSET OF DRUGS AT AFFILIATED PHARMACIES ARE NOT REPRESENTATIVE

160. Plan sponsors provide members with access to a wide variety of drugs—including branded and generic drugs, and specialty and non-specialty drugs—and, in an attempt to minimize overall drug plan costs, plan sponsors typically issue RFPs and take bids from PBMs for facilitating coverage of a basket of drugs. Because of this, an analysis such as the FTC staff's that focuses on a small subset of drugs—certain specialty generics—could be misleading if the implication is that PBMs have elevated the cost of all drugs to plan sponsors and members and thereby are earning very high margins or markups. In this section, we show that the FTC staff's analysis does not apply more broadly and that the FTC staff's analysis is therefore not indicative of a systematic problem with PBM drug pricing.

1. The FTC staff's estimated markups are flawed because they focus on too narrow a set of drugs and ignore operating costs

161. Observing that markups are "high" for individual drugs is not informative as to whether a pharmacy is earning excess profits. The FTC staff does not calculate markups or margins on categories of drugs other than certain specialty generics, but there is no logical requirement that a multiproduct firm must charge similar markups or earn similar margins across each of its many products. It is more appropriate to consider the overall PBM margin if one is concerned with overall drug expenditures.[235] Given the small percentage of overall drug spending accounted for by specialty generics, it is especially important to examine whether patterns found for certain

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235 If one looks at specialty pharmacy margins, the margin should be considered overall for the specialty pharmacy rather than for a subset of drugs. It is not clear, however, that assessing margins earned by the specialty pharmacies affiliated with PBMs is probative of whether PBMs are contributing to high drug prices overall. First, operating specialty pharmacies is only one way in which PBMs may earn revenues and incur costs. Second, the margins earned by affiliated specialty pharmacies are determined, in part, by reimbursements received from their affiliated PBM. Such payments involve transfer prices, as discussed previously. (*See* note 150.)

specialty generics also hold for other categories of drugs before coming to conclusions about the need for policy intervention.

162. In addition, the percentage markups calculated by the FTC staff (or related gross margins) do not take into account the costs associated with dispensing drugs and providing patient services.[236] Operating margins take into account these costs and thus provide a better measure of profitability than the FTC staff's markups.[237] Failure to account for operating costs can cause the FTC staff's "markups" to be misleading because they do not accurately reflect the profitability of dispensing individual drugs. For example, higher "markups" (or associated gross margins) may exist for some products when acquisition costs are low to reflect the need to cover operating costs, though that need not imply higher per unit profit. To see how ignoring operating costs can bias calculations of relative markups or margins, consider a specialty drug that requires the pharmacy to provide additional services to assist the patient with management of the drug (and for simplicity that these represent all costs associated with operating the pharmacy in addition to acquisition costs).[238] Suppose that the reimbursement rate is such that the pharmacy

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236 The FTC staff estimates the percentage markup on a drug as the average reimbursement rate per 30-day prescription divided by the average NADAC cost per 30-day prescription, minus 1, times 100%. Because FTC staff is using NADAC as a proxy for actual acquisition costs, these markups may not reflect markups based on actual acquisition costs.

When comparing the total dollar value of markups on the 51 specialty generic drugs it analyzed to overall PBM operating income, the FTC staff tried to adjust for operating costs but did not use actual PBM operating costs; instead it used an estimate based on the standard markup employed by the Mark Cuban Cost Plus Drug Company. *See* FTC Second Interim Report (2025), p. 24 and note 98. The FTC staff does not explain why the Mark Cuban Cost Plus Drug Company, which is not itself a pharmacy, provides a good benchmark for the services incurred by pharmacies affiliated with the PBMs. (Cost Plus Drug Company, "FAQs: Who fills my prescription?" available at https://www.costplusdrugs.com/ (accessed April 1, 2025). "We work with HealthDyne, our trusted fulfillment partner to fill your prescriptions. HealthDyne's accredited pharmacists will ensure your medication is safe and delivered to your doorstep on time.")

237 As noted previously, comparing accounting measures of profitability across firms often raises concerns as different firms may record revenues and costs differently. *See* note 151.

238 For this simplified example, we assume that operating costs can be described as only acquisition costs and dispensing costs. More generally, there may be operating costs that cannot be ascribed to the dispensing of an individual drug.

earns $10 in profit after all its costs. Further suppose that the specialty branded drug's acquisition cost is $100, the generic drug's acquisition cost is $10, and the pharmacist's time required to provide services to the patient costs $10. The reimbursement rate to the pharmacy that covers the pharmacy's acquisition cost, pharmacist's cost, and pharmacy profit is $120 for the branded drug but only $30 for the generic. Notice two things. First, it is cheaper for the plan sponsor and patient to purchase the specialty generic drug than to purchase the specialty branded drug. Second, the markup, as calculated by the FTC staff, is 200% (((30/10)-1)*100%) for the specialty generic but only 20% for the specialty branded drug (((120/100)-1)*100%). Despite the percentage markup being much higher on the specialty generic drug in this hypothetical example, the plan sponsor and patient save money by buying the specialty generic rather than the specialty branded drug. The pharmacy's profit is the same for both drugs. Furthermore, if one calculated the margin over NADAC, but also accounting for dispensing costs, that margin would be only 50%, rather than 200%, for the generic drug.

163. In general, ignoring operating costs, as the FTC staff does in its percentage markup calculations, can be expected to lead to higher markups on some low-priced items compared to some high-priced items. This phenomenon is not unusual. For example, according to its website, the Mark Cuban Cost Plus Drug Company sells 30 10mg capsules of fluoxetine (the generic for Prozac) for $10.37; with a manufacturing cost (reported on the website) of $0.32, the markup on generic fluoxetine is more than 3000%.[239] In contrast, the Mark Cuban Cost Plus Drug Company sells 30 100mg tablets of the branded drug Invokana (canagliflozin) for $540.02; with a manufacturing cost of $460.89, the markup on branded Invokana is 17%.[240] As another example, grocery stores often sell both branded items and cheaper, store brand items. The gross

[239] Cost Plus Drug Company, "Fluoxetine (Generic for Prozac)," available at https://www.costplusdrugs.com/medications/fluoxetine-10mg-capsule/ (accessed April 1, 2025).

[240] Cost Plus Drug Company, "Invokana (Canagliflozin)," available at https://www.costplusdrugs.com/medications/invokana-100mg-tablet-30/ (accessed April 1, 2025).

margin (ignoring operating costs) is often much higher on the store brands than on the corresponding branded items.[241]

2. PBM financials show that gross and operating margins for the PBMs overall and for PBM-affiliated specialty pharmacies are under 10%, which is inconsistent with the FTC staff's suggestion that the large markups (greater than 100%) on many of the subset of specialty generics they examined are typical of all drugs

164. If PBM-affiliated pharmacies were systematically receiving very high markups for all drugs, then one would expect that the overall PBM margin would be high.[242] In Section V, however, we provided an analysis of overall margins for the three PBMs. Those margins include not only revenues and costs associated with affiliated mail-order and specialty pharmacies but also revenues and costs for providing other PBM services, including revenues from the retail spread earned by PBMs and any rebate retention.[243] We showed that average margins are relatively low and not growing: the PBMs' average overall gross margin decreased from 8.4% in 2017 to 7.6% in 2022 and their average operating margin decreased from 5.6% in 2017 to 4.5% in 2022.[244]

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241 *See* Ratula Chakraborty, "Do Retailers Manipulate Prices to Favour Private Label over Brands?" Working Paper 18-2, *Centre for Competition Policy* (2018): 1-40 at 4; Dennis W. Carlton and James D. Dana, Jr., "Product Variety and Demand Uncertainty: Why Markups Vary with Quality," *The Journal of Industrial Economics* LVI, no. 3 (2008): 535-552 at 548.

