SENIOR CARE PHARMACY COALITION

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May 25, 2022

Via Electronic Submission

The Honorable Lina Kahn
Chair
Federal Trade Commission
600 Pennsylvania Avenue, NW
Washington, DC 20580

RE: Solicitation for Public Comments on the Impact of Prescription Benefit Managers' Business Practices; FTC-2022-0015

Dear Chair Kahn:

The Senior Care Pharmacy Coalition (SCPC) appreciates the opportunity to comment on the practices of Pharmacy Benefit Managers (PBMs) and their impact on patients, physicians, employers, independent and chain pharmacies, and other businesses across the pharmaceutical distribution system.[1] SCPC is the only Washington-based organization exclusively representing the interests of long-term care (LTC) pharmacies. SCPC's membership includes 80% of all independent LTC pharmacies in the country.[2] Our members serve one million residents daily in skilled nursing facilities and assisted living communities across the country.[3] Given the distinct characteristics of the LTC patient population and the LTC pharmacy market, we offer unique perspectives on PBM business practices and their impact, particularly their impact on patients who need LTC and services and the independent LTC pharmacies that serve them.

We have focused our comments on the specific topics the Commission raised in its solicitation for public comments. Before sharing views on those topics, however, we provide important information essential to the Commission's consideration of our comments and recommendations.

Scope of FTC Authority

The Commission exists to protect consumers and promote competition. While the Commission has responsibility for enforcing more than 80 consumer protection laws, the inquiry into PBMs

[1] On February 24, 2022, the Federal Trade Commission issued a Solicitation for Public Comments on the Business Practices of Pharmacy Benefit Managers and Their Impact on Independent Pharmacies and Consumers. Following an extension, the deadline for submitting comments is May 25, 2022.

[2] SCPC defines "independent LTC pharmacies" as pharmacies that are not affiliated with insurers or PBMs. The largest LTC pharmacy in the country, Omnicare, is a subsidiary of CVS Health. Given this affiliation, Omnicare is not an independent LTC pharmacy. Omnicare's market share is uncertain since its results are not reported to the public independent of overall CVS Health performance, but reasonable estimates suggest that Omnicare represents 35-40% of the LTC pharmacy market. SCPC represents 80% of the market excluding Omnicare.

[3] This figure is based on pre-pandemic facility occupancy rates. Our members also serve an increasing number of individuals with LTC needs, including Medicare beneficiaries, living in community settings and at home.

primarily implicates the agency's authority to enforce the antitrust laws pursuant to the Federal Trade Commission Act (FTC Act),[4] which is designed to prevent unfair methods of competition, and the Clayton Act,[5] which is designed to prevent unlawful tying contracts, mergers, acquisitions, and interlocking directorates. Congress enacted the FTC and Clayton Acts to broaden and strengthen federal antitrust laws, expanding federal authority beyond the business practices regulated by the Sherman Antitrust Act. [6] In evaluating whether businesses engage in unfair methods of competition pursuant to the FTC Act, however, the Commission relies in part on elements of the antitrust laws beyond the provisions of the Clayton Act, particularly the Sherman Antitrust Act.

Since their inception, the antitrust laws have had the same basic objective: "to protect the process of competition for the benefit of consumers, making sure there are strong incentives for businesses to operate efficiently, keep prices down, and keep quality up."[7] Courts have consistently held that anticompetitive actions are not those "that merely injure individual competitors, but [are] actions that harm the competitive process, a process that aims to bring consumers the benefits of lower prices, better products and more efficient production methods."[8] The Supreme Court has also recognized this central concept, holding repeatedly that the antitrust laws are designed to protect competition, not competitors.[9]

This fundamental purpose of the antitrust laws – the protection of competition and the competitive process – has often focused on consumer costs and price competition (*i.e.*, a firm's ability to raise price or reduce output). The Federal Trade Commission ("FTC") and the courts also have emphasized that *nonprice* competition (*i.e.*, a firm's ability to reduce quality and innovation) is an important metric by which the antitrust laws scrutinize market behaviors.[10]

In the context of the markets in which pharmacy benefit managers ("PBMs") operate, nonprice competition is particularly important, as lower consumer costs alone can be an insufficient metric

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[4] 15 U.S.C. §§ 41-58, as amended, originally enacted in 1914.
[5] 15 U.S.C. §§ 12-27, as amended, originally enacted in 1914.
[6] 15 U.S.C. §§ 1-58, enacted in 1890.
[7] *See* Federal Trade Commission, *Guide to Antitrust Laws*, available at https://www.ftc.gov/advice-guidance/competition-guidance/guide-antitrust-laws/antitrust-laws.

[8] *Interface Grp. V. Massachusetts Port Auth.*, 816 F.2d 9, 10 (1st Cir. 1987).

[9] *See Spectrum Sports, Inc. v. McQuillan*, 506 U.S. 447, 458 (1993); *Atlantic Richfield Co. v. USA Petroleum Co.*, 495 U.S. 328, 338 (1990); *Cargill, Inc. v. Monfort of Colo., Inc.*, 479 U.S. 104, 109-10 (1986); *Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc.*, 429 U.S. 477, 488 (1997).

