



FEDERAL TRADE COMMISSION

Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies

Interim Staff Report

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I. EXECUTIVE SUMMARY

This Interim Report is part of an ongoing study by the Federal Trade Commission (“FTC” or the “Commission”) of pharmacy benefit managers (“PBMs”) and their impact on access to and affordability of medicines. It describes how, amidst increasing vertical integration and concentration, these powerful middlemen may be profiting by inflating drug costs and squeezing Main Street pharmacies.

PBMs are at the center of the complex pharmaceutical distribution chain that delivers a wide variety of medicines from manufacturers to patients. PBMs serve as middlemen, negotiating the terms and conditions for access to prescription drugs for hundreds of millions of Americans. Due to decades of mergers and acquisitions, the three largest PBMs now manage nearly 80 percent of all prescriptions filled in the United States. They are also vertically integrated, serving as health plans and pharmacists, and playing other roles in the drug supply chain as well. As a result, they wield enormous power and influence over patients’ access to drugs and the prices they pay. This can have dire consequences for Americans, with nearly three in ten surveyed Americans reporting rationing or even skipping doses of their prescribed medicines due to high costs.¹

PBMs also exert substantial influence over independent pharmacies, who struggle to navigate contractual terms imposed by PBMs that they find confusing, unfair, arbitrary, and harmful to their businesses. Between 2013 and 2022, about ten percent of independent retail pharmacies in rural America closed. Closures of local pharmacies affect not only small business owners and their employees, but also their patients. In some rural and medically underserved areas, local community pharmacies are the main healthcare option for Americans, who depend on them to get a flu shot, an EpiPen, or other lifesaving medicines.²

PBMs oversee critical decisions about access to and affordability of medications without transparency or accountability to the public. Indeed, PBM business practices and their effects remain extraordinarily opaque. Accordingly, in 2022, the FTC issued special orders pursuant to

¹ Ashley Kirzinger et al., *Public Opinion on Prescription Drugs and Their Prices*, KAISER FAM. FOUND. (Aug. 21, 2023), <https://www.kff.org/health-costs/poll-finding/public-opinion-on-prescription-drugs-and-their-prices>; see also Laryssa Mykyta & Robin A. Cohen, *Characteristics of Adults Aged 18–64 Who Did Not Take Medication as Prescribed to Reduce Costs: United States, 2021*, NAT’L CTR. FOR HEALTH STAT. DATA BRIEF, June 2023, at 5 (finding by Centers for Disease Control and Prevention that 9.2 million adults in U.S. not taking prescription drugs as prescribed due to high medication costs).

² See Nat’l Rural Health Ass’n, FTC-2022-0015-0846-A1, at 3 (May 17, 2022), <https://www.regulations.gov/comment/FTC-2022-0015-0846> (“Given the unique size of rural pharmacies, they’re often the only outfit in town.”); JOANNE CONSTANTIN ET AL., RUPRI CTR. FOR RURAL HEALTH POL’Y ANALYSIS, RURAL AND URBAN PHARMACY PRESENCE – PHARMACY DESERTS 4 (2022), <https://rupri.public-health.uiowa.edu/publications/policybriefs/2022/Pharmacy%20Deserts.pdf> (“[M]ail-order services fail to replace the other fundamental functions provided by pharmacists beyond filling prescriptions, such as health screenings, patient education and counseling, and vaccinations.”); see also Remarks of Chair Lina M. Khan Regarding the 6(b) Study on Pharmacy Benefit Managers, FTC File No. P221200, at 1 (Feb. 17, 2022), https://www.ftc.gov/system/files/ftc_gov/pdf/p221200khanstatementrepbms.pdf (“[S]mall, local, and family-owned pharmacies—the backbone of so many communities across the nation . . . [are the] types of community institutions [that] have at times proven themselves to be superior at delivering for their patients and customers.”); Statement of Comm’r Alvaro M. Bedoya Regarding the 6(b) Orders to Study Contracting Practices of Pharmacy Benefit Managers (June 7, 2022), https://www.ftc.gov/system/files/ftc_gov/pdf/Bedoya_Statement_re_PBM_Study_%28FINAL%29_6-7-2022.pdf (“People say independent pharmacies are a ‘critical part’ of the healthcare infrastructure. In many parts of rural and urban America, independent pharmacies are the healthcare infrastructure, full stop.”).

Section 6(b) of the Federal Trade Commission Act (the “6(b) Orders” or “Orders”) to the six largest PBMs—Caremark Rx, LLC; Express Scripts, Inc.; OptumRx, Inc.; Humana Pharmacy Solutions, Inc.; Prime Therapeutics LLC; and MedImpact Healthcare Systems, Inc. (the “PBM respondents” or “respondents”).³ The Orders requested data and documents regarding these six large PBMs’ businesses and business practices. In May and June 2023, the FTC issued supplemental Orders to produce data and documents to three additional PBM-affiliated entities.⁴

The FTC’s ongoing review of materials produced by the PBMs to date, and publicly available data, focuses on the impact of increased consolidation and vertical integration involving the six largest PBMs on the accessibility and affordability of prescription drugs.

Although the FTC issued its Orders to the PBMs over two years ago, some of the PBM respondents have not yet fully complied; they have not yet completed their required submissions. The failure of certain respondents to timely produce data and documents has hindered the ability of the Commission to perform its statutory mission. FTC staff has demanded that the companies finalize their productions required by the Orders promptly and eagerly awaits promised productions. If, however, any of the companies fail to fully comply with the Orders or engage in further delay tactics, the FTC can take them to court to compel compliance.

Even as FTC staff continues to press the PBM respondents to turn over the required information, the Commission is committed to ensuring that delay tactics by some companies do not prevent it from sharing preliminary findings with the public and policymakers as quickly as possible. This Interim Report accordingly provides the following key insights supported by the documents and data obtained to date, as well as by publicly available information:

- ***The market for pharmacy benefit management services has become highly concentrated, and the largest PBMs are now also vertically integrated with the nation’s largest health insurers and specialty and retail pharmacies.*** Over the past two decades, the PBM industry has undergone substantial change as a result of horizontal consolidation and vertical integration. The top three PBMs processed nearly 80 percent of the approximately 6.6 billion prescriptions dispensed by U.S. pharmacies in 2023, while the top six PBMs processed more than 90 percent.⁵ All of the top six PBMs are vertically integrated downstream, operating their own mail order and specialty pharmacies, while one PBM owns and operates the largest chain of retail pharmacies in the nation. Pharmacies affiliated with the three largest PBMs now account for nearly 70 percent of all specialty drug revenue. In addition, five of the top six

³ See Press Release, Fed. Trade Comm’n, FTC Launches Inquiry Into Prescription Drug Middlemen Industry (June 6, 2022), <https://www.ftc.gov/news-events/news/press-releases/2022/06/ftc-launches-inquiry-prescription-drug-middlemen-industry>. These entities will be referred to herein, respectively, as “CVS Caremark,” “Express Scripts” or “ESI,” “OptumRx,” “Humana Pharmacy Solutions” or “HPS,” “Prime,” and “MedImpact.”

⁴ See Press Release, Fed. Trade Comm’n, FTC Deepens Inquiry into Prescription Drug Middlemen (May 17, 2023), <https://www.ftc.gov/news-events/news/press-releases/2023/05/ftc-deepens-inquiry-prescription-drug-middlemen> (issuing 6(b) Orders to two PBM-affiliated GPOs, Zinc Health Services, LLC (“Zinc”) and Ascent Health Services, LLC (“Ascent”)); Press Release, Fed. Trade Comm’n, FTC Further Expands Inquiry Into Prescription Drug Middlemen Industry Practices (June 8, 2023), <https://www.ftc.gov/news-events/news/press-releases/2023/06/ftc-further-expands-inquiry-prescription-drug-middlemen-industry-practices> (issuing 6(b) Order to Emisar Pharma Services LLC (“Emisar”).

⁵ See ADAM J. FEIN, DRUG CHANNELS INST., THE 2024 ECONOMIC REPORT ON U.S. PHARMACIES AND PHARMACY BENEFIT MANAGERS 51, 163 (2024) [hereinafter “DCI 2024 Report”] (estimating 2023 prescriptions and PBM shares).

PBMs are now part of corporate healthcare conglomerates that also own and operate some of the nation's largest health insurance companies, including three of the five largest health insurers in the country.⁶ Four of the PBMs are owned by publicly traded parent companies that own affiliates that operate health care clinics. Three have recently expanded into the drug private labeling business, partnering with drug manufacturers to distribute drug products under different trade names.⁷ Four healthcare conglomerates now account for an extraordinary 22 percent of all national health expenditures, as compared to 14 percent eight years ago.⁸

- ***As a result of this high degree of consolidation and vertical integration, the leading PBMs can now exercise significant power over Americans' access to drugs and the prices they pay.*** Decades ago, PBMs began as administrative service providers working to validate and process pharmacy benefits provided by separate insurance plans. They then expanded into negotiating with pharmaceutical manufacturers on behalf of those plan clients, developing reimbursement terms and conditions for pharmacies, and developing formularies (i.e., lists of drugs a health plan will cover and reimburse for). But now, after years of acquisitions, the leading PBMs are each part of massive healthcare conglomerates that are often comprised of a health insurer, pharmacies, and the PBM negotiator between health insurers and pharmacies—all rolled into one. The result is that the dominant PBMs can often exercise significant control over which drugs are available, at what price, and which pharmacies patients can use to access their prescribed medications.
- ***Vertically integrated PBMs may have the ability and incentive to prefer their own affiliated businesses, which in turn can disadvantage unaffiliated pharmacies and increase prescription drug costs.*** Vertical integration in PBM business structures, particularly with respect to integrated health insurers and specialty and mail order pharmacies, likely creates the ability and incentive for PBMs to increase utilization of certain drug products at affiliated pharmacies to generate the greatest revenue and profits for their respective conglomerates. As a result of vertical integration, PBM-affiliated pharmacies now compete with the unaffiliated pharmacies to distribute medications to patients. Our initial analyses in Section III suggest that certain PBMs may be steering patients to their affiliated pharmacies and away from unaffiliated pharmacies. Our analyses also highlight examples of affiliated pharmacies receiving significantly higher reimbursement rates than those paid to unaffiliated pharmacies for two case study drugs. These practices have allowed pharmacies affiliated with the three largest PBMs to retain levels of dispensing revenue well above estimated drug acquisition costs, resulting in nearly \$1.6 billion of additional revenue on just two cancer drugs in under three years.⁹
- ***Evidence suggests that increased concentration may give the leading PBMs the leverage to enter into complex and opaque contractual relationships that may disadvantage smaller, unaffiliated pharmacies and the patients they serve.*** Independent pharmacies generally lack the leverage to negotiate terms and rates when enrolling in PBMs' pharmacy networks, and subsequently may face effectively unilateral changes in contract terms without meaningful choice and alternatives. The proliferation of complex and opaque contract terms and

⁶ See *infra* § II.D.1.

⁷ See *infra* § II.D.3.

⁸ See *infra* § II.A.

⁹ See *infra* § III.B.2.

adjustments has increased uncertainty in pharmacy reimbursements, which can make it difficult for smaller pharmacies to manage basic business operations. For instance, the rates in PBM contracts with independent pharmacies often do not clearly reflect the amount the pharmacy will ultimately be paid.

- ***PBMs and brand drug manufacturers sometimes negotiate prescription drug rebates that are expressly conditioned on limiting access to potentially lower cost generic alternatives.*** While this Interim Report principally focuses on the relationship between PBMs and pharmacies, we share evidence that PBMs and brand pharmaceutical manufacturers sometimes enter agreements to exclude generic drugs and biosimilars from certain formularies in exchange for higher rebates from the manufacturer.¹⁰ These exclusionary rebates may cut off patient access to lower-cost medicines and warrant further scrutiny by the Commission, policymakers, and industry stakeholders.

To date, FTC staff has reviewed more than 1,200 public comments to identify predominant areas of concern,¹¹ as well as initial submissions of internal documents and data from PBM respondents and their affiliates. Staff has also interviewed various industry experts and participants and reviewed other public data and information. The insights gained thus far underscore the importance and urgency of scrutinizing the role and influence of PBMs in the nation’s health care system. This is especially important since federal and state governments are the largest purchasers of healthcare.¹² We remain committed to providing timely updates as we receive and review additional information.

¹⁰ See *infra* § IV.

¹¹ Regulations.gov, Solicitation for Public Comments on the Impact of Prescription Benefit Managers’ Business Practices, FTC-2022-0015 (Feb. 24, 2022), <https://www.regulations.gov/docket/FTC-2022-0015>. Specifically, the FTC received 1,238 unique comments.

¹² See CTRS. FOR MEDICARE & MEDICAID SERVS., CMS ROADMAPS FOR THE TRADITIONAL FEE-FOR-SERVICE (FFS) PROGRAM: OVERVIEW 1 (2020) (“The Centers for Medicare & Medicaid Services (CMS) is the single largest payer for health care in the United States. Nearly 90 million Americans rely on health care benefits through Medicare, Medicaid, and the State Children’s Health Insurance Program”); Submission of Documents from 6(b) Order Respondents [hereinafter “Respondent(s) Document Submission(s)”] [REDACTED]

II. PBMS HAVE GAINED SIGNIFICANT POWER OVER PRESCRIPTION DRUG ACCESS AND PRICES THROUGH INCREASED CONCENTRATION AND VERTICAL INTEGRATION

Over the past 20 years, pharmacy benefit services have become increasingly concentrated. In 2004, the top three PBMs served a combined 190 million people and managed 52 percent of prescription drug claims.¹³ Today, the top three PBMs—CVS Caremark, Express Scripts, and OptumRx (together, the “Big 3”)—manage 79 percent of prescription drug claims for approximately 270 million people.¹⁴ With the next three largest PBMs—Humana Pharmacy Solutions, MedImpact, and Prime—the six largest PBMs (together, the “Big 6”) now manage 94 percent of prescription drug claims in the United States.¹⁵





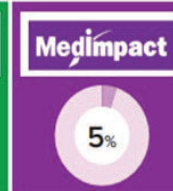

In addition to this high degree of horizontal concentration, the Big 6 PBMs have become vertically integrated within massive conglomerates that provide a broad range of services across the pharmaceutical supply chain and other segments of the healthcare sector, as illustrated in Figure 1. Various PBMs are now vertically integrated with upstream suppliers of goods and services, including drug private labelers and provider groups. PBMs are also vertically integrated with midstream distributors, including retail, mail order, and specialty pharmacies. Downstream, PBMs are vertically integrated with large health insurers which, through their health plans and plan sponsor services, provide coverage for hundreds of millions of Americans.

¹³ The top three PBMs at the time were Caremark Rx (later acquired by CVS), Medco Health Solutions (later acquired by Express Scripts), and Express Scripts. See Robert F. Atlas, *The Role of PBMs in Implementing the Medicare Prescription Drug Benefit*, 23 HEALTH AFFS. 504, 506 (2004) (reporting PBM covered lives, including Caremark Rx (80 million members), Medco Health Solutions (60 million members), and Express Scripts (50 million members)); DAN MENDELSON & HEALTH STRATEGIES CONSULTANCY LLC, FOLLOW THE PILL: UNDERSTANDING THE U.S. COMMERCIAL PHARMACEUTICAL SUPPLY CHAIN 16 (2005) (reporting PBM market shares by number of prescriptions, including Caremark Rx (20 percent), Medco Health Solutions (18 percent), and Express Scripts (14 percent)); see also FED. TRADE COMM’N, PHARMACY BENEFIT MANAGERS: OWNERSHIP OF MAIL ORDER PHARMACIES 1-4 (2005) (providing background on PBM industry during this time period).

¹⁴ CVS Caremark services 103 million members. See *By the Numbers*, CVS CAREMARK, <https://www.caremark.com/about-us.html> (last visited June 17, 2024); ESI services more than 100 million members. See *Express Scripts in 2023: Supporting Clients, Patients, and Health Plans*, EVERNORTH HEALTH, INC. (Dec. 13, 2023), <https://www.express-scripts.com/corporate/about>; OptumRx services over 66 million members. See *Pharmacy Benefit Management Solutions*, OPTUMRX, <https://professionals.optumrx.com/services/pbm.html> (last visited June 17, 2024).

¹⁵ See DCI 2024 Report, *supra* note 5, at 163.

Figure 1. PBMs: Ownership and Vertical Integration¹⁶

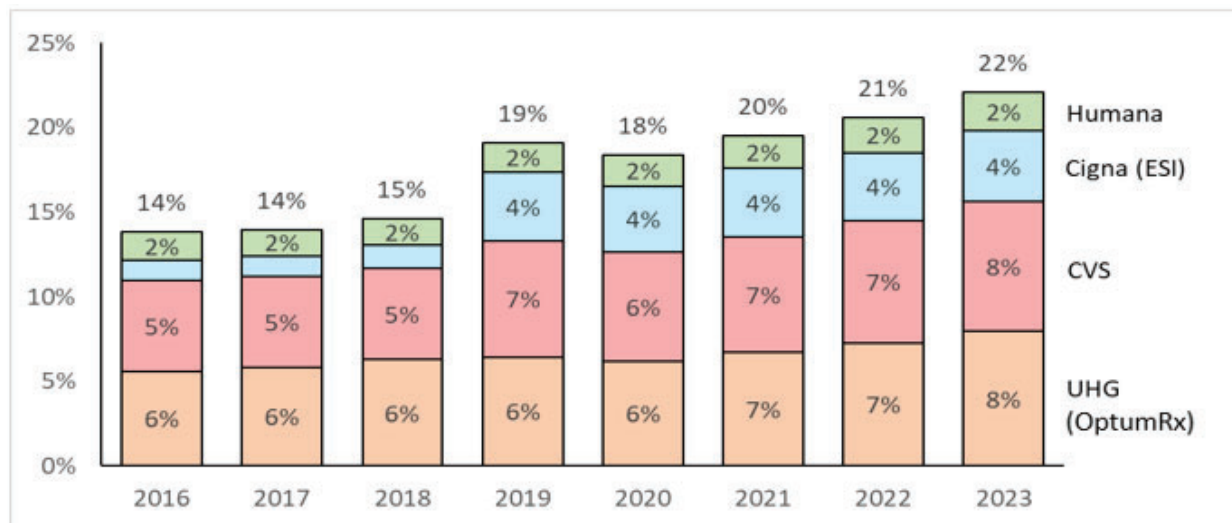
Parent/Owner	CVS Health Corporation	The Cigna Group	UnitedHealth Group Inc.	Humana Inc.	MedImpact Holdings Inc.	19 BlueCross BlueShield plans
Drug Private Labeler	Cordavis Limited	Quallent Pharmaceuticals	NUVAILA			
Health Care Provider	MinuteClinic, Signify Health	Evernorth Care Group	Optum Health	CenterWell		
Pharmacy Benefit Manager						
"PBM GPO"/ Rebate Aggregator	Zinc Health Services	Ascent Health Services	Emisar Pharma Services	Ascent (via contract)	Prescient Holdings Group LLC	Ascent (minority owner)
Pharmacy - Retail	CVS Pharmacy					
Pharmacy - Mail Order	CVS Caremark Mail Service Pharmacy	Express Scripts Pharmacy	Optum Rx Mail Service Pharmacy	CenterWell Pharmacy	Birdi, Inc.	Express Scripts Pharmacy (via contract)
Pharmacy - Specialty	CVS Specialty Pharmacy	Accredo	Optum Specialty Pharmacy	CenterWell Specialty Pharmacy	Specialty by Birdi	Accredo (via contract)
Health Insurer	Aetna	Cigna Healthcare	UnitedHealthcare	Humana		19 BlueCross BlueShield plans

This increased concentration and vertical integration has resulted in enormous healthcare conglomerates that can exercise vast control over huge swaths of the healthcare sector. Four of the PBM respondents are part of publicly traded healthcare conglomerates: UnitedHealth Group Inc. (“United” or “UHG”), CVS Health Corp. (“CVS”), The Cigna Group (“Cigna”), and Humana Inc. (“Humana”). In 2016, the combined revenue of these four conglomerates totaled \$456 billion and equaled 14 percent of national health expenditures in the United States. Today, their combined revenue exceeds \$1 trillion and equals 22 percent of national health expenditures, as illustrated in Figure 2 below. At the same time, the four entities also greatly expanded their profits as combined

¹⁶ Figure prepared by FTC staff. PBM shares are based on total equivalent prescription claims managed in 2023. The vertical segments include selected entities; not all affiliated entities are listed. For example, in December 2022, Prime completed an acquisition of Magellan Rx, which included specialty and mail order pharmacy and PBM business units. See DCI 2023 Report, *infra* note 59, at 87, n. 200. In addition, the figure is simplified in certain respects. For example, PBMs are presented as intermediaries between the upstream (drug private labeler and health care provider) and midstream (pharmacy) segments, though they also act as intermediaries between the upstream and downstream (insurer) and the midstream and downstream segments.

adjusted operating profits and net income grew by 133 and 159 percent, respectively, over the 2016 to 2023 period.¹⁷

Figure 2. PBM Parent Entity Revenue As a Percent of National Health Expenditures, 2016-2023¹⁸



Much of the growth experienced by the four healthcare conglomerates in Figure 2 has been driven by mergers and acquisitions. According to PitchBook, these four entities and their subsidiaries (which include the largest PBMs) collectively engaged in more than 190 transactions over the 2016 to 2023 period (United, 88; CVS, 53; Humana, 39; and Cigna, 14).¹⁹ Illustrating the matter, the

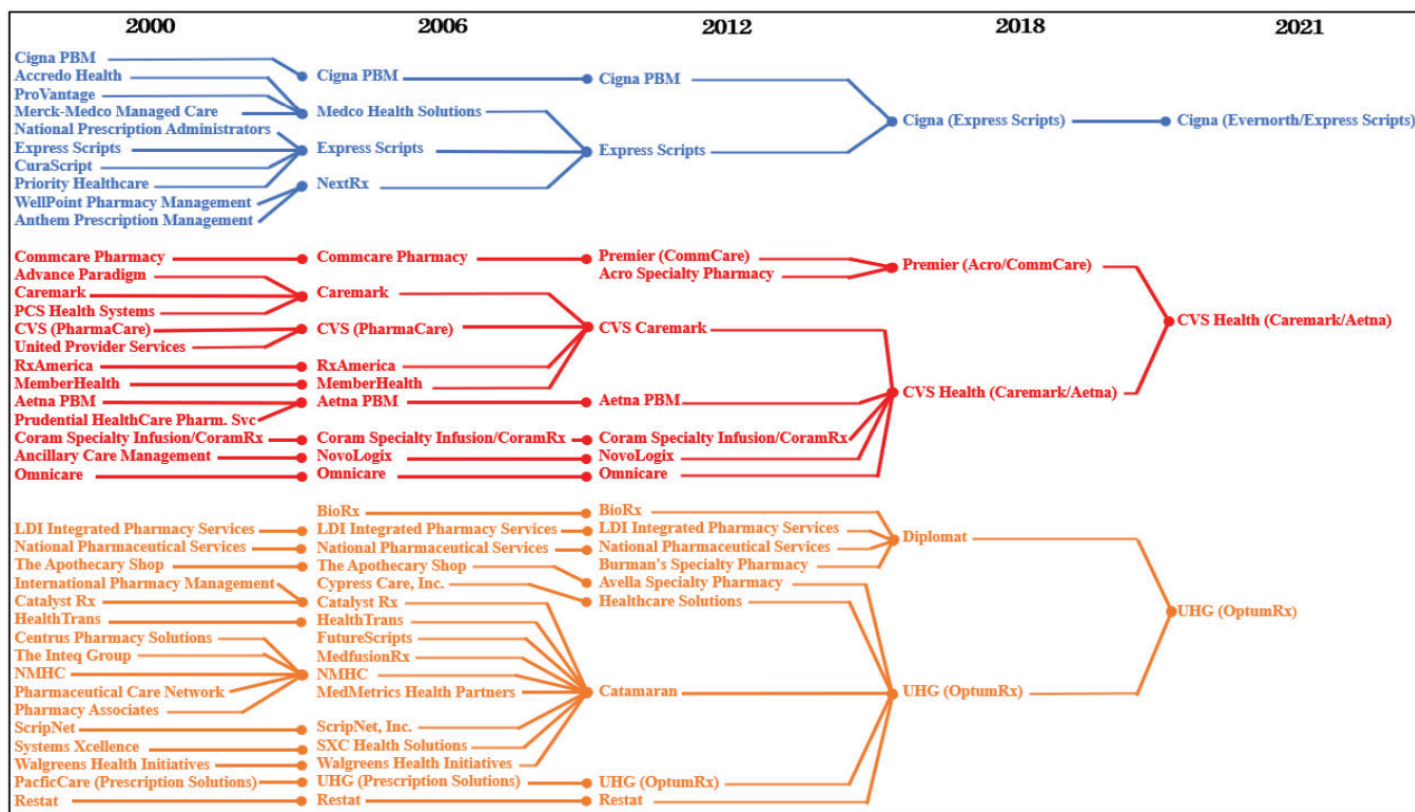
¹⁷ Company financial data compiled from Forms 10-K of UnitedHealth Group Inc., CVS Health Corp., Cigna Group, and Humana, Inc. See UnitedHealth Group Inc., Annual Report, at 36, 38 (Form 10-K, 2017); UnitedHealth Group Inc., Annual Report, at 26-27 (Form 10-K, 2023); CVS Health Corp., Annual Report, at 3, 6 (Form 10-K, 2017); CVS Health Corp., Annual Report, at 81, 109 (Form 10-K, 2023); Cigna Group, Annual Report, at 36, 38 (Form 10-K, 2017); Cigna Group, Annual Report, at 52, 75 (Form 10-K, 2023); Humana Inc., Annual Report, at 45, 132-33 (Form 10-K, 2017); Humana Inc., Annual Report, at 49, 117-18 (Form 10-K, 2023).

¹⁸ Figure prepared by FTC staff. Values presented at top of bars reflect the four companies' combined revenues as a percent of national health expenditures. Company financial data compiled from UnitedHealth Group Inc., Annual Report, Forms 10-K 2016-2023 (2016 at 59; 2017 at 34; 2018 at 41; 2019 at 50; 2020 at 79; 2021 at 79; 2022 at 78; 2023 at 75); CVS Health Corp., Annual Report, Forms 10-K 2016-2023 (2016 at 30; 2017 at 39; 2018 at 111; 2019 at 57; 2020 at 101; 2021 at 103; 2022 at 106; 2023 at 109); Cigna Group, Annual Report, Forms 10-K 2016-2023 (2016 at 59; 2017 at 58; 2018 at 41; 2019 at 50; 2020 at 79; 2021 at 79; 2022 at 78; 2023 at 70); Humana Inc., Annual Report, Forms 10-K 2016-2023 (2016 at 38; 2017 at 81; 2018 at 79; 2019 at 68; 2020 at 48; 2021 at 69; 2022 at 75; 2023 at 70). National Health Expenditure data are compiled from CMS data. See *NHE Summary, Including Share of GDP, CY 1960-2022*, CTRS. FOR MEDICARE & MEDICAID SERVS. (Excel document) (last modified Dec. 13, 2023), <https://www.cms.gov/data-research/statistics-trends-and-reports/national-health-expenditure-data/historical>; *NHE Projections, Table 1: National Health Expenditures and Selected Economic Indicators*, CTRS. FOR MEDICARE & MEDICAID SERVS. (Excel document) (last modified June 12, 2024), <https://www.cms.gov/data-research/statistics-trends-and-reports/national-health-expenditure-data/projected> (2023 projected).

¹⁹ FTC analysis of PitchBook Data, Inc. data. See also David Wainer, *What Happens When Your Insurer Is Also Your Doctor and Your Pharmacist: Health Insurers Like UnitedHealth Group Are Seeking to Control Many Parts of Our Healthcare System, Creating Potential Conflicts of Interest*, WALL ST. J. (June 13, 2024), <https://www.wsj.com/health/healthcare/what-happens-when-your-insurer-is-also-your-doctor-and-your-pharmacist->

Arkansas Attorney General diagrammed some of the mergers and acquisitions among the Big 3 PBMs' parent entities between 2000 and 2021, as shown in Figure 3 below. For the two nonpublic PBMs in our study, PitchBook reported only four acquisitions over the 2016 to 2023 period (Prime, 3; MedImpact, 1).²⁰

Figure 3. PBM Parent Entity Consolidation²¹



Additionally, the healthcare conglomerates appear to be driving growth by generating increasing levels of revenue from their vertically integrated affiliates. For example, a study by the Brookings Institution found that over the 2016 to 2019 period, United's share of spending associated with its affiliates rose by more than 250 percent to 17 percent of the company's total spending, and CVS' share of affiliate spending increased more than five-fold to nearly 13 percent of total spending.²²

8df727af (noting United's non-insurer subsidiaries "spent about \$82 billion on nearly 100 acquisitions" over last 20 years).

²⁰ FTC analysis of PitchBook Data, Inc. data.

²¹ Complaint ¶ 312, Arkansas *ex rel.* Rutledge v. Eli Lilly & Co., No. 60cv-22-2976, (May 11, 2022), https://content.govdelivery.com/attachments/ARAG/2022/05/11/file_attachments/2156162/2022-05-11-%20Insulin%20Complaint%20FINAL%20DRAFT.pdf.

²² Richard G. Frank & Conrad Milhaupt, *Medicare Advantage Spending, Medical Loss Ratios, and Related Businesses: An Initial Investigation*, BROOKINGS INST. (Mar. 24, 2023), <https://www.brookings.edu/articles/medicare-advantage-spending-medical-loss-ratios-and-related-businesses-an-initial-investigation>; *see also* Wainer, *supra* note 19 (noting as conglomerates have become more vertically integrated, "they are increasingly paying themselves," resulting in "UnitedHealth's so-called intercompany eliminations more than doubl[ing] in five years to \$136 billion in 2023").

Moreover, there is significant common ownership of publicly traded shares of United, CVS, Cigna, and Humana, which can reduce incentives of companies to compete and raise other competitive concerns, as the Commission and the Department of Justice (“DOJ”) have previously explained.²³ Shareholders with stakes in at least three of these four companies own almost one quarter of a trillion dollars, or 35.5 percent, of the companies’ combined market value, while shareholders with stakes in all four companies own 28 percent.²⁴

Below we provide brief overviews of the services provided by PBMs and the various vertically integrated goods and services offered by their parent and affiliated entities.