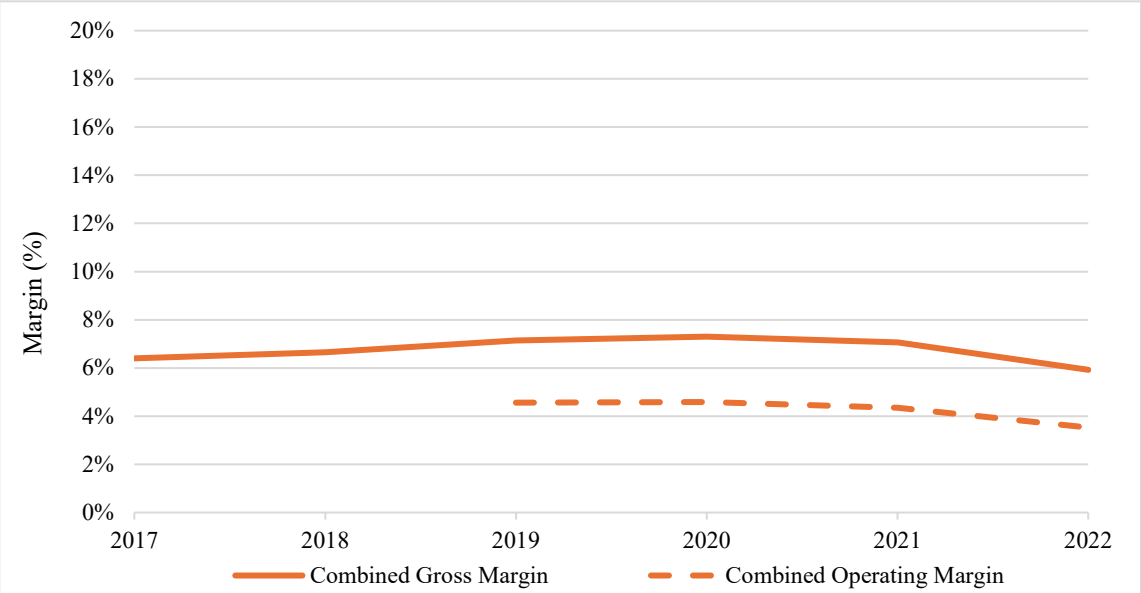
242 Percentage margins are typically measured as a percentage of revenues (*i.e.*, revenue minus cost, divided by revenue), but can also be presented as a percentage of costs (what the FTC staff calls a "markup"), as there is a fixed relationship between the two measures. If M is the percentage margin as a percent of revenue, then the markup as a percent of cost is M/(1-M). For further discussion of PBM margins, *see* note 154.

243 The FTC staff also analyzed the total dollar value associated with the retail spreads earned by PBMs on the 51 specialty generics in the Second Interim Report although FTC staff acknowledged that taking into account adjustments likely would lower this amount. (*See* FTC Second Interim Report (2025), pp. 23-24). Our analysis of PBM margins already takes these spreads into account.

244 *See* ¶ 96 above. If we converted these gross margins to a percentage markup over acquisition costs, consistent with the approach taken by the FTC staff, the gross markup over COGS for 2022 would equal 8.2%.

165. Because the FTC staff focuses on specialty generic drugs, it also could be informative to investigate the validity of any suggestion that PBM-affiliated specialty pharmacies are earning high margins. PBM financials include gross and operating margin estimates for their affiliated specialty pharmacies (primarily, CVS Specialty for Caremark, Optum Specialty Pharmacy for Optum Rx, and Accredo for Express Scripts).[245] Figure 19 shows average gross and operating margins for affiliated specialty pharmacies for the three PBMs combined using internal financial data from the PBMs. Average gross margins for the affiliated specialty pharmacies are around 7% through the period and average operating margins are around 4%.[246]

Figure 19: Margins at PBM-Affiliated Specialty Pharmacies



Sources: Caremark internal data, Express Scripts internal data, Optum Rx internal data.
Notes: Aetna is excluded from CVS Caremark gross margins and operating margins.

245 The margins at affiliated specialty pharmacies include all sales at the specialty pharmacy whether the sale was to a member of a plan using the affiliated PBM or a non-affiliated PBM for claims adjudication.

246 The gross margins at specialty pharmacies are calculated as specialty pharmacy revenues less COGS (PBM financials break out their affiliated pharmacy revenues and costs into specialty pharmacy and regular mail-order buckets). COGS includes the cost to purchase drugs for affiliated pharmacies and direct costs associated with dispensing drugs. Operating margins are calculated as gross margins less operating costs, which include costs such as labor costs and Sales, General, and Administrative ("SGA") costs.

166. The 7% average gross margins for PBM affiliated specialty pharmacies are calculated as a percentage of revenues.[247] If instead we calculate these as a percentage of cost (in order to make the calculation comparable to the FTC staff's calculation of markups), the average gross margin as a percentage of cost at PBM affiliated pharmacies is 7.2%. Thus, the overall gross markup earned at the affiliated specialty pharmacies are far less than the markups reported by the FTC staff for a subset of specialty generic drugs (which are on average around 309%). As another point of comparison, consider the Mark Cuban Cost Plus Drug Company, which the FTC staff uses to estimate operating costs for affiliated pharmacies.[248] The Mark Cuban Cost Plus Drug Company offers certain prescription drug products online, charging patients a standard markup over acquisition cost of 15%, plus $10 in fees (a $5 dispensing fee and a $5 shipping fee).[249] The 7.2% markup at affiliated specialty pharmacies is substantially lower than the markup at the Mark Cuban Cost Plus Drug Company. To the extent critics believe the PBMs' affiliated specialty pharmacy markups are "too high" and that the Mark Cuban Cost Plus Drug Company provides a relevant reference point, they should consider that the markups at the Mark Cuban Cost Plus Drug Company are substantially higher.

167. Fundamentally, the overall margins earned by the PBMs and by the specialty pharmacies affiliated with the PBMs are much lower than suggested by the FTC staff's markup calculations, and this indicates that the markups for the specialty generic drugs selected by the FTC staff are not indicative of those for all drugs.

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247 The gross margin for the three PBMs affiliated specialty pharmacies was around 6.5% in 2017 and 2018. This margin is comparable to other specialty pharmacies at the time. For example, Diplomat, which was acquired by Optum in 2020, had a gross margin of around 6% during the same period. Diplomat Pharmacy, Inc. Form 10-K for the year ended December 31, 2018, p. 111. According to the Fein Report, "Diplomat's prescription profitability figures were typical for a business that dispenses primarily brand-name specialty medications and few generic prescriptions." Fein Report (2024), p. 344.

248 *See* note 236 above.

249 *See* Cost Plus Drug Company, "Here's exactly how we price your drugs," available at https://www.costplusdrugs.com (accessed March 17, 2025).

3. The FTC staff's analysis of the markup of select specialty generic reimbursement rates over estimated acquisition costs at affiliated pharmacies is not representative of all drugs and therefore does not provide a reasonable basis for policymaking

168. In both interim reports, the FTC staff analyzes the markup on individual drugs, defined as the ratio of the amount pharmacies affiliated with PBMs are reimbursed for individual specialty generic drugs and the estimated acquisition cost for those drugs using estimates of drug acquisition costs from NADAC.[250, 251] In the First Interim Report, the FTC staff analyzes two specialty generic drugs and calculates that the markup is 25-40 times the NADAC acquisition cost of the two drugs. In the Second Interim Report, the FTC staff analyzes 51 specialty generic drugs and reports that several of these drugs have very high markups, in excess of 1000%, but doesn't report the weighted average over the drugs analyzed. We have calculated the weighted average (weighting by share of NADAC acquisition costs) and find that the weighted average markup of the drugs selected by the FTC staff is 309%. Based on its analyses of this limited set of drugs, the FTC staff suggests that there is a systematic problem that has allowed certain specialty generic drug prescriptions sold at PBM-affiliated pharmacies to be "highly profitable," and appears to suggest that PBM pricing practices overall thus deserve closer scrutiny. Even if one accepts the FTC staff's calculation of markups as being relevant, the FTC staff's suggestion of a systematic problem is not supported by a more comprehensive analysis that goes beyond the 51 selected drugs.

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250 FTC Second Interim Report (2025), p. 6.