[10] The emphasis on the impact of market behaviors on quality and innovation is well-developed. Section 6.4 of the DOJ/FTC 2010 Horizontal Merger Guidelines "Merger Guidelines" makes clear that competition may be harmed if a merger reduces the merged firm's incentives to improve quality and innovate: "The Agencies may consider whether a merger is likely to diminish innovation competition by encouraging the merged firm to curtail its innovative efforts below the level that would prevail in the absence of the merger." Merger Guidelines available at https://www.ftc.gov/sites/default/files/attachments/merger-review/100819hmg.pdf.

to justify certain market behaviors. The FTC has recognized the importance of nonprice and price competition in the context of PBMs. The FTC has, for example, scrutinized attempts to vertically integrate pharmaceutical manufacturers and PBMs in light of the potential for a manufacturer to favor its own drugs for the PBM's formularies.[11] The FTC has contended that vertical mergers between pharmaceutical manufacturers and PBMs might lead to foreclosure of competing pharmaceutical manufacturers from the PBM formulary, elimination of the PBM as an independent negotiator of pharmaceutical prices with manufacturers, coordinated interaction between the acquiring manufacturer and other vertically integrated pharmaceutical companies, and impediments to new entry, thereby causing pharmaceutical quality and innovation to diminish and prices to increase.[12]

In summary, the purpose of the antitrust laws is to ensure vigorous competition in all markets by keeping sellers and suppliers honest, forcing them to strive continually not only to lower costs, but also to improve their goods and services and to offer them on favorable terms. Customers benefit from this competition. The antitrust laws are meant to ensure that the incentives to compete and the resulting product quality, service excellence, and lower costs flourish in every market.

Background Information

As the Commission is already aware, PBMs themselves do not actually provide any services to consumers, but instead are recent intermediaries and third parties in the delivery of LTC pharmacy services that has existed for decades. To evaluate PBMs and how they abuse their market power, however, it is important that the Commission consider not only individuals who need LTC as consumers of prescription drugs and related LTC pharmacy services, but also LTC pharmacies as consumers of PBM services and. It also is important that the Commission understand the inverse correlation between lower consumer out-of-pocket costs for prescription drugs and higher consumer premiums for prescription drug coverage, particularly with respect to the Medicare program. Background concerning the nature of the LTC market, and the role of the various actors in that market, including the LTC pharmacies, will illuminate these considerations.

Scope of LTC Pharmacy Services. LTC pharmacies primarily serve consumers who need LTC services, which the Medicare and Medicaid programs define as individuals who need "an institutional level of care."[13] Generally, individuals must require assistance with two or more activities of daily living to qualify for an institutional level of care.[14] LTC pharmacies historically

[11] *See, e.g., Eli Lilly & Co.*, 120 F.T.C. 243 (1995), *set aside by* 127 F.T.C. 577 (1999); *Merck & Co.*, 127 F.T.C. 156 (1999).

[12] *Eli Lilly & Co.*, 120 F.T.C. at 254.

[13]Center for Medicaid and CHIP Services, Institutional Long Term Care.

[14]Activities of daily living (ADLs) are basic activities most people perform daily without assistance, and are used to evaluate an individual's level of independent functioning, which in turn determines whether an individual qualifies for Medicaid or long-term care insurance coverage. See Elder Law Answers, "Activities of Daily Living Measure the Need for Long-Term Care Assistance" (March 5, 2021). There are six activities of daily living generally used when

focused on residents in nursing homes, but as the need for LTC has grown and the LTC market has diversified, LTC pharmacies now serve residents in assisted living communities, younger adults with intellectual and developmental disabilities living in intermediate care facilities, and individuals living in private homes.

LTC pharmacies provide enhanced clinical and specialized services that differentiate them from retail or mail order pharmacies. The extensive clinical services that LTC pharmacies provide include:

- Direct and ongoing consultation with residents and their families.
- Participation in resident care management teams, including direct interactions with and recommendations to the facility medical director, nursing staff, and administration. This engagement requires familiarity with the resident's medical records and complete prescription drug profile.
- Drug utilization review to prevent over- or under-utilization of prescription drugs and to improve outcomes and reduce costs when medically appropriate.
- Medication therapy management for Part D Plans, including comprehensive medication reviews and targeted medication reviews for all LTC beneficiaries.
- Medication reconciliation, including at least daily reconciliation for opioids.
- Direct and ongoing training and contact with facility nursing staff.
- Pharmacist availability to provide medication and patient care services 24/7/365.
- Direct placement of peripherally inserted central catheters and insertion of Midline and PICC lines.
- Antibiotic stewardship and infection control.
- Specialized packaging to improve adherence and reduce medication errors.
- Access to prescription medications at all times, pursuant to which residents must receive medications as soon as two hours after the pharmacy receives the prescription.

LTC pharmacies also provide broader specialized services, including:

- Patient-specific, unit-dose packaging to reduce medication errors
- Systematic packaging for entire facility
- 24/7/365 medication delivery

Medicaid programs consider eligibility for LTC, including bathing or showering; dressing, getting in and out of a bed or a chair, walking, using the toilet, and eating. According to CMS, if a person "has difficulty performing an activity by himself/herself and without special equipment, or does not perform the activity at all because of health problems, the person is deemed to have a limitation in that activity."

While there is no federal statutory definition of LTC pharmacy,[15] the Medicare and Medicaid Requirements of Participation include pharmacy services requirements that skilled nursing facilities (SNFs), nursing facilities (NFs) and Intermediate Care Facilities (ICFs) must satisfy to participate in these programs.[16] These federally defined LTC facilities uniformly contract with LTC pharmacies to serve all facility residents. The Centers for Medicare and Medicaid Services (CMS), the agency charged with implementation and oversight of both programs, has promulgated extensive regulations regarding these statutory pharmacy services requirements,"[17] and has provided detailed guidance regarding both the relevant statutory and regulatory provisions in the State Operations Manual.[18] Pursuant to their contracts with LTC facilities, LTC pharmacies must satisfy these statutory, regulatory, and administrative standards.