A. PBMS INCREASINGLY CONTROL AMERICANS’ ACCESS TO DRUGS AND THE PRICES THEY PAY

PBMs started providing claims processing and administrative services for health insurers in the late 1960s.²⁵ Over time, their service offerings expanded and PBMs soon acted as intermediaries between various segments of the pharmaceutical supply chain, including drug manufacturers (upstream suppliers), pharmacies (midstream distributors), and payers, including health insurers, employers, unions, and federal and state governments (downstream providers of health plans for beneficiaries).²⁶ Today, PBMs provide services for commercial health plans, Medicare Part D prescription drug plans, and Medicaid managed care plans, including plans offered by affiliated health insurers and other payers.

1. Overview of PBM services

Key services offered by PBMs include:

Drug Formulary Design. PBMs and their health plan clients²⁷ often specify the brand, generic, and specialty drugs that will be included on drug formularies (and therefore covered by payers for

²³ See U.S. DEP’T OF JUSTICE & FED. TRADE COMM’N, MERGER GUIDELINES 28 (Dec. 18, 2023) (noting common ownership “can reduce competition by softening firms’ incentives to compete, even absent any specific anticompetitive act or intent”). Other competition concerns relate to (i) “giving the partial owner the ability to influence the competitive conduct of the target firm” and (ii) “giving competing firms or their common owners access to non-public, competitively sensitive information about each other.” *Id.* at 28-29. There is a growing academic literature (both legal and economic) examining common ownership, or horizontal shareholding. See, e.g., Einer Elhauge, *Horizontal Shareholding*, 129 HARV. L. REV. 1267, 1268-69 (2016); Fiona Scott Morton & Herbert Hovenkamp, *Horizontal Shareholding and Antitrust Policy*, 127 YALE L.J. 2026, 2036 (2018); José Azar et al., *Anticompetitive Effects of Common Ownership*, 74 J. FIN. 1, 2 (2018); Martin Schmalz, *Recent Studies on Common Ownership, Firm Behavior, and Market Outcomes*, 66 ANTITRUST BULL. 1, 6 (2021).

²⁴ As of March 21, 2024, Vanguard owns over nine percent of each company and its investments across the four companies total \$64 billion; Blackrock owns about seven to nine percent of each company and its investments total \$55.7 billion; State Street owns roughly four-and-a-half to five percent of each company and its investments total \$33.7 billion. Common ownership data compiled from Yahoo! Finance. See *UnitedHealth Group Incorporated (UNH): Holders*, YAHOO! FIN., <https://finance.yahoo.com/quote/UNH/holders> (last visited June 20, 2024); *CVS Health Corporation (CVS): Holders*, YAHOO! FIN., <https://finance.yahoo.com/quote/CVS/holders> (last visited June 20, 2024); *The Cigna Group (CI): Holders*, YAHOO! FIN., <https://finance.yahoo.com/quote/CI/holders>; *Humana Inc. (HUM): Holders*, YAHOO! FIN., <https://finance.yahoo.com/quote/HUM/holders> (last visited June 20, 2024).

²⁵ See LAWTON ROBERT BURNS, THE HEALTHCARE VALUE CHAIN: DEMYSTIFYING THE ROLE OF GPOS AND PBMS 436-38 (1st ed. 2022); T. Joseph Mattingly & David A. Hyman, *Pharmacy Benefit Managers: History, Business Practices, Economics, and Policy*, 4 JAMA HEALTH F. 1, 2 (2023).

²⁶ See BURNS, *supra* note 25, at 433 (describing evolution of PBM service offerings over past fifty years).

²⁷ For ease of reference, “health plans” in this context also refer to self-insured employers that contract with PBMs.

their beneficiaries) and the associated patient cost-sharing requirements.²⁸ PBMs use formulary development committees,²⁹ which are generally comprised of PBM employees from across a range of functional areas, to determine formulary drug placements.³⁰ While these committees review clinical recommendations made by another committee (the pharmacy and therapeutics committee), our initial review of the PBM respondents’ internal documents finds that they also take into account business considerations and make formulary determinations to maximize profits (for themselves and their health plan clients).³¹ Formulary designs may be broad (covering all or most drugs), narrow (covering a limited set of drugs), or tiered (requiring lower cost sharing for preferred drugs and higher cost sharing for nonpreferred drugs).³² PBMs generally maintain multiple formularies to accommodate the preferences of their different health plan clients.³³ PBM and health plan decisions about formulary designs influence whether insured Americans can access the drugs their doctors prescribe, and at what cost. As discussed below, certain formulary designs may have the effect of preferencing the PBMs’ own affiliated pharmacies, even if an unaffiliated rival pharmacy may provide health plans with the same drugs at a better price.³⁴

Drug Manufacturer Contracting. PBMs often enter into rebate contracts with drug manufacturers, under which the manufacturer provides a payment to PBMs (which may be largely or entirely passed on to health plans) in exchange for favorable formulary placement of the rebated product as well as various administrative fees. While PBMs historically negotiated these contracts directly with drug manufacturers, the Big 3 PBMs recently established separate entities—

²⁸ *But see infra* note 158 and accompanying text (discussing information asymmetries that may hinder health plans from making fully informed decisions regarding drug formularies).

²⁹ Each of the Big 3 PBMs have formulary development committees but they refer to them using different names: CVS Caremark refers to its committee as the Formulary Review Committee, ESI refers to its committee as the Value Assessment Committee, and OptumRx refers to its committee as the Formulary Management Committee. *See* STAFF OF S. COMM. ON FIN., 116TH CONG., REP. ON INSULIN: EXAMINING THE FACTORS DRIVING THE RISING COST OF A CENTURY OLD DRUG 30-31 (Comm. Print 2021) [hereinafter “Senate Insulin Report”]. Subject to the recommendations of the PBMs’ pharmacy and therapeutics (“P&T”) committees, the PBMs’ formulary development committees make final formulary decisions based on “evaluating net cost, rebates, discounts, plan sponsor costs, utilization trends, and business benefit considerations.” *Id.* Some large health insurers use their own P&T committees to customize their formularies. *Id.*

³⁰ *See* Senate Insulin Report, *supra* note 29, at 36-37 (noting committees “may include representatives from formulary management, product management, trade relations, human resources, and clinical account management”).

³¹ *See, e.g.,* Respondent Document Submission [REDACTED]; Respondent Document Submission [REDACTED] (diagram of formulary development showing business factors and P&T recommendations flowing through formulary development committee); *see also* Senate Insulin Report, *supra* note 29, at 31; Mattingly & Hyman, *supra* note 25, at 3-4; DCI 2024 Report, *supra* note 5, at 150-51.

³² Cost sharing is “the amount of money spent by individuals on health care that is not paid for by [their] health insurance,” and may include “copays, deductibles, [and] coinsurance.” Cynthia Cox et al., *Health Care Costs and Affordability*, KAISER FAM. FOUND. (May 28, 2024), <https://www.kff.org/health-policy-101-health-care-costs-and-affordability/?entry=table-of-contents-introduction>. Patients are often responsible for different cost-sharing requirements depending on their health plan.

³³ *See* Mattingly & Hyman, *supra* note 25, at 3; DCI 2024 Report, *supra* note 5, at 150-51.

³⁴ *See infra* § III.A (showing PBMs steering commercial health plan members to affiliated pharmacies); § III.B (showing PBMs paying affiliated pharmacies very high reimbursement rates for selected drugs).

sometimes called rebate aggregators³⁵—to conduct these negotiations on behalf of the affiliated PBMs and their commercial clients, as discussed further below.³⁶ As a result of drug manufacturer rebates, the net prices of drugs to payers are often substantially less than the point-of-sale prices that determine patient cost sharing and deductibles at the pharmacy counter.³⁷ Below we share evidence showing that PBMs and drug manufacturers sometimes enter rebate agreements expressly conditioned on excluding generic drugs from coverage.³⁸

Pharmacy Contracting and Network Design. PBMs enter pharmacy contracts to create networks of pharmacies where insured patients may fill their prescriptions. PBM pharmacy contracts commonly include reimbursement rate and post-sale adjustment provisions that determine the amounts pharmacies are ultimately reimbursed.³⁹ To meet health plan client demands, some PBMs manage as many as several thousand pharmacy networks in any given year,⁴⁰ each with varying pharmacy compositions and features.⁴¹ A network can be open (including most pharmacies as in-network and imposing the same cost-sharing requirements across pharmacies) or limited (restricting the number of pharmacies available to health-plan beneficiaries).⁴² Another design,

³⁵ The PBMs refer to these entities as group purchasing organizations (or “GPOs”), though they do not perform traditional GPO functions. *See infra* § II.C.

³⁶ *See infra* § II.C.

³⁷ PBMs may retain and/or pass through to their health plan clients some or all of the rebates. *See* Mattingly & Hyman, *supra* note 25, at 5; DCI 2024 Report, *supra* note 5, at 285.

³⁸ *See infra* § IV.

³⁹ *See infra* § III.C.

⁴⁰ During the study period from 2017 to mid-2022, the number of unique pharmacy networks managed by PBM respondents ranged widely, with two PBMs having dozens of networks, two having from 100 to 300 networks, and two having roughly 2,000 to 5,000 networks.

[REDACTED]

[REDACTED] See Written Responses by 6(b) Order Respondents [hereinafter “Respondents Responses to 6(b) Order”]

[REDACTED]

⁴¹ *See, e.g.*, Respondent Responses to 6(b) Order [REDACTED] (noting some health plans choose pharmacy networks based on cost considerations while others choose based on convenience and their members’ preferences for local pharmacy locations and/or home delivery).

⁴² *See* Mattingly & Hyman, *supra* note 25, at 3; DCI 2024 Report, *supra* note 5, at 237-240; Respondents Responses to 6(b) Order [REDACTED] Only commercial health plans use limited pharmacy networks; Part D plans must contract with any interested pharmacy that meets the plan’s standard terms and conditions for network participation pursuant to Medicare’s “any willing pharmacy” requirement. 42 U.S.C. § 1395w-104(b)(1)(A); 42 C.F.R. § 423.120(a)(8).

often used by Medicare Part D plans, is the preferred network,⁴³ which includes many pharmacies as in-network and offers lower patient cost-sharing requirements when prescriptions are filled at preferred pharmacies.⁴⁴ Pharmacies participating in limited or preferred networks generally accept lower payments in exchange for higher prescription volume from the PBM, as the network restrictions and lower cost-sharing requirements drive patients to preferred pharmacies.⁴⁵ However, PBMs may also use network design, such as narrow networks, to steer patients to their own vertically integrated affiliated pharmacies—even if a rival unaffiliated pharmacy may provide the same or better pricing and terms to the PBM for its pharmacy services.⁴⁶

Utilization Management. PBMs offer various clinical management services that affect when and how patients can access drugs prescribed by their doctor—often referred to as “drug utilization.” Drug utilization management services help payers limit their costs, though concerns are routinely raised regarding potentially abusive utilization management practices that put payers’ financial interests before patients’ best interests.⁴⁷ As part of these services, PBMs can adopt and impose policies on prior authorization (which involves a review by a PBM-employed health care provider before a patient can obtain a prescribed drug), step therapy (which requires a patient to use a preferred, often lower-cost drug until the patient’s doctor determines that it has failed to treat the underlying condition before approving a non-preferred drug), and quantity limits (such as restricting the number of doses a patient can receive for a particular condition).⁴⁸ Below we share evidence that PBMs and drug manufacturers sometimes enter agreements that require prior authorization and step therapy to discourage patients’ utilization of generic drugs.⁴⁹

⁴³ 42 C.F.R. § 423.120(a)(9) (“[A] Part D plan that provides coverage other than defined standard coverage may reduce copayments or coinsurance for covered Part D drugs obtained through a preferred pharmacy . . .”).

⁴⁴ See Mattingly & Hyman, *supra* note 25, at 5-6; DCI 2024 Report, *supra* note 5, at 237-39; Respondents Document Submissions [REDACTED]

⁴⁵ See Mattingly & Hyman, *supra* note 25, at 5; DCI 2024 Report, *supra* note 5, at 237-39.

⁴⁶ See *infra* § III.B (showing PBMs steering to affiliated pharmacies and paying very high rates for selected drugs).

⁴⁷ See, e.g., Paula Span, *When ‘Prior Authorization’ Becomes a Medical Roadblock*, N.Y. TIMES (May 25, 2024); Michael McCauliff, *States Tackle Prior Authorizations Amid Outcry*, MOD. HEALTHCARE (Feb. 9, 2024); Wesam W. Ismail et al., *The Association Between Cost Sharing, Prior Authorization, and Specialty Drug Utilization: A Systemic Review*, 29 J. MANAGED CARE & SPECIALTY PHARMACY 449, 460 (May 2023) (reviewing literature and finding prior authorization requirements result in treatment delays); *2023 AMA Prior Authorization Physician Survey*, AM. MED. ASS’N (June 18, 2024), <https://www.ama-assn.org/system/files/prior-authorization-survey.pdf> (noting physician concerns with prior authorization requirements resulting in delayed care, abandoned treatments, and increased use of emergency department and hospital visits); see also Karen Van Nuys et al., USC Schaeffer, Leonard D. Schaeffer Center for Health Policy & Economics, FTC-2022-0015-0999, at 10 (May 25, 2022), <https://www.regulations.gov/comment/FTC-2022-0015-0999> (noting conflict of interest raised by PBMs managing prior authorization (“PA”) because PBMs “choos[e] how many and which drugs on formulary require a PA” while also generating fees for each PA reviewed); Geoffrey Joyce et al., *Medicare Part D Plans Greatly Increased Utilization Restrictions on Prescription Drugs, 2011–20*, 43 HEALTH AFFS 391, 391 (2024) (finding prior authorization, step therapy, and formulary exclusion restrictions increasing in Part D plans, “rising from an average of 31.9 percent of compounds restricted in 2011 to 44.4 percent restricted in 2020”).

⁴⁸ See Mattingly & Hyman, *supra* note 25, at 3-5; DCI 2024 Report, *supra* note 5, at 158-59.

⁴⁹ See *infra* § IV.

Claims Processing. PBMs use electronic communications systems to route patient prescription information between pharmacies and the PBMs. The systems communicate information to pharmacists regarding reimbursement rates for drugs and patient health insurance coverage and cost-sharing requirements. These communications generally use claims formats and drug product identifiers developed by the National Council for Prescription Drug Programs (“NCPDP”).⁵⁰

Other Health Insurer Services. Other services offered by PBMs include maintaining beneficiary enrollment information and generating periodic drug utilization and spending reports to assist the PBM’s health plan clients with managing drug costs.⁵¹

2. The provision of PBM services is highly concentrated among the largest PBMs

There are dozens of PBMs in the United States but just six manage 94 percent of prescription drug claims in the country. Figure 4 presents the share of prescription claims managed by the six largest PBMs between 2016 and 2023, which reflects the increasing concentration in this segment. The Big 3 PBMs’ share of claims managed increased from 70 percent in 2016 to 79 percent in 2023, and the combined shares of the Big 6 PBMs climbed into the mid-90 percent range for six of the past eight years. Moreover, PBMs may control significantly higher shares of select regional and state areas based on certain measures.⁵² For example, a study by the American Medical Association found that OptumRx managed 83 percent of retail pharmacy network management services for commercial health plans in South Carolina in 2021, while Prime managed 85 percent of these services in Alabama—shares far exceeding their nationwide shares.⁵³

Apart from the Big 6 PBMs, about 60 smaller PBMs operate in the United States,⁵⁴ often offering more transparent contracting terms.⁵⁵ However, this long tail of smaller PBMs currently accounts for just six percent of prescription claims managed. Moreover, smaller PBMs commonly contract with larger ones for various PBM services, which further concentrates market power.⁵⁶ As one industry analyst has observed, when the Big 3 PBMs’ contracts with other PBMs are considered, “the brand and specialty market is effectively controlled by three players: CVS/AET[NA], Cigna/ESI and UnitedHealth/OptumRx.”⁵⁷

⁵⁰ See DCI 2024 Report, *supra* note 5, at 177-78.

⁵¹ See *id.* at 147.

⁵² JOSÉ R. GUARDADO, AM. MED. ASS’N, COMPETITION IN COMMERCIAL PBM MARKETS AND VERTICAL INTEGRATION OF HEALTH INSURERS WITH PBMs: 2023 UPDATE, 9-10, 18 (2023).

⁵³ *Id.* at 23.

⁵⁴ See *Pharmacy Benefit Managers*, NAT’L ASS’N INS. COMM’RS, <https://content.naic.org/insurance-topics/pharmacy-benefit-managers> (last visited June 20, 2024) (noting about 66 PBMs currently operate in United States); see also *The PBM Marketplace Continues to Evolve*, PHARM. CARE MGMT. ASS’N (Apr. 2023), https://www.pcmanet.org/wp-content/uploads/2023/04/PBM-Marketplace-Continues-to-Evolve_r4.pdf (noting 73 PBMs in operation).

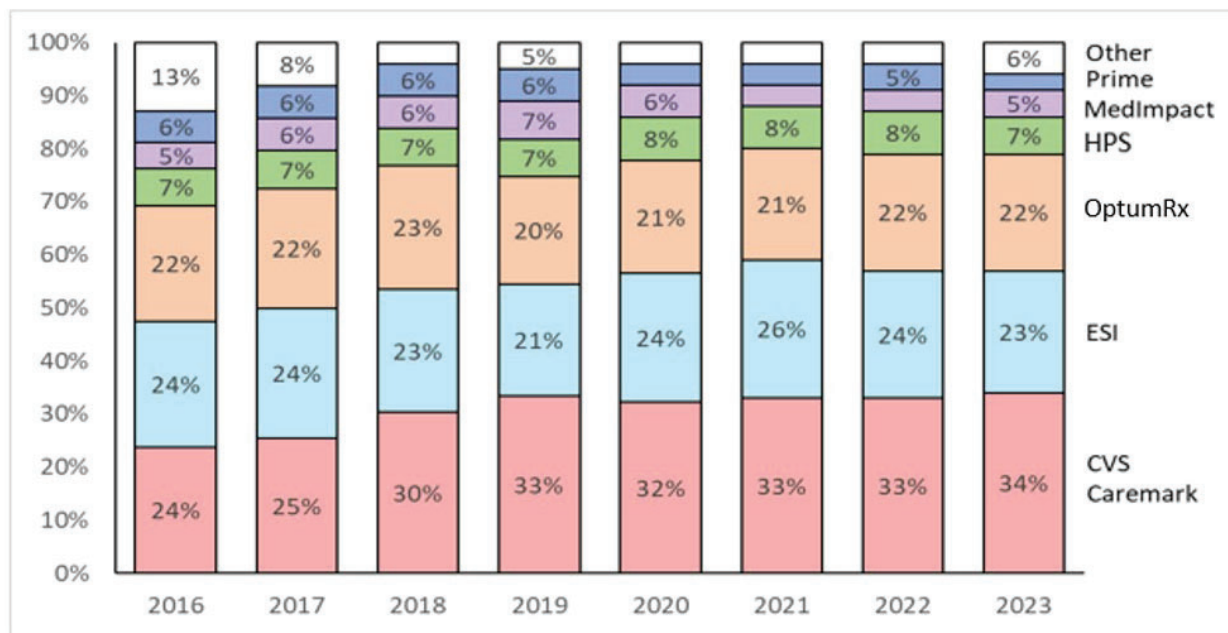
⁵⁵ See DCI 2024 Report, *supra* note 5, at 171.

⁵⁶ See, e.g., DCI 2024 Report, *supra* note 5, at 199, n. 411, n. 412 (noting Elevance Health’s PBM CarelonRx contracts with CVS Health for PBM services, including claims processing and prescription fulfillment); ERIC PERCHER, NEPHRON RSCH., UNITED HEALTH GROUP (UNH): OPTUM LAUNCHES ‘EMISAR’ CONTRACTING ENTITY; NAVITUS ALIGNS WITH ASCENT VIA PRIME 7 (2021) (noting smaller Big 6 PBMs Humana Pharmacy Solutions, MedImpact, and Prime contract with the Big 3 PBMs for PBM services, including manufacturer rebate negotiations).

⁵⁷ PERCHER, *supra* note 56, at 7.

Today, if the Big 3 PBMs were standalone companies, each would rank among the 40 largest companies in the United States by revenue.⁵⁸ Given the current level of consolidation, pharmacists, health insurers, and drug manufacturers often have little choice but to interact with the large, dominant PBMs when distributing certain drugs.

Figure 4. PBM Services Shares, 2016-2023⁵⁹
(% of total equivalent prescription claims managed)



Notably, the Big 3 PBMs gained share in the provision of PBM services in part through mergers and acquisitions during the 2010s, none of which were challenged by the antitrust enforcement agencies. For example, Express Scripts acquired Medco Health Solutions in 2012 (combining the first and third largest PBMs by shares of claims managed),⁶⁰ OptumRx acquired Catamaran in

⁵⁸ Rebecca Robbins & Reed Abelson, *The Opaque Industry Secretly Inflating Prices for Prescription Drugs*, N.Y. TIMES (June 21, 2024), <https://www.nytimes.com/2024/06/21/business/prescription-drug-costs-pbm.html>.

⁵⁹ Figure prepared by FTC staff. Data estimates compiled and derived from the exhibit “PBM Market Share, by Total Equivalent Prescription Claims Managed” in each of the following reports: ADAM J. FEIN, DRUG CHANNELS INST., THE 2017 ECONOMIC REPORT ON U.S. PHARMACIES AND PHARMACY BENEFIT MANAGERS 100 (2017) [hereinafter “DCI 2017 Report”]; ADAM J. FEIN, DRUG CHANNELS INST., THE 2018 ECONOMIC REPORT ON U.S. PHARMACIES AND PHARMACY BENEFIT MANAGERS 112 (2018) [hereinafter “DCI 2018 Report”]; ADAM J. FEIN, DRUG CHANNELS INST., THE 2019 ECONOMIC REPORT ON U.S. PHARMACIES AND PHARMACY BENEFIT MANAGERS 118 (2019) [hereinafter “DCI 2019 Report”]; ADAM J. FEIN, DRUG CHANNELS INST., THE 2020 ECONOMIC REPORT ON U.S. PHARMACIES AND PHARMACY BENEFIT MANAGERS 131 (2020) [hereinafter “DCI 2020 Report”]; ADAM J. FEIN, DRUG CHANNELS INST., THE 2021 ECONOMIC REPORT ON U.S. PHARMACIES AND PHARMACY BENEFIT MANAGERS 143 (2021) [hereinafter “DCI 2021 Report”]; ADAM J. FEIN, DRUG CHANNELS INST., THE 2022 ECONOMIC REPORT ON U.S. PHARMACIES AND PHARMACY BENEFIT MANAGERS 142 (2022) [hereinafter “DCI 2022 Report”]; ADAM J. FEIN, DRUG CHANNELS INST., THE 2023 ECONOMIC REPORT ON U.S. PHARMACIES AND PHARMACY BENEFIT MANAGERS 153 (2023) [hereinafter “DCI 2023 Report”]; DCI 2024 Report, *supra* note 5, at 163.

⁶⁰ See Dissenting Statement of Comm’r Brill Concerning the Proposed Acquisition of Medco Health Solutions Inc. (Medco) by Express Scripts, Inc. (ESI), FTC File No. 111-0210, at 2 (Apr. 2, 2012), <https://www.ftc.gov/legal->

2015 (combining the third and fourth largest PBMs with 13 percent and nine percent shares),⁶¹ and CVS merged with Aetna in 2018 (Aetna operated a PBM at the time, which increased CVS Caremark’s share by five percentage points to 30 percent).⁶²

B. PBMS HAVE EXPANDED THEIR PHARMACY DISPENSING SHARES OF HIGH-PRICED SPECIALTY DRUGS

In general, there are two main pharmacy dispensing formats through which the general public can fill prescriptions—retail (i.e., brick-and-mortar) pharmacies and mail order pharmacies.⁶³ As illustrated in Figure 1 above, the Big 6 PBMs are vertically integrated with many of the largest pharmacies in the country, including pharmacies that dispense traditional and specialty medications.⁶⁴ In this section, we describe the retail and mail order dispensing formats as well as the rapidly expanding specialty pharmacy segment. We then examine the PBM-affiliated pharmacies’ expansion into specialty drug dispensing.

1. Overview of pharmacy dispensing formats and the specialty pharmacy segment

Retail pharmacies. There are currently over 71,000 pharmacy locations in the United States, an estimated 86 percent of which are brick-and-mortar retail pharmacies, with the rest being mostly hospital, clinic, and long-term care pharmacies.⁶⁵ Retail pharmacies include chain pharmacies, independent pharmacies, and pharmacies located within retailers such as supermarkets and mass merchants.⁶⁶ Small and mid-sized independent pharmacies often contract with PBMs through a

library/browse/cases-proceedings/closing-letters/proposed-acquisition-medco-health-solutions-inc-express-scripts-inc. The FTC investigated this transaction and closed its review without challenging the merger.

⁶¹ Press Release, OptumRx, Catamaran Complete Combination (July 23, 2015), <https://www.businesswire.com/news/home/20150723006578/en/OptumRx-Catamaran-Complete-Combination>; *see also Catamaran Corp.: Historical Data*, YAHOO! FIN., <https://finance.yahoo.com/quote/CCT.TO/history/> (last visited June 24, 2024).

⁶² Bruce Japsen, *CVS-Aetna Deal Closes With Vow To Change ‘Consumer Health Experience’*, FORBES (Nov. 28, 2018), <https://www.forbes.com/sites/brucejapsen/2018/11/28/cvs-aetna-deal-closes-with-vow-to-change-consumer-health-experience>; *CVS Health Corporation (CVS): Historical Data*, YAHOO! FIN., <https://finance.yahoo.com/quote/CVS> (last visited June 20, 2024); The U.S. Department of Justice investigated this transaction and agreed not to challenge the merger conditional on Aetna’s divestiture of its Medicare Part D prescription drug plan business for individuals. *See* Press Release, Judge Decides CVS-Aetna Final Judgment is in the Public Interest and Grants United States’ Motion (Sept. 4, 2019), <https://www.justice.gov/opa/pr/judge-decides-cvs-aetna-final-judgment-public-interest-and-grants-united-states-motion> [hereinafter “DOJ Press Release re CVS-Aetna Final Judgment”].

⁶³ Additional dispensing formats include pharmacies embedded within institutional settings, such as long-term care facilities and hospitals. These pharmacies fill only prescriptions for patients of the institution, not the general public. *See, e.g., The Important Role of LTC Pharmacies*, SENIOR CARE PHARMACY COAL., <https://seniorcarepharmacies.org/ltc-pharmacies> (last visited June 21, 2024).

⁶⁴ Traditional drugs tend to be small molecule, non-biologic drugs that patients can take without special assistance. Specialty drugs may be characterized by their need for specialty handling and administration, and high cost. *See infra* note 80 and accompanying text. There is, however, no uniform definition of a specialty drug. Accordingly, some PBMs may classify a medication as a traditional drug and others as a specialty drug, and vice versa. *See infra* note 188 and accompanying text.

⁶⁵ FTC staff analysis of NCPDP DataQ data.

⁶⁶ *See DCI 2024 Report, supra* note 5, at 51. CMS defines a retail pharmacy (in the context of regulating Medicare Part D) as “any licensed pharmacy that is open to dispense prescription drugs to the walk-in general public from

Pharmacy Services Administrative Organization (“PSAO”), the largest of which are operated by the three main U.S. drug wholesalers.⁶⁷ At this time, CVS Caremark is the only one of the Big 6 PBMs with a significant network of affiliated retail pharmacies.⁶⁸ CVS entered the pharmacy business over 50 years ago, and it currently operates the largest chain of retail pharmacies in the country with more than 9,700 locations.⁶⁹ Over the 2013 to 2022 period, the number of CVS-owned retail pharmacies increased by 28 percent, from about 7,600 locations to over 9,700 locations. During the same time period, other retail pharmacies declined by seven percent overall (from roughly 55,200 locations to 51,400 locations) and by ten percent within rural areas (from about 11,100 to 10,000).⁷⁰ In rural and medically underserved communities, independent pharmacies are often the sole provider of medication counseling and management as well as the main source for immunizations and rescue medications like EpiPens for allergic reactions.⁷¹ According to one study, in over eight percent of U.S. counties in 2022, a majority of residents lived more than ten miles from the nearest pharmacy.⁷² Academic researchers have found that

which Part D enrollees could purchase a covered Part D drug without being required to receive medical services from a provider or institution affiliated with that pharmacy.” 42 C.F.R. § 423.100. There is no uniform definition of a chain pharmacy. The NCPDP defines chain pharmacies as four or more commonly owned pharmacies, though certain PBM respondents indicated that they use different thresholds (*e.g.*, 10 or 15 locations) to define chain pharmacies. *See Chain Pharmacies, ECL and Data Dictionary*, NAT’L COUNCIL FOR PRESCRIPTION DRUGS, <https://standards.ncpdp.org/Standards-Table-Data.aspx> (last visited June 24, 2024); the NCPDP defines independent pharmacies as three or fewer commonly owned pharmacies. *Id.*

⁶⁷ Of the three primary drug wholesalers, Cardinal Health’s PSAOs have over 6,600 pharmacy members; McKesson’s Health Mart Atlas PSAO has 6,100 pharmacy members; and AmerisourceBergen’s Elevate PSAO has 5,200 pharmacy members. DCI 2024 Report, *supra* note 5, at 181-182.

⁶⁸ *See supra* Fig. 1.

⁶⁹ *See Our History*, CVS HEALTH, <https://www.cvshealth.com/about/our-strategy/company-history.html> (last visited June 21, 2024); CVS Health Corp., Annual Report, at 3 (Form 10-K, 2023); FTC analysis of NCPDP DataQ data.