251 Although NADAC may not be representative for measuring specialty drugs' acquisition costs, we nonetheless accept the use of NADAC for purposes of this analysis in order to point out the other pitfalls of the FTC staff's approach. *See* FTC Second Interim Report (2025), p. 7; CMS, "Methodology for Calculating the National Average Drug Acquisition Cost (NADAC) for Medicaid Covered Outpatient Drugs," December 2024, available at https://www.medicaid.gov/medicaid-chip-program-information/by-topics/prescription-drugs/ful-nadac-downloads/nadacmethodology.pdf, pp. 7, 10 (explaining that surveys used to calculate NADAC are limited to chain and independent retail community pharmacies and that specialty pharmacies are currently excluded).

a) The specialty generics selected by the FTC staff are extreme outliers in terms of markups over NADAC at affiliated pharmacies

169. As we described above, specialty generics account for a tiny fraction of spending on drugs by plan sponsors and members or reimbursements by PBMs. We find that the subset of specialty generics selected by the FTC staff is also not representative of other drugs, because the selected drugs' markups are outliers among all drugs.

170. We use the FTC staff's method for estimating markups to determine whether the results for specialty generics are representative of all drugs.[252] We limit the analysis to NDCs for which information on acquisition costs is available from NADAC. Figure 20 below shows the distribution of markups for pharmacy reimbursements at affiliated pharmacies for 2020-2022, across all payors, for the NDCs for which NADAC information is available.[253]

171. As Figure 20 below shows, the weighted average markup[254] for the FTC staff's specialty generic drugs is 309%. The drugs focused on by FTC staff are extreme outliers compared to other drugs.[255, 256] In fact, the majority of reimbursements to affiliated pharmacies are for drugs

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252 The percentage markup on an NDC is ((total pharmacy reimbursement per 30-day prescription / NADAC cost per 30-day prescription) minus 1) x 100%. This is consistent with our understanding of how the FTC staff has defined percentage markup. The total pharmacy reimbursement is equal to the reimbursement by the PBM, plus member payments, plus any other payments received by the pharmacy. The NADAC cost is the average NADAC per unit cost per year multiplied by a unit-to-30-day prescription conversion (the conversion is calculated at the NDC level using the claims data: affiliated + non-affiliated quantity divided by affiliated + non-affiliated 30-day prescriptions. The NADAC cost is thus the same regardless of whether the drug is purchased from an affiliated or non-affiliated pharmacy.).

253 We note that there is no mathematical limit on how large a positive markup can be, but a negative markup can be no larger than -100%. (This is because a markup of -100% means that the price of the drug is zero.)

254 We use cost shares as weights.

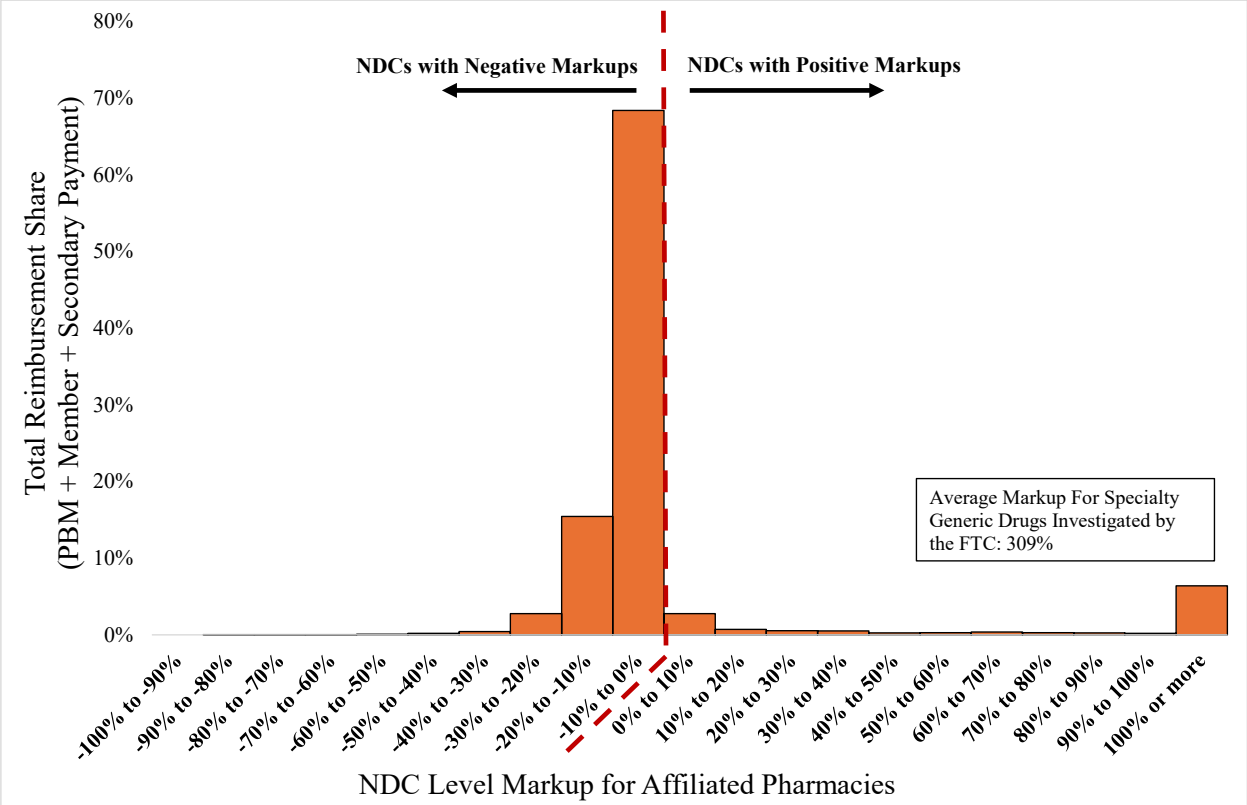
255 Note that the average is calculated across all specialty generic drugs identified by the FTC report for which we have NADAC data. The average expressed as a percent is calculated as total pharmacy reimbursement for the relevant specialty generic drugs for affiliated pharmacies divided by the total NADAC cost (NADAC per 30-day prescription * number of affiliated prescriptions) minus 1, and then multiplied by 100%.

256 We have not determined what accounts for the different markups across specific drugs for the more than 1,000 drugs for which data was provided to the FTC. However, our

where the markup is between 0% and negative 10%, *i.e.*, the reimbursement rate is below NADAC acquisition costs.

understanding is that some of the large PBMs are now offering an option to plan sponsors in which the payment by plan sponsors and members for a particular drug is more tailored to that individual drug's cost. *See, e.g.*, CVS Health, "Helping enable a more transparent, simple health care system," March 19, 2024, available at https://www.cvshealth.com/news/pharmacy/helping-enable-a-more-transparent-simple-health-care-system.html (accessed August 29, 2024); Written Testimony of Adam Kautzner, President, Express Scripts, Before the House Committee on Oversight and Accountability, U.S. House of Representatives, July 23, 2024, p. 18; UnitedHealth Group, "New Optum Rx payment solutions continue to empower clients with more choice, transparency in pharmacy benefits," April 24, 2023, available at https://www.unitedhealthgroup.com/newsroom/posts/2023/2023-04-24-optum-rx-enhancements-preserving-choice.html (accessed August 30, 2024)); UnitedHealth Group, "Optum Rx to Modernize Pharmacy Payment Models," March 20, 2025, available at https://www.unitedhealthgroup.com/newsroom/2025/2025-03-20-orx-modernize-payment-models.html (accessed April 1, 2025).

Figure 20: Distribution of Markups Over NADAC by Size of Markup for Affiliated Pharmacies



Sources: Specs 12-14 of Caremark, Express Scripts, and Optum Rx 6(b) Submissions to the FTC, 2020-2022 Medicaid NADAC Data
Notes: The percentage markup on an NDC is (total pharmacy reimbursement per 30-day prescription / NADAC cost per 30-day prescription) minus 1 x 100%. Bar height is determined based on the share of total reimbursements for all NDCs in a given markup bucket.

b) Applying the FTC staff's methodology to all drugs shows that average markups over NADAC are negative for affiliated pharmacies

172. The FTC staff focuses its analysis on 51 specialty generic drugs, but those specialty generics are a small subset of all drugs and have markups that are outliers. One must instead consider the full set of drugs. In this section, we apply the FTC staff's approach to all drugs and show that the average markup over NADAC for affiliated pharmacies is negative, *i.e.*, reimbursements to affiliated pharmacies are less than NADAC pricing on average. For comparison, we also show in the next section that the average markup over NADAC for non-affiliated pharmacies is positive, *i.e.*, reimbursements to non-affiliated pharmacies are more than NADAC pricing on average and thus higher than at affiliated pharmacies.