LTC pharmacies also provide these clinical and specialized services to individuals who live in settings other than federally defined LTC facilities,[19] such as assisted living communities or private homes. While the legal obligations imposed on federally defined LTC facilities do not extend to these other settings, LTC pharmacies nonetheless typically provide them regardless of the setting in which the consumer lives, both for the benefit of the consumer and due to provisions of the Medicare Part D program.[20]

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[15] The Long-Term Care Pharmacy Definition Act of 2021, currently pending in the Senate as S. 1574 and in the House as H.R. 5632, would add a definition of LTC pharmacy to the Medicare statute.

[16]Long-term care (LTC) facilities participating in Medicare and Medicaid must provide pharmacy services to all facility residents. Medicare requires that Skilled Nursing Facilities (SNFs), and Medicaid requires that Nursing Facilities (NFs) and Intermediate Care Facilities (ICFs) provide "pharmaceutical services (including procedures that assure the accurate acquiring, receiving, dispensing, and administering of all drugs and biologicals) to meet the needs of each resident." 42 U.S.C. § 1395i-3 (pertaining to SNFs participating in the Medicare program) and 42 U.S.C. § 1396r(b)(4)(a)(iii) (pertaining to NFs participating in the Medicaid program) and 42 C.F.R. §§ 440.150(b)(1) & 483.460 (j) (pertaining to ICFs participating in the Medicaid Program). ICFs are facilities for individuals with intellectual disability, Center for Medicaid and CHIP Services, "Intermediate Care Facilities for Individuals with Intellectual Disability."

[17] 42 C.F.R. §§ 483.1-483.95.

[18] State Operations Manual, Appendix PP – Guidance to Surveyors for Long Term Care Facilities (Rev. 173, 11-22-17).

[19] The Medicare and Medicaid statutes define LTC facility to include SNFs, NFs, and ICFs. 42 U.S.C. § 1395i-3(a)(SNFs) & 42 U.S.C. § 1396r(a)(NFs, which include ICFs). However, for some data purposes, CMS classifies Medicare beneficiaries residing in ALFs as residents of LTC facilities. For example, CMS maintains the Medicare Current Beneficiary Survey, which defines LTC facilities to encompass SNFs, NFs, ICFs, and ALFs. These comments generally use the terms "federally defined LTC facilities" and to include SNFs, NFs, and ICFs but not ALFs, unless otherwise noted.

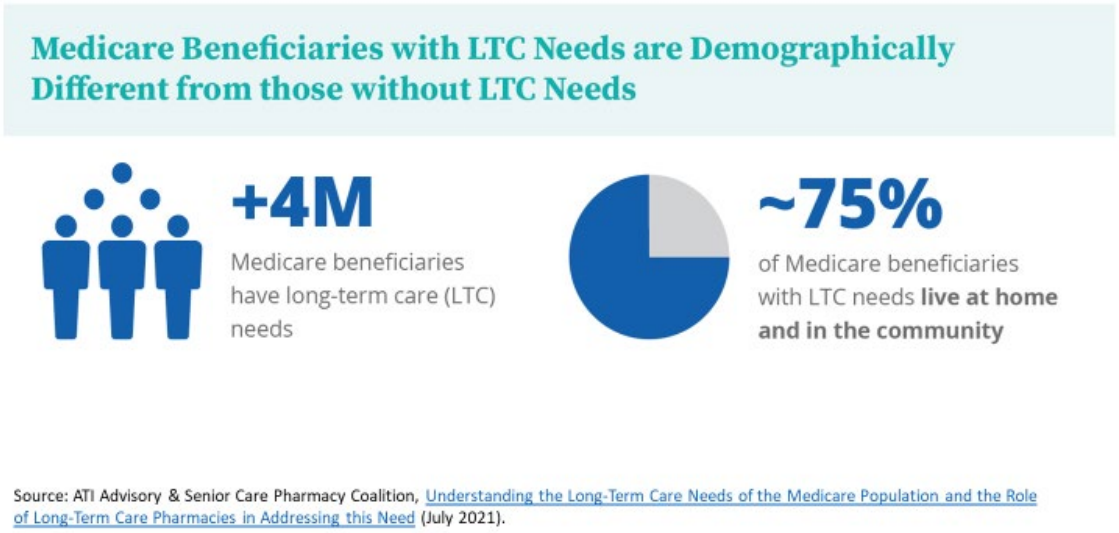
[20] For example, Chapter 5 ,§ 50.5.2 of the Medicare Prescription Drug Manual (the Part D Manual), authorizes Prescription Drug Plans to pay enhanced dispensing fees (LTC pharmacy dispensing fees) to pharmacies providing enhanced clinical and specialized services to Part D beneficiaries who reside in assisted living facilities, provided that the beneficiary requires an institutional level of care. In December 2021, CMS issued similar guidance regarding beneficiaries with institutional level of care needs residing in private homes. See Memorandum from Amy Larrick Chavez-Valdez, Direct, Medicare Drug Benefit and C & D Data Group to All Part D Sponsors regarding Part D Dispensing Fees and Enrollees with Institutionalized Level of Care Needs (December 15, 2021)(Larrick Memo).