⁷⁰ FTC analysis of NCPDP DataQ data. Rural areas defined as “micropolitan” and “noncore” areas using USDA’s Rural Urban Commuting Areas. *See Rural-Urban Commuting Area Codes*, U.S. DEP’T OF AGRIC., ECON. RES. SERV., <https://www.ers.usda.gov/data-products/rural-urban-commuting-area-codes> (last updated Sept. 25, 2023). While not the focus of this Interim Report, investigative reporters have found that PBMs “are driving independent drugstores out of business by not paying them enough to cover their costs,” which “limits health care access for poorer communities but ultimately enriches the P.B.M.s’ parent companies” through their “own drugstores or mail-order pharmacies.” *See also* Robbins & Abelson, *supra* note 58.

⁷¹ *See Nat’l Rural Health Ass’n*, *supra* note 2; *see also* Anonymous, FTC-2022-0015-0973, at 1 (May 21, 2022), <https://www.regulations.gov/comment/FTC-2022-0015-0973> (independent pharmacy offering drug compounding services and packaging drugs in rapid pack system that chain pharmacies in area do not offer); Drilling Morningside Pharmacy, FTC-2022-0015-0383, at 1-2 (Apr. 12, 2022), <https://www.regulations.gov/comment/FTC-2022-0015-0383> (providing blood pressure monitoring, A1C counseling, and other clinical services to patients and noting that “local pharmacies help patients with compliance on their meds and introduce programs to help with blood pressure and diabetes issues”); Carvajal Pharmacy, FTC-2022-0015-0504, at 1 (Apr. 18, 2022), <https://www.regulations.gov/comment/FTC-2022-0015-0504> (providing medication therapy management and drug compounding); Condo Pharmacy, FTC-2022-0015-1196, at 1 (May 17, 2022), <https://www.regulations.gov/comment/FTC-2022-0015-1196> (pharmacy’s compounding lab allows pharmacy to provide patients with “custom medication for hormone replacement therapy, pain medication protocols, [and] pediatric dosage tailoring”).

⁷² Lucas A. Berenbrok et al., *Access to Community Pharmacies: A Nationwide Geographic Information Systems Cross-Sectional Analysis*, 62 J. AM. PHARMACISTS ASS’N 1816, 1816 (2022).

pharmacy closures are associated with significant declines in patient adherence to medication, which can lead to adverse health outcomes.⁷³

Mail order pharmacies. These pharmacies focus on filling maintenance prescriptions that are taken regularly by patients with chronic illnesses, as well as patient-administered specialty drugs (i.e., drugs that can be taken without the assistance of a health care provider).⁷⁴ Mail order pharmacies operate highly automated, centrally located facilities that fill and ship prescriptions directly to patients.⁷⁵ The Big 3 PBM-affiliated mail order pharmacies now account for nearly three quarters of dispensing revenue—the revenue that pharmacies take in through dispensing drugs as opposed to revenue from non-drug products (e.g., bandages)—within this segment.⁷⁶ All the Big 6 PBMs are vertically integrated with an affiliated mail order pharmacy.⁷⁷ Over the past several years, cash-pay pharmacies—such as the Mark Cuban Cost Plus Drug Company and Blueberry Pharmacy—have started offering medications via mail order at wholesale prices plus a markup, circumventing traditional PBM channels.⁷⁸

Specialty pharmacies. While sometimes described as a distinct dispensing format, specialty pharmacies may be retail or mail order pharmacies. As the term “specialty” suggests, specialty pharmacies primarily dispense specialty drugs.⁷⁹ Historically, specialty drugs were characterized by their need for special handling and administration. There is no standard definition, however, for a specialty drug, and today specialty drugs may be characterized by a variety of factors, including their high cost.⁸⁰ Consequently, specialty drug designations can differ significantly

⁷³ Dima M. Qato et al., *Association Between Pharmacy Closures and Adherence to Cardiovascular Medications Among Older US Adults*, 2 JAMA NETWORK OPEN 1, 1 (2019).

⁷⁴ See DCI 2024 Report, *supra* note 5, at 77-79.

⁷⁵ U.S. GOV'T ACCOUNTABILITY OFF., GAO-19-520, MEDICARE: LIMITED INFORMATION EXISTS ON THE EFFECTS OF SYNCHRONIZING MEDICATION REFILLS 3 n. 8 (2019) (“Mail order pharmacies are highly automated facilities that fill prescriptions from a central location and deliver the medications directly to the patient.”).

⁷⁶ Including both traditional and specialty drug prescriptions. See *infra* Fig. 6.B.

⁷⁷ See *supra* Fig. 1.

⁷⁸ Cash-pay pharmacies may dispense both generic and specialty drugs, and some also operate retail locations. See *Daily Briefing: Why ‘Cash’ Pharmacies are Booming—and What it Means for Health Care*, ADVISORY BD. (Aug. 24, 2022), <https://www.advisory.com/daily-briefing/2022/08/24/cash-pharmacies>; *No Middlemen. No Price Games. Huge Drug Savings.*, COST PLUS DRUG CO., <https://costplusdrugs.com/> (last updated June 21, 2024); *Welcome to a New Kind of Pharmacy*, BLUEBERRY PHARMACY, <https://blueberrypharmacy.com/> (last visited June 21, 2024).

⁷⁹ See NAT’L ASS’N OF SPECIALTY PHARMACY, WHAT IS SPECIALTY PHARMACY? 1 (2018), <https://naspnet.org/wp-content/uploads/2019/08/What-Is-Specialty-Pharmacy-090718.pdf> (“A specialty pharmacy is a state-licensed pharmacy that solely or largely provides medications for people living with serious health conditions requiring complex therapies.”). There is, however, no standard definition of a specialty pharmacy, and any pharmacy can self-designate as one. PBMs and health insurers often rely on accreditation organizations to verify the specialty dispensing capabilities of pharmacies. See DCI 2024 Report, *supra* note 5, at 74-75, 81.

⁸⁰ DCI 2024 Report, *supra* note 5, at 22-25. Indeed, Medicare regulations only permit drugs to be classified on specialty formulary tiers for Part D plans if the price negotiated with plan sponsors “exceed[s] the dollar-per-month amount established by CMS.” CTRS. FOR MEDICARE & MEDICAID SERVS., MEDICARE PRESCRIPTION DRUG BENEFIT MANUAL, CH. 6 – PART D DRUGS AND FORMULARY REQUIREMENTS § 30.2.4 (2016). CMS’ specialty drug cost threshold in 2023 was \$890 per 30-day equivalent prescription. See Memorandum Regarding Contract Year (CY) 2023 Final Part D Bidding Instructions from Amy Larrick Chavez-Valdez, Director, Medicare Drug Benefit and C & D Data Group, Ctrs. for Medicare & Medicaid Servs., to All Prescription Drug Plans, Medicare Advantage-Prescription Drug Plans, Section 1876 Cost Plans, Medicare-Medicaid Plans, and PACE plans, at 3-5 (Feb. 3, 2022),

across formularies.⁸¹ Specialty drugs now account for a significant and growing proportion of pharmacy dispensing revenue (estimates range from nearly 40 percent to over 50 percent), but only a small fraction of total prescription volume (roughly two percent).⁸² All of the Big 6 PBMs are vertically integrated with affiliated specialty pharmacies, and the pharmacies affiliated with the Big 3 PBMs account for over two thirds of specialty dispensing revenue.⁸³

2. Dispensing revenue growth and PBM-affiliated pharmacies' increasing share of specialty

Over the 2016 to 2023 period, specialty drugs have grown much faster than traditional drugs as a source of dispensing revenue for pharmacies. Figure 5 below presents retail and mail order dispensing revenue of U.S. pharmacies broken out by traditional and specialty prescriptions during this period. Total dispensing revenue grew by over 50 percent from \$393 billion in 2016 to \$600 billion in 2023, with growth disproportionately generated by specialty dispensing revenue—which more than doubled from \$113 billion in 2016 to \$237 billion in 2023.⁸⁴

<https://www.cms.gov/files/document/2023partdbiddinginstructions.pdf>; *see also* Letter From Lauren Rowley, Pharm. Care Mgmt. Ass'n, Senior Vice President of State Aff., To Joe Hilbert, Deputy Comm'r, Va. Dep't of Health, at 1 (May 18, 2021), https://townhall.virginia.gov/L/GetFile.cfm?File=meeting%5C58%5C32445%5CMinutes_VDH_32445_v2.pdf (proposing following specialty drug definition: “a prescription drug that typically is high cost and that: is prescribed for a person with a (a) chronic, complex, or life-threatening condition, and/or (b) rare medical condition; has limited or exclusive distribution; or requires (a) specialized product handling and/or administration by the dispensing pharmacy, or (b) specialized clinical care, including frequent adjustments, intensive clinical monitoring, or expanded services for patients, including intensive patient counseling, education, or ongoing clinical support beyond traditional dispensing activities, such as individualized disease and therapy management to support improved health outcomes.”); DCI 2024 Report, *supra* note 5, at 22-25.

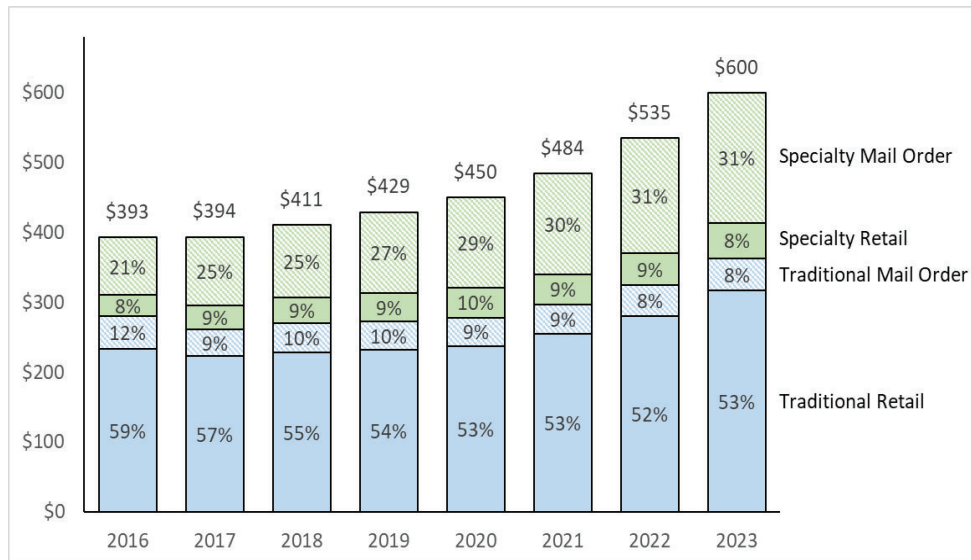
⁸¹ *See infra* note 188 and accompanying text.

⁸² *See infra* Fig. 5 (estimating specialty dispensing revenue accounts for 39 percent of total dispensing revenue); *What are Specialty Pharmacies?*, PHARM. CARE MGMT. ASS'N, <https://www.pcmnet.org/specialty-pharmacies> (last visited May 2, 2024) (“Specialty medications constitute approximately 51% of all prescription drug spend and only 2.1% of total prescription volume.”); Jennie Iverson, *What Is Drug Trend and How to Manage it*, EVERNORTH HEALTH SERVS. (Apr. 20, 2022), <https://www.evernorth.com/articles/specialty-drug-trends-and-utilization> (noting “[e]ven though less than 2% of the population uses specialty drugs, those prescriptions account for a staggering 51% of total pharmacy spending” based on selected ESI data from 2021); *Specialty Drug Prices Giving You Sticker Shock?: Specialty Challenge*, OPTUM, <https://www.optum.com/en/business/insights/pharmacy-care-services/page.hub5.defusing-specialty-drug-prices.html> (last visited May 28, 2024) (“Despite making up approximately 2% of overall prescription volume, specialty medications now account for 53% of total annual pharmacy spending.”).

⁸³ *See infra* Fig. 6.C.

⁸⁴ Including both mail order and retail specialty dispensing revenue. *See infra* Fig. 6.C.

Figure 5. Dispensing Revenue of U.S. Pharmacies, 2016-2023⁸⁵
 (\$ in billions)

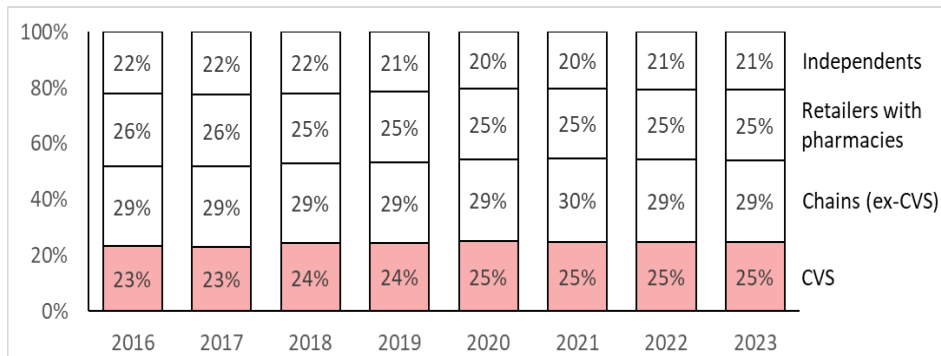


At the same time, and as illustrated in Figure 6 below, it appears that pharmacies affiliated with the Big 3 PBMs that dispense specialty medications have particularly benefited from this growth, significantly expanding their share of the specialty segment from 54 percent in 2016 to 68 percent in 2023, even as their retail and mail order shares remained relatively stable.

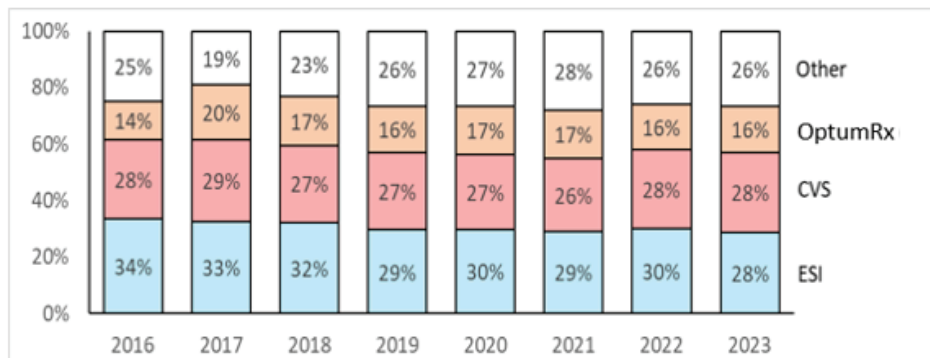
⁸⁵ Figure prepared by FTC staff. Dispensing revenue estimates compiled and derived from the exhibits, “Prescription Dispensing Revenues, by Dispensing Format” (total dispensing revenue and retail and mail order dispensing revenue for both traditional and specialty prescriptions) and “Specialty Drug Prescription Revenues, by Dispensing Format” (retail and mail order dispensing revenue for specialty prescriptions only). Long-term care pharmacy dispensing revenue, which ranged from 3.3 to 4.4 percent of total dispensing revenue during the period, is excluded. See DCI 2017 Report, *supra* note 59, at 40, 54; DCI 2018 Report, *supra* note 59, at 42, 66; DCI 2019 Report, *supra* note 59, at 43, 69; DCI 2020 Report, *supra* note 59, at 47, 75; DCI 2021 Report, *supra* note 59, at 84, 94; DCI 2022 Report, *supra* note 59, at 55, 81; DCI 2023 Report, *supra* note 59, at 57, 84; DCI 2024 Report, *supra* note 5, at 59, 88.

Figure 6. PBM-Affiliated Pharmacy Dispensing Shares, 2016-2023⁸⁶
 (% dispensing revenue)

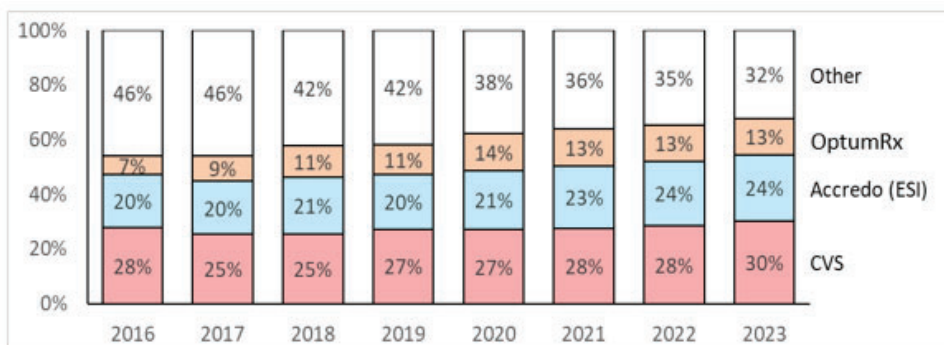
A. Retail Dispensing Shares



B. Mail Order Dispensing Shares



C. Specialty Dispensing Shares (Retail and Mail Order)



⁸⁶ Figure prepared by FTC staff. Retail and mail order shares are based on both traditional and specialty drug dispensing revenue. Specialty shares are based on specialty dispensing revenue from mail order, retail, and long-term care pharmacies. Retail dispensing revenue estimates compiled and derived from the exhibits “Prescription Dispensing Revenues, By Dispensing Format” and “Largest 15 U.S. Pharmacies Ranked by Total Prescription Revenue” (for CVS data); mail order dispensing revenue estimates compiled and derived from the exhibit “Share of Mail Pharmacy Dispensing Revenues, by Company,” and specialty dispensing revenue estimates compiled and derived from the exhibit “Prescription Revenues and Market Share from Specialty Pharmaceuticals, by Company.” See DCI 2017 Report, *supra* note 59, at 36, 40, 49, 57; DCI 2018 Report, *supra* note 59, at 38, 42, 52, 63; DCI 2019

The growth of the specialty segment, and of the Big 3 PBM-affiliated specialty pharmacies' share of the segment, may be driven by a number of factors. The majority of new drugs being brought to market are deemed specialty medications,⁸⁷ including many limited distribution drugs.⁸⁸ At the same time, as detailed in Section III.A.2 below, PBMs are increasing the number of drugs they classify as specialty, a trend that appears to relate to distinct PBM classification decisions as well as the number of new specialty drugs. The specialty segment also has undergone significant consolidation with at least 135 specialty pharmacy merger and acquisition transactions publicly announced over the past decade.⁸⁹ The largest of these transactions often involved one of the Big 3 PBMs.⁹⁰ In addition, it appears that the growth in the specialty pharmacy segment may correspond with PBMs' ability and incentive to steer patients to their vertically integrated, affiliated pharmacies and away from unaffiliated pharmacies, as well as the incentive to inflate the reimbursement rates paid to their affiliated pharmacies for certain specialty drugs.⁹¹

C. CORPORATE RESTRUCTURING OF PBM REBATE NEGOTIATION SERVICES RAISES CONCERNS

The Big 3 PBMs all recently established separate, affiliated entities that they refer to as group purchasing organizations, so-called "PBM GPOs." These entities, however, are not traditional GPOs that purchase drugs and other medical supplies on behalf of health care providers like hospitals.⁹² Rather, the entities—which we refer to as "rebate aggregators"—negotiate contracts, including rebates, with drug manufacturers—a task that PBMs historically engaged in directly. These rebate aggregator entities were apparently formed as a result of corporate restructuring of

Report, *supra* note 59, at 39, 43, 54, 64; DCI 2020 Report, *supra* note 59, at 43, 47, 59, 70; DCI 2021 Report, *supra* note 59, at 51, 56, 68, 79; DCI 2022 Report, *supra* note 59, at 51, 55, 66, 77; DCI 2023 Report, *supra* note 59, at 52, 57, 69, 80; DCI 2024 Report, *supra* note 5, at 55, 59, 73, 84.

⁸⁷ See *infra* note 187 and accompanying text.

⁸⁸ Limited distribution (or exclusive network) drugs are those for which the drug manufacturer contracts with selected specialty pharmacies to exclusively or semi-exclusively distribute the drug product. Presently, more than 360 specialty drugs are subject to limited distribution arrangements, up from 290 specialty drugs the prior year. See DCI 2024 Report, *supra* note 5, at 108; DCI 2023 Report, *supra* note 59, at 107-08.

⁸⁹ See DCI 2024 Report, *supra* note 5, at 85.

⁹⁰ For example, OptumRx acquired Avella Specialty Pharmacy in 2018 (one of the largest independent specialty pharmacies at the time) and Diplomat Pharmacy in 2019 (the largest publicly traded specialty pharmacy and infusion business and the fifth largest specialty pharmacy at the time), and CVS acquired US Bioservices from AmerisourceBergen in 2022. See Adam J. Fein, *Specialty Pharmacy M&A: Our Look at 2018's Deals*, DRUG CHANNELS INST. (Jan. 3, 2019), <https://www.drugchannels.net/2019/01/specialty-pharmacy-m-our-look-at-2018s.html> (discussing Avella acquisition); Press Release, UnitedHealth Group, Diplomat, OptumRx Combining to Advance Access to Specialty Pharmacy Care and Infusion Services, Improve Health Outcomes (Dec. 9, 2019), <https://www.unitedhealthgroup.com/newsroom/2019/2019-12-9-optumrx-diplomat-combination.html> (discussing Diplomat acquisition); Press Release, Anton Health, US Bioservices Acquired By CVS (June 23, 2022), <https://antonhealth.com/us-bioservices-acquired-by-cvs> (discussing US Bioservices acquisition).

⁹¹ See *infra* § III.A (showing disproportionately higher percentage of specialty drugs filled by PBM affiliated pharmacies); *infra* § III.B (showing PBMs paying very high reimbursement rates to their affiliated pharmacies for selected specialty drugs).

⁹² Perhaps this is why at least some PBMs initially did not consider these entities to be GPOs. See Adam Fein, *Five (or Maybe Six?) Reasons that the Largest PBMs Operate Group Purchasing Organizations*, DRUG CHANNELS INST. (May 24, 2023), <https://www.drugchannels.net/2023/05/five-or-maybe-six-reasons-that-largest.html> ("A couple of years ago, Express Scripts' PR team told me in no uncertain terms: 'Ascent is not a GPO.' The company has since changed its tune . . .").

existing PBM functions, not as an expansion into a new segment of the pharmaceutical supply chain. The rebate aggregators of the Big 3 PBMs are Ascent (affiliated with Express Scripts and Prime, and also serving Humana Pharmacy Solutions), Zinc (affiliated with CVS), and Emisar (affiliated with OptumRx).

The PBMs contend that their recently formed rebate aggregators provide the PBM and other clients with greater bargaining leverage by “aggregat[ing] purchasing volume to negotiate greater savings from pharmaceutical manufacturers.”⁹³ However, according to industry experts and members of Congress who have participated in hearings relating to PBM business practices, the PBMs may have spun off these rebate aggregators as separate entities for other purposes, such as to retain revenue from incremental fee structures.⁹⁴ As a former OptumRx executive who helped establish Emisar explained, “[t]he intention of the G.P.O. [rebate aggregator] is to create a fee structure that can be retained and not passed on to a client.”⁹⁵ Internal PBM documents appear to show novel methods of fee generation from these new rebate aggregators.⁹⁶ One report estimates that since the PBMs spun off their rebate aggregators, they have extracted from drug manufacturers billions of dollars in additional fees, which doubled from \$3.8 billion in 2018 to \$7.6 billion in 2022.⁹⁷

Other reasons given by commentators for the creation of these new rebate aggregators include to avoid potential regulatory or legislative PBM reform,⁹⁸ including by framing themselves as GPOs

⁹³ See, e.g., *Group Purchasing Organizations and Ascent*, EVERNORTH HEALTH SERVS., <https://www.evernorth.com/esfacts/key-topics/group-purchasing-organizations-ascent> (last visited June 11, 2024).

⁹⁴ See ERIC PERCHER, NEPHRON RSCH., *TRENDS IN PROFITABILITY AND COMPENSATION OF PBMS & PBM CONTRACT ENTITIES 9-11* (2023) (discussing incremental and “novel fees” such as data/portal fees and vendor fees in addition to rebate administration fees associated with managed number of lives); *Peeking Behind the PBM-lead GPO Curtain*, EVERSANA (Apr. 13, 2023), <https://www.eversana.com/insights/peeking-behind-the-pbm-led-gpo-curtain> (charging administrative, enterprise, and data fees); *Drug Pricing in America: A Prescription for Change, Part III: Hearing Before the S. Comm. on Finance, 116th Cong.* (2019); *The Role of Pharmacy Benefit Managers in Prescription Drug Markets Part II: Not What the Doctor Ordered: Hearing Before the H. Comm. Oversight and Accountability, 118th Cong.* (2023).

⁹⁵ Robbins & Abelson, *supra* note 58.

⁹⁶ Respondent Document Submissions

Respondent Responses to 6(b) Order

(discussing administrative fees and fees to access rebate aggregator’s data and analytic tools); Respondent Responses to 6(b) Order

(discussing manufacturer administrative fees, data administrative fees, formulary rebate administrative fees, and participation fees).

⁹⁷ See Robbins & Abelson, *supra* note 58 (citing Nephron Research).

⁹⁸ PBMs were aware of and wanted to circumvent proposed rulemaking to limit or eliminate regulatory safe harbors allowing PBMs to retain rebate dollars. See, e.g., Pharm. Care Mgmt. Ass’n, *Comment Letter on Fraud and Abuse; Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals* (Apr. 8, 2019), <https://www.pcmnet.org/wp-content/uploads/2019/04/PCMA-Comments-on-Safe-Harbor-Proposed-Regulations.pdf>; Robbins & Abelson, *supra* note 58 (former OptumRx executive who helped establish Emisar

in order to argue that they fall within the safe harbor for GPOs under the Anti-Kickback Statute,⁹⁹ and to limit oversight (e.g., audits) by PBMs' health plan clients, as two of the PBMs' rebate aggregators are offshore entities.¹⁰⁰ Further, regulators have questioned the legality of PBMs using rebate aggregators to potentially increase their own bargaining leverage when negotiating with drug manufacturers, citing concerns with collusion over drug prices and deceptive business practices.¹⁰¹

In May and June 2023, the Commission issued supplemental 6(b) Orders to the Big 3 PBMs' rebate aggregators to learn more about their operations and obtain data and documents.¹⁰² FTC staff has engaged in ongoing negotiations with these entities regarding their required productions of documents and data, with some stating that they currently do not anticipate completing productions until 2025.

Summary information about the PBMs' rebate aggregators is presented in Figure 7. Notably, all the entities were established within the past several years and two are headquartered overseas.¹⁰³

explained, “the industry feared that the rule would make the rebate system illegal”). Rebate aggregators claim that they can retain fees from drug manufacturers through the GPO safe harbor instead. PERCHER, *supra* note 56, at 2, 5, 6, 8; *see also Safe Harbor Regulations*, U.S. DEP'T HEALTH & HUM. SERVS., OFF. INSPECTOR GEN., <https://oig.hhs.gov/compliance/safe-harbor-regulations/> (last visited June 21, 2024) (describing the timetable and process for the moratoria on enactment by Congress on implementation of the 2020 Final Rule for limiting rebate safe harbor protections until 2032).

⁹⁹ Safe harbor regulations for GPOs under the Anti-Kickback Statute exclude certain fees paid by vendors to GPOs from the definition of “remuneration.” 42 C.F.R. § 1001.952(j). *See, e.g.*, PERCHER, *supra* note 56, at 5 (“When Ascent was initially introduced in 2019, it was our view that the structure had been designed to comply with the GPO safe harbor and so could serve [or] play a defensive role should legislative or administrative action undercut the pharmaceutical rebate/discount safe harbor.”).

¹⁰⁰ *See, e.g., The Role of Pharmacy Benefit Managers in Prescription Drug Markets Part II: Not What the Doctor Ordered: Hearing Before the H. Comm. Oversight and Accountability*, 118th Cong. (2023) (written testimony of Lori M. Reilly, Chief Operating Officer, PhRMA), <https://oversight.house.gov/wp-content/uploads/2023/09/Tesimony-to-House-Oversight-Reilly.pdf> (noting that Ascent's information is protected by restrictive Swiss privacy laws).

¹⁰¹ For example, the State of Ohio filed a lawsuit in March 2023 against Ascent and several PBMs, alleging primarily that these entities colluded to fix drug prices and inputs to drug prices (*e.g.*, manufacturer rebates). *See* Complaint at ¶¶ 28-29, 180-199, *State of Ohio v. Ascent Health et al.*, 23-cv-H-03-0179 (Mar. 27, 2023) (noting that “on information and belief, Ascent has provided a convenient vehicle for Express Scripts, Prime Therapeutics, and Ascent's PBM customers to aggregate and access each other's pricing, discount, rebate, and negotiations information and “act in concert to harmonize their Manufacturer negotiations and demands, effectively eliminating all competition between themselves and further ensuring that they continue to profit from supracompetitive drug prices.”). *Id.* ¶¶ 28, 29.

¹⁰² *See supra* note 4 and accompanying text.

¹⁰³ Ascent and Emisar are both domiciled in the State of Delaware. *See* Fein, *supra* note 92.

Figure 7. Overview of “PBM GPOs” / Rebate Aggregators¹⁰⁴

“PBM GPO” / Rebate Aggregator	Parent / Owner	Year Established	Headquarters Location	Selected Clients
Ascent Health Services	Cigna (ESI), Prime, Kroger	2019	Switzerland	ESI, Prime, Kroger, HPS
Zinc Health Services	CVS	2020	United States	CVS Caremark
Emisar Pharma Services	United (OptumRx)	2021	Ireland	OptumRx

D. PBMS HAVE EXPANDED INTO OTHER VERTICALLY INTEGRATED HEALTH CARE SEGMENTS

The large healthcare conglomerates that own and operate the largest PBMs have not only vertically integrated with pharmacies (as described in Section II.B) but also with other segments of the pharmaceutical supply chain and the healthcare sector generally (illustrated in Figure 1 above). Three segments with which PBMs are now vertically integrated—health insurers, health care providers, and drug private labelers—are discussed below.

1. Health insurers

Five of the Big 6 PBMs are vertically integrated with some of the largest health insurers in the country.¹⁰⁵ These health insurers offer fully-insured and administrative services only (“ASO”) health plans for commercial beneficiaries as well as Medicare Part D prescription drug plans and Medicaid managed care plans.¹⁰⁶ Some health insurers reportedly do not permit their clients to comparison shop for PBM services; rather, the client must use the PBM affiliated with the health insurer.¹⁰⁷ As described above, PBMs provide a range of services for health insurers, such as drug formulary development, pharmacy network design, and drug utilization management. Health insurers that are affiliated with PBM respondents are briefly described below.