173. Table 12 shows the average markup at affiliated pharmacies, by category of drugs (brand/generic and specialty/non-specialty). The analysis shows that average markups at affiliated pharmacies are negative overall (-2.1%). In general, branded drugs have small negative markups while generic drugs have positive markups (although of course generic drugs are generally lower priced than branded drugs so that any percentage markup may be very small in dollar terms; see discussion below). Markups on specialty generics are higher than markups on other categories of drugs. Although the FTC staff's report states that the markups over NADAC at affiliated pharmacies for its selected specialty generics total $7.3 billion from 2017-2022 across the three PBMs, this ignores that markups are negative for branded drugs and negative overall, more than offsetting the markup for the selected specialty generics. If the FTC staff's measure of markup over NADAC is meaningful, it is important to note that, overall, markups over NADAC at affiliated pharmacies are not $7.3 billion and in fact are not even positive. Instead, total markups over NADAC at affiliated pharmacies for all drugs are *negative* $15.9 billion.[257, 258] In contrast to the FTC staff's suggestion, these findings show that PBMs are keeping drug costs below NADAC on average at their affiliated pharmacies, showing—using the FTC staff's own logic—that reimbursements by PBMs to their affiliated pharmacies are not contributing to high drugs costs.

[257] FTC Second Interim Report (2025), p. 19. The FTC staff's calculation is based on prescriptions covered by commercial and Medicare payors only. Our calculation includes all payors, including Medicaid in addition to commercial and Medicare payors. In addition, the data processing and methodology used by FTC staff to calculate the $7.3 billion markup may be different from ours. When we attempt to replicate the FTC staff's calculation for commercial and Medicare, our results are similar.

[258] Although the markup analyses in FTC staff's Second Interim Report are generally based on data from 2020 to 2022, the $7.3 billion figure is based on data from 2017 to 2022. *See* FTC Second Interim Report (2025), note 8. To be consistent with the FTC staff's analysis, the markup analyses in this report are also based on data from 2020 to 2022 and the *negative* $15.9 billion figure is based on data from 2017 to 2022.

Table 12: Average Markup of Reimbursement Rates Over NADAC for Affiliated Pharmacies, All Payor Types, 2020-2022

Specialty Status	Brand or Generic	Affiliated Markup
All	All	-2.1%
All	Branded	-8.0%
All	Generic	102.7%
Non-Specialty	All	-3.4%
Non-Specialty	Branded	-11.6%
Non-Specialty	Generic	73.2%
Specialty	All	-0.9%
Specialty	Branded	-5.0%
Specialty	Generic	309.0%

Sources: NADAC data; Specs 12-14 of Caremark, Express Scripts, and Optum Rx 6(b) Submissions to the FTC.
Notes:
1. Markup calculated as Reimbursement / NADAC Amount -1.
2. Reimbursement reflects: amount paid by PBM to pharmacy + patient pay amount + other payor recognized amount.
3. Restrictions (brand vs generic, specialty vs non-specialty) are based on PBM internal drug designations.

174. The fact that generics generally have higher percentage markups than branded drugs should not by itself raise concerns. First, because generics typically have much lower prices than branded drugs, a higher percentage margin need not lead to a higher per-prescription (dollar) margin for the generic versus the comparable brand.[259] Second, to the extent there is a set cost for dispensing a prescription, lower cost drugs will need a higher percentage margin to cover that cost. Third, PBMs and plan sponsors want to incentivize pharmacies to dispense generic drugs where possible since generic drugs are typically substantially cheaper for plan sponsors and patients than branded drugs. One way to create this incentive is to enable pharmacies to earn higher margins on generic drugs than on branded drugs.

175. For the analyses we have described in this section, we have followed the FTC staff's use of reimbursement rates when calculating markups. Arguably, the more relevant metric is what plan sponsors and members pay because it reflects total actual spending on drugs (including the

[259] *See* ¶ 163 above.

retail spread, if any, earned or lost by PBMs) and avoids potential concerns about transfer prices between PBMs and their affiliated pharmacies. In the Appendix, we show a version of Table 12 where markups are calculated using gross spending by plan sponsors and members (See Appendix B Table 17). The patterns are similar to those shown above.[260]

C. THE FTC STAFF'S ANALYSIS SUGGESTS THERE IS A LARGE DIFFERENCE BETWEEN MARKUPS AT AFFILIATED AND NON-AFFILIATED PHARMACIES, BUT A MORE COMPREHENSIVE ANALYSIS OF ALL DRUGS SHOWS THIS IS INCORRECT

176. Based on its analysis of a subset of specialty generics, the FTC staff estimates that markups for certain specialty generic drugs at affiliated pharmacies far exceed those at non-affiliated pharmacies. This limited analysis is not sufficient for concluding that affiliated pharmacies are being paid more across all drugs than non-affiliated pharmacies. Examining markups on less than 2% of drug expenditures does not reliably indicate that markups or prices overall are higher at affiliated pharmacies compared to non-affiliated pharmacies.

177. As an analogy to the FTC staff's study, consider two grocery stores, each of which sells thousands of products. The prices of similar (or even identical) products need not be the same at the two stores for them to provide similar value overall to consumers. Consumers will generally consider the cost of the total basket of groceries they purchase, not the cost of one item. Observing that flour costs $2 at Brown's Market and $1 at Green's Market does not establish that shoppers at Brown's are paying twice as much for their groceries than shoppers at Green's. Perhaps flour is more expensive at Brown's, for example, but milk is cheaper. Consumers who purchase both flour and milk do not necessarily spend more on the basket of groceries if they shop at Brown's than at Green's. Because consumers buy a basket of items, one cannot know whether shoppers on average are paying more at Brown's than at Green's unless one analyzes the cost of the basket of goods that shoppers purchase at Brown's and at Green's. What the FTC staff has done is akin to focusing on the cost of flour alone to conclude that Brown's has high markups or is a more expensive store than Green's. It would be similarly inappropriate to focus

[260] We also calculate average markups based on net spending by plan sponsors and members for the PBM where we had the necessary disaggregated net spending data. Those results are similar to results based on gross spending by plan sponsors and members.

on the cost of milk alone and conclude that Brown's has lower markups or is a less expensive store than Green's.

178. Using a variety of methodologies, we now examine whether the data support the FTC staff's suggestion that, generally, markups at affiliated pharmacies may be substantially higher than markups at non-affiliated pharmacies or that affiliated pharmacies are substantially more expensive for plan sponsors and members than non-affiliated pharmacies. We find that the data do not support such conclusions.

1. Applying the FTC staff's markup methodology to all drugs purchased at affiliated and at non-affiliated pharmacies

179. Examining markups at non-affiliated pharmacies, we find that they follow a similar pattern to those at affiliated pharmacies.[261] As shown in Table 13, overall markups are low compared to the markups on specialty generics analyzed by the FTC staff, markups on branded products are negative, and markups on both specialty and non-specialty generics are positive. Moreover, although markups on specialty generics are higher than other categories of drugs, as Table 12 and Table 13 show, this is true for both affiliated and non-affiliated pharmacies. Therefore, if the FTC staff is condemning the pricing of specialty generic drugs at PBM affiliated pharmacies, it should be similarly condemning the pricing at non-affiliated pharmacies.[262]

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261 *See* note 227.

262 Of course, "high" reimbursements at non-affiliated pharmacies conflicts with the theory that non-affiliated pharmacies are underpaid and are consequently being driven out of business.

Table 13: Average Markup of Reimbursement Rates Over NADAC for Non-Affiliated Pharmacies, All Payor Types, 2020-2022

Specialty Status	Brand or Generic	Non-Affiliated Markup
All	All	3.8%
All	Branded	-5.1%
All	Generic	93.6%
Non-Specialty	All	5.2%
Non-Specialty	Branded	-5.2%
Non-Specialty	Generic	89.3%
Specialty	All	-0.5%
Specialty	Branded	-4.8%
Specialty	Generic	145.4%

Sources: NADAC data; Specs 12-14 of Caremark, Express Scripts, and Optum Rx 6(b) Submissions to the FTC.
Notes:
1. Markup calculated as Reimbursement / NADAC Amount -1.
2. Reimbursement reflects: amount paid by PBM to pharmacy + patient pay amount + other payor recognized amount.
3. Restrictions (brand vs generic, specialty vs non-specialty) are based on PBM internal drug designations.