Due to the clinical complexity of LTC facility residents, who rely on an average of 12 prescription drugs each day, SNFs and NFs generally contract with one LTC pharmacy to serve all residents in the facility regardless of payer. This significantly improves patient adherence and substantially reduces medication errors, because it allows standardized drug packaging specifically designed to reduce errors and to improve efficiency for the nursing staff conducting medication passes in these facilities. ALFs generally do not adopt a one-facility-one-pharmacy policy, but many ALFs will contract with LTC pharmacies as a "preferred provider" for facility residents.

Medicare generally does not recognize pharmacies as providers that may directly bill the program for reimbursement. However, the Part D program requires that each Prescription Drug Plan (PDP) demonstrate that it has an adequate network of LTC pharmacies to assure that enrollees have appropriate access to LTC pharmacy services. [21] CMS has established criteria that a pharmacy must satisfy for a PDP to establish LTC pharmacy network adequacy. In other words, pharmacies must satisfy these criteria to be recognized as LTC pharmacies eligible to participate in Part D networks.[22] The Part D criteria apply not only to Part D beneficiaries living in federally defined LTC facilities, but also to Part D beneficiaries who need LTC and who reside in assisted living facilities or private homes.

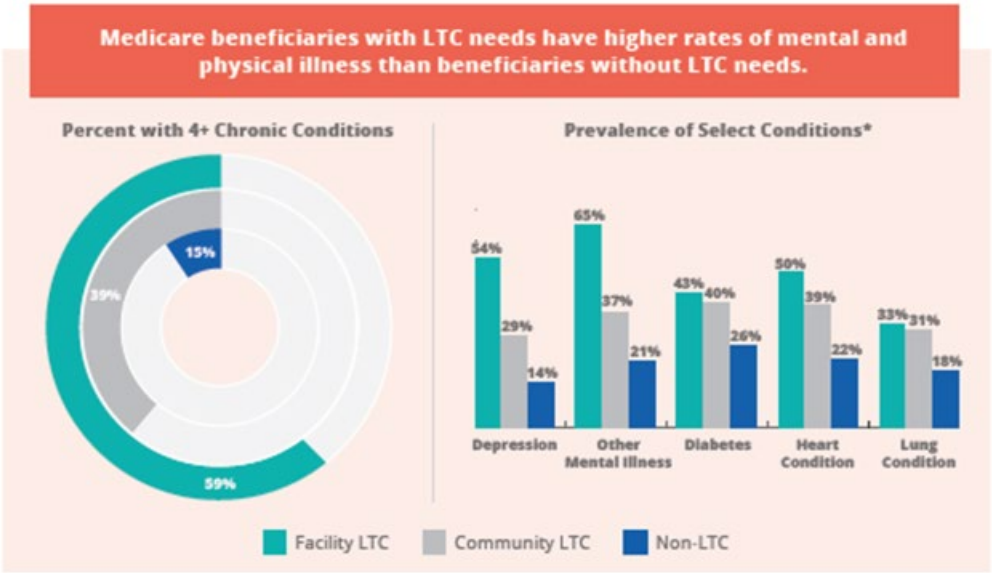
LTC Pharmacy Patient Population. The cohort of the population that needs LTC is substantially similar regardless of place of residence (nursing home, assisted living facility, or private home) and is collectively dissimilar from the cohort that does not need LTC. For example, roughly 4.2 million Medicare beneficiaries need LTC, 25% of whom live in LTC facilities (defined in the relevant Medicare database as those who reside in nursing homes or assisted living facilities), and 75% of whom live in the community (principally in private homes).

[21]Part D Manual, at § 50.5.
[22] Performance and Service Criteria for Network Long-Term Care Pharmacies (NLTCPs), Part D Manual at § 50.5.2.



Source: ATI Advisory & Senior Care Pharmacy Coalition, Understanding the Long-Term Care Needs of the Medicare Population and the Role of Long-Term Care Pharmacies in Addressing this Need (July 2021).

Medicare beneficiaries who need LTC are more clinically complex than Medicare beneficiaries who do not need LTC. They have higher rates of cognitive impairment and of mental and of chronic conditions.



Source: ATI Advisory & Senior Care Pharmacy Coalition, Understanding the Long-Term Care Needs of the Medicare Population and the Role of Long-Term Care Pharmacies in Addressing this Need (July 2021).

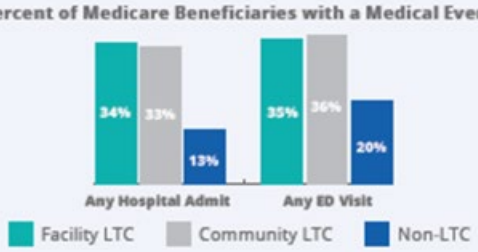
Not surprisingly, Medicare beneficiaries with LTC needs have higher utilization rates for health care and for prescription drugs.

Healthcare and Prescription Drug Utilization is High Among Medicare Beneficiaries with LTC Needs

Regardless of residence, Medicare beneficiaries with LTC needs have considerable medical and pharmacy complexity and require a more intense level of care, service integration, and care management than their non-LTC peers. This is reflected in their higher medical and prescription drug utilization compared to beneficiaries without LTC needs.

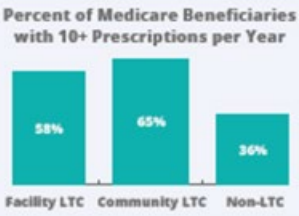
Healthcare Utilization

Medicare beneficiaries with LTC needs are **more likely to have an inpatient hospital admission or emergency department (ED) visit** than beneficiaries without LTC needs.