¹⁰⁴ See DCI 2024 Report, *supra* note 5, at 175-76; Respondent Document Submissions [REDACTED]

¹⁰⁵ MedImpact is the only Big 6 PBM not vertically integrated with a health insurer. See Press Release, MedImpact, MedImpact Celebrates 30 Years Making Pharmacy Benefits Transparent, Understandable, and Affordable (Sept. 26, 2019), <https://www.medimpact.com/clients/resources/press-releases/medimpact-celebrates-30-years-making-pharmacy-benefits-transparent>.

¹⁰⁶ BURNS, *supra* note 25, at 365-414; *Pharmacy Benefit Managers and Their Role in Drug Spending*, THE COMMONWEALTH FUND (Apr. 22, 2019), <https://www.commonwealthfund.org/publications/explainer/2019/apr/pharmacy-benefit-managers-and-their-role-drug-spending>.

¹⁰⁷ See, e.g., Robbins & Abelson, *supra* note 58 (“UnitedHealth required [its client] to use Optum Rx as its P.B.M. Price shopping for a different P.B.M. was not permitted.”).

Aetna (CVS Caremark). CVS acquired Aetna in 2018.¹⁰⁸ Aetna is the third largest health insurer in the United States, providing coverage for 35 million members.¹⁰⁹ In 2023, Aetna reported revenue of approximately \$105.6 billion.¹¹⁰ Aetna offers medical, pharmacy, and other insurance plans in the commercial, Medicare Advantage, and Managed Medicaid markets.¹¹¹

Cigna (Express Scripts). The fourth largest health insurer nationally, Cigna acquired Express Scripts in 2018.¹¹² Cigna’s insurance segment, Cigna Healthcare, provides coverage for U.S. and international clients and customers, resulting in \$51.2 billion in revenue in 2023.¹¹³ It has approximately 18.2 million members in the United States and offers commercial and Medicare Advantage medical, pharmacy, and other insurance plans.¹¹⁴

UnitedHealth Group (OptumRx). United acquired OptumRx in 2005.¹¹⁵ United offers health insurance and related services through its UnitedHealthcare (“UNH”) subsidiary. With approximately \$281.4 billion in revenue in 2023, UNH is the largest health insurer in the country.¹¹⁶ UNH provides commercial, Medicare, and Medicaid plans for 27.3 million members.¹¹⁷

Humana (Humana Pharmacy Solutions). Humana has historically offered commercial, Medicare, and Managed Medicaid plans,¹¹⁸ though in February 2023 it announced it was exiting the commercial market.¹¹⁹ Humana is the second largest health insurer offering Medicare

¹⁰⁸ Japsen, *supra*, note 62. The DOJ investigated this transaction and agreed not to challenge the merger conditional on Aetna’s divestiture of its Medicare Part D prescription drug plan business for individuals. See DOJ Press Release re CVS-Aetna Final Judgment, *supra* note 62. The DOJ required the divestiture of CVS’ Part D plan business because, as the DOJ alleged, allowing merging parties to combine their Part D businesses would “substantially lessen competition and harm consumers” in “16 Part D regions covering 22 states.” Complaint at ¶¶ 30, 31, 40, United States, et al. v. CVS Health Corp. & Aetna, Inc., C.A. No. 18-cv-02340 (D.D.C. Oct. 10, 2018).

¹⁰⁹ AM. MED. ASS’N, COMPETITION IN HEALTH INSURANCE: A COMPREHENSIVE STUDY OF U.S. MARKETS 11 (2023) [hereinafter “AMA Insurance Report”]; CVS Health Corp., Annual Report, at 75. (Form 10-K, 2023).

¹¹⁰ See CVS Health Corp., Annual Report, at 130 (Form 10-K, 2023).

¹¹¹ See *About Us*, AETNA, INC., <https://www.aetna.com/medicare/footers/about-us.html?&redirect=akamai> (last visited June 24, 2024).

¹¹² See AMA Insurance Report, *supra* note 109, at 11; see Press Release, Cigna Group, Cigna Completes Combination with Express Scripts, Establishing a Blueprint to Transform the Health Care System (Dec. 1, 2018), <https://newsroom.thecignagroup.com/Cigna-Completes-Combination-with-Express-Scripts-Establishing-a-Blueprint-to-Transform-the-Health-Care-System>.

¹¹³ See Cigna Group, Annual Report, at 2, 52 (Form 10-K, 2023).

¹¹⁴ See *id.* at 2, 68; *Cigna Healthcare*, CIGNA, <https://www.thecignagroup.com/our-capabilities/cigna-healthcare> (last visited June 24, 2024).

¹¹⁵ See Press Release, UnitedHealth Group, UnitedHealth Group Announces “Optum” Master Brand for Its Health Services Businesses (Apr. 11, 2011), <https://www.businesswire.com/news/home/20110411005701/en/UnitedHealth-Group-Announces-%E2%80%9COptum%E2%80%9D-Master-Brand-for-Its-Health-Services-Businesses>.

¹¹⁶ See UnitedHealth Group Inc., Annual Report, at 28 (Form 10-K, 2023); AMA Insurance Report, *supra* note 109, at 11.

¹¹⁷ See UnitedHealth Group Inc., Annual Report, at 3-5 (Form 10-K, 2023).

¹¹⁸ See Humana Inc., Annual Report, at 4-9 (Form 10-K, 2023).

¹¹⁹ See Press Release, Humana Inc., Humana to Exit Employer Group Commercial Medical Products Business, (Feb. 23, 2023), <https://press.humana.com/news/news-details/2023/Humana-to-Exit-Employer-Group-Commercial-Medical-Products-Business>.

Advantage plans in the United States.¹²⁰ Humana’s insurance segment has 17 million members and reported approximately \$106.4 billion in revenue in 2023.¹²¹

Blue Cross Blue Shield Plans (Prime). Formed in 1998 by Blue Cross and Blue Shield (BCBS) plans in Minnesota and Nebraska, today Prime is owned by a collection of 19 Blue Cross Blue Shield health plans, subsidiaries, and affiliates. Selected BCBS owners include Florida Blue, BCBS of North Carolina, BCBS of Rhode Island, Health Care Services Corporation, and Blue Plans in North Dakota, Wyoming, and Kansas, among others.¹²² Additionally, some unaffiliated BCBS and non-BCBS health insurers also contract with Prime for PBM services.¹²³

2. Health care providers

Four PBM respondents are part of healthcare conglomerates that are vertically integrated with various provider groups, as illustrated in Figure 1 above. While PBMs do not directly contract with health care providers, providers play a central role in prescribing medications to patients. Descriptions of selected PBM-affiliated provider groups are provided below.

CVS Health Services Segment (CVS Caremark). CVS’ Health Services Segment owns and operates various provider groups, including MinuteClinic and Signify Health.¹²⁴ MinuteClinic is a network of walk-in clinics staffed by nurse practitioners and physician assistants who conduct routine medical checks, perform lab tests, and prescribe medications, among other services.¹²⁵ With over 1,000 locations, MinuteClinic is the largest provider of walk-in clinics in the country.¹²⁶ Signify Health, acquired by CVS in 2023, manages a network of more than 10,000 clinicians who perform in-home health evaluations to support insurer value-based care programs.¹²⁷

Evernorth Health Services (Express Scripts). Cigna’s Evernorth Health Services owns and operates providers of in-home care (including primary care, care coordination, and enablement

¹²⁰ See AMA Insurance Report, *supra* note 109, at 13.

¹²¹ Humana Inc., Annual Report, at 4, 70 (Form 10-K, 2023).

¹²² See *Company Information*, PRIME THERAPEUTICS (Sept. 24, 2021), <https://www.primetherapeutics.com/news/company-information>; *Our History*, PRIME THERAPEUTICS, <https://www.primetherapeutics.com/about/our-history> (last visited June 24, 2024).

¹²³ Including, *e.g.*, Blue Cross and Blue Shield of Illinois, Blue Cross and Blue Shield of Montana, Blue Cross and Blue Shield of New Mexico, Blue Cross and Blue Shield of Oklahoma, Blue Cross and Blue Shield of Texas, Blue Cross and Blue Shield of Minnesota, Blue Cross and Blue Shield of Nebraska, Blue Cross and Blue Shield of Alabama, BlueCross BlueShield of Tennessee, Capital Health Plan, Alignment Healthcare, Vibra Healthcare, Arkansas Blue Cross and Blue Shield, Horizon Healthcare of New Jersey, Inc., Regence BlueShield (WA), Regence BlueCross BlueShield of Oregon, Regence BlueShield of Idaho, Regence BlueCross BlueShield of Utah, and Asuris Northwest Health. See *About Prime*, PRIME THERAPEUTICS, <https://www.myprime.com/en/about-prime.html>. (last updated Mar. 28, 2024).

¹²⁴ See CVS Health Corp., Annual Report, at 9-12 (Form 10-K, 2023).

¹²⁵ See *Our History*, CVS HEALTH, <https://www.cvshealth.com/about/our-strategy/company-history.html> (last visited June 24, 2024); *Frequently Asked Questions: What is MinuteClinic?*, CVS HEALTH, <https://www.cvs.com/minuteclinic/info> (last visited June 24, 2024).

¹²⁶ See CVS Health Corp., Annual Report, at 12 (Form 10-K 2023); *Increasing Accessibility and Affordability through MinuteClinic*, CVS HEALTH (Apr. 18, 2019), <https://www.cvshealth.com/news/pharmacy/increasing-accessibility-and-affordability-through-minuteclinic.html>.

¹²⁷ See Press Release, Signify Health, CVS Health Completes Acquisition of Signify Health (Mar. 29, 2023), <https://www.signifyhealth.com/news/cvs-health-completes-acquisition-of-signify-health>; *Our Story*, SIGNIFY HEALTH, <https://www.signifyhealth.com/our-story> (last visited June 24, 2024).

services), virtual care (including primary care, urgent care, behavioral health care, and other services), and office-based primary care services.¹²⁸ Additionally, Evernorth holds a minority stake in VillageMD, a network of primary care, specialty care, and urgent care providers that serve millions of patients across 26 markets.¹²⁹

Optum Health (OptumRx). United, through its Optum Health subsidiary, provides in-clinic care (including “primary, specialty, urgent and ambulatory surgical care through medical groups, independent practice associations and specialty partnerships”), home care, and behavioral health care, among other services.¹³⁰ In 2023, Optum Health reported \$95.3 billion in revenue.¹³¹ Optum Health is the largest employer of physicians in the country with 90,000 employed or affiliated physicians—ten percent of all U.S. physicians¹³²—working in more than 2,200 facilities, and another 40,000 advanced practice clinicians.¹³³

CenterWell (Humana Pharmacy Solutions). Humana’s CenterWell business segment offers various healthcare services, including primary care for seniors provided at nearly 300 clinics across 11 states and home health services delivered through over 350 locations in 40 states.¹³⁴ Humana is also a minority owner (with a 35 percent stake) in Gentiva, the leading hospice provider in the United States.¹³⁵ CenterWell reported 2023 revenue of \$4.2 billion from primary care services and \$2.9 billion from home care services.¹³⁶

3. Drug private labelers

The parent companies of the Big 3 PBMs recently established offshore entities focused on private labeling of drugs, i.e., partnering with drug manufacturers to produce and package drugs under the private labeler’s name.¹³⁷ These entities are briefly described below.

Cordavis Limited (CVS Caremark). CVS launched Cordavis Limited (“Cordavis”) in September 2023. Headquartered in Ireland, Cordavis partners with drug manufacturers to “commercialize

¹²⁸ See Cigna Group, Annual Report, at 6 (Form 10-K, 2023).

¹²⁹ VillageMD is majority-owned by Walgreens Boots Alliance, Inc. In 2022, Cigna made a \$2.7 billion investment in VillageMD preferred equity. See *id.* at 56.

¹³⁰ See OPTUM, OVERVIEWS AND HIGHLIGHTS 12 (2022), https://www.unitedhealthgroup.com/content/dam/UHG/PDF/investors/2022/conference/UHG_IC_22_Optum_Consolidated.pdf; See also UnitedHealth Group Inc., Annual Report, at 2 (Form 10-K, 2023).

¹³¹ See UnitedHealth Group Inc., Annual Report, at 65 (Form 10-K, 2023).

¹³² See Bob Herman, *UnitedHealth Group Now Employs or is Affiliated With 10% of All Physicians in the U.S.*, STAT NEWS (Nov. 29, 2023), <https://www.statnews.com/2023/11/29/unitedhealth-doctors-workforce>.

¹³³ See Rylee Wilson, *Optum Now Has 90,000 Physicians*, BECKER’S HOSP. REV. (Nov. 29, 2023), <https://www.beckershospitalreview.com/legal-regulatory-issues/optum-added-nearly-20-000-physicians-in-2023.html>; OPTUM, *supra* note 130, at 12.

¹³⁴ See Humana Inc., Annual Report, at 10-12 (Form 10-K, 2023); Press Release, Humana Inc., Humana Finalizes Launch of CenterWell Home Health (Sept. 1, 2022), <https://press.humana.com/news/news-details/2022/Humana-Finalizes-Launch-of-CenterWell-Home-Health/#gsc.tab=0>.

¹³⁵ See Humana Inc., Annual Report, at 12 (Form 10-K, 2023); *Your Care is Our Calling*, GENTIVA, <https://www.gentivahs.com/> (last visited May 3, 2024).

¹³⁶ See Humana Inc., Annual Report, at 10-11, 117 (Form 10-K, 2023).

¹³⁷ “Private label distribution” refers to “commercial distribution of a drug under the label or trade name of a person who did not manufacture, repack, relabel, or salvage that drug.” 21 C.F.R. § 207.1.

and/or co-produce” biosimilar products.¹³⁸ For its first partnership, Cordavis is working with Sandoz Group to jointly market and distribute Hyrimoz, a biosimilar for Humira (adalimumab), which is used to treat rheumatoid arthritis, Crohn’s disease, plaque psoriasis, ankylosing spondylitis, and ulcerative colitis.¹³⁹ After launching Hyrimoz in 2023, CVS Caremark removed Abbvie’s branded Humira from its standard commercial formulary in April 2024, replacing it with its own Hyrimoz biosimilar and two other adalimumab biosimilars.¹⁴⁰ This formulary swap led to a sharp increase in Hyrimoz’s share of prescriptions, which jumped from five percent to 35 to 45 percent of adalimumab products within a month, even though the list price for Hyrimoz is not the lowest of the biosimilars—a move that could add an estimated \$50 million to \$100 million to CVS’ adjusted operating income on an annual basis.¹⁴¹

Quallent Pharmaceuticals (Express Scripts). Cigna established Quallent Pharmaceuticals (“Quallent”) in 2021.¹⁴² Based in the Cayman Islands, Quallent oversees manufacturing and quality processes for approximately 50 pharmaceutical products.¹⁴³ Similar to CVS/Cordavis’ Hyrimoz, Cigna recently announced that its Accredo specialty pharmacy division will offer a biosimilar for Humira sourced through Quallent.¹⁴⁴

NUVAILA (OptumRx). OptumRx established NUVAILA in mid-2024 through its subsidiary in Ireland, Optum Health Solutions. NUVAILA’s trademark application states that it performs

¹³⁸ See CVS Health Corp., Annual Report, at 9 (Form 10-K, 2023); Press Release, CVS Health, CVS Health Launches Cordavis (Aug. 23, 2023), <https://www.cvshealth.com/news/pbm/cvs-health-launches-cordavis.html> [hereinafter “CVS Press Release re Cordavis Launch”].

¹³⁹ CVS Press Release re Cordavis Launch, *supra* note 138.

¹⁴⁰ Joshua Cohen, *CVS Caremark’s Policy Shift On Humira Biosimilars May Not Be What The Doctor Ordered*, FORBES (May 2, 2024), <https://www.forbes.com/sites/joshuacohen/2024/05/02/cvs-caremarks-policy-shift-on-humira-biosimilars-may-not-be-what-the-doctor-ordered>.

¹⁴¹ See David Wainer, *Coming to a CVS Near You: A Store Brand Monoclonal Antibody*, WALL ST. J. (Apr. 29, 2024), <https://www.wsj.com/health/pharma/cvs-biosimilar-drugs-production-08227182>. While Hyrimoz sells for far less than branded Humira, it “isn’t necessarily the most inexpensive” biosimilar available. Cohen, *supra* note 140; see also Matthew J. Klebanoff et al., *Formulary Coverage of Brand-Name Adalimumab and Biosimilars Across Medicare Part D Plans*, 332 JAMA 74, 75 (2024) (noting that “[b]iosimilars [of Humira] available at different list prices include adalimumab-adaz (available as a lower-priced unbranded drug and as higher-priced branded Hyrimoz”); Letter from Sen. Lankford to CVS Pres. and CVS Caremark Pres., at 1 (Feb. 1, 2024), <https://www.lankford.senate.gov/wp-content/uploads/2024/02/2024-2-1-Senator-Lankford-Letter-to-CVS.pdf> (“Instead of allowing for coverage of all of the lowest-cost biosimilar products on the market, incentivizing low costs and patient choice, CVS chose to cover the biosimilar that another CVS Health subsidiary, Cordavis, co-manufactured.”). As one health economist explained, “instead of competing on the best price,” vertically integrated PBM-insurer-drug private labeler entities will “manage the price” of the drugs they choose to market and distribute. See Wainer, *supra*.

¹⁴² *About Us*, QUALLENT PHARM., <https://www.quallentpharmaceuticals.com/about-us> (last visited May 2, 2024); Adam J. Fein, *What’s Behind CVS Health’s Novel Vertical Integration Strategy for Humira Biosimilars*, DRUG CHANNELS INST. (Sept. 6, 2023), <https://www.drugchannels.net/2023/09/whats-behind-cvs-healths-novel-vertical.html>.

¹⁴³ See *Quallent Pharmaceuticals Health LLC*, DUN & BRADSTREET, https://www.dnb.com/business-directory/company-profiles/quallent_pharmaceuticals_health_llc.68ad6598ccb1d4fd4cb256eff8e88028.html (last visited June 24, 2024); QUALLENT PHARM., *supra* note 142; *Products*, QUALLENT PHARM., <https://www.quallentpharmaceuticals.com/products> (last visited May 2, 2024).

¹⁴⁴ See Press Release, Evernorth Health Servs., Evernorth Announces Humira Biosimilar Available at \$0 Out of Pocket for Accredo Patients in June (Apr. 25, 2024), <https://www.evernorth.com/articles/evernorth-announces-humira-biosimilar-available-0-out-pocket-accredo-patients-june>; see also CVS Press Release re Cordavis Launch, *supra* note 138.

procurement of pharmaceuticals as well as custom manufacture of pharmaceutical products and generic prescription drugs.¹⁴⁵

Industry experts have identified several potential rationales for the formation of these vertically integrated drug private labelers, including increased earnings from biosimilar manufacture, discounted prices for PBM-affiliated specialty pharmacies, increased prices for non-affiliated pharmacies, assurance of supply, and bargaining leverage in negotiations with biosimilar manufacturers.¹⁴⁶

¹⁴⁵ U.S. Trademark Application Serial No. 98583378 (filed June 4, 2024). Adam J. Fein, *Drug Channels News Roundup, June 2024: Cordavis Humira Update, OptumRx's New Biosim Biz, Generic Drugs' Wild Ride, IRA Predictions, and Dr. G on Med School*, DRUG CHANNELS INST. (June 25, 2024), <https://www.drugchannels.net/2024/06/drug-channels-news-roundup-june-2024.html>.

¹⁴⁶ See Fein, *supra* note 142; PERCHER, *supra* note 56, at 11.

III. INCREASED CONCENTRATION AND VERTICAL INTEGRATION MAY HAVE ENABLED PBMS TO LESSEN COMPETITION, DISADVANTAGE RIVALS, AND INFLATE DRUG COSTS

Increasing PBM concentration, including through consolidation, and vertical integration have raised various competitive concerns over access to and affordability of medicines. Among these concerns is that vertical integration may have created financial conflicts of interest and given large PBM-insurer-pharmacy entities the ability and incentive to preference their affiliated entities over rival entities, potentially resulting in a lessening of competition at various levels of the pharmaceutical supply chain.

Before issuing its 6(b) Orders, the Commission sought and received more than 600 public comments expressing concerns about increased vertical integration across the pharmaceutical supply chain.¹⁴⁷ A PBM advocacy group stated that increased concentration and vertical integration has resulted in cost savings and efficiencies.¹⁴⁸ However, the vast majority of commenters—including hundreds of independent pharmacists as well as patients, clinicians, state pharmacist associations, and congressional representatives, among others—discussed the harms associated with PBM concentration and vertical integration. They suggest that horizontal consolidation along with vertical integration may have created and compounded financial conflicts of interest and incentives for self-dealing as well as other PBM business practices that lessen competition, disadvantage rivals, and inflate drug costs—all to the detriment of patients.¹⁴⁹

In this section, we explore selected concerns related to the steering of prescriptions by PBMs to their vertically integrated, affiliated specialty pharmacies, the preferential rates paid to these affiliated pharmacies, and the disparate bargaining dynamics between large PBMs with outsized power vis-à-vis smaller independent pharmacies.

A. SPECIALTY PRESCRIPTION STEERING TO PBM-AFFILIATED PHARMACIES: STEERING MECHANISMS AND INITIAL EVIDENCE

The size of the specialty drug market is increasing over time. Total specialty dispensing revenue at all U.S. pharmacies increased at a compound annual growth rate of 11.2 percent over the 2016 to 2023 period, nearly three times faster than dispensing revenue for traditional drugs.¹⁵⁰ At the

¹⁴⁷ Or roughly half of the 1,238 publicly displayed comments received. *See supra* note 11.

¹⁴⁸ *See The Role of Pharmacy Benefit Managers in Prescription Drug Markets Part II: Not What the Doctor Ordered: Hearing Before the H. Comm. on Oversight and Accountability*, 118th Cong. (Sept. 19, 2023) (written testimony of Juan Carlos Scott, President & CEO, Pharmaceutical Care Management Association), <https://oversight.house.gov/wp-content/uploads/2023/09/PCMA-Oversight-Written-Testimony-Scott.pdf>; *see also Drug Pricing in America: A Prescription for Change, Part III: Hearing Before the S. Comm. on Finance*, 116th Cong. 14 (Apr. 9, 2019) (statement of Steve Miller, Executive VP & Chief Clinical Officer, Cigna Corporation), <https://www.govinfo.gov/content/pkg/CHRG-116shrg43563/pdf/CHRG-116shrg43563.pdf> (“[T]he consolidation in the industry is actually in an effort to really take better care of patients.”); *see generally* Pharm. Care Mgmt. Ass’n, FTC-2022-0015-0988 (May 25, 2022), <https://www.regulations.gov/comment/FTC-2022-0015-0988>.

¹⁴⁹ *See, e.g.*, Indep. Pharmacy Coop., FTC-2022-0015-1239, at 2 (May 25, 2022), <https://www.regulations.gov/comment/FTC-2022-0015-1239>; Rep. Earl L. “Buddy” Carter & Rep. Diana Harshbarger, FTC-2022-0015-0643, at 1-2 (May 24, 2022), <https://www.regulations.gov/comment/FTC-2022-0015-0643>; Am. Pharmacies, FTC-2022-0015-0651, at 1 (May 25, 2022), <https://www.regulations.gov/comment/FTC-2022-0015-0651>; Cmty. Oncology All., FTC-2022-0015-1131, at 1 (May 24, 2022), <https://www.regulations.gov/comment/FTC-2022-0015-1131>.

¹⁵⁰ *See supra* Fig. 5. Dispensing revenue for traditional drugs grew at a compound annual growth rate of 3.8 percent over the 2016 to 2023 period.

same time, the Big 3 PBMs' affiliated pharmacies increased their share of specialty dispensing revenue by 25 percent.¹⁵¹

One factor that may be contributing to this growth is the steering of prescriptions by PBMs to their affiliated pharmacies and away from unaffiliated pharmacies.¹⁵² While this section focuses on mechanisms and initial evidence of steering, numerous public comments received for this study highlight the unique challenges that steering practices present for patients:

- “I am forced by my health insurance company, Regence Blue Shield, and their pharmacy benefits manager, Prime Therapeutics, to order my specialty medications through Accredo Specialty Pharmacy [affiliated with Express Scripts, and has a contractual arrangement with Prime]. I have never been able to receive a new medication in a timely manner from Accredo . . . I generally have to place around 20 phone calls, often spending upwards of 10 hours on the phone with Accredo, before my medication finally gets shipped. In total I am waiting 3+ weeks to receive my medication . . . I have explained to my insurance company that the requirement to use Accredo results in delays receiving my medication, but they refuse to authorize me to use an alternative pharmacy . . . in my community that could provide me my medication the same day.”¹⁵³
- “I am trying to help my patient access Ibrance for her breast cancer. Her copay is ~\$2000. I have found a pharmacy who has an internal grant fund that she qualified for and they will cover her copay. However, she cannot use this pharmacy because her insurance / PBM mandates she use CVS Specialty pharmacy. Therefore, she will not be able to afford her life-saving/prolonging medication.”¹⁵⁴
- “I am a [diabetic] patient[.] I am given ONE chain option for local pharmacy use for my maintenance medicines, and get nasty letters in the mail if I take on anything less than a ninety-day supply, to boot. This pharmacy chain is already so overlaid, that sometimes it can take weeks, plural, to get medicines filled. My other option is mail order, and when the mail order option fails to fill after waiting a week to ten days, I then have to wait more days to have the already overloaded local pharmacy fill my prescription.”¹⁵⁵

1. Steering mechanisms and evidence of specialty prescription steering

PBMs may steer prescriptions to their affiliated pharmacies in numerous ways. Pharmacy network and drug formulary design are among the core services that PBMs provide, as discussed in Section II.A.1 above. PBMs routinely create narrow and preferred pharmacy networks that can advantage

¹⁵¹ See *supra* Fig. 6.C (showing Big 3 PBM-affiliated pharmacies' share of dispensing revenue increasing from 54 percent in 2016 to 68 percent in 2023).

¹⁵² In this report, we use the term “steering” broadly to include practices that may nudge patients toward making particular choices in addition to practices that more directly force patient choices.

¹⁵³ Rachel Marren, FTC-2022-0015-0075 (Mar. 3, 2022), <https://www.regulations.gov/comment/FTC-2022-0015-0075>.

¹⁵⁴ Cathy Spencer, FTC-2022-0015-0059 (Feb. 28, 2022), <https://www.regulations.gov/comment/FTC-2022-0015-0059>.

¹⁵⁵ Justin Holey, FTC-2022-0015-0002 (Feb. 25, 2022), <https://www.regulations.gov/comment/FTC-2022-0015-0002>.

their own pharmacies while excluding rivals,¹⁵⁶ and PBMs regularly adjust formularies, including by designating drugs as specialty medications, which triggers exclusivity provisions in contracts with certain payers that require use of the PBM’s affiliated specialty pharmacy.¹⁵⁷ While PBM payer clients may choose which pharmacy networks and drug formularies to use, information asymmetries can hinder these payers’ ability to make fully informed decisions. For example, one organization representing numerous health plans filed a public comment indicating that “[p]lan sponsors are currently unable to obtain [] information” from PBMs that would allow the plan sponsors to assess whether a PBM is “steering plan participants” to provide a “financial advantage to the PBM.”¹⁵⁸

Additionally, PBMs may use any number of “[o]ptimization levers” to steer patients to affiliated specialty pharmacies,¹⁵⁹ as internal documents and public comments confirm. For specialty drugs administered in a clinical setting, the American Medical Association reports that PBM contracts may require that a patient’s provider obtain the drug from a PBM-affiliated pharmacy (known as “white bagging”), or they may require the patient to do so and then bring the drug to the provider’s office for administration (“brown bagging”), even when the provider could have otherwise obtained the drug for the patient from the pharmacy typically used by the provider.¹⁶⁰ In addition, PBM contracts may bundle exclusive services and assets (such as limited distribution drugs) to

¹⁵⁶ See *supra* § II.A; T. Leigh Hester, FTC-2022-0015-0349, at 1 (Apr. 11, 2022), <https://www.regulations.gov/comment/FTC-2022-0015-0349> (“I see patients of mine that are steered to PBM-owned pharmacies due to network limitations which are established by PBMs whether this is beneficial to the patient or not.”); Med. Arts Pharmacy, FTC-2022-0015-0321, at 3 (Apr. 8, 2022), <https://www.regulations.gov/comment/FTC-2022-0015-0321> (“Another unfair practice is that PBMs always put their own pharmacies into ‘Preferred Network,’ and place other pharmacies into other categories. The ‘Preferred Network’ cost patients less copay to certain groups of patients, and [PBMs] use this as a tactic to drive patients to their own pharmacies.”); Middletown Pharmacy & Wellness, FTC-2022-0015-0014, (Feb. 26, 2022), <https://www.regulations.gov/comment/FTC-2022-0015-0014> (“I own an independent pharmacy and have several elderly patients that reside in a senior living community up the road from us. We deliver medications and OTC items to them when they need something free of charge. Straight to their door. I truly care about them and all of my patients. One of my elderly patients is having to transfer her medications back to a big box store as they are giving her medicine for FREE if she gets it there and are charging her a decent copay at my store; for the SAME EXACT medication. She doesn’t have endless amounts of money to spend so she is going to have to go back to that pharmacy. She was so upset when she found this out. The big box store she is being financially forced to use is randomly closed due to staffing issues, [and] when they are open, there are incredibly long wait times and lines, she can never get ahold [sic] of them to ask a simple question, and the most upsetting thing is that they will not deliver to her. She is in her 90s and does not drive so her medicine access is now going to significantly diminish.”).

¹⁵⁷ See *infra* § III.A.2 (discussing steering through expanded specialty drug lists). Certain drugs may be varyingly classified as specialty or traditional, so while we refer to growth of the PBMs’ “affiliated specialty pharmacies,” we note some medications included in our analysis may also be dispensed by the PBMs’ affiliated mail order or retail pharmacies.

¹⁵⁸ Nat’l Coordinating Comm. for Multiemployer Plans, FTC-2022-0015-1096, at 4 (May 24, 2022), <https://www.regulations.gov/comment/FTC-2022-0015-1096>.