180. Comparing Table 12 and Table 13 shows that the FTC staff's suggestion regarding relative markups at affiliated and non-affiliated pharmacies are contradicted by an analysis of all drugs. The FTC staff calculated that markups for certain specialty generics are higher at affiliated pharmacies than at non-affiliated pharmacies, but when applying the same calculation across all drugs, we find that markups are lower at affiliated pharmacies than at non-affiliated pharmacies.[263] In fact, overall markups at affiliated pharmacies are negative (-2.1%) while markups at non-affiliated pharmacies are positive (+3.8%). In the aggregate, markups are also lower for all specialty drugs at affiliated pharmacies than at non-affiliated pharmacies. To the extent that high-priced, non-affiliated pharmacies are excluded by plan sponsors from pharmacy networks to reduce drug costs, our results and the FTC staff's results may understate the markups at non-affiliated pharmacies.

[263] The same conclusion applies if we analyze Medicare and commercial plan sponsors separately.

2. Applying the FTC staff's markup methodology to the entire basket of drugs purchased, adjusting for drug mix

181. The analysis in Table 12 and Table 13 is based on the actual number of and type of prescriptions dispensed at affiliated and non-affiliated pharmacies in the data provided to the FTC. Because the mix of drugs sold at each type of pharmacy may differ, differences in markups across pharmacy types could be driven by differences in the mix of drugs purchased at different pharmacy types. To control for this, we calculate markups assuming that the entire basket of drugs purchased at affiliated and non-affiliated pharmacies combined is purchased at affiliated pharmacies and compare that to the markup assuming that the entire basket of drugs is purchased at non-affiliated pharmacies. The results show very similar patterns to Table 12 and Table 13: affiliated markups overall are lower than non-affiliated markups (see Appendix B Table 18), and the dollar value of the difference in markups between affiliated and non-affiliated pharmacies across all drugs is *negative* $19.4 billion. (See Appendix B Table 19 and Table 20).

3. Examining total payments for the entire basket of drugs purchased

182. Another way to analyze the FTC staff's suggestion that affiliated pharmacies are generally more costly than non-affiliated pharmacies is simply to look at total payments by plan sponsors and members to affiliated and non-affiliated pharmacies. We find that the data do not support the FTC staff's suggestion that affiliated pharmacies are substantially more expensive than non-affiliated pharmacies, across all drugs.

183. Just as the mix of drugs purchased can affect the comparison of markups at affiliated and non-affiliated pharmacies, as discussed above, mix can also affect a comparison of total payments at affiliated and non-affiliated pharmacies. We therefore analyze what the basket of all drugs purchased by plan sponsors and members at both affiliated and non-affiliated pharmacies combined would cost plan sponsors and members if the entire basket were purchased at affiliated pharmacies versus what it would cost if the entire basket were purchased at non-affiliated pharmacies. Our analysis indicates that total payments (from plan sponsors and members combined) are about the same at affiliated pharmacies and non-affiliated pharmacies, although the amount can be a little more or a little less, depending on the methodology. Table 21 in the

Appendix shows that the ratio of total payments at affiliated pharmacies to total payments at non-affiliated pharmacies is 1.01 across all NDCs, PBMs, payors, and years.[264]

184. Although our analysis uses what we consider to be reasonable assumptions to estimate the "prices" paid at affiliated and non-affiliated pharmacies—or simply adopts the FTC staff's assumptions—these assumptions can influence the calculations, and there are adjustments one could try to make to confirm the robustness of the results. For example, instead of using the FTC staff's convention of using the number of 30-day prescriptions, we could use a different measure of quantity; the ratio of affiliated to non-affiliated decreases slightly to 1.00 if we use quantity dispensed.[265] (See Table 22 in Appendix B.)

185. As another example, PBMs and plan sponsors also may negotiate discount rate guarantees specific to affiliated pharmacies that are not typically recorded in the available FTC data at the claim level. These guarantees would further reduce the cost of drugs at affiliated pharmacies in our analyses once accounted for.

186. In addition, we understand that the data we have are more likely to exclude out-of-network prescriptions for non-affiliated pharmacies compared to affiliated pharmacies. Since out-of-network pharmacies are likely to have higher prices than in-network pharmacies, this will likely bias upward our calculations of prices at affiliated pharmacies compared to non-affiliated pharmacies, causing our calculated ratio of costs at affiliated to non-affiliated pharmacies to be higher than the actual ratio.[266]

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264 The same conclusion applies if we analyze Medicare and commercial plan sponsors separately.

265 Quantity dispensed refers to "the number of units, grams, milliliters, or other relevant unit indicating the amount of an individual drug product included in a transaction or transactions." Federal Trade Commission, *Order to File a Special Report*, FTC Matter No. P221200 (June 6, 2022), p. 13.

266 As an alternative approach to analyzing the differences in payments to affiliated and non-affiliated pharmacies for the basket of drugs purchased, we separately estimated a regression relating the gross plan sponsor + patient payment per 30-day prescription for an NDC (in logarithms) to an indicator variable for affiliated pharmacy, indicator variables for years (2017 through 2022), indicator variables for the type of payor (commercial/Medicare/Medicaid), indicator variables for each of the three largest PBMs, and indicator variables for NDCs. We estimated versions both weighting by 30-day

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187. In summary, the FTC staff suggests that broad conclusions about the PBMs' treatment of overall drug costs at affiliated and non-affiliated pharmacies can be drawn from an analysis of a very small set of drugs, notwithstanding the reality that plan sponsors negotiate for and purchase a large basket of drugs. From the perspective of plan sponsors, who care about the overall cost of providing prescription drug benefits to their members, "high" prices or markups on some drugs may be offset by "low" prices or markups on other drugs. Our broader analyses—using the FTC staff's markup methodology as well as examining total payments by plan sponsors and members—show that the data do not support the FTC's suggestion. Our analysis shows that, when calculated across all drugs, markups are *negative* at affiliated pharmacies and are not higher at affiliated pharmacies than non-affiliated pharmacies. Furthermore, the overall cost to plan sponsors and members of the total basket of drugs purchased by plan sponsors and members would be about the same at affiliated pharmacies and non-affiliated pharmacies.

D. THE FTC STAFF ALSO INCORRECTLY SUGGESTS THAT NON-AFFILIATED PHARMACIES' SURVIVAL IS THREATENED BECAUSE PBMS MAY BE STEERING PRESCRIPTIONS TO AFFILIATED PHARMACIES

188. The FTC staff raises concerns that the PBMs may be steering prescriptions away from non-affiliated pharmacies and towards their affiliated pharmacies, with the implication that this may be putting the survival of the non-affiliated pharmacies in jeopardy.[267]

189. The data do not support the FTC staff's suggestion that steering of prescriptions to affiliated pharmacies is driving non-affiliated pharmacies out of business. Spending by plan sponsors and members on drugs at non-affiliated pharmacies has grown significantly over time,