Source: ATI Advisory & Senior Care Pharmacy Coalition, Understanding the Long-Term Care Needs of the Medicare Population and the Role of Long-Term Care Pharmacies in Addressing this Need (July 2021).

Prescription Drug Utilization



- Medicare beneficiaries with LTC needs who reside in a facility or institutional setting average **12 prescriptions per year**.
- Those with LTC needs who live at home or in other community settings average **14 prescriptions per year**.
- This compares with **8 prescriptions per year** among Medicare beneficiaries without LTC needs.

Medicare Spending

Total Medicare Part A and B medical **spending is 2x-3x higher** among beneficiaries with LTC needs than those without LTC needs.

Facility LTC: **$27,317** Community LTC: **$19,790** Non-LTC: **$7,472**

Total Medicare Part D drug **spending is nearly twice** as high among beneficiaries with LTC needs than those without LTC needs.

Facility LTC: **$6,327** Community LTC: **$6,311** Non-LTC: **$3,825**

Source: ATI Advisory & Senior Care Pharmacy Coalition, Understanding the Long-Term Care Needs of the Medicare Population and the Role of Long-Term Care Pharmacies in Addressing this Need (July 2021).

Of particular relevance to the FTC's consideration of PBMs, Medicare beneficiaries with LTC needs average prescriptions for 12-14 different drugs per year, while Medicare beneficiaries without LTC needs average prescriptions for only 8 different drugs per year. The average resident in SNFs and NFs take an average of 12 different medications each day as well.[23]

Payment for LTC Pharmacy Services. Roughly 75% of LTC pharmacy revenues are from commercial insurers registered as Part D Plans under the Medicare Part D program. Part D extends to enrollees who need LTC and who reside in nursing facilities (NFs), intermediate care facilities (ICFs), assisted living facilities (ALFs), and private homes. Since most Medicaid beneficiaries living in nursing facilities are dually eligible for both Medicare and Medicaid, Part D becomes the payer for prescription drugs and related services for most NF residents. Most ALF residents are not dually eligible but are 65 or older and therefore are eligible to enroll in Part D. Most ALF residents do have Medicare coverage. Part D does covers prescription drugs and related pharmacy services for these ALF residents if they are enrolled in Part D.[24]

Roughly 20% of LTC pharmacy revenues derive indirectly from the Medicare Part A and Medicare Part C skilled nursing benefit.[25] Medicare beneficiaries are eligible for skilled nursing care, provided that they meet certain level of care and administrative requirements. Those who qualify for the skilled nursing benefit typically received care and services in a SNF. Both Part A and Part C payment systems reimburse SNFs through integrated payment models that include reimbursement for the cost of prescription drugs and related LTC pharmacy services. SNFs, in turn, use a portion of those payments to reimburse LTC pharmacies for the prescription drugs and related LTC pharmacy services provided to SNF residents. SNFs and LTC pharmacies contract for provision of and reimbursement provided to SNF residents.

The remaining 5% of LTC pharmacy revenues are from all other payers – Medicaid, commercial insurance, and consumer-out-of-pocket expenditures. Medicaid pays for prescription drugs and related pharmacy services for low-income residents of NFs or ICFs if these residents are not dually eligible for Medicare. Commercial insurance comprises a small fraction of revenues, typically for residents in ALFs or living in private homes.

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[23] SCPC has contracted with an independent third party to analyze proprietary LTC pharmacy data. This analysis found that SNF residents took an average of 13 prescription drugs a day, while NF and ALF residents took an average of 12 prescription drugs a day.

[24] In 2019, 61.5 million Americans were enrolled in Medicare, 74% of whom (45.5 million) were enrolled in Medicare Part D. CMS, Medicare Beneficiaries at a Glance, 2021 Edition.

[25] As explained in the narrative, SNFs receive payments from Medicare Part A designed to include reimbursement for prescription drugs and related LTC pharmacy services. Medicare Part C program payments (Medicare Advantage Medicare managed care) to SNFs are modeled on the Part A payment system, such that SNFs receive payments designed to include reimbursement for prescription drugs and related LTC pharmacy services as well. The estimated 20% of LTC pharmacy revenues derive from payments SNFs receive under both Medicare Part A and Medicare Part C. Ironically, in many cases the Medicare managed care health insurers are part of the same health care conglomerates that own the PBMs administering the Part D Plans that also are owned by the parent conglomerate and that provide Part C and Part D coverage to residents in SNFs. See infra at 40-41 for a discussion of these conglomerates and the degree to which they amplify the anticompetitive impact of PBM practices.

Consumer out-of-pocket payments overwhelmingly are from Part D beneficiaries who are not dually eligible, regardless of the setting in which they live. Given that most long stay residents in federally defined LTC facilities are duals, most LTC pharmacy revenues from co-pays come from residents in ALFs or individuals living in the community.

LTC Pharmacy Markets. The LTC pharmacy market is diffuse. There are an estimated 1,400 LTC pharmacies across the country,[26] but only two have sufficient size to consistently manage PBM relationships without assistance. The remainder contract with pharmacy services administrative organizations (PSAOs) to provide administrative services and negotiate group contracts with PBMs and PDPs, subject to structural limitations imposed by federal antitrust laws.

Given that most LTC pharmacies are small businesses both in an absolute sense and especially in comparison to PBMs, most LTC pharmacies contract with PSAOs to provide an array of back office administrative and operational services that these pharmacies otherwise would have difficulty managing. For example, many LTC pharmacies lack the staff or legal expertise to effectively manage audits and payment reconciliation as required by PBM contracts. These pharmacies rely on PSAOs for the operational support needed to undertake claims validation, manage reimbursement, and navigate audit risk assessments. PSAO services often include identification and correction of pharmacies' claims and monitoring PBM reimbursement to ensure payments comply with contracted rates.