¹⁵⁹ Respondent Document Submission [REDACTED] (discussing specialty growth and “[o]ptimization levers.”).

¹⁶⁰ See Am. Med. Ass’n, FTC-2022-0015-0638, at 5-6 (Apr. 26, 2022), <https://www.regulations.gov/comment/FTC-2022-0015-0638>; see also DCI 2024 Report, *supra* note 5, at 259-265; DCI 2020 Report, *supra* note 59, at 224 (noting the growth of white bagging especially in physician practices for oncology and immunotherapies).

promote the use of their affiliated pharmacies,¹⁶¹ and expedite the resolution of drug utilization management requirements (which the PBMs impose) if physicians send patient prescriptions to affiliated pharmacies.¹⁶² PBMs also use information obtained through their vertically integrated insurers to conduct marketing campaigns targeting patients and specialty providers.¹⁶³ The National Association of Specialty Pharmacy and other public commenters report that these marketing campaigns employ inaccurate information to coerce patients into switching to affiliated pharmacies.¹⁶⁴ For example, one independent pharmacy reported that the PBM sent its patient a letter which erroneously stated that the pharmacy had been terminated from the network, noting that the patient would “need to select a new specialty pharmacy,” and “[based] on medication [the patient] is taking, we recommend getting your medicine from a network specialty pharmacy.”¹⁶⁵

In addition to having the ability to steer prescriptions to their affiliated pharmacies, PBMs may also have a particularly strong incentive to capture specialty prescriptions at their affiliated

¹⁶¹ Respondents Document Submissions [REDACTED]

¹⁶² Respondents Document Submissions [REDACTED]

¹⁶³ Respondent Document Submission [REDACTED]

[REDACTED] (describing results of behavioral experiment to shift specialty patients to specialty pharmacy using direct mail, email, provider email, and letters); Respondent Document Submission [REDACTED] (summarizing elements of strategy to grow PBM’s affiliated specialty pharmacy market share, including obtain and retain limited distribution drug contracts, upsell to use the PBM’s affiliated specialty pharmacy exclusively, and convert PBM patients filling specialty medicines).

¹⁶⁴ See Nat’l Ass’n of Specialty Pharmacy, FTC-2022-0015-0648, at 6 (May 25, 2022), <https://www.regulations.gov/comment/FTC-2022-0015-0648> (“Vertically integrated PBMs can see a patient’s insurance information and will use the information to call or send a letter to a patient or prescriber, instructing them to transfer their prescription to the PBM-owned specialty pharmacy, or otherwise risk losing drug coverage. Extremely sick and vulnerable patients are then threatened to lose their coverage for a drug they otherwise may not be able to afford or access if they do not comply with the PBM’s demands.”); see also Thomas J. Hunt, FTC-2022-0015-0326, at 1 (Apr. 8, 2022), <https://www.regulations.gov/comment/FTC-2022-0015-0326> (“Our constant battle to keep our customers is never ending. Many receive letters telling them we are no longer in their prescription program, BUT WE ARE. They use this tactic to direct my patients to PBM owned pharmacies or their preferred pharmacies.”).

¹⁶⁵ Infinity Pharmacy Sols., FTC-2022-0015-1138, at 9 (May 24, 2022), <https://www.regulations.gov/comment/FTC-2022-0015-1138> (including photograph of 2019 letter) (commenting: “The [] letter was sent to one of Infinity’s patients despite the fact that Infinity had not been terminated from the relevant pharmacy network, and the patient had not requested a different pharmacy.”); Respondent Document Submission [REDACTED]

pharmacies, given their high prices and margins.¹⁶⁶ As an internal PBM board presentation stated, “[s]teering to . . . captive specialty pharmacies” is a “major” driver of value for PBMs.¹⁶⁷

Consistent with the above evidence, an FTC staff analysis of data produced in response to the 6(b) Orders¹⁶⁸ suggests that PBMs may be steering a high proportion of specialty prescriptions filled by commercial health plan members to their affiliated pharmacies.¹⁶⁹ We compared the proportions of specialty prescriptions (based on 30-day equivalents¹⁷⁰ and dispensing revenue¹⁷¹) filled by plan members managed by two of the Big 3 PBMs¹⁷² through affiliated and unaffiliated pharmacies over the 2017 to 2022 period.¹⁷³ We separately evaluated prescriptions filled by commercial and Medicare Part D plan members.¹⁷⁴ Weighted average results are presented in Figure 8.

¹⁶⁶ Specialty prescriptions account for only about two percent of total prescription volume but roughly 40 to 50 percent of pharmacy dispensing revenue due to their high prices. *See supra* note 82 and accompanying text.

¹⁶⁷ Respondent Document Submission [REDACTED]

¹⁶⁸ The analysis employs data produced in response to specification 14 of the 6(b) Orders. Specification 14 requested data for “each drug on the Company’s Specialty Drug List,” which includes all drugs “referenced as ‘specialty’ drugs” on “any list of prescription drugs” maintained by the PBM.

¹⁶⁹ In the analysis, a PBM-affiliated pharmacy is designated as affiliated with a PBM only when members of health plans managed by that PBM fill prescriptions at the pharmacy; when members of health plans not managed by the PBM fill prescriptions at the pharmacy, the pharmacy is designated as unaffiliated. Pharmacy-PBM affiliation was determined based on staff analysis of information from the NCPDP DataQ database of pharmacy demographics. All pharmacies that were included in both the data provided by the PBMs and the NCPDP data were included in the totals.

¹⁷⁰ A 30-day equivalent is a unit of measurement that adjusts prescription counts to correspond to a standard 30-day prescription; a 90-day prescription, for example, equals three 30-day equivalent prescriptions. More formally, CMS regulations define 30-day equivalent as follows: “If the days’ supply reported on a PDE [Prescription Drug Event] is less than or equal to 34, the number of 30-day equivalent supplies equals one. If the days’ supply reported on a PDE is greater than 34, the number of 30-day equivalent supplies is equal to the number of days’ supply reported on each PDE divided by 30.” 42 C.F.R. § 423.104(d)(2)(iv)(A)(2) (2024).

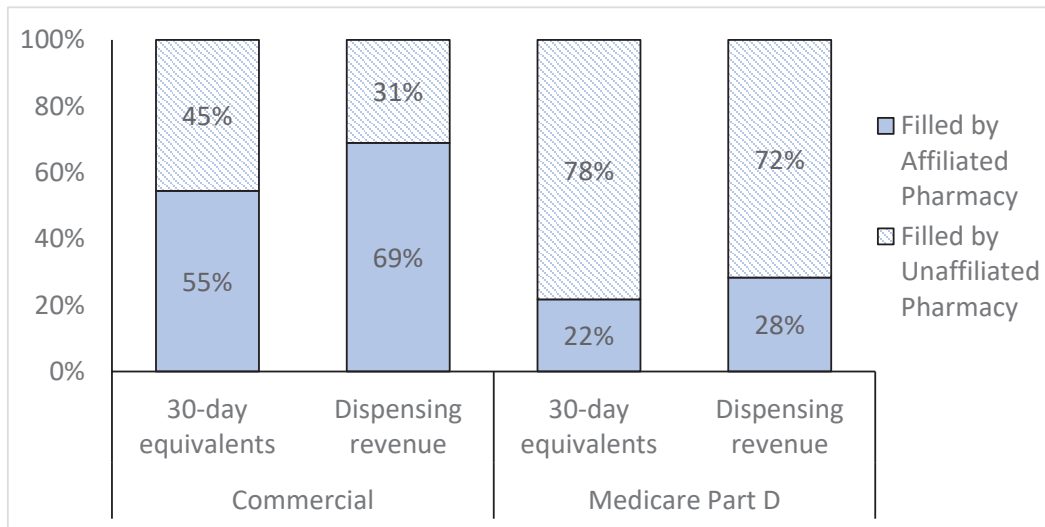
¹⁷¹ Dispensing revenue based on gross reimbursements to pharmacies before post-sale adjustments.

¹⁷² We focused on the Big 3 PBMs because these entities’ affiliated pharmacies fill the majority of specialty prescriptions. *See supra* Fig. 6.C (estimating Big 3 PBM affiliated pharmacies collectively account for 68 percent of specialty dispensing revenue). This analysis excludes one of the Big 3 PBM respondents that had not yet produced sufficient data. [REDACTED]

¹⁷³ PBM respondents were required to produce data through June 6, 2022; some produced additional months of data for 2022, in which case we also analyzed the additional data. References in this report to 2022 data produced by the PBM respondents generally should be interpreted to mean the data produced by each PBM for the year.

¹⁷⁴ Differences in the commercial and Medicare Part D patient populations may affect the mix of drugs filled, and therefore, the mix of dispensing pharmacies. However, we also examined prescriptions for two drugs that are widely used by both commercial and Medicare Part D patients (abiraterone acetate and imatinib mesylate, which we analyze further in § III.B *infra*) and found qualitatively similar trends in affiliated and unaffiliated pharmacy fill rates.

Figure 8. Proportion of Specialty Prescriptions Filled by Affiliated and Unaffiliated Pharmacies For Members of Commercial and Medicare Part D Plans Managed By Two of the Big 3 PBMs, 2017-2022¹⁷⁵



Members of commercial health plans managed by two of the Big 3 PBMs filled a significantly larger proportion of their specialty prescriptions at PBM-affiliated pharmacies (67 to 70 percent of dispensing revenue, on average, as shown in the commercial charts in Figure 8) compared with the pharmacies’ overall shares of dispensing revenue (ranging from nine to 28 percent per pharmacy, as shown in Figure 6.C). The high rates of dispensing at PBM-affiliated pharmacies compared with the pharmacies’ overall shares suggests that the PBMs may be steering many of the specialty prescriptions filled by members of the health plans they manage.¹⁷⁶

By contrast, PBMs appear less able to steer prescriptions for these drugs to affiliated specialty pharmacies within Part D likely due in part to Medicare’s “any willing pharmacy” requirements, which require Part D plans to contract with any interested pharmacy that meets the plan’s standard terms and conditions for network participation.¹⁷⁷ As shown in Figure 8, Medicare Part D members filled far fewer specialty prescriptions at affiliated pharmacies than commercial health plan

¹⁷⁵ FTC staff analysis of data produced in response to the 6(b) Orders, specification 14. Results are anonymized and aggregated pursuant to section 6 of the FTC Act. 15 U.S.C. § 46(f). [REDACTED]

¹⁷⁶ The results in Figure 8 (based on FTC staff analysis) and estimates in Figure 6.C (from Drug Channels Institute) were prepared using different methodologies, making comparisons imprecise. Nonetheless, the large differences support the view that these PBMs may be steering many of the health plan members they manage to their affiliated pharmacies. *See also* Respondent Document Submission, Specialty Strategy Review Presentation [REDACTED] (noting magnitude of affiliated pharmacy’s specialty market growth). This document further projects that [REDACTED]

¹⁷⁷ *See supra* note 42 and accompanying text. While Medicare Part D prescription drug plans are not permitted to use limited pharmacy networks, PBMs can develop preferred pharmacy networks for Part D plans. Such preferred networks are not covered by the existing any willing pharmacy requirements. *See supra* § II.A.

members—both when measured as a proportion of 30-day equivalents (20 to 24 percent, on average, across all years) and dispensing revenue (27 to 29 percent).¹⁷⁸

Additionally, PBM-affiliated pharmacies’ share of dispensing revenue exceeds their share of prescriptions for both commercial and Medicare Part D plans, suggesting that the PBMs are disproportionately filling higher value prescriptions at their own pharmacies.

2. Steering through expanded specialty drug lists

One potential mechanism that PBMs may use to steer prescriptions to their affiliated pharmacies is to classify drugs as specialty. As detailed in Section II.B.1. above, PBMs and their health plan clients have relatively broad discretion to make specialty classification decisions given the lack of an industry standard or regulatory definition for a specialty drug.¹⁷⁹ Once a drug is added to a PBM’s specialty drug lists, this may trigger exclusivity provisions in contracts with certain payers that require use of the PBM’s affiliated specialty pharmacy,¹⁸⁰ among various other related steering mechanisms.¹⁸¹ Moreover, the Big 3 PBMs’ affiliated pharmacies may be more likely to fill prescriptions for the drug designated as specialty by virtue of their significant share of the specialty dispensing segment.¹⁸²

Public commenters have indicated, for example, that “[m]any PBMs will re-classify a medication as a ‘specialty drug’ primarily based on a very high cost” and then “forc[e] their plan members to fill specialty medications only at pharmacies directly owned by the PBMs.”¹⁸³ The Senior Care Pharmacy Coalition, representing more than 300 long-term care pharmacies, similarly stated that PBMs “classify their medications as specialty drugs subject to the convoluted and opaque process whereby pharmacy access to specialty medications is restricted based on largely specious criteria created simply to allow PBMs to drive a significant percentage of specialty pharmacy revenue to payer-affiliated specialty pharmacies.”¹⁸⁴

To preliminarily assess the extent to which PBMs are designating drugs as specialty, FTC staff calculated the number of specialty drugs covered by five of the six PBM respondents during each

¹⁷⁸ The unaffiliated pharmacies’ high specialty dispensing rates for Part D members also demonstrate that these pharmacies are capable of filling specialty prescriptions.

¹⁷⁹ See *supra* § II.B.

¹⁸⁰ See Respondent Document Submission [REDACTED] (discussing specialty growth and “[o]ptimization levers” including [REDACTED]).

¹⁸¹ See *supra* § III.A.1.

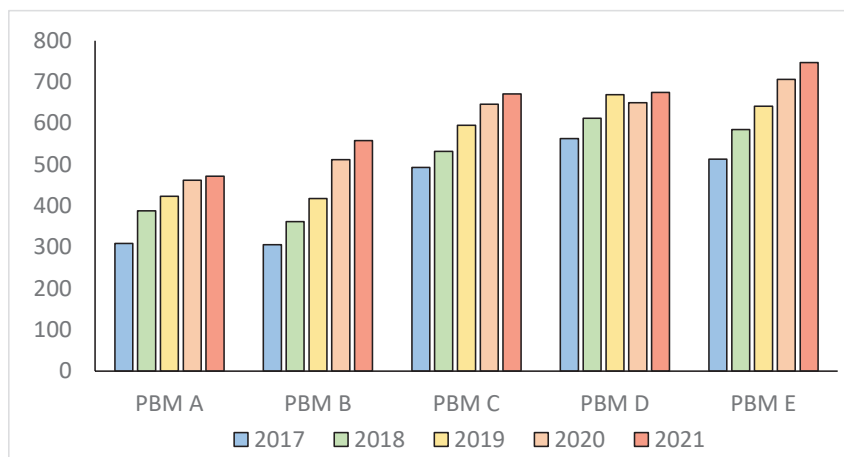
¹⁸² See *supra* Fig. 6.C.

¹⁸³ Carolina Health Ctrs., Inc., FTC-2022-0015-0886, at 7 (May 25, 2022), <https://www.regulations.gov/comment/FTC-2022-0015-0886>; see also Jagindra Mangru, FTC-2022-0015-0134, at 2 (Mar. 9, 2022), <https://www.regulations.gov/comment/FTC-2022-0015-0134> (noting PBMs “steer patients . . . to medications that are mandated to come from specialty pharmacies that they own.”); see also *supra* note 80 and accompanying text (discussing specialty drug designation factors, including high cost).

¹⁸⁴ Senior Care Pharmacy Coal., FTC-2022-0015-0979, at 39 (May 25, 2022), <https://www.regulations.gov/comment/FTC-2022-0015-0979>; see also N.D. Pharmacists Ass’n, FTC-2022-0015-1087, at 2 (May 20, 2022), <https://www.regulations.gov/comment/FTC-2022-0015-1087> (“In all most [sic] every instance, the PBM is the one who determines which drugs are going to be included on the PBM[’s] specialty drug list.”).

year from 2017 to 2021 (one of the six PBMs has not yet produced relevant data).¹⁸⁵ As illustrated in Figure 9, the number of drugs characterized by PBMs as specialty increased steadily over the study period.

Figure 9. Number of Specialty Drugs Covered by PBMs, 2017-2021¹⁸⁶



All PBMs increased the overall number of drugs on their specialty drug lists over the 2017 to 2021 period. While our trend analysis does not assess the factors underlying these increases in the number of specialty drugs, the trend appears to relate not only to the number of new specialty drugs brought to market,¹⁸⁷ but also to PBM specialty classification decisions that vary widely given the lack of regulation and industry standards governing what constitutes a specialty drug. Some PBMs designated far more drugs as specialty than others. For example, PBM E designated over 50 percent more drugs as specialty than PBM A during each year. Further demonstrating that specialty designations can differ widely across PBMs, one recent study found that only 32 percent of specialty drugs were included on all of the Big 3 PBMs’ specialty drug lists and 23 percent were included on two of their lists; the remaining 45 percent of specialty drugs were unique to a single

¹⁸⁵ The analysis employs data produced in response to specification 14 of the 6(b) Orders as well as RxTerms data. RxTerms includes a variable called `sxdg_rxcui`, which is a unique identifier for the entity represented by the drug and intended route. See *RxTerms*, NAT’L LIBR. MED., <https://lhncbc.nlm.nih.gov/MOR/RxTerms> (last visited June 21, 2024). Drugs were aggregated at the `sxdg_rxcui`-level and those with at least one prescription filled by a PBM during a year were counted in the analysis. Drugs packaged in packs are excluded, though some or all of these drugs may be represented by non-pack versions of the same drug.

¹⁸⁶ FTC staff analysis of data produced in response to the 6(b) Orders, specification 14. Results are anonymized pursuant to section 6 of the FTC Act. 15 U.S.C. § 46(f). Anonymization designations may differ between figures.

¹⁸⁷ See Marcia Macphearson et al., *Specialty Drugs: A Prescription for Managing Rising Cost and Care Needs*, 3 OLIVER WYMAN HEALTH INNOVATION J. 58 (2019) (noting specialty drugs accounted for more than half of novel drugs approved by FDA in recent years); *Specialty Drug Growth is Here to Stay*, CARELONRX (Jan. 24, 2024), <https://www.carelonrx.com/perspectives/specialty-drug-growth> (highlighting trend over past decade of larger share of new drug approvals for specialty drugs, which accounted for 59 percent of new-to-market drugs in 2022).

PBM—i.e., the drugs were designated as specialty by only one of the PBMs while the others covered the drugs as traditional drugs or not at all.¹⁸⁸

Another notable trend with regard to specialty drug coverage relates to generic drugs that PBMs have designated as specialty (“specialty generics”). As shown in Figure 10, while specialty generics comprise a relatively small proportion of the number of specialty drugs covered by PBMs (ranging from 11 to 15 percent in 2021), most of the PBM respondents added generics to their specialty drug lists at a significantly faster rate than brand drugs over the 2017 to 2021 period.

Figure 10. Growth and Mix of Specialty Drugs Covered by PBMs for Commercial Members, 2017-2021¹⁸⁹

	Growth in Number of Drugs Covered, 2017-2021		Specialty Generic As Percent of Total, 2021
	Specialty Brand	Specialty Generic	
PBM A	70%	268%	13%
PBM B	44%	233%	11%
PBM C	41%	94%	13%
PBM D	31%	73%	15%
PBM E	20%	19%	15%

B. REIMBURSEMENT RATES AND DISPENSING REVENUE RECEIVED BY PBM-AFFILIATED PHARMACIES FOR SPECIALTY GENERICS: TWO CASE STUDIES

When insurers and health plans contract with PBMs to manage their prescription drug benefits, those health plans reportedly pay the PBMs’ affiliated pharmacies higher reimbursement rates for specialty drugs, including specialty generics, compared with unaffiliated pharmacies.

Public comments received by the FTC highlight this concern,¹⁹⁰ and numerous reports have confirmed cases in which federal payers paid higher rates for specialty generics compared with pharmacy acquisition costs and point-of-sale prices at cash-pay pharmacies.¹⁹¹ Relatedly, the

¹⁸⁸ See DCI 2024 Report, *supra* note 5, at 24 (referencing *How PBMs Distort and Undermine Specialty Drug Pricing Guarantees*, 46BROOKLYN (May 10, 2023), <https://www.46brooklyn.com/research/2023/5/10/how-pbms-distort-and-undermine-specialty-drug-pricing-guarantees-blac>). This study examined specialty drugs at the National Drug Code (“NDC”) level.

¹⁸⁹ FTC staff analysis of data produced in response to the 6(b) Orders, specification 14. Results are anonymized pursuant to section 6 of the FTC Act. 15 U.S.C. § 46(f). Anonymization designations may differ between figures.

¹⁹⁰ See, e.g., N.D. Pharmacists Ass’n, *supra* note 184, at 2 (“PBMs pay[] themselves more than their direct competitors with whom they control all contracting aspects.”).

¹⁹¹ See, e.g., Stacie B. Dusetzina et al., *Broken Promises—How Medicare Part D Has Failed to Deliver Savings to Older Adults*, 383 NEW ENG. J. MED. 2299, 2300 (2020); Brian D. Cortese et al., *Projected Savings for Generic Oncology Drugs Purchased via Mark Cuban Cost Plus Drug Company Versus in Medicare*, 41 J. CLINICAL ONCOLOGY 4664, 4666 (2023); see also Hussain S. Lalani et al., *Potential Medicare Part D Savings on Generic Drugs from the Mark Cuban Cost Plus Drug Company*, 175 ANNALS OF INTERNAL MED. 1053, 1053 (2022); THREE AXIS ADVISORS, *SUNSHINE IN THE BLACK BOX OF PHARMACY BENEFITS MANAGEMENT: FLORIDA MEDICAID*

Department of Health and Human Services (“HHS”) Office of Inspector General recently opened an audit to investigate the “concern . . . that, by owning many links in the chain, a vertically integrated Medicare Part D sponsor may inflate drug prices.”¹⁹² As noted above, several PBMs have affiliated Medicare Part D plans and manage these plans for many other payers.¹⁹³

In this section, we evaluate reimbursement rates and pharmacy dispensing revenue for two specialty generic drugs: (1) generic Zytiga (abiraterone acetate), used to treat prostate cancer; and (2) generic Gleevec (imatinib mesylate), used to treat leukemia (the “case study drugs”). Using data obtained pursuant to our 6(b) Orders, FTC staff examined prescriptions for the case study drugs filled by members of commercial health plans and Medicare Part D prescription drug plans managed by the Big 3 PBMs¹⁹⁴ at PBM-affiliated and unaffiliated pharmacies.¹⁹⁵ The analyses cover the period from 2020 through part of 2022.¹⁹⁶

The two case study drugs are widely used. In 2021, the last period for which PBM respondents produced full-year data, the Big 3 PBMs processed 232,000 abiraterone acetate (generic Zytiga) 30-day equivalent prescriptions for commercial and Part D plan members (who accounted for 31 percent and 69 percent of the prescriptions, respectively), and 182,000 imatinib mesylate (generic Gleevec) 30-day equivalent prescriptions for commercial and Part D members (50 percent each).¹⁹⁷

Our findings show that health plans managed by PBMs reimburse their PBM-affiliated pharmacies for the two case study drugs at rates that are higher than the National Average Drug Acquisition Cost (“NADAC”),¹⁹⁸ a common measure of pharmacy acquisition costs of drugs based on amounts

PHARMACY CLAIMS ANALYSIS (2020), <https://static1.squarespace.com/static/5c326d5596e76f58ee234632/t/5e384f26fc490b221da7ced1/1580748598035/FL+Master+Final+Download.pdf>.

¹⁹² HHS stated in the public announcement of the audit: “In recent years, the pharmaceutical market has experienced a wave of vertical integration between PBMs, health insurers, and pharmacies. Concern has been raised about the vertically integrated model. One such concern is that, by owning many links in the chain, a vertically integrated Medicare Part D sponsor may inflate drug prices. We will determine the impact of related entity transactions within select vertically integrated entities on the prices for covered Part D drugs.” *Audit of Vertically Integrated Medicare Part D Sponsors*, U.S. DEP’T HEALTH & HUM. SERVS., OFF. INSPECTOR GEN. (Apr. 2024), <https://oig.hhs.gov/reports-and-publications/workplan/summary/wp-summary-0000849.asp>.

¹⁹³ See *supra* § II.A.

¹⁹⁴ We focused on the Big 3 PBMs because these entities’ affiliated pharmacies fill the majority of specialty prescriptions. See *supra* Fig. 6.C (estimating Big 3 PBM affiliated pharmacies collectively account for 68 percent of specialty dispensing revenue).

¹⁹⁵ See *supra* note 169 discussing affiliated and unaffiliated pharmacy designations.

¹⁹⁶ See *supra* note 172 discussing partial year data produced by one or more PBM respondents for 2022.

¹⁹⁷ FTC staff analysis of data produced in response to the 6(b) Orders, specification 14.

¹⁹⁸ NADAC is an index of drug acquisition costs based on surveys of invoices voluntarily provided primarily by small, independent pharmacies. See *Retail Price Survey*, MEDICAID.GOV (May 31, 2024), <https://www.medicare.gov/medicaid/prescription-drugs/retail-price-survey/index.html>. Because small, independent pharmacies generally pay more than large chain and mail order pharmacies for the same drugs, NADAC is likely higher than the acquisition costs of large pharmacies. See Respondent Document Submission [REDACTED]

[REDACTED] (recognizing NADAC prices are “[i]nflated because larger players aren’t submitting prices to NADAC, but smaller pharmacies do”); Respondent Document Submission [REDACTED] (noting a PBM-affiliated pharmacy’s “acquisition cost is always lower” than the acquisition cost of a cash-pay

reported to the Centers for Medicare & Medicaid Services (“CMS”) by pharmacies (Section III.B.1). Our findings also show that health plans managed by PBMs reimburse their PBM-affiliated pharmacies more than unaffiliated pharmacies for the same two case study drugs (Section III.B.1). In addition, our findings suggest vertically integrated PBM-insurer-pharmacy entities are able to shift revenue among their affiliates to retain excess revenue (Section III.B.2). Although our findings are necessarily limited to the two case study drugs, they suggest that PBMs may very well be able to do the same for other drugs.

1. Pharmacies affiliated with the Big 3 PBMs are often paid 20- to 40-times NADAC, and significantly more than unaffiliated pharmacies, for the two case study specialty generic drugs

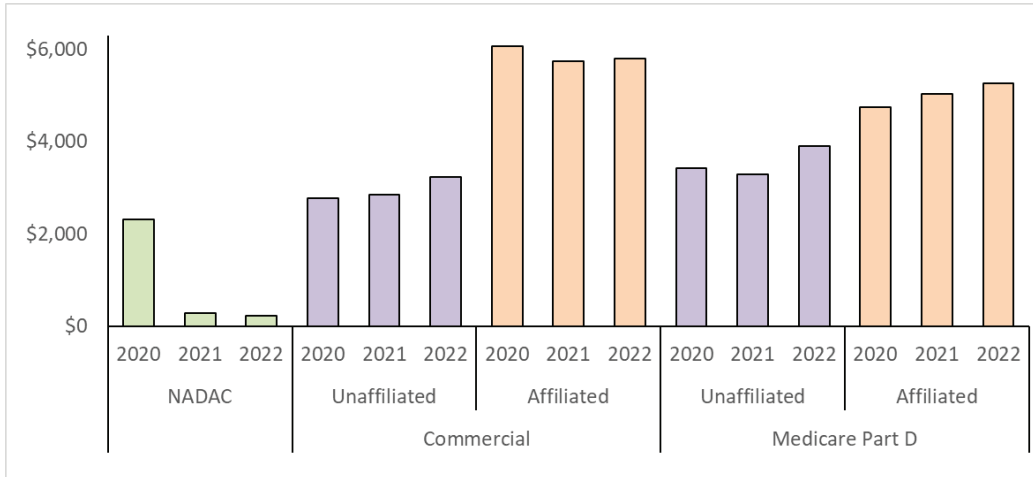
In assessing reimbursement rates for our two case study drugs, we compared gross reimbursement rates paid by Big 3 PBM-managed payers to their PBM’s affiliated pharmacies with NADAC, and with the rates paid to unaffiliated pharmacies.¹⁹⁹ These comparisons are presented in Figure 11 segmented by commercial and Medicare Part D payers for 2020 through 2022. The Big 3 PBMs’ reimbursement rates have been combined into weighted average results.

pharmacy). Therefore, NADAC may be viewed as an estimate for small, independent pharmacy acquisition costs while large pharmacy acquisition costs are generally lower.

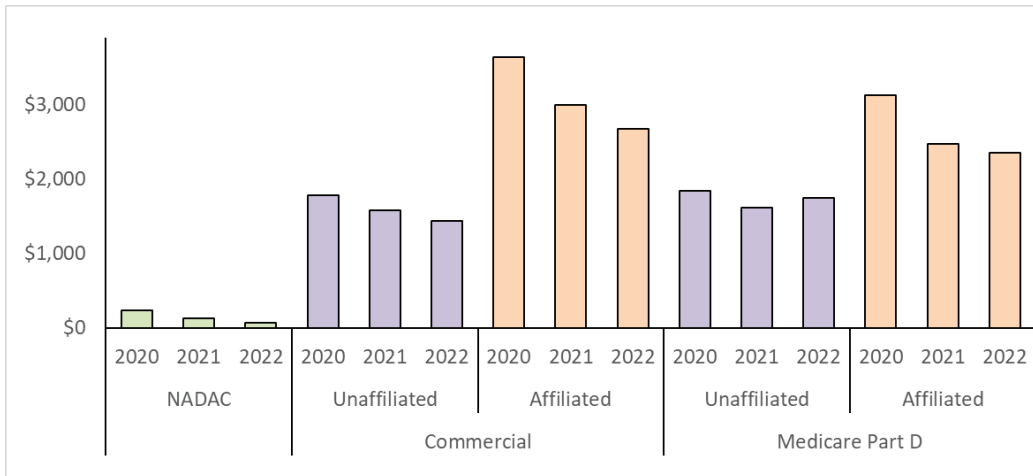
¹⁹⁹ Gross reimbursement to a pharmacy is the sum of the amounts paid by the PBM, the patient, and any other payers (*e.g.*, a secondary insurer), as applicable. NADAC is based on the maximum NADAC observed each year for the most commonly dispensed dose of the drug. NADAC was not always available for other doses of the drug. The acquisition costs for those drugs may be lower or higher than the NADAC for the most commonly dispensed dose.