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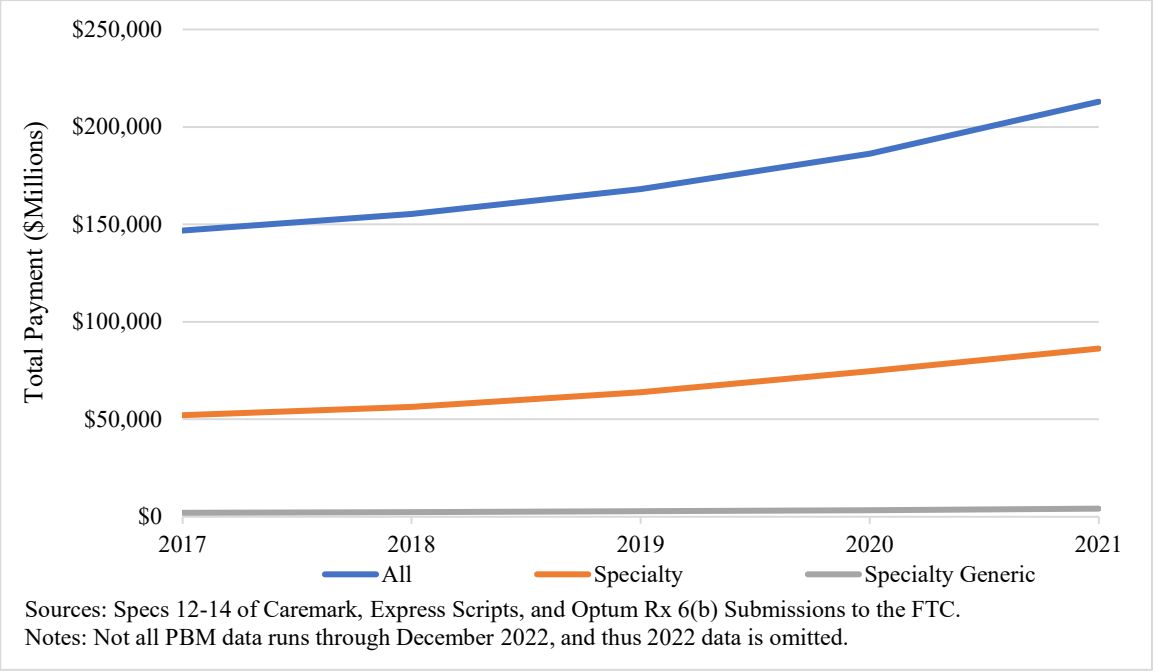
prescriptions and without weighting. Both regressions are reported in Appendix B Table 25. The results of the weighted regression indicate that total payments on all drugs in the basket would be about 3.6% lower at affiliated pharmacies than they would be at non-affiliated pharmacies. The results of the unweighted regression indicate that total payments on all drugs in the basket would be about 2.2% lower at affiliated pharmacies than they would be at non-affiliated pharmacies.

267 The FTC staff does not consider that there may be other reasons why affiliated pharmacies have higher shares of certain specialty generic drugs than non-affiliated pharmacies, such as the ability to provide services that may be more important for certain specialty drugs than for other drugs.

whether one considers all drugs, all specialty drugs, or specialty generic drugs.[268] (See Figure 21; see also Figure 18 in Section VI.) Thus, sales at these pharmacies are not declining and non-affiliated pharmacies are not losing revenue in absolute terms.

Figure 21: Total Spending by Plan Sponsors and Members at Non-Affiliated Pharmacies, 2017-2021



Sources: Specs 12-14 of Caremark, Express Scripts, and Optum Rx 6(b) Submissions to the FTC.
Notes: Not all PBM data runs through December 2022, and thus 2022 data is omitted.

190. Moreover, although the non-affiliated pharmacies' share of total spending declines from 62% to 59% between 2017 and 2021, PBMs continue to rely on non-affiliated pharmacies to fill prescriptions accounting for more than half of all drug payments. (See Table 23 in Appendix B.) These results are inconsistent with the suggestion that PBMs are threatening the viability of non-affiliated pharmacies by steering prescriptions.

[268] We obtain similar results for pharmacy reimbursement (amount paid by PBM to pharmacy, patient pay amount, and other payor recognized amount) over time.

VIII. CONCLUSION

191. Our analysis focuses on the role of pharmacy benefit managers in the healthcare industry and investigates various claims that PBMs are causing increases in the cost of prescription drugs that contribute to increasing healthcare costs generally. Claims that PBMs are harming plan sponsors and beneficiaries of drug benefit plans—by earning large and growing profits, retaining large percentages of the rebates received from manufacturers, retaining large percentages of the amounts plan sponsors pay to pharmacies, causing drug prices to rise more than they otherwise would, causing independent pharmacies to go out of business, and raising reimbursements to affiliated pharmacies in order to enrich themselves and raise the cost of drugs—are not supported by the data. Our results are consistent with other studies that find that PBMs play an important role in containing prescription drug costs and thus overall health care costs. We intend to continue to study the PBM industry and may update this report when and if relevant data or topics, including comments on this report, arise.

APPENDICES

APPENDIX A: CONTRACT DETAILS

1. General Terms

192. A plan sponsor may represent certain types of members (referred to as "Lines of Business"), *e.g.* commercial only, Medicare only, Medicaid only, Affordable Care Health only, or a combination of different types of members. When representing multiple types of members, the plan sponsor may negotiate different contract terms for each member type as there may be regulatory requirements that apply to certain member groups but not others.[269]

193. Each Line of Business may have what are termed "subtypes." This term describes how the plan sponsors pay the PBM when drugs are dispensed to patients under the drug benefit plan provided by the plan sponsor. "Transparent" subtype means pass-through pricing, *i.e.*, the plan sponsor would pay to the PBM the exact amount reimbursed to the pharmacy (so the PBM does not earn any retail spread) and typically would also pay an administrative fee to compensate the PBM for its services. "Traditional" subtype means retail spread pricing, *i.e.*, the plan sponsor pays a fixed, negotiated amount to the PBM for each type of drug dispensed by the pharmacy and shifts risk to the PBM of pharmacy prices changing. In this case, the plan sponsor typically would not pay an administrative fee as with the Transparent model. Plan sponsors can also choose to use a combination of Traditional and Transparent models, depending on the drug type or dispensing channel.

194. Contracts typically last between one and five years. Plan sponsors may negotiate contract terms that are either fixed for the duration of the contract or vary by year.

2. Administrative Fees

195. As discussed above, the level of administrative fees paid by the plan sponsors to PBMs for processing each prescription claim may vary depending on the other ways in which PBMs may be compensated. Plan sponsors who pay administrative fees can choose among many options as to how the administrative fee is to be paid. For example, the fee may be paid on a per claim basis, with the amount varying by the dispensing channel (retail, mail-order, or specialty),

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269 One large PBM's 6(b) Submission to the FTC.

by formulary type, or by network type. Alternatively, the fee may be based on other metrics that are not directly tied to the number of claims processed, such as a flat monthly fee, or per employee per month, or per member per month. Plan sponsors decide which PBM compensation model best meets their needs and circumstances.

196. Plan sponsors can also negotiate the frequency of the billing from the PBM to the plan sponsors for the administrative fee as well as the frequency of the billing for the claims. Similarly, plan sponsors can choose the frequency of the payments they make to the PBMs for administrative fees and claims.

3. Pharmacy Reimbursement Terms

197. Plan sponsors reimburse PBMs for pharmacy payments with terms varying by the type of drug (branded or generic) and by pharmacy type (retail, mail-order, or specialty). Pharmacy reimbursements have two components – i) payments for the drugs that are generally in terms of a discount off AWP for each drug type; and ii) dispensing fees for each drug type. Moreover, the plan sponsors may negotiate pricing guarantees in the contracts for each drug type, whereby the PBM would owe money to the plan sponsor if the PBM fails to achieve the guaranteed discount level. For example, if the actual discount off AWP on generic drugs dispensed at retail is below the guaranteed discount threshold, a PBM may be required to reconcile the difference by returning to the plan sponsor the difference between the actual discount rate and the guaranteed rate.

4. Rebate Terms

198. Plan sponsors can negotiate the fraction of manufacturer rebates that the PBM is allowed to keep as a compensation for its services, whether the PBM must guarantee certain minimum rebates, or a hybrid approach. For example, plan sponsors may negotiate a certain pass-through rate (*e.g.*, the plan sponsor gets 100% of rebates, or the plan sponsor gets 99% of rebates and the PBM keeps 1%). There may also be a hybrid approach with both a split of rebates and guaranteed amounts.

199. Plan sponsors can also negotiate the frequency at which the rebates are paid to the plan sponsors – for example, terms could be 30 days, 90 days, or some other interval.

APPENDIX B: ANALYSIS SENSITIVITIES

1. Section V Sensitivities

Table 14: Relationship between Rebate Percentages and Rate of Growth in List Prices, Caremark, Express Scripts, and Optum Rx Estimated Together, Unweighted

Dependent Variable: AWP_t / AWP_{t-1}

	All PBMs
Rebate as a Percentage of AWP ($Rebate_t / AWP_t$)	-0.044
Observations	9,274

Sources: Specs 12-14 of Caremark, Express Scripts, and Optum Rx 6(b) Submissions to the FTC; internal Caremark rebate data; internal Express Scripts rebate data; internal Optum Rx rebate data.
Notes:
1. *** $p < 0.01$, ** $p < 0.05$, * $p < 0.1$; Clustered standard errors on NDC are used.
2. The analysis is performed at the NDC/year level using Caremark, Express Scripts, and Optum Rx claims data.
3. The regression includes fixed effects for NDC, year (2018-2022), and PBM.