PSAOs also are able to efficiently negotiate payment rates and other terms with PBMs.[27] Importantly, due to constraints imposed by the antitrust laws PSAOs cannot bind their member pharmacies to any contracts or any terms they may negotiate with PBMs. Each pharmacy must individually accept or reject all contract terms, including terms PSAOs may have negotiated on behalf of its member pharmacies.

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[26] Adam Fein, Ph.D., Drug Channels, Institute, "The 2022 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers" 46 (March 2022)(Fein, 2022 Economic Report). Exhibit 25 shows that there are about 1,400 LTC pharmacies in the country.

[27] *See generally,* Avalere Health*, The Role of Pharmacy Services Administrative Organizations for Independent Retail and Small Chain Pharmacies* (Sept. 2021), available at https://www.hda.org/~/media/pdfs/government-affairs/the-role-of-psaos-for-independent-retail-small-chain-pharmacies.ashx. The PBMs intentionally mischaracterize PSAOs as "little-known but powerful collective groups…" *See https://www.pcmanet.org/pharmacy-services-administrative-organizations-psaos-and-their-little-known-connections-to-independent-pharmacies/#:~:text=Pharmacy%20services%20administrative%20organizations%20(PSAOs)%20are%20little%2Dknown%20but,pharmacies%20contract%20with%20a%20PSAO*. That is simply false. As the PBMs themselves know, the reason that PBMs negotiate with PSAOs is to benefit from the market efficiencies of not having to otherwise contract with each individual pharmacy. In relative bargaining strength, however, the PSAOs have virtually no leverage in negotiating contract terms, and are often offered the very same "take it or leave it" contracts with uncommercial contract terms that the PBMs offer to individual pharmacies (addressed below). Further, there are three different leading PSAOs – Managed Healthcare Associates, Innovatix, and GeriMed, further diffusing the "powerful" leverage that the PBMs falsely accuse the PSAOs of having.

As a result, PSAOs have limited negotiating leverage based not only on comparative market power but by structural limitations imposed under the antitrust laws. By contrast, PBMs face no antitrust constraints in simultaneously representing multiple insurance companies regarding multiple prescription drug plans, thereby multiplying their negotiating leverage. Hence, the antitrust laws themselves give PBMs disproportionate negotiating power while preventing pharmacies from similarly aggregating collective market power into better negotiating leverage. PBMs may – and do - threaten to exclude PSAO member pharmacies from many PBM-controlled pharmacy networks unless the PSAOs accept otherwise onerous "take it or leave it" contract terms that often become the basis for PBM contracts with individual pharmacies.

In addition, PBMs need not negotiate with PSAOs at all. For example, since the inception of the Part D program in 2006, Humana has refused to negotiate with LTC pharmacy PSAOs, demanding instead that each LTC pharmacy "negotiate" its own contracts directly with Humana. The result, not surprisingly, is that terms in Humana contracts consistently are less favorable to LTC pharmacies than similar terms in contracts with other PBMs or PDPs.

The key consideration for the Commission's analysis is that the antitrust laws place structural constraints on PSAOs in aggregating LTC pharmacy market power that those laws do not place on PBMs in aggregating insurer market power. Consequently, independent of market-driven imbalances in the comparative negotiating power of LTC pharmacies and PBMs, the antitrust laws themselves create structural disproportionality in comparative negotiating power.

Due to the Part D program's LTC pharmacy network adequacy requirement, CMS requires that PDPs allow all LTC pharmacies to participate in Part D networks to assure that Part D enrollees who live in federally defined LTC facilities have access to an LTC pharmacy regardless of the facility in which they reside.[28] The Part D program encourages but cannot legally require PDPs to pay higher dispensing fees to LTC pharmacies in recognition of the additional services they must provide as compared to retail or mail order pharmacies.[29] PBMs and PDPs consistently negotiate higher dispensing fees for Part D beneficiaries living in SNFs and NFs. However, they are less likely to pay enhanced dispensing fees to LTC pharmacies serving beneficiaries with LTC needs living in assisted living facilities or private homes, despite the fact that LTC pharmacies provide enhanced services in these settings and the fact that CMS explicitly allows PDPs to pay enhanced dispensing fees to LTC pharmacies serving Part D beneficiaries with institutional level of care need living in ALFs or private homes.[30]

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[28] "Long-Term Care [LTC] Pharmacy Access," & "Convenient Access to LTC Pharmacies," Medicare Prescription Drug Benefit Manual § 50.5 & §50.5.1.

[29] "Performance and Service Criteria for Network Long-Term Care Pharmacies (NLTCPs)," Medicare Prescription Drug Benefit Manual § 50.5.2.

[30] "Dispensing Fees," Part D Manual at § 20.7 (beneficiaries in ALFs) and Larrick Memo (beneficiaries in private homes). This CMS guidance allows PDPs to pay enhanced dispensing fees if the Part D beneficiary needs "an institutional level of care." As explained supra at 3, institutional level of care need is the criterion on which the Medicare and Medicaid programs determine whether a beneficiary is eligible for LTC.