**Figure 11. Gross Pharmacy Reimbursement Rates
For a One-Month Supply of Two Specialty Generics
Paid to PBM-Affiliated and Unaffiliated Pharmacies
By Commercial and Medicare Part D Plans and Members
Managed By the Big 3 PBMs, and NADAC, 2020-2022²⁰⁰**

A. Abiraterone Acetate (generic Zytiga for prostate cancer)



B. Imatinib Mesylate (generic Gleevec for leukemia)



The PBMs’ affiliated pharmacies received high gross reimbursement rates from the health plans they manage for the two case study drugs, often roughly 20- to 40-times higher than NADAC. This is the case for both the commercial and Medicare Part D payer groups. For example, commercial health plans reimbursed affiliated pharmacies for abiraterone acetate (generic Zytiga) in 2022 more than \$5,800 per month, on average—or approximately 25-times the \$229 acquisition

²⁰⁰ FTC staff analysis of data produced in response to the 6(b) Orders, specification 14. Results are anonymized and aggregated pursuant to section 6 of the FTC Act. 15 U.S.C. § 46(f).

cost reflected by NADAC.²⁰¹ That year, Part D plan reimbursements to affiliated pharmacies for abiraterone acetate averaged 23-times NADAC. For imatinib mesylate (generic Gleevec), commercial health plan reimbursements to affiliated pharmacies averaged roughly \$2,700 per month in 2022, more than 40-times higher than the NADAC acquisition cost of \$66. Part D plans similarly reimbursed affiliated pharmacies nearly 36-times NADAC for imatinib mesylate in 2022. We observed similar patterns between affiliated pharmacies and NADAC when we examined each PBM separately, though the magnitude of the differences varied by PBM, drug, year, and payer group.²⁰²

Moreover, the reimbursement rate-NADAC multiples cited above understate the actual spreads that vertically integrated PBM-insurer-pharmacy entities maintain because PBM-affiliated pharmacies' acquisition costs are generally lower than NADAC.²⁰³ One PBM presentation, for example, presents data indicating that it billed payers almost 250-times its acquisition cost for imatinib mesylate (generic Gleevec) in 2021.²⁰⁴ The following year, the PBM was questioned by one of its consultants about its high prices on imatinib mesylate, which had prompted client "concerns" over the pricing of specialty generics generally.²⁰⁵ An executive of another PBM's parent corporation expressed concerns about the "optics" of its mail order pharmacy's high prices on imatinib mesylate when compared with preferred and non-preferred retail pharmacy prices:

[Y]ou can get the drug [imatinib mesylate] at a non-preferred pharmacy (Costco) for \$97, at Walgreens (preferred) for \$9000, and at preferred home delivery for \$19,200. CMS expects that plans that offer preferred pharmacy constructs have lower pricing in the preferred channel. Compounding the challenge/optics is the fact that we've created plan designs to aggressively steer customers to home delivery where the drug cost is ~200 times higher. The optics are not good and must be addressed.²⁰⁶

²⁰¹ According to the New York Times, Express Scripts charged employees of the hotel company Hyatt \$1,500 per month for abiraterone acetate, and CVS Caremark charged Blue Shield of California members \$3,000 per month, compared to a wholesale price of \$160. *See* Robbins & Abelson, *supra* note 58. In response, the PBMs defended their pricing practices. *See id.* ("Some executives acknowledged that there were times when they overcharged for specific drugs, but the companies said they offered the lowest overall prices to their clients. (The system's opacity makes that claim impossible to verify.)").

²⁰² In particular, we observed differences in reimbursement rates for abiraterone acetate across PBMs.

²⁰³ *See* discussion of NADAC *supra* note 198.

²⁰⁴ *See* Respondent Document Submission [REDACTED] (reporting average rates for generic Gleevec in 2021, including [REDACTED])

²⁰⁵ *See* Respondent Document Submission [REDACTED]

²⁰⁶ Respondent Document Submission [REDACTED]

As shown in Figure 11, PBM-affiliated pharmacies also received significantly higher gross reimbursement rates than unaffiliated pharmacies for the two case study drugs. In 2022, commercial health plans paid affiliated pharmacies roughly 80 to 90 percent more than unaffiliated pharmacies for abiraterone acetate (generic Zytiga) and imatinib mesylate (generic Gleevec), while Part D plans paid affiliated pharmacies over 30 percent more than unaffiliated pharmacies for both drugs. At the same time, gross reimbursement rates paid to unaffiliated pharmacies also exceeded NADAC.²⁰⁷ We observed similar patterns between affiliated and unaffiliated pharmacies when we examined each PBM separately, though the magnitude of the differences varied by PBM, drug, year, and payer group.

In addition to assessing gross reimbursement rates, we examined net reimbursement rates after post-sale adjustments for the two case study drugs for two of the Big 3 PBM respondents (one of the PBMs has not yet produced post-sale adjustment data).²⁰⁸ For commercial claims, the differences between net and gross reimbursement rates paid for the two case study drugs were de minimis, on average, for both the affiliated and unaffiliated pharmacies. For Medicare Part D claims, net reimbursement rates were consistently lower than gross rates—averaging roughly 4 to 5 percent less for affiliated pharmacies and 7.5 to 8.5 percent less for unaffiliated pharmacies, though the differences generally grew between 2020 and 2022 and also varied by PBM and drug.²⁰⁹

The high reimbursement rates on the two case study drugs may also translate into high out-of-pocket costs for patients, particularly Medicare Part D plan members.²¹⁰ For example, the average

²⁰⁷ In 2022, gross reimbursements to unaffiliated pharmacies averaged roughly 15-times higher than NADAC for abiraterone acetate and more than 20-times higher than NADAC for imatinib mesylate.

²⁰⁸ Net reimbursement to a pharmacy is calculated as gross reimbursement less an estimated post-sale adjustment. Post-sale adjustments are often not tied to a particular prescription or drug, so the PBMs were asked to allocate the adjustments at the drug level. These allocations may be based on shares of prescriptions or some dollar measure, such as average wholesale price (“AWP”). See CTRS. FOR MEDICARE & MEDICAID SERVS., PRESCRIPTION DRUG DATA COLLECTION (RXDC) REPORTING INSTRUCTIONS 56 (2024) (describing allocation methods for similar purpose). Since post-sale adjustments are generally calculated for a large set of drugs based on reimbursement and pharmacy performance metrics, a drug-level allocation essentially reflects an average adjustment that may not represent the drug’s actual contribution to the post-sale adjustment applied to the pharmacy as a whole. Therefore, caution should be taken when interpreting these drug-level adjustments; they are likely more informative when examining aggregate reimbursements across a large set of drugs. See also discussion of post-sale adjustments *infra* § III.C.4.

²⁰⁹ After adjustment for post-sale adjustments, the net reimbursement rates paid to unaffiliated pharmacies are higher than NADAC. One study suggests that independent pharmacies are typically reimbursed less than NADAC, though more than NADAC on selected drugs. See *Understanding Pharmacy Reimbursement Trends in Oregon*, THREE AXIS ADVISORS (Oct. 27, 2022), <https://www.3axisadvisors.com/projects/2022/10/27/understanding-pharmacy-reimbursement-trends-in-oregon> (indicating “for every 100 prescriptions filled [by a typical retail pharmacy in Oregon] . . . the majority of claims (75 out of 100) dispensed . . . were insufficient to cover approximate pharmacy labor and drug costs” while “a small number of claims (2 out of 100) were reimbursed extremely well.”). The unaffiliated pharmacies may have received net reimbursements in excess of NADAC on the two case study drugs. However, it is also possible that the net reimbursement rates paid to unaffiliated pharmacies were actually lower than reported (closer to NADAC) due to issues with the post-sale adjustments data. See *supra* note 208.

²¹⁰ See U.S. GOV’T ACCOUNTABILITY OFF., GAO-23-105270, MEDICARE PART D: CMS SHOULD MONITOR EFFECTS OF REBATES ON PLAN FORMULARIES AND BENEFICIARY SPENDING (2023), <https://www.gao.gov/assets/gao-23-105270.pdf> (“[D]rugs with higher gross costs generally result in higher beneficiary payments relative to payments for competing drugs with lower gross costs.”).

cost sharing for Part D members on abiraterone acetate (generic Zytiga) was higher than NADAC in 2021, the last period for which PBM respondents produced full-year data.²¹¹ In other words, these patients paid more out of pocket, on average, than the estimated acquisition cost of their drugs.

2. Pharmacies affiliated with the Big 3 PBMs retained nearly \$1.6 billion in dispensing revenue in excess of NADAC for the two case study specialty generic drugs from 2020 through part of 2022

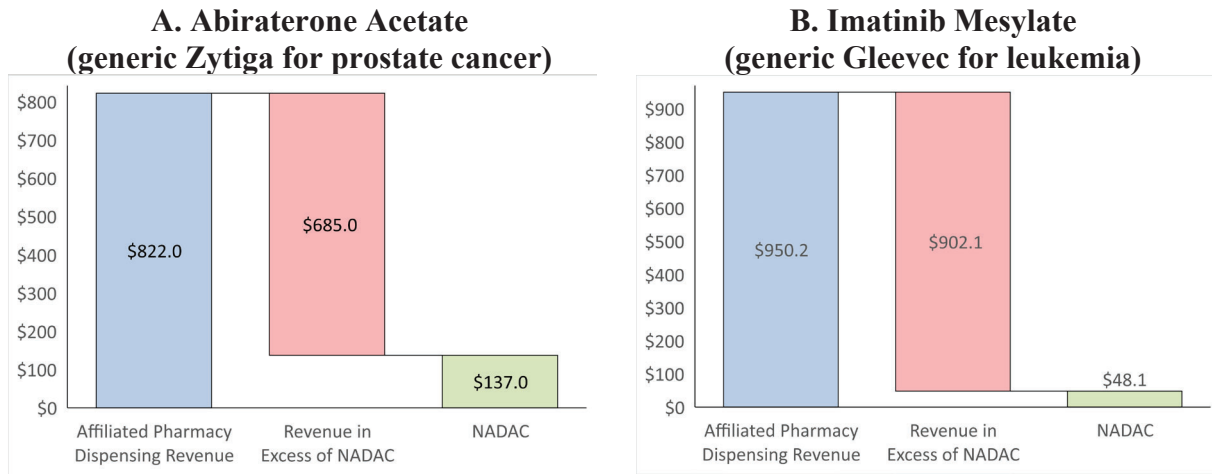
In the aggregate, the high reimbursement rates paid to PBM-affiliated pharmacies translate into substantial revenue gains for these pharmacies. Based on reimbursement rates weighted by the quantities of commercial and Part D prescriptions dispensed,²¹² we find that the dispensing revenue of pharmacies affiliated with the Big 3 PBMs exceeded NADAC by nearly \$1.6 billion over the period from 2020 through part of 2022,²¹³ including by \$685 million for abiraterone acetate (generic Zytiga) and by \$902.1 million for imatinib mesylate (generic Gleevec). These findings are illustrated in Figure 12 below.

²¹¹ FTC staff analysis of data produced in response to the 6(b) Orders, specification 14. This was the case for abiraterone acetate (generic Zytiga) prescriptions filled at both affiliated and unaffiliated pharmacies. The out-of-pocket costs paid by Part D members on imatinib mesylate (generic Gleevec) was less than NADAC, on average, and commercial plan members' out-of-pocket costs on both of the case study drugs were lower, likely as a result of drug manufacturer coupons. See *The Abiraterone Acetate Instant Savings* Program is Now Extended!*, APOTEX, <https://www.abirateronesavings.com/patient-assistance> (last visited June 13, 2024); *Novartis Oncology Universal Co-pay Program*, NOVARTIS, <https://www.copay.novartisoncology.com/?name=gleevec> (last visited June 13, 2024); see generally So-Yeon Kang et al., *Patterns of Manufacturer Coupon Use for Prescription Drugs in the US, 2017-2019*, 6 JAMA NETWORK OPEN 1 (2023).

²¹² Pharmacy reimbursements were calculated based on net reimbursement rates for two of the PBMs and gross reimbursement rates for the third due to data limitations. See *supra* note 208 and accompanying text.

²¹³ See *supra* note 172 discussing partial year data produced by one or more PBM respondents for 2022.

Figure 12. Pharmacy Dispensing Revenue in Excess of NADAC for Two Specialty Generics Received by Pharmacies Affiliated with the Big 3 PBMs For Commercial and Medicare Part D Prescriptions, 2020-2022 (partial)²¹⁴
(\$ in millions)



The amount by which affiliated pharmacy dispensing revenue exceeds NADAC for the two case study drugs is significant because NADAC provides an estimate of the price pharmacies pay to acquire generic products.²¹⁵ Accordingly, pharmacy dispensing revenue in excess of NADAC provides a rough estimate of pharmacy-level gross profits.

The above analyses of our two case study drugs suggest a misalignment of incentives where PBMs are not lowering prices for drugs used by patients to treat severe diseases like prostate cancer and leukemia. Rather, it appears that PBMs are having the commercial health plans and Medicare Part D prescription drug plans that they manage pay their affiliated pharmacies rates that are grossly in excess of drug acquisition costs as measured by NADAC, and significantly more than the rates paid to unaffiliated pharmacies.²¹⁶

* * *

The high levels of dispensing revenue in excess of NADAC that PBM-affiliated pharmacies are receiving for the two specialty generic case study drugs are relevant for several reasons. As described below, these reasons vary by health plan type (fully-insured versus ASO) and payer type (commercial versus Medicare Part D), and by whether the PBM is affiliated with the insurer covering the claim—a reflection of the complexity that can arise when seeking to understand the incentives of vertically integrated PBM-insurer-pharmacy entities.

Fully-insured health plans offered by the PBM’s affiliated insurer. Payments to affiliated pharmacies by a PBM-affiliated fully insured health plan represent internal transfers from the

²¹⁴ FTC staff analysis of data produced in response to the 6(b) Orders, specification 14. Results are anonymized and aggregated pursuant to section 6 of the FTC Act. 15 U.S.C. § 46(f).

²¹⁵ See MEDICAID.GOV, *supra* note 198.

²¹⁶ See *supra* Fig. 11.

PBM's vertically integrated insurer to its pharmacies. These internal transfers may have implications for medical loss ratios ("MLRs"), which are regulated under the Affordable Care Act and represent the percentage of premium revenue that health plans are required to spend on clinical care and quality improvement initiatives (80 to 85 percent) rather than administrative expenses and contributions to plan profits.²¹⁷ Industry experts have raised concerns that vertically integrated healthcare entities can game MLR requirements by shifting funds between affiliated entities.²¹⁸ For example, if an affiliated insurer pays an inflated price for a specialty generic to its affiliated pharmacy, the higher payment is credited as spending on clinical care and helps the affiliated insurer satisfy its MLR obligations. At the same time, the payment is credited as revenue to the affiliated pharmacy. Because the pharmacy's revenue has no bearing on the affiliated insurer's MLR calculation, this transfer payment allows the vertically integrated PBM-insurer-pharmacy entity to retain revenue and profits while formally satisfying the MLR rule—but without providing the clinical care and quality improvements that the rule is meant to promote.

ASO (self-funded) health plans managed by the PBM's affiliated insurer. When reimbursement payments to affiliated pharmacies are billed to ASO health plans managed by PBM-affiliated insurers, these billed amounts constitute costs passed through to third-party payer entities—i.e., clients of the PBMs' vertically integrated insurers, such as large employers. Inflated reimbursement payments thus increase these third parties' healthcare costs.

Health plans (fully-insured and ASO) not offered or managed by the PBM's affiliated insurer. Payments to affiliated pharmacies billed to unaffiliated health plans may also represent costs passed through to third-party payer entities, depending on the terms of the PBM-payer contract.

Medicare Part D prescription drug plans. Payments to affiliated pharmacies by Medicare Part D plans impact both government and beneficiary spending. High reimbursement rates result in beneficiaries moving into Part D's catastrophic phase more quickly, after which the government pays a percentage of drug costs.²¹⁹ High reimbursement rates during a given year also raise Part D

²¹⁷ *Medical Loss Ratio*, NAT'L ASS'N INS. COMM'RS (Oct. 26, 2022), https://topics-naic-cms.pantheonsite.io/cipr-topics/medical-loss-ratio#_edn1 (noting MLR statutory requirement of 80 percent for individual and small group health plans and 85 percent for large group health plans). MLRs are regulated for commercial fully insured health plans, but not ASO (self-funded) health plans. *See, e.g.*, SUZANNE M. KIRCHHOFF, CONG. RSCH. SERV., R42735, MEDICAL LOSS RATIO REQUIREMENTS UNDER THE PATIENT PROTECTION AND AFFORDABLE CARE ACT (ACA): ISSUES FOR CONGRESS (2015) ("The MLR provisions apply to fully funded health plans, which are plans where insurance companies assume full risk for incurred medical expenses. The MLR does not extend to self-funded plans, which are health care plans offered by businesses where the employer assumes the risk for, and pays for, medical care.").

²¹⁸ *See* Richard G. Frank & Conrad Milhaupt, *Related Businesses and Preservation of Medicare's Medical Loss Ratio Rules*, BROOKINGS INST. (June 29, 2023), <https://www.brookings.edu/articles/related-businesses-and-preservation-of-medicare-medical-loss-ratio-rules>; *see also* DCI 2024 Report, *supra* note 5, at 395 ("[I]ntegration into pharmacy and provider services can allow the companies to retain a greater share of total healthcare spending. Put another way, a healthcare service that counts as a cost for the MLR computation could represent revenue to a related business.").

²¹⁹ Historically, Medicare paid 80 percent of Part D drug costs above the catastrophic threshold (in 2024, beneficiaries reached the catastrophic phase after paying \$8,000 in out-of-pocket costs). In 2025, Medicare's share of Part D drug costs above the catastrophic threshold will be reduced to 20 or 40 percent. *See Final CY 2025 Part D Redesign Program Instructions Fact Sheet*, CTRS. FOR MEDICARE & MEDICAID SERVS. (Apr. 1, 2024), <https://www.cms.gov/newsroom/fact-sheets/final-cy-2025-part-d-redesign-program-instructions-fact-sheet>.

plans' expected cost projections used to prepare bids, which may result in increased payments from Medicare in the following year.²²⁰ Additionally, high rates paid to PBM-affiliated pharmacies within Medicare Part D could potentially raise the same MLR issues described above in the context of commercial health plans.²²¹

In addition, reimbursement rates are correlated with the point-of-sale prices, which often provide a basis for patient cost-sharing requirements.²²² For specialty drugs, these cost-sharing requirements can be significant,²²³ as evidenced by our two case study drugs.²²⁴ Academic studies have shown that high patient cost sharing discourages utilization of drugs, including medically necessary drugs,²²⁵ which may result in poor health outcomes.²²⁶ In addition, inflated drug costs over time also result in higher premiums, both for commercial and Medicare Part D members, as well as higher taxes to support increased Medicare expenditures.

²²⁰ Part D plans bid prospectively based on expected costs, and these bids influence Medicare payment rates. *See 2025 Medicare Advantage and Part D Rate Announcement*, CTRS. FOR MEDICARE & MEDICAID SERVS. (Apr. 1, 2024), <https://www.cms.gov/newsroom/fact-sheets/2025-medicare-advantage-and-part-d-rate-announcement> (noting plan sponsors submit bids based on expected enrollee costs); CTRS. FOR MEDICARE & MEDICAID SERVS., CMS-10142, INSTRUCTIONS FOR COMPLETING THE PRESCRIPTION DRUG PLAN BID PRICING TOOL FOR CONTRACT YEAR 2025, at 9 (2024), https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/CY2025%20Part%20D%20BPT%20Instructions_2024_04_05.pdf (instructing plans to use prior year claims data to project expected costs).

²²¹ *See supra* note 218 and accompanying text. Part D plans are required to spend 85 percent of premium revenue on clinical care and quality improvement. *See Medical Loss Ratio*, CTRS. FOR MEDICARE & MEDICAID SERVS. (Sept. 6, 2023), <https://www.cms.gov/medicare/health-drug-plans/medical-loss-ratio> (noting MLR statutory requirement of 85 percent for Medicare Part D prescription drug plans); 42 C.F.R. § 423.2410. However, because Medicare's reinsurance has grown over time, MLR may not be triggered for many plans. *See REPORT TO THE CONGRESS: MEDICARE PAYMENT POLICY*, MEDPAC 338 tbl. 11-4 (2024). This, however, may change when the catastrophic threshold is reduced in 2025. *See supra* note 219 and accompanying text.

²²² *See, e.g., CMS Releases 2024 Projected Medicare Part D Premium and Bid Information*, CTRS. FOR MEDICARE & MEDICAID SERVS. (July 23, 2023), <https://www.cms.gov/newsroom/fact-sheets/cms-releases-2024-projected-medicare-part-d-premium-and-bid-information>.

²²³ For example, Medicare permits Part D prescription drug plans to impose patient coinsurance requirements of up to 33 percent. *See REPORT TO THE CONGRESS, CHAPTER 2: RESTRUCTURING MEDICARE PART D FOR THE ERA OF SPECIALTY DRUGS*, MEDPAC 25 (2019), https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/jun19_ch2_medpac_reporttocongress_sec.pdf.

²²⁴ *See supra* § III.B.1.

²²⁵ *See, e.g., Rohan Khera et al., Cost-Related Medication Nonadherence in Adults With Atherosclerotic Cardiovascular Disease in the United States, 2013 to 2017*, 140 CIRCULATION 2067, 2067 (2019) (finding 12.6 percent of patients with atherosclerotic cardiovascular disease went without medicine due to cost, which was associated with high comorbidity); Yu-Chyn Chiang et al., *The Association Between Cost-Related Non-Adherence Behaviors and Diabetes Outcomes*, 36 J. AM. BD. FAM. MED. 15, 15 (2023).

²²⁶ Caroline A. Walsh et al., *The Association Between Medication Nonadherence and Adverse Health Outcomes in Ageing Populations: A Systematic Review and Meta-analysis*, 85 BRIT. J. CLINICAL PHARMACOLOGY 2464, 2472 (2019) (finding medication non-adherence in older adults associated with higher rates of hospitalization and mortality); Amitabh Chandra et al., *The Health Costs of Cost Sharing 1* (Nat'l Bureau of Econ. Rsch., Working Paper No. 28439, 2024) (finding Medicare Part D beneficiaries cut back on medications when faced with higher costs, resulting in increased mortality rates).

C. THE LARGEST PBMS' OUTSIZED BARGAINING LEVERAGE MAY OPERATE TO THE DISADVANTAGE OF SMALLER UNAFFILIATED PHARMACIES

We now turn to the bargaining dynamics between increasingly concentrated PBMs and pharmacies. A pharmacy may be reimbursed for filling prescriptions for a health plan's beneficiaries only by first entering a network contract with the PBM serving that plan. As outlined in Section II, PBMs design and administer a range of pharmacy networks for their clients, health plans and plan sponsors, who use these networks to provide their beneficiaries with access to prescription benefits. To be a part of a PBM's network, or to obtain "preferred" status in the network—and thus to capture larger volumes of business from patients—a pharmacy may provide to the PBM favorable terms such as pricing (e.g., lower rates of reimbursement to the pharmacy).²²⁷ Because the Big 6 PBMs control over 90 percent of dispensing volume and the Big 3 cover approximately 270 million people,²²⁸ pharmacies often have little choice but to contract with the dominant PBMs to serve patients. This can give these largest PBMs both enormous leverage over unaffiliated, independent pharmacies and the ability and incentive to act in ways that are detrimental to those pharmacies with limited recourse over unfavorable terms offered by the PBM.

1. The largest PBMs employ lopsided and unilateral contracting practices

The study received over a thousand comments regarding the leverage PBMs wield in negotiating with pharmacies for participation in networks. Commenters reported that increased consolidation and vertical integration have exacerbated uneven bargaining power.²²⁹ In addition, numerous independent pharmacies and a large PSAO have commented that they are generally forced to enter into one-sided, non-negotiable contracts with the leading PBMs.²³⁰ Pharmacies that decline terms offered by the largest PBMs—who are affiliated with the largest plans with the highest numbers of beneficiaries—may forgo potential business from all covered patients.²³¹

²²⁷ See *supra* § II.A.1; see also Respondent Responses to 6(b) Order [REDACTED]

²²⁸ See *supra* notes 14 & 15 and accompanying text.

²²⁹ See, e.g., Rep. Earl L. "Buddy" Carter & Rep. Diana Harshbarger, *supra* note 149, at 1-2; Am. Pharmacies, *supra* note 149, at 1; Cmty. Oncology All., *supra* note 149, at 1; Am. Econ. Liberties Project, FTC-2022-0015-1241, at 1 (May 25, 2022), <https://www.regulations.gov/comment/FTC-2022-0015-1241>.

²³⁰ See, e.g., Anonymous, FTC-2022-0015-0028 (Feb. 26, 2022), <https://www.regulations.gov/comment/FTC-2022-0015-0028> ("I can attest that there is actually very little 'negotiation' with PBMs, even for large chain pharmacy organizations. There are now 3 major PBMs that ... have unprecedented power when negotiating with pharmacies. Their attitude is typically 'take it or leave it.'"); Pharmacists United for Truth & Transparency, FTC-2022-0015-1172, at 1 (May 24, 2022), <https://www.regulations.gov/comment/FTC-2022-0015-1172> ("Pharmacies are regularly forced to enter into non-negotiable, one-sided contracts with the largest PBMs in order to keep serving their patients."); Anonymous, FTC-2022-0015-0625 (Apr. 25, 2022), <https://www.regulations.gov/comment/FTC-2022-0015-0625> ("PBM contracts are entirely non-negotiable"); AmerisourceBergen, FTC-2022-0015-0744, at 3 (May 25, 2022), <https://www.regulations.gov/comment/FTC-2022-0015-0744> ("[T]he largely unregulated market power of PBMs to dictate these contract terms represents exactly the type of anticompetitive behavior that the FTC can and should address.").

²³¹ See, e.g., Infinity Pharmacy Sols., *supra* note 165, at 4 ("[I]n Texas, a PBM controls an overwhelming portion of the market, [and] the pharmacy must 'agree' to the terms and conditions the PBM dictates, or risk being excluded from those crucial networks. In other words, because of their market dominance, PBMs have created an atmosphere

This concern can be even more acute for independent pharmacies when considering pharmacy consolidation at a local level. In twenty U.S. states, the single top PBM held at least 50 percent market share for retail pharmacy network management services for commercial health plans; in 35 states, the top PBM had market share of at least 40 percent.²³² Similarly, in many U.S. regions, only one or two health insurers are considered “dominant.”²³³ Were a local pharmacy to reject a PBM’s network terms, it could “lose access to a significant percentage of its patient base.”²³⁴

Our initial review of internal PBM documents relating to pharmacy communications appears to corroborate accounts of PBMs’ vast bargaining leverage, particularly as to independent pharmacies. For instance, multiple PBMs have during negotiations referred to their “no redlining policy” (i.e., no editing policy) for standard contract terms and conditions, even with large PSAOs.²³⁵

Under CMS regulations governing Medicare, PBMs and health plans must provide a certain level of prescription drug access to beneficiaries where they reside.²³⁶ Due to these geographic access requirements for their networks, PBMs may be incentivized to negotiate somewhat more favorable terms with remotely located rural pharmacies in comparison to urban and suburban counterparts.²³⁷

in which every pharmacy contract is a contract of adhesion—pharmacies have no meaningful opportunity to negotiate such contracts, and must simply accept the harshest possible terms and conditions”); Senior Care Pharmacy Coal., *supra* note 184, at 20 (“PBMs hold such disproportionate market power that pharmacies must accept such unfair and onerous terms because pharmacies must contract with all payers or risk such dramatic loss of customers . . .”).

²³² GUARDADO, *supra* note 52, at 23-24, (Exhibit A2) (showing 2021 market shares in each state for the top two PBMs, and calculating an average HHI of over 3,000 for states and metropolitan statistical areas (“MSAs”) with at least 80 percent of each being highly concentrated).

²³³ Indep. Pharmacy Coop., *supra* note 149, at 3 (stating such); *see also* AMA Insurance Report, *supra* note 109, at 2, tbl.A-1 (finding 73 percent of MSAs were highly concentrated (HHI > 2500) and that, in 33 states, the largest insurer’s market share was greater than 40 percent, with shares often larger per MSA).

²³⁴ Indep. Pharmacy Coop., *supra* note 149, at 3.

²³⁵ *E.g.*, Respondent Document Submission [REDACTED] (email from PBM to PSAO clarifying that it cannot accept any language changes to our standard PSAO agreement); Respondent Document Submission [REDACTED] (PSAO draft amendment in which PBM staff rejects PSAO’s redlines); Respondent Document Submission [REDACTED] (having told a specialty pharmacy no redlines were allowed but later allowing “some” redlines); *accord* AmerisourceBergen, *supra* note 230, at 2-3; Tara Hayes et al., *Generic Drug Pricing Under Part D*, MEDPAC, at 20 (Apr. 12, 2024) (“We consistently heard from interviewees that PSAOs have little effect on determining pharmacy reimbursements.”).

²³⁶ *See supra* notes 42 & 43 (42 C.F.R. § 423.120); Access to Covered Part D Drugs, 42 U.S.C. § 1395w-104(b)(1)(A); *see also* Respondent Document Submission [REDACTED] (discussing internally a preference against including high-cost smaller providers in networks except rural providers); Respondent Document Submission [REDACTED] (discussing access requirements and plan sponsor waiver decisions).

²³⁷ *See, e.g.*, Respondent Document Submission [REDACTED] (PBM’s independent pharmacy standard rates (2017-2022) detailing different tiers between “standard,” “rural,” and “frontier” pharmacies across the PBM’s networks); Respondent Document Submission [REDACTED] (PBM spreadsheet that shows rates for “rural” pharmacies); *see also* Respondent Document Submission [REDACTED] (encouraging outreach to “extremely rural” pharmacy to offer preferred terms because no other

However, where substitutes or customized network conditions exist, PBMs' internal documents show that those rural pharmacies may need to operate under worse, sometimes take-it-or-leave-it rates.²³⁸

General contracting processes can also disadvantage smaller, unaffiliated pharmacies. Internal documents reviewed to date show that PBMs do negotiate bilateral contracts with large, unaffiliated pharmacies—including national chains, larger regional chains, grocery stores, and big box stores—often through formal requests for proposals and bids for participation in narrower pharmacy networks.²³⁹ For smaller, independent pharmacies, the process and dynamics can differ.