2. Section VI Sensitivities

Table 15: Comparison of Reimbursement Rates Paid to Retail Pharmacies: Independent Pharmacies and Non-Affiliated Chain Pharmacies, Non-Specialty Branded Drugs and Non-Specialty Generic Drugs, Unweighted

Dependent Variable: Log Total Reimbursement (PBM + Member + Secondary Insurer) per 30-Day Equivalent Rx

	Branded	Generic
	(1)	(2)
Non-Affiliated Chain Pharmacy Dummy Coefficient	-0.005	-0.060***
Observations	66,609	646,288

Sources: Specs 12-14 of Caremark, Express Scripts, and Optum Rx 6(b) Submissions to the FTC.
Notes:
1. *** p < 0.01, ** p < 0.05, * p < 0.1; Clustered standard errors on NDC are used.
2. Includes non-specialty NDCs with at least 100 30-day prescriptions for each type of pharmacy, in each year.
3. The regression includes year fixed effects (2017-2022), payor fixed effects (Commercial, Medicare, Medicaid), and NDC fixed effects.

3. Section VII Sensitivities

Table 16: Payments and Volume of Prescriptions by Drug Type at Affiliated Pharmacies (2017-2022)[270]

Drug Type	Share
Gross Plan Sponsor + Member Payment	
FTC Specialty Generic Drugs	2.2%
Other Specialty Generic	0.5%
Specialty Branded	63.1%
Non-Specialty Generic	7.2%
Non-Specialty Branded	27.0%
Reimbursement	
FTC Specialty Generic Drugs	2.1%
Other Specialty Generic	0.5%
Specialty Branded	62.9%
Non-Specialty Generic	7.0%
Non-Specialty Branded	27.4%
No. of 30-Day Prescriptions	
FTC Specialty Generic Drugs	0.3%
Other Specialty Generic	0.0%
Specialty Branded	1.5%
Non-Specialty Generic	87.5%
Non-Specialty Branded	10.7%

Sources: Specs 12-14 of Caremark, Express Scripts, and Optum Rx 6(b) Submissions to the FTC.

[270] Values might not add to 100% due to rounding. Other specialty generic drugs comprise 0.02% of 30-day prescriptions.

Table 17: Average Markup of Gross Sponsor + Patient Payment Rates Over NADAC for Affiliated and Non-Affiliated Pharmacies, All Payor Types, 2020-2022

Specialty Status	Brand or Generic	Affiliated Markup	Non-Affiliated Markup
All	All	-3.4%	4.6%
All	Branded	-9.5%	-5.5%
All	Generic	104.7%	106.1%
Non-Specialty	All	-5.1%	6.0%
Non-Specialty	Branded	-13.7%	-5.8%
Non-Specialty	Generic	74.7%	100.4%
Specialty	All	-1.9%	0.4%
Specialty	Branded	-6.0%	-4.6%
Specialty	Generic	314.3%	175.5%

Sources: NADAC data; Specs 12-14 of Caremark, Express Scripts, and Optum Rx 6(b) Submissions to the FTC.

Notes:

1. Markup calculated as Gross Payment / NADAC Amount -1.
2. Gross Payment reflects: gross amount sponsor paid to PBM + patient pay amount.
3. Restrictions (brand vs generic, specialty vs non-specialty) are based on PBM internal drug designations.

Table 18: Average Markup of Reimbursement Rates Over NADAC for Affiliated and Non-Affiliated Pharmacies While Controlling for Product Mix, All Payor Types, 2020-2022

Specialty Status	Brand or Generic	Affiliated Markup	Non-Affiliated Markup
All	All	-2.7%	0.3%
All	Branded	-8.6%	-5.3%
All	Generic	86.8%	85.6%
Non-Specialty	All	-3.7%	2.0%
Non-Specialty	Branded	-10.9%	-5.4%
Non-Specialty	Generic	71.3%	78.8%
Specialty	All	-1.1%	-2.7%
Specialty	Branded	-5.0%	-5.2%
Specialty	Generic	235.8%	150.6%

Sources: NADAC data; Specs 12-14 of Caremark, Express Scripts, and Optum Rx 6(b) Submissions to the FTC.

Notes:

1. Markup calculated as Mix Adjusted Reimbursement Price / Mix Adjusted NADAC Price -1.
2. Reimbursement reflects: amount paid by PBM to pharmacy + patient pay amount + other payor recognized amount.
3. Restrictions (brand vs generic, specialty vs non-specialty) are based on PBM internal drug designations.
4. This analysis includes overlapping NDCs with at least 100 30-day prescriptions for each PBM, at each type of pharmacy, in each year.

Table 19: Total Dollar Markup of Reimbursements Over NADAC for Affiliated and Non-Affiliated Pharmacies (millions USD) While Controlling for Product Mix, All Payor Types, 2020-2022

Specialty Status	Brand or Generic	Affiliated Dollar Markup	Non-Affiliated Dollar Markup
All	All	-$17,413	$1,985
All	Branded	-$51,444	-$31,733
All	Generic	$34,184	$33,700
Non-Specialty	All	-$14,811	$8,156
Non-Specialty	Branded	-$40,087	-$19,972
Non-Specialty	Generic	$25,429	$28,108
Specialty	All	-$2,628	-$6,170
Specialty	Branded	-$11,383	-$11,761
Specialty	Generic	$8,755	$5,592

Sources: NADAC data; Specs 12-14 of Caremark, Express Scripts, and Optum Rx 6(b) Submissions to the FTC.

Notes:

1. Markup calculated as Mix Adjusted Reimbursement Price - Mix Adjusted NADAC Price.
2. Reimbursement reflects: amount paid by PBM to pharmacy + patient pay amount + other payor recognized amount.
3. Restrictions (brand vs generic, specialty vs non-specialty) are based on PBM internal drug designations.
4. This analysis includes overlapping NDCs with at least 100 30-day prescriptions for each PBM, at each type of pharmacy, in each year.

Table 20: Difference between the Affiliated and Non-Affiliated Total Dollar Markup of Reimbursements Over NADAC (millions USD) While Controlling for Product Mix, All Payor Types, 2020-2022

Specialty Status	Brand or Generic	Affiliated Less Non-Affiliated Dollar Markup
All	All	-$19,398
All	Branded	-$19,710
All	Generic	$484
Non-Specialty	All	-$22,967
Non-Specialty	Branded	-$20,115
Non-Specialty	Generic	-$2,679
Specialty	All	$3,542
Specialty	Branded	$378
Specialty	Generic	$3,163

Sources: NADAC data; Specs 12-14 of Caremark, Express Scripts, and Optum Rx 6(b) Submissions to the FTC.

Notes:

1. Reimbursement reflects: amount paid by PBM to pharmacy + patient pay amount + other payor recognized amount.
2. Restrictions (brand vs generic, specialty vs non-specialty) are based on PBM internal drug designations.
3. This analysis includes overlapping NDCs with at least 100 30-day prescriptions for each PBM, at each type of pharmacy, in each year.

Table 21: Comparison of Total Drug Payments at Affiliated and Non-Affiliated Pharmacies (based on Gross Plan Sponsor + Member Payment per 30-Day Rx), All Payor Types, 2017-2022

Specialty Status	Brand or Generic	Ratio of Affiliated to Non-Affiliated Expenditures
All	All	1.01
All	Branded	1.01
All	Generic	0.99
Non-Specialty	All	0.97
Non-Specialty	Branded	0.98
Non-Specialty	Generic	0.95
Specialty	All	1.05
Specialty	Branded	1.04
Specialty	Generic	1.20

Sources: Specs 12-14 of Caremark, Express Scripts, and Optum Rx 6(b) Submissions to the FTC.

Notes:

1. Average payment per 30-day equivalent prescription is calculated at the year, payor type, PBM level for both affiliated and non-affiliated pharmacies for each overlapping NDC.

2. This analysis includes overlapping NDCs with at least 100 30-day prescriptions for each PBM, at each type of pharmacy, in each year.

Methodology: Affiliated and Non-Affiliated Expenditure Comparison with Gross Payments

To compare the overall cost of drugs purchased at affiliated and non-affiliated pharmacies, we first consider what plan sponsors and members' total payment would be if all drugs were purchased at the average cost at affiliated pharmacies and compare this to what their total payment would be if all drugs were purchased at the average cost at non-affiliated pharmacies.