LTC represents a small but distinct market within the larger market of prescription drug spending, and LTC pharmacy represents a small but distinct market within the larger PBM market. In 2021, the 59,000 retail, mail order, LTC, and specialty pharmacies dispensed 6.2 billion 30-day equivalent prescriptions and generated $500 billion prescription revenues.[31] LTC pharmacies accounted for $16.9 billion in revenues (3% of total revenues), 400 million prescriptions (6% of total 30-day equivalent prescriptions), and 1,400 pharmacy locations (2% of total pharmacy locations). There are two reasons that individuals who need LTC and the LTC pharmacies that serve them constitute a separate market for antitrust analysis and for FTC consideration.

First, individuals who need LTC constitute a distinct health care patient population that relies disproportionately on prescription drugs. As compared to their peers who do not need LTC, Medicare beneficiaries who need LTC suffer a much higher incidence of multiple chronic conditions and of dementia and other cognitive impairments. They receive substantially more prescriptions for different drugs annually and they take significantly more prescription drugs each day than their peers. Their annual health care costs dramatically exceed those of their peers, and their annual prescription drug costs on average are 165% higher than their peers.[32]

Second, the payer mix for LTC pharmacies differs dramatically from the payer mix for the prescription drug market overall:

Payer	Overall[33]	LTC
Employer-Sponsored Private Insurance	36%	> 1%
Individually Purchased Private Insurance	4%	> 1%
Medicare	32%	95%
Medicaid	10%	> 5%
Out-of-Pocket	13%	> 5%
Other	5%	> 1%

Effectively, with Medicare Part D accounting for the lion's share of LTC pharmacy revenues, that program's requirements largely shape the nature of services LTC pharmacies provide and structure the manner in which PBMs negotiate and develop contracts with LTC pharmacies, which are different from contracts with retail, mail order, or specialty pharmacies. Importantly, however, Congress explicitly designed the Part D program to allow for free markets, such that CMS may establish ground rules for PDP and therefore PBM operations, but CMS cannot interfere in any

[31] Fein, 2022 Economic Report at 46.
[32] ATI Advisory and Senior Care Pharmacy Coalition, "Understanding the Long-Term Care Needs of the Medicare Population and the Role of Long-Term Care Pharmacies in Addressing this Need," (July 2021). This information is discussed in more detail supra at 6-9.
[33] Data concerning the payer distribution for the overall prescription drug market is taken from Fein, 2022 Economic Report at 112.

way in contract negotiations between PDPs/PBMs and pharmacies.[34] From the FTC perspective, this legislatively mandated free market flexibility means that the Commission may investigate PBM practices with respect to the Part D program without running afoul of the state action doctrine.

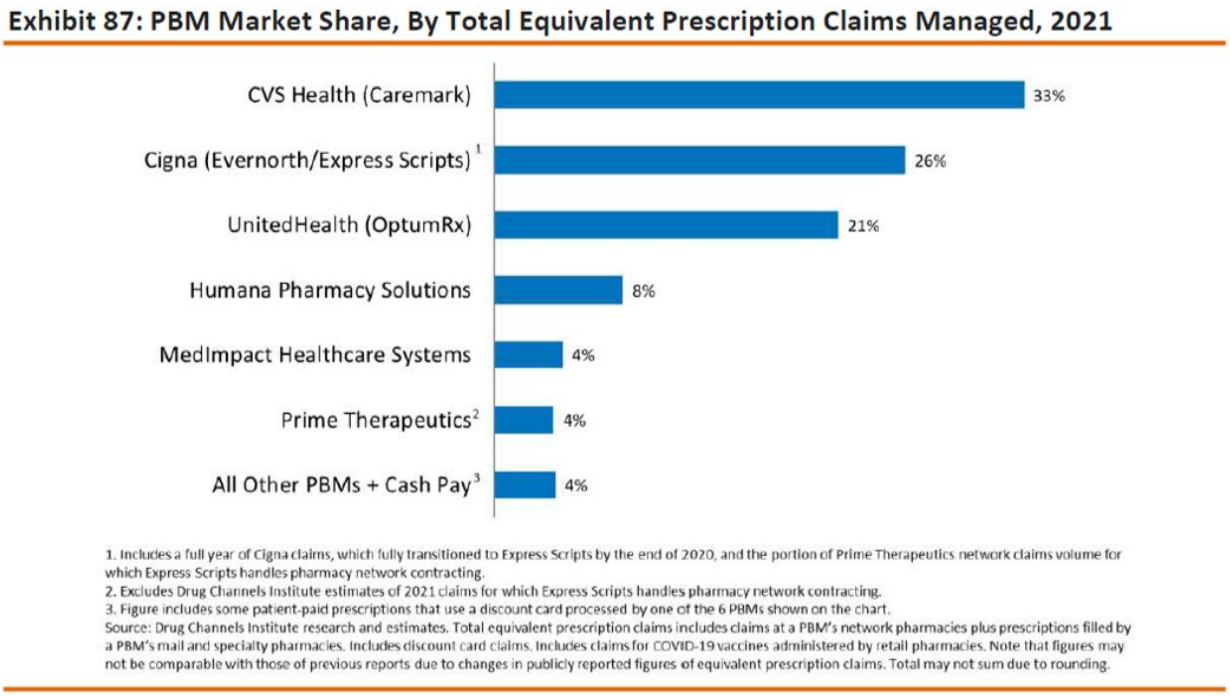
While a portion of the LTC pharmacy market deserves consideration independent of the broader prescription drug market, a portion of the LTC pharmacy market operates in a manner consistent with the broader market such that the FTC should include LTC pharmacy considerations in evaluation of the broader market as well. Although Part D remains the primary payer for LTC pharmacy services for beneficiaries regardless of where they live, the CMS ground rules differ for Part D beneficiaries who reside outside federally defined LTC facilities. For example, CMS does not consider settings other than such LTC facilities when determining a PDP's LTC pharmacy network adequacy and does not require that PDPs allow all LTC pharmacies to participate in pharmacy networks serving enrollees in such settings. Given less CMS scrutiny, PBMs negotiating contracts with LTC pharmacies generally offer less favorable terms – lower dispensing fees for pharmacies, higher administrative fees for PBMs and PDPs – to LTC pharmacies for beneficiaries residing in ALFs or private homes than those residing in SNFs, NFs, or ICFs. This is so despite the fact that beneficiaries who need LTC would benefit from LTC pharmacy services and the fact that CMS allows, but cannot require, PDPs to pay higher dispensing fees for beneficiaries in ALFs or at home in recognition of these additional LTC pharmacy services. In this sense, PBMs treat LTC pharmacies like retail or mail order pharmacies such that this portion of the LTC pharmacy business should be considered as part of the FTC's evaluation of the overall market.