Our initial review of internal PBM documents shows that unilateral and passive contracts can frustrate meaningful choices by independent pharmacies. After a pharmacy has enrolled in the PBM network, subsequent amendments to that pharmacy's terms and rates, shifts in participation in specific networks, or even pharmacy classification (e.g., retail as opposed to other formats),²⁴⁰ are often unilateral in effect, due in part to how difficult it is for pharmacies to opt out in time. Indeed, our initial review found that some PBMs may refer to their own contracts as "unilateral."²⁴¹ Similarly, some PBMs deploy what they call "passive contracts," which are described as a notification outlining terms that take effect without the need for affirmative consent or signature.²⁴² These passive contracts can make up a large percentage of contracts sent out by PBMs,²⁴³ often to

pharmacies were within tens of miles of that zip code); Respondent Document Submission [REDACTED] (describing different treatment of rural "must have" pharmacies from other independent pharmacies in more populated areas).

²³⁸ Respondent Document Submission [REDACTED] Respondent Document Submission [REDACTED] (explaining that rural rates are only applicable in some standard broader national networks and are non-negotiable in other networks); Respondent Document Submission [REDACTED] (explaining that to address "any willing provider" rules, a certain network's rates are non-negotiable, but states that the PBM team will take counter rates back to review).

²³⁹ See, e.g., Respondent Document Submission [REDACTED] (letter template inviting pharmacies to participate in certain networks); Respondent Document Submission [REDACTED]

²⁴⁰ Respondent Document Submission [REDACTED] (PSAO complaining of appearance of PBM's unilateral recategorization of member pharmacy as non-retail due to dispensing product mix).

²⁴¹ E.g., Respondent Document Submission [REDACTED]

²⁴² E.g., Respondent Document Submission [REDACTED] (chart marking independents and small chains as passive, versus several large retail pharmacy chains and grocery chains being without passive indicator); Respondent Document Submission [REDACTED] (describing passive agreement as rates being non-negotiable without need for signature, and only needing confirmation of participation).

²⁴³ E.g., Respondent Document Submission [REDACTED]

independents and smaller chains.²⁴⁴ Mass notifications, including through communications using facsimile machines, called “fax blasts,” typically automatically enroll the pharmacy into new terms and conditions.²⁴⁵ Figure 13 is an example of a facsimile from a PBM to a pharmacy provider.

Figure 13. PBM Facsimile to Pharmacy²⁴⁶

April 15, 2022

Dear Pharmacy Provider:

Please find the enclosed [REDACTED] Form for the following network:

- Medicare Part D [REDACTED] Network Program [REDACTED]

The following [REDACTED] Form documents consist of:

- [REDACTED] Form Medicare Part D [REDACTED] Network Program [REDACTED]
 - o Exhibit A – Medicare Part D [REDACTED] Network Program: [REDACTED]
 - o Addendum 1: Specialty Drug Reimbursement Addendum Medicare Part D [REDACTED] Network Programs

The [REDACTED] Form begins on page two of this notification. The [REDACTED] Form includes multiple reimbursement fee schedules that will be applied at the direction of the Medicare Part D Plan Sponsors that choose to utilize this Medicare Part D Retail Network and will apply to all Covered Items as indicated by a Plan's dispensing limitations for all its plan members.

You will be enrolled effective January 1, 2023 as a provider in the Medicare Part D [REDACTED] Network Program [REDACTED] for the entire plan year under the terms detailed in the attached [REDACTED] Form, unless you notify [REDACTED] in writing (via facsimile) no later than May 16, 2022, that you do not want to enroll.

²⁴⁴ See generally *supra* note 242.

²⁴⁵ E.g., Respondent Document Submission [REDACTED] (notifying pharmacies and PSAOs of changes to the provider manual); Respondent Document Submission [REDACTED] (directing network pharmacies to monitor and comply with changes to the provider manual); see also Respondent Responses to 6(b) Order [REDACTED]

²⁴⁶ Anonymous, FTC-2022-0015-0517, (May 26, 2022), <https://www.regulations.gov/comment/FTC-2022-0015-0517> (“Please see the attached cover letter and rates sent to independent pharmacies as an addendum to their current contract. This is a take it or leave it offer that includes rates that are below pharmacy cost in every instance”); Respondent Document Submissions [REDACTED]

Smaller pharmacies often lack the resources required to meaningfully review and make choices about continuing to do business with PBMs—even assuming they have another choice.²⁵¹

2. PBMs may be using their market power across the distribution chain to set reimbursement rates at untenably low levels for independent pharmacies

According to public comments from pharmacists, PBMs have used their market power to set reimbursement rates to levels below independent pharmacies’ costs.²⁵² Internal PBM documents reveal similar reports from pharmacists and PSAOs who flag concerns about untenable rates to their PBMs’ pharmacy contracting staff. The PBMs’ responses vary. Some instances eventually lead to rates shifting to accommodate requests for higher reimbursement to the pharmacy,²⁵³ but in other instances, the PBMs hold firm and pharmacies may accept the terms or may drop out of network.²⁵⁴

PBM respondents have not yet produced all data required by our 6(b) Orders pertaining to their reimbursement rates. Moreover, as elaborated below, the PBM-pharmacy contracts we have obtained and reviewed are opaque, complex, and conditional, making it challenging to understand what pharmacies will ultimately be paid for any given drug.

That said, our initial review of documents received thus far reveals that PBMs can have the ability and incentive to put downward pressure on reimbursement rates for rival, unaffiliated pharmacies—including to a degree that may be unsustainable for small, independent pharmacies. Importantly, internal PBM employee discussions describe a lack of interest in maintaining certain

²⁵¹ See, e.g., Carvajal Pharmacy, *supra* note 71, at 1 (stating that the independent pharmacist must accept the PBMs’ contracts without “legitimate negotiation” including not just the initial contracts but unilateral amendments on rates and networks terms, resulting in arbitrary reimbursement prices on 90 percent of the drugs dispensed); accord Ill. Pharmacists Ass’n, FTC-2022-0015-0650, at 2 (May 24, 2022), <https://www.regulations.gov/comment/FTC-2022-0015-0650>; Randy Armbruster, FTC-2022-0015-0824, at 1 (May 25, 2022), <https://www.regulations.gov/comment/FTC-2022-0015-0824> (noting that PBMs can change reimbursement and any terms at any time without pharmacists’ approval, and that changes are “usually done with a broadcast fax.”).

²⁵² See, e.g., Ne. Pharmacy Serv. Corp., FTC-2022-0015-0309, at 2 (Apr. 8, 2022), <https://www.regulations.gov/comment/FTC-2022-0015-0309> (stating PBMs “are forcing pharmacies to accept reimbursement below cost”); Bruce Landers, FTC-2022-0015-0427, at 1 (Apr. 13, 2022), <https://www.regulations.gov/comment/FTC-2022-0015-0427> (noting that reimbursement is “50 percent of the time below our cost”). Discussion of reimbursement processes is below in § III.C.3 and 4.

²⁵³ See, e.g., Respondent Document Submission [REDACTED]

²⁵⁴ See, e.g., Respondents Document Submissions [REDACTED]

pharmacies in-network,²⁵⁵ with some evidence suggesting that these PBMs may be engaged in programmatic or network “right-sizing” or “network pruning” of pharmacies.²⁵⁶

In addition to increasing market power from consolidation, leading PBMs have vertically integrated not only with their own retail pharmacies, but also with specialty and mail order pharmacies. This vertical integration may be increasing PBMs’ ability and incentive to disadvantage rival, independent pharmacies that directly compete with the PBMs’ affiliated pharmacies. One internal PBM document—from a PBM that does not operate a retail pharmacy—makes clear that smaller, unaffiliated pharmacies are viewed as competitors with even the PBMs’ non-retail affiliated pharmacies: “Retailers are our competitors. There is no win-win solution. We are seeking the same Rx. We need the best rates.”²⁵⁷

To the extent that the PBMs have engaged in conduct to harm competition in the market for pharmacy services, such as by pushing smaller pharmacies out of the market, such conduct could ultimately lead to higher costs and lower quality services for people around the country. Community pharmacies provide a range of benefits to their patients, including providing timely medical guidance and screening services that play an important role in better health outcomes, especially for vulnerable individuals who otherwise have limited access to care.²⁵⁸ In an opaque industry with non-disclosure and confidentiality agreements that are actively asserted on pharmacies,²⁵⁹ the combination of consolidation and vertical integration may be enabling PBM-

²⁵⁵ See, e.g., Respondent Document Submission [REDACTED] [REDACTED] (“I don’t know why we would go out of our way to offer better pricing to a specialty provider.”); accord Respondent Document Submission [REDACTED] (noting that PBM has a robust specialty and mail pharmacy network with all major players in-network and suggesting that unaffiliated pharmacy has the ability to exercise termination if unhappy with offered rates).

²⁵⁶ Respondents Document Submissions [REDACTED]

²⁵⁷ Respondent Document Submission [REDACTED]

²⁵⁸ See, e.g., Am. Pharmacies, *supra* note 149, at 1 (May 25, 2022) (“[E]asy access to pharmacies and pharmacist counseling (especially in underserved and rural communities) promotes patient adherence to prescribed medication”); Nat’l Rural Health Ass’n, *supra* note 2, at 3 (“Given the unique size of rural pharmacies, they’re often the only outfit in town.”); Joanne Constantin et al., *Rural and Urban Pharmacy Presence – Pharmacy Deserts*, RUPRI CTR FOR RURAL HEALTH POL’Y ANALYSIS 4 (Aug. 2022), <https://rupri.public-health.uiowa.edu/publications/policybriefs/2022/Pharmacy%20Deserts.pdf> (“[M]ail-order services fail to replace the other fundamental functions provided by pharmacists beyond filling prescriptions, such as health screenings, patient education and counseling, and vaccinations.”); see also Remarks of Chair Lina M. Khan *supra* note 2; Carter & Harshbarger, *supra* note 149, at 1 (Independent pharmacies are “often the sole provider of needed health care services in our rural and medically underserved communities [and] provide essential services like chronic and complex disease management, wellness and prevention services, vaccines, certain testing, and disease education.”).

²⁵⁹ Respondents Document Submissions [REDACTED]

conglomerates to squeeze unaffiliated competitors. Opportunities for such PBM conduct are numerous.

3. Pharmacy reimbursement calculations are opaque and unpredictable

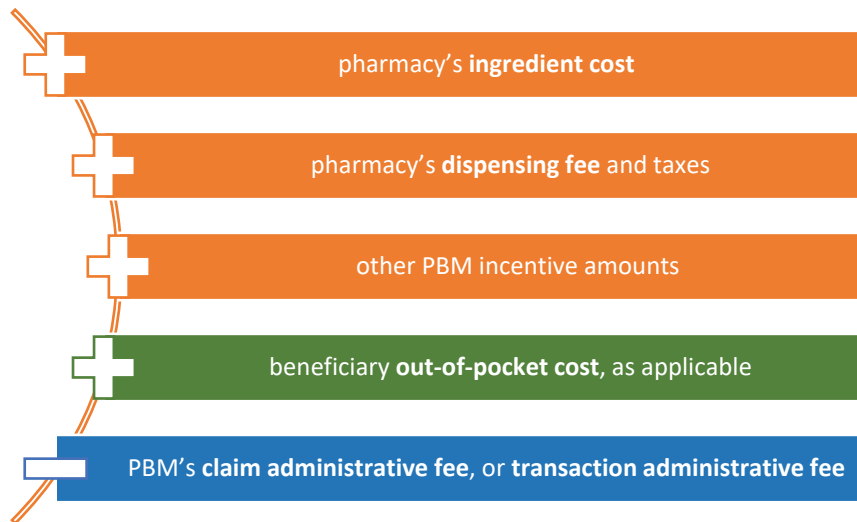
PBMs use a large variety of contract terms for pharmacy reimbursement which operate based on complicated and unclear calculations. This is on top of the inherent complexity of the prescription reimbursement system, where, when a health-plan beneficiary purchases prescription medicine at a retail pharmacy, the payment flows through several entities, including the patient, pharmacy, PBM, health plan, insurer, and plan sponsor. Pharmacy reimbursement payments are ultimately based on a series of contractual agreements, including, but not limited to, contracts (1) between the payers and PBMs, (2) between the PBMs and pharmacies or PSAOs, (3) if applicable, between the PSAO and pharmacies, (4) between the pharmacies and drug wholesalers, (5) between the drug manufacturers and the PBMs, and (6) between the health-plan beneficiaries and the health plans.

At the point of sale, the pharmacy submits a claim to the health plan through the relevant PBM's electronic claims adjudication engine, and the PBM then reimburses the pharmacy for dispensing the drug. The health plan's design determines the amounts charged to the patient and plan sponsor and the financial distributions paid to the pharmacy and the PBM itself.²⁶⁰ While variations exist, the point-of-sale reimbursements paid to pharmacies are generally calculated based on the components listed in Figure 15.

[REDACTED]

²⁶⁰ *E.g.*, Respondents Responses to 6(b) Order [REDACTED]

Figure 15. Pharmacy Point-of-Sale Reimbursement Components²⁶¹



Most pharmacies, especially independents and small chain pharmacies, lack the resources to understand the financial arrangements that determine their reimbursement and revenue streams, which can make it difficult to stay in business.²⁶² For example, a 2016 survey of 600 community pharmacies found that two thirds reported having no detail on how and when direct and indirect remuneration was assessed.²⁶³ Rather, the claims adjudication engine and resulting calculations are essentially a black box.

Importantly, even if a small pharmacy is given more leniency in the contracting process (e.g., a rural pharmacy that is necessary to add to a pharmacy network due to geography-based access regulations may receive higher base reimbursement rates, as discussed above), the pharmacy will still experience difficulties in operating their business due to the built-in structural opacity of reimbursement calculations.

PBM's with their clients, that is, health plans and plan sponsors, set the reimbursement for the pharmacy's cost of the drug. We refer to the base reimbursement amount as "ingredient cost," the first component of typical PBM pharmacy reimbursement above in Figure 15. This component is

²⁶¹ Orange represents payment to the pharmacy from the PBM; green represents payment from a third party, and blue represents payment from the pharmacy to the PBM.

²⁶² For instance, multi-faceted contractual arrangements may result in pharmacy reimbursement components being negotiated beforehand by the PBM and other contracting entities, before network pharmacies being informed. *See, e.g., Respondent Document Submission* [REDACTED]

²⁶³ *Survey of Community Pharmacies: Impact of Direct and Indirect Remuneration (DIR) Fees on Pharmacies and PBM-Imposed Copay Clawback Fees Affecting Patients*, NAT'L CMTY. PHARMACISTS ASS'N (June 2016), https://www.ncpa.co/pdf/dir_fee_pharmacy_survey_june_2016.pdf. Further discussion of direct and indirect remuneration is found below in § III.C.4.a.

supposed to cover the pharmacy’s cost of acquiring a drug.²⁶⁴ Ingredient cost is set using index prices for each drug product, where the base for the reimbursement amount is determined using an equation built into the network contracting documents that allows the PBM to choose the lowest price among various price indices, which uses “lesser of” logic: For example, the PBM reimburses based on the lesser of (1) Average Wholesale Price (“AWP”), (2) Wholesale Acquisition Cost (“WAC”), (3) Usual and Customary Price (“U&C”), (4) Submitted Cost, or (5) Maximum Allowable Cost (“MAC”), etc.²⁶⁵ Some of these indices may be set by drug manufacturers and may not reflect market-based acquisition prices.²⁶⁶ Furthermore, through language within various contracts, PBMs can typically build additional variability into the price indices that allows PBMs to further adjust reimbursement amounts.²⁶⁷

In particular, PBMs include as part of the lesser of logic an index called the Maximum Allowable Cost (“MAC”) price. MAC or “MAC lists” refer to proprietary price lists that are created, maintained, and continuously updated by PBMs, sometimes on a weekly basis or even more frequently.²⁶⁸ MAC prices are proprietary and confidential and are based on a range of possible

²⁶⁴ Ingredient cost is *not* the pharmacy’s actual cost to acquire drugs from pharmaceutical wholesalers, which may differ in amount. *See infra* note 265 and accompanying text.

²⁶⁵ *E.g.*, Respondents Responses to 6(b) Order [REDACTED]

²⁶⁶ This is true particularly for generic drugs, which can be acquired by pharmacies for over 95 percent less than AWP prices in certain markets. Myers & Stauffer LC, *NADAC Equivalency Metrics*, MEDICAID.GOV (Dec. 28, 2023), <https://www.medicaid.gov/sites/default/files/2024-01/nadac-equiv-metrics-12282023.pdf> (showing median AWP discount for generic legend drugs with 9, 10, and 11 or more labelers as -95.1 percent, -95.0 percent, and -97.1 percent respectively).

²⁶⁷ *See, e.g.*, Respondents Document Submissions [REDACTED]

²⁶⁸ *See, e.g.*, OptumRx Provider Manual, 16 (2022), <https://professionals.optumrx.com/content/dam/optum3/professional-optumrx/resources/pdfs/OptumRxPharmacyProviderManual2022.pdf> (“Administrator reserves the right to update its MAC pricing methodology and to use alternative, reputable sources at its discretion.”); *infra* note 269 and accompanying text.

source pricing indices, including private third-party prices. As one large PBM’s pharmacy provider manual states:

“MAC prices are subject to change, which can occur at least on a weekly basis and are based on marketplace trends and dynamics and price fluctuations. MAC price lists and/or pricing formulas are [the PBM’s] confidential and proprietary information.”²⁶⁹

Each PBM develops and maintains its own set of MAC price lists. Vast disparity appears to exist between how many lists each PBM respondent maintains, with one having tens of thousands of lists represented in its data, while others have under 200.²⁷⁰

One study analyzing 2020 pharmacy claims determined that MAC appears to be the predominant basis of generic reimbursement (82 percent of generic claims).²⁷¹ Furthermore, generic drugs account for the large majority (80 percent) of prescriptions filled in the U.S.²⁷² This means that PBMs’ own, proprietary price was the lowest and therefore prevailing price for the large majority of generic drug claims.²⁷³

Pharmacies will not know the amount of base pay until after they run a claim. Pharmacies therefore are often missing a critical variable for basic operational business planning and for making informed choices about which PBMs, which networks, and which drug claims would pay the best—or sustainable—rates.²⁷⁴ In other words, pharmacies are commonly reimbursed based on an algorithm with numerous opaque, shifting price inputs. Public comments received by the study have explained:

- “[P]harmacies are often not even allowed to see the MAC list. Additionally, the MAC pricing is a moving target, and prices can change as often as daily.”²⁷⁵

²⁶⁹ See Respondent Document Submission [REDACTED]

²⁷⁰ FTC staff analysis of data produced for 2017 to mid-2022, in response to the 6(b) Orders, specification 11.

²⁷¹ THREE AXIS ADVISORS, UNRAVELLING THE DRUG PRICE BLAME GAME 40 (2023), [https://static1.squarespace.com/static/5c326d5596e76f58ee234632/t/650924780b6b9c590edfa2b4/1695097983750/Unravelling the Drug Pricing Blame Game 3AA APCI 0923.pdf](https://static1.squarespace.com/static/5c326d5596e76f58ee234632/t/650924780b6b9c590edfa2b4/1695097983750/Unravelling+the+Drug+Pricing+Blame+Game+3AA+APCI+0923.pdf); see also Respondents Responses to 6(b) Order [REDACTED]

²⁷² ASSISTANT SEC’Y FOR PLAN. & EVALUATION, OFF. SCI. & DATA POL’Y, TRENDS IN PRESCRIPTION DRUG SPENDING, 2016-2021, at 1 (2022), <https://aspe.hhs.gov/sites/default/files/documents/88c547c976e915fc31fe2c6903ac0bc9/sdp-trends-prescription-drug-spending.pdf>.

²⁷³ See THREE AXIS ADVISORS, *supra* note 271.

²⁷⁴ See, e.g., COOPHARMA, FTC-2022-0015-1152, at 2 (May 24, 2022), <https://www.regulations.gov/comment/FTC-2022-0015-1152> (“PBMs use very aggressive adherence contracts w[h]ere the formulas for their MAC pricing and from which the prices of the drugs are not disclosed to the contracted independent pharmacies”).

²⁷⁵ Anonymous, FTC-2022-0015-0028, at 1 (Feb. 26, 2022), <https://www.regulations.gov/comment/FTC-2022-0015-0028>.

- “PBMs may arbitrarily assign MAC prices when it benefits them to do so. Pharmacies have little visibility into how the PBM determined the price they assigned to a claim.”²⁷⁶
- A PBM’s “contract tends to just put AWP - x%, WAC - x%, MAC - x%, etc. Price of medication changes all the time. Pharmacies won’t know when PBMs update the AWP/WAC/MAC.”²⁷⁷
- “Contracts/rates are negotiated by [a] PSAO on behalf of most smaller pharmacies. Until recently, we could not even see the rates. Now, when you do, the language is so confusing you would need a law and accounting degree to understand most of it. All we can really look for is to compare our cost to what we get paid and hope it is a profit.”²⁷⁸

In effect, the PBMs often fail to commit in their contracts to any identifiable or readily ascertainable rate for generic reimbursements. Despite ongoing state efforts to regulate the use of MAC lists,²⁷⁹ these contracts reflect a vast information asymmetry in which independent pharmacies do not know how much they will be paid under the contract, or when (as discussed in Section III.C.4 below). Moreover, confirmation of the accuracy of the ultimate reimbursement amount can require a costly formal appeal process, which—thanks to appeal and arbitration clauses in these contracts and provider manuals²⁸⁰—the PBMs control.

4. PBMs’ post-sale adjustments showcase the unpredictability of reimbursement

The foregoing described the opacity and complexity of point-of-sale reimbursement, and offered some detail on just one of many inputs into reimbursement calculations. Another key factor adding to pharmacies’ difficulties in understanding and predicting reimbursement is the financial adjustments PBMs make many weeks and months after the point of sale.²⁸¹ These adjustments exacerbate information asymmetries that disadvantage unaffiliated pharmacies, including those

²⁷⁶ Tom Greenlee, FTC-2022-0015-1190, at 3 (May 24, 2022), <https://www.regulations.gov/comment/FTC-2022-0015-1190>.

²⁷⁷ Medical Arts Pharmacy, FTC-2022-0015-0321, at 2 (Apr. 8, 2022), <https://www.regulations.gov/comment/FTC-2022-0015-0321>.

²⁷⁸ Anonymous, FTC-2022-0015-0601, at 2 (Apr. 23, 2022), <https://www.regulations.gov/comment/FTC-2022-0015-0601>.

²⁷⁹ See, e.g., ARK. CODE ANN. § 17-92-507 (West 2024) (requiring pharmacy access to Maximum Allowable Costs list in addition to several procedural requirements intended to protect pharmacies).

²⁸⁰ E.g., Respondents Document Submissions, [REDACTED]

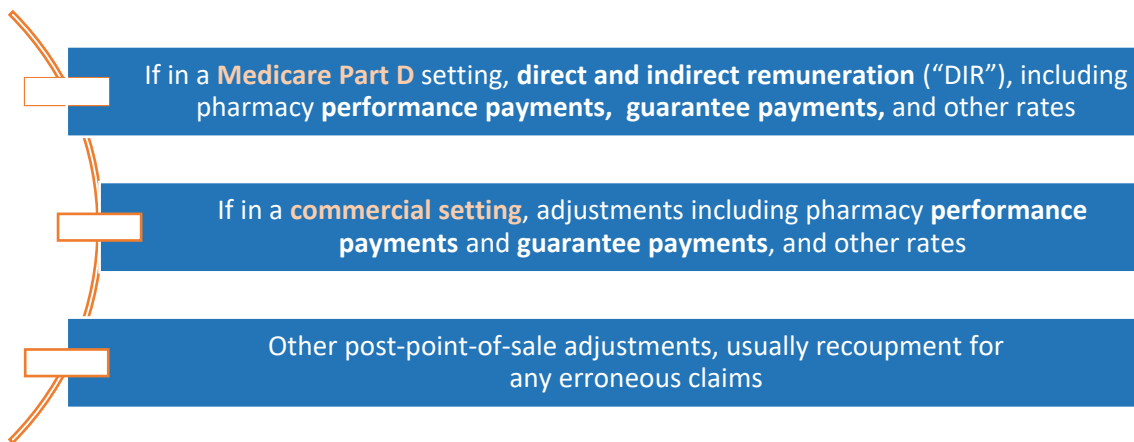
Cnty. Oncology All., *supra* note 149, at 14 (“PBMs also extract other ‘fees’ from Pharmacy Providers, such as assessing audit fees up to 20 percent of any discrepancies identified by the PBM or requiring independent pharmacy providers to place \$50,000 in escrow as a pre-condition to begin disputes against them.”).

²⁸¹ See, e.g., INMAR INTEL., DIRECT AND INDIRECT REMUNERATION (DIR) PERFORMANCE AND THE IMPACT ON PHARMACIES SERVING MEDICARE PART D BENEFICIARIES 5-6, 11 (2019), <https://www.nacds.org/pdfs/government/2019/DIR-Whitepaper.pdf> [hereinafter “Inmar DIR report”] (“Final financial settlement for a particular plan year can take place as much as 18 months after a prescription was dispensed to a patient.”); Am. Oncology Network, FTC-2022-0015-1141, at 1 (May 24, 2022), <https://www.regulations.gov/comment/FTC-2022-0015-1141> (pointing out that often DIR fees are imposed months after the point-of-sale and pharmacies frequently end up getting paid less than their cost of the drug).

enrolled as members of PSAOs.²⁸² Through these adjustments, PBMs often extract significant fees and clawback payments from pharmacies.

These amounts are often referred to as post-sale adjustments, but other terms encompass these adjustments fully or in part—including “pharmacy Direct and Indirect Remuneration” (known as “pharmacy DIR” or “DIR”), “pharmacy rebates,” or “clawbacks.” Complexity further increases as different PBMs have different reimbursement processes,²⁸³ with some designating third-party vendors to reconcile adjustments.²⁸⁴ Some common components of post-sale adjustment amounts are outlined at a high level in Figure 16.

Figure 16. Post-Sale Adjustment Components



Such adjustments are widely discussed within Medicare Part D. In 2024, CMS’ rule to eliminate retroactive DIR went into effect, requiring that any DIR be shifted to the point of sale.²⁸⁵ Prior to

²⁸² AmerisourceBergen, *supra* note 230, at 3, 8 (noting that “[u]nfortunately, the current opaque PBM reimbursement model, with respect to price concessions and incentive payments tied to undisclosed and variable performance measures, does not allow pharmacies to make clear and fully informed decisions about which networks may offer them opportunities for success” as well as expressing “concern[] that pharmacy quality measures used by plans are not transparent to pharmacies and lack specificity in how, when, and why they are applied.”).

²⁸³ For instance, administrative error-based claims adjustments may be aggregated with performance programs. Respondents Responses to 6(b) Order [REDACTED]

²⁸⁴ Respondent Responses to 6(b) Order [REDACTED]

²⁸⁵ Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs, 87 Fed. Reg. 27704, 27899, 27902 (May 9, 2022) (codified at 42 C.F.R. § 423) (modifying “negotiated price” definition and adding definition of “price concession” within 42 C.F.R. § 423.100).

the 2024 rule change, the Medicare statute’s “carveout” for DIR²⁸⁶ allowed PBMs to retain savings for themselves and their clients,²⁸⁷ including, ultimately, affiliated health insurers. These Part D DIR payments extracted from U.S. pharmacies in 2021 amounted to over \$10 billion dollars.²⁸⁸

- a. Pre-2024 DIR adjustments to pharmacy reimbursements may financially disadvantage unaffiliated pharmacies.

The following discussion about Part D DIR payments concerns pre-2024 practices in place during the period covered by our 6(b) Orders, 2017 to mid-2022. Independent pharmacies have raised concerns that the 2024 CMS rule change could expose them to what has been called a “DIR cliff,” in which retroactive DIR fees associated with the year 2023 are due simultaneously with point-of-sale 2024 DIR fees, resulting in significant cash flow problems for many independent pharmacies.²⁸⁹ However, examination of such issues is beyond the scope of our 6(b) Orders.

A 2019 study of seven large PBMs characterized two broad approaches to DIR adjustments: (1) a tiered performance scale with a financial penalty to lower-performing pharmacies;²⁹⁰ and (2) an upfront flat fee pharmacy payment to the PBM that may be earned back through high performance.²⁹¹ A pharmacy that performs well based on various metrics—e.g., helping patients

²⁸⁶ This stated that all negotiated prices should be taken into account for covered Part D drugs, but the definition of negotiated price excluded “those contingent price concessions that cannot reasonably be determined at the point-of-sale.” 42 C.F.R. § 423.100 (2023).

²⁸⁷ For example, effective rate reconciliations may have allowed PBMs to “circumvent” certain regulatory pricing minimums. Cmty. Oncology All., *supra* note 149, at 76 (“Because of its after-the-fact assessment applied across an entire network of pharmacy providers, Effective Rates allow PBMs to circumvent Maximum Allowable Cost laws enacted by many states . . . and hinders pharmacy providers’ ability to challenge underwater reimbursements”); *see also* FRIER LEVITT, LLC, PHARMACY BENEFIT MANAGER EXPOSÉ: HOW PBMs ADVERSELY IMPACT CANCER CARE WHILE PROFITING AT THE EXPENSE OF PATIENTS, PROVIDERS, EMPLOYERS, AND TAXPAYERS 76 (2022), https://communityoncology.org/wp-content/uploads/2022/02/COA_FL_PBM_Expose_2-2022.pdf (similar); Respondents Document Submissions [REDACTED]

²⁸⁸ HEALTH CARE SPENDING AND THE MEDICARE PROGRAM, MEDPAC 158 chart 10-19 (2023), https://www.medpac.gov/wp-content/uploads/2023/07/July2023_MedPAC_DataBook_SEC.pdf.