For each PBM in each year 2017-2022, we identify all NDCs that had at least 100 30-day prescriptions covered by the PBM at an affiliated pharmacy and at least 100 30-day prescriptions covered by the PBM at a non-affiliated pharmacy. We then calculate, for each NDC/PBM/payor type/year combination, the average total payment per 30-day prescription by plan sponsors and members at affiliated pharmacies (P_a) and at non-affiliated pharmacies (P_n). We also calculate the total number of 30-day prescriptions for that NDC/PBM/payor type/year combination across both affiliated and non-affiliated pharmacies (Q). We then calculate what the total payment for each combination would have been if all purchases were made at (i) affiliated pharmacies (by multiplying the payment (P_a) by the quantity (Q) such that $TE_a = P_a * Q$); and (ii) non-affiliated pharmacies (by multiplying the payment (P_n) by the quantity (Q) such that $TE_n = P_n * Q$). We sum these total payments across all NDC/PBM/payor type/year combinations for affiliated pharmacies and for non-affiliated pharmacies and calculate the ratio of the two sums.

Table 22: Comparison of Total Drug Payments at Affiliated and Non-Affiliated Pharmacies (based on Gross Plan Sponsor + Member Payment per Unit), All Payor Types, 2017-2022

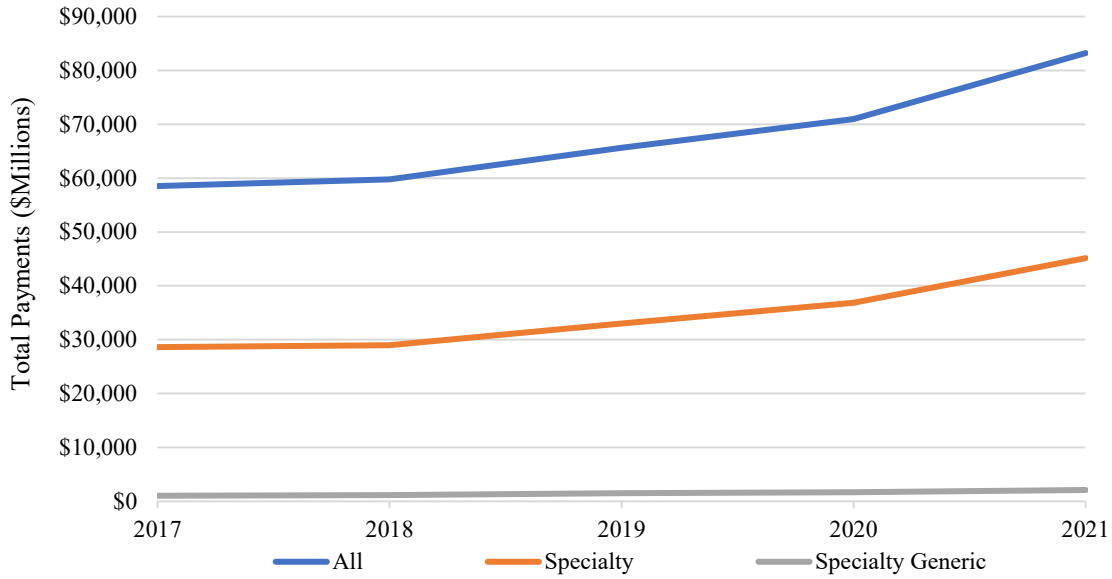
Specialty Status	Brand or Generic	Ratio of Affiliated to Non-Affiliated Expenditures
All	All	1.00
All	Branded	1.01
All	Generic	0.96
Non-Specialty	All	0.93
Non-Specialty	Branded	0.93
Non-Specialty	Generic	0.93
Specialty	All	1.08
Specialty	Branded	1.08
Specialty	Generic	1.17

Sources: Specs 12-14 of Caremark, Express Scripts, and Optum Rx 6(b) Submissions to the FTC.

Notes:

1. Average payment per unit equivalent prescription is calculated at the year, payor type, PBM level for both affiliated and non-affiliated pharmacies for each overlapping NDC.
2. This analysis includes overlapping NDCs with at least 100 30-day prescriptions for each PBM, at each type of pharmacy, in each year.

Figure 22: Total Spending by Plan Sponsors and Members at All Non-Affiliated Independent Pharmacies 2017-2021



Sources: Specs 12-14 of Caremark, Express Scripts, and Optum Rx 6(b) Submissions to the FTC.
Notes: Not all PBM data runs through December 2022, and thus 2022 data is omitted.

Table 23: Non-Affiliated Pharmacy Share of Total Spending and Volume

Drug Type	2017	2018	2019	2020	2021	2022
Gross Sponsor + Patient Pay						
All Drugs	62.0%	60.8%	60.1%	59.2%	59.3%	58.2%
Specialty	48.4%	47.3%	46.8%	46.6%	46.8%	45.1%
Specialty Generic	52.9%	50.2%	48.1%	46.6%	48.0%	48.4%
Pharmacy Reimbursement						
All Drugs	61.6%	60.3%	59.6%	58.8%	58.9%	57.8%
Specialty	48.2%	47.1%	46.6%	46.4%	46.4%	44.8%
Specialty Generic	50.9%	47.3%	45.9%	45.3%	46.0%	45.2%
Volume						
All Drugs	72.7%	71.8%	71.3%	70.9%	71.2%	71.9%
Specialty	56.9%	55.5%	55.1%	54.4%	54.7%	53.5%
Specialty Generic	65.6%	65.0%	64.4%	64.5%	65.7%	66.1%

Sources: Specs 12-14 of Caremark, Express Scripts, and Optum Rx 6(b) Submissions to the FTC.

Table 24: Non-Affiliated Independent Pharmacy Share of Total Spending and Volume

Drug Type	2017	2018	2019	2020	2021	2022
Gross Sponsor + Patient Pay						
All Drugs	24.7%	23.4%	23.5%	22.6%	23.2%	22.8%
Specialty	26.6%	24.3%	24.2%	23.0%	24.5%	24.2%
Specialty Generic	25.5%	24.6%	25.2%	24.0%	24.3%	24.5%
Pharmacy Reimbursement						
All Drugs	24.7%	23.2%	23.3%	22.4%	23.1%	22.7%
Specialty	26.4%	24.1%	24.0%	22.9%	24.3%	24.0%
Specialty Generic	25.0%	23.2%	23.9%	23.4%	23.8%	23.8%
Volume						
All Drugs	19.8%	19.5%	19.5%	19.2%	18.6%	17.8%
Specialty	28.0%	25.8%	24.8%	23.7%	24.6%	24.2%
Specialty Generic	23.4%	23.5%	23.2%	22.8%	23.6%	23.7%

Sources: Specs 12-14 of Caremark, Express Scripts, and Optum Rx 6(b) Submissions to the FTC.

Table 25: Regression Analysis of Total Drug Payments at Affiliated and Non-Affiliated Pharmacies (based on Gross Plan Sponsor + Member Payment per 30-Day Rx), All Payor Types, 2017-2022

Dependent Variable: Log of Gross Sponsor + Member Payments per 30-Day Equivalent Prescription

	Specialty Drugs Only	Non-Specialty Drugs Only	Specialty Drug Share of Total Payments	Weighted Average of Exponentiated Coefficients
	(1)	(2)		
Affiliated Pharmacy Dummy Coefficient (30-Day Rx Weight)	0.064***	-0.144***	49%	-0.036
Affiliated Pharmacy Dummy Coefficient (Unweighted)	0.071***	-0.121***	49%	-0.022
Observations	76,428	318,055		

Sources: Specs 12-14 of Caremark, Express Scripts, and Optum Rx 6(b) Submissions to the FTC.

Notes:

1. *** p < 0.01, ** p < 0.05, * p < 0.1; Clustered standard errors on NDC are used; Observations are weighted by 30-day Rx volume.

2. Includes NDCs with at least 100 30-day prescriptions for each PBM, at each type of pharmacy, in each year.

3. The regression includes year fixed effects (2017-2022), payor fixed effects (commercial, Medicare, Medicaid), PBM fixed effects, and NDC fixed effects.

4. The weighted average coefficient is calculated as the sum of the specialty and non-specialty shares of drug total payments multiplied by their associated exponentiated coefficient values.