²⁸⁹ *See, e.g., NCPA Survey: Majority of Independents Concerned About, Prepping for “DIR Hangover,”* NAT’L CMTY. PHARMACISTS ASS’N (June 2, 2023), <https://ncpa.org/newsroom/news-releases/2023/06/02/ncpa-survey-majority-independents-concerned-about-prepping-dir>.

²⁹⁰ *See* Inmar DIR report, *supra* note 281, at 7, Exhibit 4; *see also* Respondent Document Submission [REDACTED]

(contract including performance adjustment).

²⁹¹ *See* Inmar DIR report, *supra* note 281, at 5, 7 (describing how “the PBMs and plans deduct a certain amount from each prescription (averages ranging from \$2-\$7/ traditional prescription based on (a) percentage of AWP; (b) percentage of the ingredient cost paid; or (c) a flat fee; and this amount can be more significant for specialty medications) with the possibility that pharmacies can mitigate the amount of the fine depending on their performance against contract criteria . . . However, the net impact results in reduced revenue to the pharmacy. While it is possible for pharmacies to earn more revenue in certain cases, the net impact is negative to all pharmacies. Pay in and earn back today is not completed at Point-of-Sale. In most cases, the ‘pay in’ happens in the payment cycle for the claim which is about 15-30 days later and payment is less than the real time adjudication amount because the ‘pay in’ amount is subtracted at this point.”); Respondent Document Submission [REDACTED]

(noting participation fees for pharmacies assessed on flat

achieve higher adherence to certain medications, improved patient medical outcomes—is rewarded with higher reimbursements, while a lower performer is penalized through “clawbacks.”²⁹²

The metrics assessing pharmacy performance are established by CMS and industry representatives, including PBMs.²⁹³ However, the finite capacity of regulators to monitor in detail the numerous individual PBM performance programs creates risks that these metrics—which in theory incentivize pharmacies to improve patient quality of care²⁹⁴—may act primarily as financial levers for profit-seeking PBMs,²⁹⁵ who also own competing pharmacies, and their clients. Indeed, one PBM’s internal documents state that “while having measurements aligned with CMS quality measures, [the PBMs’ performance networks, which include DIR] are primarily intended to provide competitive financial benefit to [PBM] clients.”²⁹⁶

Industry-wide criticism exists over the construction and execution of DIR metrics and programs, with comments stating that DIR fees are “unexplainable,” create “needless uncertainty for

fee per claim or flat percentage fees collected after the point of sale); Respondent Document Submission [REDACTED]

[REDACTED]

²⁹² *E.g.*, Respondents Responses to 6(b) Order [REDACTED]

²⁹³ CMS and other standard-setting organizations such as Pharmacy Quality Alliance (PQA) and National Committee for Quality Assurance (NCQA) are involved. *E.g.*, Respondent Document Submission [REDACTED]

[REDACTED] Metrics are periodically updated. *See, e.g.*, Respondent Document Submission [REDACTED]

²⁹⁴ *E.g.*, Respondent Document Submission [REDACTED]

²⁹⁵ Respondent Document Submission [REDACTED]

[REDACTED] (“[CMS] said that they do not have the capacity to review individual plan standards beyond what might be developed by a standard setting organization. The consensus from the [CMS-PCMA] workgroup [to discuss possible DIR enhancements] was that PCMA did not need to engage CMS further at this time on pharmacy DIR”); Respondent Document Submission [REDACTED]

[REDACTED] Respondent Document Submission [REDACTED] (discussing whether to use performance network to incentivize pharmacies to fill 90-day scripts instead of multiple 30-day scripts, which pharmacies may do to recover additional dispensing fees).

²⁹⁶ Respondent Document Submission [REDACTED] (noting one PBM’s performance networks, “while having measurements aligned with CMS quality measures, are primarily intended to provide competitive financial benefit to [PBM] clients.”).

pharmacies,” and are “a charade.”²⁹⁷ Independent pharmacists have pointed out that they should not be penalized in reimbursements for events over which they have little to no control, such as when patients may be delayed in picking up or taking medication, or simply choose not to continue due to side effects or contraindications—which all lead to lower pharmacy performance based on metrics measuring patient adherence to medications.²⁹⁸ In a similar vein, internal PBM documents reviewed to date show PBM staff discussing how certain assessment metrics make little sense in application, such as applying non-specialty metrics to specialty pharmacies.²⁹⁹

Importantly, pharmacies are generally “graded on a curve,” with their reimbursement assessed based on relative performance compared to a set of other pharmacies or a set of prescription claims.³⁰⁰ Such an arrangement sets up a large information disparity between small pharmacies and the entities administering their reimbursements—be it the PBMs or the PSAOs they may have joined to contract with the PBMs. One 2019 in-depth study analyzing confidential pharmacy contract terms reported that “there is no transparency into which pharmacies are included in any given comparison groups.”³⁰¹

²⁹⁷ Rocking Horse Cmty. Health Ctr., FTC-2022-0015-0446, at 3 (Apr. 14, 2022), <https://www.regulations.gov/comment/FTC-2022-0015-0446>; Am. Med. Ass’n, *supra* note 160, at 6; Am. Pharmacies, *supra* note 149, at 1.

²⁹⁸ *See, e.g.*, Medicine Counter Pharmacy, FTC-2022-0015-0443, at 2 (Apr. 14, 2022), <https://www.regulations.gov/comment/FTC-2022-0015-0443> (“Studies have shown [that patients] taking maintenance medicines on time have a better impact on health[;] however, there is little control that pharmacist[s] have on medication adherence. Our pharmacy enrolls patients in auto-refills, refill reminders, offers monthly pill packs, patient education, and free delivery[;] however for those patients who don’t want to we are unable to force patients to put the medicine in their mouths for those who don’t care about their health. Patients should be incentivized or penalized for picking up their medicines on time, NOT pharmacies.”); Dokimos Nevada City Pharmacy, FTC-2022-0015-0128, at 1 (Feb. 15, 2022), <https://www.regulations.gov/comment/FTC-2022-0015-0128> (“If a patient isn’t on certain medications (often due to a side effect or some contraindication determined by their doctor) we are punished and must pay higher fees. If a patient stops a medication for some reason, is hospitalized and not using their medication from home [and] so is deemed ‘non-compliant,’ we are also punished.”).

²⁹⁹ *E.g.*, Respondent Document Submission [REDACTED] (“There are many PBMs that do not have specialty quality measures and apply non-specialty measures to specialty pharmacies and take DIR.”); *see also* Respondent Document Submission [REDACTED] (letter noting that pharmacy focused on treating cancer patients being evaluated solely on quality measures for unrelated therapeutic categories like Hepatitis C and multiple sclerosis, resulting in low scores and withheld fees); Respondent Document Submission [REDACTED] (similar). *But see* Respondent Document Submission [REDACTED] (listing specialty metrics separately).

³⁰⁰ Respondent Responses to 6(b) Order [REDACTED] Respondent Document Submission [REDACTED] Inmar DIR report, *supra* note 281, at 5-6 (“These can include weighing pharmacy performance against an undefined network, peer group, or other benchmark, market share. . . criteria are used in both stand-alone assessments, where just a single criterion, such as GDR [generic dispense rate], will determine the DIR, or through the use of a complex matrices of criteria used to calculate a performance score that is then benchmarked against other participants and weighted.”).

³⁰¹ Inmar DIR report, *supra* note 281, at 10.

Other components of DIR present similar issues. One broad category is a guarantee payment, also known as a reconciliation payment or “true up.”³⁰² Two common types of effective rate guarantees are brand (“BER”) and generic (“GER”).³⁰³ Additional reconciliations exist, like dispensing fee effective rate (“DFER”).³⁰⁴ Some internal PBM documents suggest that these effective rate guarantees and other pharmacy adjustments may be part of targeted efforts to “gap fill” the PBM’s revenue projection shortfalls.³⁰⁵

Finally, numerous additional adjustment metrics like generic dispense rate (“GDR”)³⁰⁶ and service level guarantees³⁰⁷ all add complexity to the amount a pharmacy may ultimately owe to the PBM. As mentioned above, different PBMs use different sets of adjustments across various pharmacy networks to control reimbursement amounts.³⁰⁸

- b. Commercial post-sale adjustments continue to lack transparency.

³⁰² Respondents Responses to 6(b) Order [REDACTED]

³⁰³ FRIER LEVITT, *supra* note 287, at 76 (“GER and BER (collectively known as the ‘Effective Rate’) measure the discount that the PBM contractually must deliver for its client (i.e., plan sponsors) to a benchmark called Average Wholesale Price (AWP) for generic prescription drugs and for brand-name prescription drugs, respectively.”).

³⁰⁴ *See, e.g.*, Respondents Document Submissions [REDACTED]

³⁰⁵ *E.g.*, Respondent Document Submission [REDACTED] (describing revenue gap fill potential drivers including pharmacy network definitions and guarantee reconciliations); Respondent Document Submission [REDACTED] (describing moving PSAOs and large retail pharmacies to effective rate guarantee structures for gap fill initiative); Respondent Document Submission [REDACTED]

³⁰⁶ *E.g.*, Respondent Document Submission [REDACTED]

Respondent Responses to 6(b) Order [REDACTED]

³⁰⁷ Respondent Responses to 6(b) Order [REDACTED]

³⁰⁸ *See, e.g.*, [REDACTED]

Some PBMs operate commercial performance networks.³⁰⁹ The contractual arrangements for such networks include similar performance metrics as in Part D that track adherence to medication,³¹⁰ effective rate guarantees,³¹¹ and other adjustment terms.

While the 2024 CMS rule eliminated retroactive DIR with respect to Medicare Part D, these regulations do not apply to the private commercial market. Evidence from the earlier time period covered by our 6(b) Orders (until mid-2022) shows that pharmacy performance programs in the commercial setting were often analogous to Part D processing, although our initial analysis in Section III.B above suggests that post-sale adjustments may have been greater in Part D. Due to lack of transparency, it is unclear whether commercial adjustments in 2024 have been adjusted to reflect changes in Medicare Part D—that is, whether the elimination of retroactive DIR in Part D has led PBMs to also eliminate retroactive DIR in the commercial setting.

In practice, these post-sale adjustments can require a pharmacy to, often blindly, make payments of hundreds of thousands of dollars back to the PBM months after the relevant prescriptions are dispensed.³¹² Critics have condemned the actuarial complexity from the growth and spread of such contract terms over the last decade, while noting that some such terms offer no apparent benefits such as reducing plan sponsors’ drug spending.³¹³ The continuing evolution of PBM reimbursement methodologies may further undermine pharmacies’ ability to perform basic business planning.³¹⁴

³⁰⁹ *E.g.*, Respondent Document Submission [REDACTED]

³¹⁰ *E.g.*, Respondent Responses to 6(b) Order [REDACTED]

Respondents Document Submissions [REDACTED]

³¹¹ *E.g.*, Respondents Document Submissions [REDACTED]

[REDACTED] *What are GERs / BERs / DFERs?*, ELEVATE PROVIDER NETWORK, <https://www.alliantrx.com/wp-content/uploads/2020/05/GER-Explainer-Document.pdf> (last visited June 17, 2024) (reporting that for PSAO Elevate’s relationship with CVS Caremark and OptumRx, the “2019 and 2020 contractual arrangement for select commercial (including Managed Medicaid) Plans claims include a contracted GER/BER/DFER.”).

³¹² *See, e.g.*, CMS estimates that pharmacy DIR fees have increased 91,500 percent between 2010 and 2019. *See* CTRS. FOR MEDICARE & MEDICAID SERVS., FISCAL YEAR 2022 JUSTIFICATION OF ESTIMATES FOR APPROPRIATIONS COMMITTEES 242 (2021), <https://www.cms.gov/files/document/fy2022-cms-congressional-justification-estimates-appropriations-committees.pdf>; Carolina Health Ctrs., Inc., *supra* note 183, at 8 (highlighting that some Part D pharmacies saw DIR increase from \$9,000 to over \$100,000 in the last five years); N.M. Oncology Hematology Consultants, FTC-2022-0015-0816, at 2 (May 25, 2022), <https://www.regulations.gov/comment/FTC-2022-0015-0816> (stating that DIR amounted to \$750,000 for their practice the previous year).

³¹³ *E.g.*, FRIER LEVITT, *supra* note 287, at 76 (“PBMs have also created another pricing mechanism called Dispen[s]ing Fee Effective Rate (DFER) to recoup dispensing fees already paid to providers that provides no purpose to reduce plan sponsors’ drug spending.”).

³¹⁴ *E.g.*, Monongahela Valley Ass’n of Health Ctrs., Inc., FTC-2022-0015-1005, at 5 (May 25, 2022), <https://www.regulations.gov/comment/FTC-2022-0015-1005> (“When DIR fees are applied after point-of-sale,

IV. PBM AND BRAND DRUG MANUFACTURER REBATE CONTRACTS MAY IMPAIR OR BLOCK LESS EXPENSIVE COMPETING PRODUCTS, INCLUDING GENERIC AND BIOSIMILAR DRUGS

This Interim Report principally focuses on PBMs' relationships with pharmacies, rather than with drug manufacturers. However, consistent with our commitment to share information with the public and policymakers as quickly as possible, we also confirm several troubling rebating practices and report evidence raising concerns that brand manufacturers and PBMs may be entering into rebate contracts designed to cut off access to generic and biosimilar competitors.

Manufacturer rebate contracts can be structured in a variety of ways, but as one study reports, the main purpose of these contracts is to provide payments from the drug manufacturer to the health plan in exchange for favorable formulary placement and treatment of the branded product.³¹⁵

The Commission has long been interested in the impact of exclusionary rebate arrangements. In December 2020, Congress directed the FTC to report on efforts to address “an increasingly common anticompetitive behavior potentially distorting the U.S. biopharmaceutical market known as rebate walls,” and “urge[d] the FTC to prioritize investigations into manufacturers that erect rebate walls to block competition from new branded therapies, biosimilars, generics, and other innovative products.”³¹⁶ In May 2021, the FTC issued a report based solely on publicly available information and indicated that such practices could raise antitrust concerns.³¹⁷ In June 2022, the FTC issued a policy statement explaining that, among other things, “rebates and fees may shift costs and misalign incentives in a way that ultimately increases patients' costs and stifles competition from lower-cost drugs, especially when generics and biosimilars are excluded or disfavored on formularies.”³¹⁸

As a part of this ongoing study, the PBM respondents have produced certain of their rebate contracts with drug manufacturers. While our analysis is ongoing, our initial review of these contracts shows rebate structures that may impede and impair competition and patient access to affordable medicines.

Figure 17 presents an excerpt of a brand drug manufacturer rebate contract published in connection with the Senate Finance Committee's 2021 staff report on insulin,³¹⁹ and is illustrative of numerous

pharmacies lose control over their revenues and profitability”); Inmar DIR report, *supra* note 281, at 5-6, 11 (“Variations in assessment methodology and timing of assessments among PBMs and plans create significant business uncertainty and operational challenges for pharmacies.”).

³¹⁵ See AMANDA COLE ET AL., INST. FOR CLINICAL AND ECON. REV., VALUE, ACCESS, AND INCENTIVES FOR INNOVATION: POLICY PERSPECTIVES ON ALTERNATIVE MODELS FOR PHARMACEUTICAL REBATES 1, 3-4 (2019), <https://icer.org/wp-content/uploads/2018/12/March-2019-ICER-OHE-White-Paper-on-Rebates-Final.pdf>.

³¹⁶ H.R. REP. NO. 116-456, at 67 (2020).

³¹⁷ FED. TRADE COMM'N, REPORT ON REBATE WALLS (2021).

³¹⁸ Fed. Trade Comm'n, Policy Statement of the Federal Trade Commission on Rebates and Fees in Exchange for Excluding Lower-Cost Drug Products, Comm'n File No. P221201, at 1 (June 16, 2022), <https://www.ftc.gov/legal-library/browse/policy-statement-federal-trade-commission-rebates-fees-exchange-excluding-lower-cost-drug-products>; see also Complaint at 2, In the Matter of Amgen Inc. and Horizon Therapeutics Corp., FTC File No. 2310037 (June 22, 2023); Amgen Inc. and Horizon Therapeutics plc; Analysis of Agreement Containing Consent Order To Aid Public Comment, 88 Fed. Reg. 62786, 62789 (Sept. 13, 2023) (prohibiting Amgen from engaging in exclusionary rebating practices related to the drug portfolio it acquired in the Horizon acquisition).

³¹⁹ See U. S. Fin. Comm., Documents Produced by CVS Health Corp. (CVS Caremark), at 102 (Ex. C-1, Rebates & Administrative Fees, CVSCM_SFC_0004363 (effective Jan. 1, 2019 through Dec. 31, 2020)) [hereinafter “CVS

contracts³²⁰ with similar structures obtained from several of the PBM respondents as a part of this study—including both commercial and Part D contracts. In particular, this public document shows higher brand manufacturer rebates premised on (1) preferred positioning over other competing products on a formulary or formulary tier (that is, the rebating manufacturer is one of several, one of few, or “1 of 1” in the competitive category); (2) “additional” rebates to specifically exclude competing manufacturers of competitive products from the formulary; and (3) “additional” rebates for implementing “brand step” requirements, meaning that patients must try and fail the preferred brand before being able to try the competing brand products.”³²¹

Figure 17. Rebate Contract Excerpt

A-4 Lantus and Lantus SoloSTAR

REBATES FOR LANTUS® and LANTUS SoloSTAR® ¹ (INCLUDES ALL NDCs, STRENGTHS & PACKAGE SIZES)						
Formulary Type		1 of 1 Manufacturer Status**	1 of 2 Manufacturer Status**	1 of 3 Manufacturer Status**	1 of 4 Manufacturer Status	Listed Formulary Status
Non-Exclusion Formulary*	No Cost Share Differential	63.0%	58.0%	56.0%	N/A	N/A
	Cost Share Differential	63.0%	58.0%	56.0%	N/A	N/A
Exclusion Formulary*		63.0%	58.0%	56.0%	N/A	N/A
ACF / ACSF Closed Plans*		63.0%	58.0%	56.0%	N/A	N/A

*CVS/caremark Clients with sixty percent (60%) or more of their Plan lives that qualify for a higher Formulary Type Rebate rate shall earn the higher rate on all Client utilization. Clients that do not meet this threshold shall be evaluated on a Plan by Plan basis. Additionally, for clarity, open Plans (i.e. Plans which do not otherwise qualify as Closed Plans), will receive Closed Plan Rebate rates for any Competitive Category which qualifies as Closed.

¹ Plan must have all NDCs, strengths, package sizes of Lantus, Lantus SoloSTAR and Toujeo on the Preferred Brand Tier without restrictions to be eligible for this Rebate.

**Within the Long-Acting Insulin Category as defined in Section O.

INCREMENTAL ADDITIONAL BASE REBATE FOR ADOPTION OF EXCLUSIONS*:	
One Manufacturer of Competitive Products Excluded	2.0%
Two Manufacturers of Competitive Products Excluded	3.0%
Three Manufacturers of Competitive Products Excluded	N/A

*The incremental rebates above may be used for any current or future PBM exclusions. For avoidance of doubt, incremental additional Base Rebate for adoption of Exclusions shall not apply to Non Preferred Brand Tier Status Rebates.

NON-PREFERRED BRAND TIER STATUS FOR LANTUS® and LANTUS SoloSTAR®	
N/A	

Incremental Additional Base Rebate For Adoption of Brand Step Therapy Program:	
Implementation of Brand Step Therapy Program**	2.0%

Other common levers employed in rebate contracts include additional rebates for “prior authorization” requirements, such that the health plan must specifically authorize the patient to use

Document Production for the Senate Insulin Report”], https://www.finance.senate.gov/imo/media/doc/_FINAL%20PDF%20-%20CVS%20Caremark_Redacted.pdf. We use the contract excerpt from the Senate Finance Committee as an example due to our obligations under the FTC Act, § 6(f), 15 U.S.C. § 46.

³²⁰ See, e.g., Respondents Document Submissions [REDACTED]

³²¹ See CVS Document Production for the Senate Insulin Report, *supra* note 319, at 102.

a competing drug product. The Commission has also received reports of concerning methods to enhance the financial gains from rebate contracts, including the use of rules to indicate when the pharmacy’s substitution of a particular product is not permitted (known as “dispense as written” or “DAW”).³²²

In addition, our review of a number of contracts and internal documents summarizing such contracts reveals that some rebate contracts explicitly premise high rebates on the exclusion of AB-rated generics.³²³ These generic exclusions can be accomplished through “NDC blocks” of generic equivalents³²⁴—that is, a contractual prohibition on payments for generic drugs, as identified by their National Drug Code or “NDC” number. These findings are consistent with public comments that identify the practice of PBMs preferring higher point-of-sale price branded products over generics, which may raise out-of-pocket costs for patients.³²⁵

In brand drug manufacturer-PBM rebate contracts, the price of the branded drug to the payer may in some cases be lower than that of the excluded generic product net of rebates, but in other cases, the excluded generic may be a lower net price to the payer. Regardless of whether branded products

³²² See Mukul Kinariwalla, FTC-2022-0015-1192, at 2-3 (Apr. 14, 2022), <https://www.regulations.gov/comment/FTC-2022-0015-1192> (“One of the programs that PBMs have implemented [in] the past decade is [] called the ‘DAW = 9’ program, which means that they require a pharmacy to dispense a branded medication . . . [for] sometimes an upward of 20 times the cost of the generic equivalent that is FDA approved to be dispensed . . . The incentive for these programs to be implemented by the [PBMs] are due to the lucrative rebates drug manufacturers provide for having their brand name medication dispensed (and paid for by employers who foot the bill) rather than the FDA approved generic equivalent.”).

³²³ The FDA determines AB rating. An AB-rated generic is considered to be bioequivalent to the branded product, and by state pharmacy law automatically substitutable for the reference branded product at the pharmacy counter without any intervention by a prescribing physician or nurse practitioner. See *Orange Book Preface*, U.S. FOOD & DRUG ADMIN, <https://www.fda.gov/drugs/development-approval-process-drugs/orange-book-preface#:~:text=Drugs%20coded%20as%20AB%20under,character%20code%20under%20that%20heading> (last updated Jan. 25, 2024) (“Drugs coded as AB under a heading are considered therapeutically equivalent only to other drugs coded as AB under that heading. . . virtually every state has adopted laws and/or regulations that encourage the substitution of drug products.”).


³²⁴ NDC blocks are a common, but not the exclusive, method for excluding generics. See, e.g., Respondents Document Submissions






³²⁵ See, e.g., Hester, *supra* note 156, at 2 (“PBMs force some patients to use brand drugs that are higher in price because the practice results in higher rebates to the PBM and higher clawbacks by the PBM from my pharmacy.”); Andrew Cannon, FTC-2022-0015-0805, at 1 (May 11, 2022), <https://www.regulations.gov/comment/FTC-2022-0015-0805> (“PBMs are forcing [b]rand name medications when cheaper generics are available so they can maximize their rebates. This pushes the patient into the donut hole faster, which causes issues with them affording their life saving medications.”); Chandra et al., *supra* note 226, at 1 (finding Medicare Part D beneficiaries cut back on medications when faced with higher costs, resulting in increased mortality rates); *accord*, All. for Patient Access, FTC-2022-0015-0951 (May 25, 2022), <https://www.regulations.gov/comment/FTC-2022-0015-0951>.

are less expensive than a generic version net of rebates, agreements that exclude generics and biosimilars raise numerous concerns.

First, patient out-of-pocket cost obligations may be higher if the patient is required to take the branded (and rebated) drug product instead of its NDC-blocked generic equivalents. As the following illustration shows, in common tiered formulary structures, patient copay obligations are often lowest for generic drugs and higher for preferred, branded drug products.

Figure 18. Example of Drug Type and Cost Associated with Formulary Tiers³²⁶



Tier	Drug type	Cost to beneficiary
1	 Preferred generics	\$
2	 Generics	\$\$
3	 Preferred brands	\$\$\$
4	 Non-preferred	\$\$\$\$
5	 Specialty	\$\$\$\$\$

Source: GAO; GAO (illustrations). | GAO-23-105270

Studies focused on drug rebates have raised significant concerns over the impact of rebates on patient out-of-pocket costs. Last year, a Government Accountability Office examination of select Medicare Part D rebate arrangements and their implications for plan sponsors, beneficiaries, and Medicare spending found that payments “paid by beneficiaries or other payers on their behalf . . . were more than plan sponsor payments for the majority of the 100 highest rebated Part D drugs discussed previously after accounting for rebates.”³²⁷ Increased copay obligations can have dire consequences for some patients. Patients and providers in public comments to the FTC described that patient copay burdens can become so extreme that patients may delay taking their medication, skip doses, or even go without them entirely, sometimes with fatal results.³²⁸

Second, cash-pay patients, including the uninsured, may face collateral impact from these exclusionary rebates. When generic drugs enter a market, prices tend to fall dramatically.³²⁹ But

³²⁶ GAO-23-105270, *supra* note 210, at 10. For purposes of this Interim Report, we have modified the title of this illustration from the title in the GAO report.

³²⁷ *Id.* at 32.

³²⁸ Hepatitis B Found., FTC-2022-0015-0594, at 2 (Apr. 25, 2022), <https://www.regulations.gov/comment/FTC-2022-0015-0594> (“[T]he Foundation has received hundreds of messages from patients and providers expressing problems with the affordability of [H]epatis B medications, even with insurance coverage. Some individuals employed harmful tactics such as splitting or skipping pills in order to make their medications last longer.”); Charlene York, FTC-2022-0015-0439, (Apr. 14, 2022), <https://www.regulations.gov/comment/FTC-2022-0015-0439>; Hester, *supra* note 156.

³²⁹ Robin Feldman et al., *Empirical Evidence of Drug Pricing Games—A Citizen’s Pathway Gone Astray*, 20 STAN. TECH. L. REV. 39, 46 (2017); *see also* Herbert Hovenkamp, *Antitrust and the Patent System: A Reexamination*, 76 OHIO ST. L.J. 467, 491 (2015) (“[C]ompetition among generics drives prices to the competitive level . . .” which can be “as little as 20% of pre-generic-entry prices.”).

pharmacies will not stock what they cannot profitably sell.³³⁰ If generics are disfavored on formularies, pharmacies may be disincentivized from stocking those generics, potentially reducing accessibility to less expensive generic products for cash-pay patients.

In addition to limiting insured patients' access to generic competitor drugs, impacting patient cost-sharing obligations, and limiting uninsured patient access to affordable medicines, exclusionary rebates may have negative spillover effects on the structure of the market as a whole. That is, by limiting generic drug companies' ability to get more patient uptake, generic exclusions may deter and chill less expensive generic competitor drugs from entering the market at all. As a policy matter, rebates premised on generic exclusions frustrate state generic substitution laws³³¹ and Congress' goal in enacting the Hatch-Waxman Act³³² that created new pathways for generic product approval, which was primarily "to make available more low-cost generic drugs."³³³

Exclusionary rebates warrant further scrutiny by the Commission, law enforcement, health plans (including self-funded plans), and policymakers. As the FTC stated in its June 2022 policy statement, "[e]xclusionary rebates that foreclose competition from less expensive alternatives may constitute unreasonable agreements in restraint of trade under Section 1 of the Sherman Act; unlawful monopolization under Section 2 of the Sherman Act; or exclusive dealing under Section 3 of the Clayton Act," in addition to Section 2(c) of the Robinson-Patman Act and Section 5 of the FTC Act.³³⁴ The FTC will prioritize bringing its full authority to bear where it finds evidence of unlawful practices.

³³⁰ "Pharmacists are more likely to fill prescriptions with generic-name drugs if they are given a financial inducement to do so. Increased use of generic drugs decreases inventory costs because a pharmacy will not stock every brand of a particular drug if it will be permitted to fill most prescriptions for the drug with a generic product." See James J. Wheaton, *Generic Competition and Pharmaceutical Innovation: The Drug Price Competition and Patent Term Restoration Act of 1984*, 35 CATH. U. L. REV. 433, 446 (1986) (citing FED. TRADE COMM'N, DRUG PRODUCT SELECTION 88-89 (1979)).

³³¹ Since the passage of the Hatch-Waxman Act in 1984, every state has adopted substitution laws that suggest or require that pharmacists dispense an AB-rated generic version of a drug instead of the branded drug. See, e.g., FLA. STAT. ANN. § 465.025(2) (West 2020); KY. REV. STAT. ANN. § 217.822(1) (West 2016); N.J. STAT. ANN. § 24:6E-7 (West 1977); N.Y. EDUC. LAW § 6816-a(1) (McKinney 2017); 35 PA. STAT. AND CONS. STAT. ANN. § 960.3(a) (West 2016); WIS. STAT. ANN. § 450.13(1s) (West 2022); MASS. GEN. LAWS ANN. ch. 112 § 12D (West 2015); R.I. GEN. LAWS ANN. § 5-19.1-19 (West 2001); W. VA. CODE ANN. § 30-5-12b(f)-(g) (West 2019) (requiring substitution).

³³² 21 U.S.C. § 355.

³³³ H.R.REP. NO. 98-857, at 14 (1984) (Part 1), reprinted in 1984 U.S.C.C.A.N. 2647, 2647.

³³⁴ See Policy Statement on Rebates and Fees, *supra* note 318, at 5.

V. CONCLUSIONS AND AREAS OF ONGOING FOCUS

PBMs are at the center of the U.S. pharmaceutical system. However, their outsized influence comes not only from the expansion of their traditional, middlemen administrative services in processing patients' pharmacy prescription claims, but also from decades of consolidation and vertical integration across the healthcare delivery system. Analysis of the current industry landscape indicates the largest PBMs have come under common ownership with the largest, most dominant health insurers. In addition, these healthcare conglomerates operate some of the largest retail, mail order, and specialty pharmacies in the country, which compete with local independent pharmacies. Given these relationships, PBMs and their affiliated entities may have the incentive and ability to engage in steering a growing share of prescription revenues to their own pharmacies through specialty drug classification, self-preferential pricing, and pharmacy contracting procedures to target and control the business operations of pharmacies. While this Interim Report principally focuses on the impact of these changing market dynamics on the operation and vitality of the nation's pharmacies, we also share initial evidence about PBM and brand pharmaceutical rebating practices that urgently warrant further scrutiny and potential regulation.