While pharmacies should be considered as crucial intermediaries in market analysis of the impact of PBM behaviors on the individual consumers who are prescribed drugs, pharmacies also deserve consideration as consumers of PBM services. PBMs provide and purport to provide services to pharmacies (e.g., claims processing services or unspecified services in exchange for so-called "pharmacy price concessions"), in exchange for which they demand and receive ever-larger fees, which are discussed more fully below. In evaluating the market impact of PBM practices, therefore, the FTC should consider not only the impact of PBM practices on individuals as consumers of prescription drugs but also their impact on pharmacies as consumers of PBM services. Our comments will address the implications of PBM practices on both of these markets where appropriate throughout the discussion.

PBMs. Although there are more than 50 PBMs in the United States only three – CVS Health including Caremark and Aetna (CVC/Caremark), the Express Scripts business of Cigna (Express

[34] The Medicare Part D statute includes the so-called non-interference clause, which states that CMS "may not interfere with the negotiations between drug manufacturers and pharmacies and PDP sponsors" and "may not require a particular formulary or institute a price structure for reimbursement of Part D drugs." 42. U.S.C. § 1395w-111(i).

Scripts),[35] and the OptumRx business of UnitedHealth Group (Optum) processed 80% of all prescription claims in 2021.[36]



Source: Drug Channels Institute, The 2022 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers at 142.

CVS/Caremark, Express Scripts, and Optum process an even higher percentage of LTC pharmacy claims. These three PBMs, plus Humana Pharmacy Solutions and Prime Therapeutics, process more than 90% of all LTC pharmacy claims. Over the past decade, the PBM market has experienced substantial consolidation, driven in part by vertical integration that has created corporate health care conglomerates that own and operate commercial and government-funded health insurance plans; commercial and government funded prescription drug plans; specialty, retail, mail order, and LTC pharmacies; primary care and medical groups; ambulatory care and clinics; hospice care; and home health care.[37]

Over the past three years, PBMs have launched new group purchasing organizations (GPOs) to handle rebate negotiations with manufacturers and to provide services to manufacturers and the GPO members.[38] There are three major PBM-owned GPOs, each of which is affiliated with one

[35] Cigna recently rebranded its health care business as "Evernorth," such that Express Scripts now is a part of Evernorth. Since Evernorth has not yet been widely adopted publicly, however, these comments will reference Cigna as the corporate parent of Express Scripts.
[36] Fein, 2022 Economic Report at 141.
[37] Id. at 340-41.
[38] Fein, 2022 Economic Report at 151-52.

of the three market dominant PBMs. Two of these "PBM GPOs" are headquartered outside the United States. Ascent Health Solutions (a Swiss company) is owned by Evernorth (Cigna),[39] Prime Therapeutics, and Kroger, with four participating PBMs: Express Scripts, Kroeger Prescription Plans, Humana (commercial), and Prime Therapeutics. Prime, in turn, manages claims and performs other services for four smaller PBMs. Emisar Pharma Services (an Irish company) is owned by Optum and the sole participating PBM is OptumRx. Zinc Health Services is owned by CVS Health and Anthem, with CVS/Caremark and IngenioRx (an Anthem-owned PBM) as the participating PBMs:

Exhibit 90: PBM-Owned Purchasing Groups and Participation, 2022

	Ascent Health Solutions	Emisar Pharma Services	Zinc Health Services
Headquarters	Switzerland	Ireland	U.S.
Owners	• Evernorth (Cigna) • Prime Therapeutics • Kroger	• Optum (UnitedHealth Group)	• CVS Health • Anthem[2]

Participating PBMs	• Express Scripts
	• Kroger Prescription Plans
	• Humana (commercial)
	• Prime Therapeutics[1]
	  ○ Costco Health Solutions
	  ○ Elixir (Rite Aid)
	  ○ Navitus Health Solutions
	  ○ Southern Scripts
		• OptumRx	• CVS Caremark
			• IngenioRx (Anthem)

1. List includes smaller PBMs that access rebates via Prime Therapeutics' membership in Ascent
2. Not confirmed.
Source: Drug Channels Institute research; Nephron Research.

Source: Drug Channels Institute, The 2022 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers at 152.

The PBMs have formed these new organizations to **"[p]rovide PBMs with a hedge against potential reform of PBM practices.** For example, various regulatory and legislative proposals would prohibit manufacturers from paying PBMs. However, there is no parallel effort to alter GPO safe harbor rules.[40]

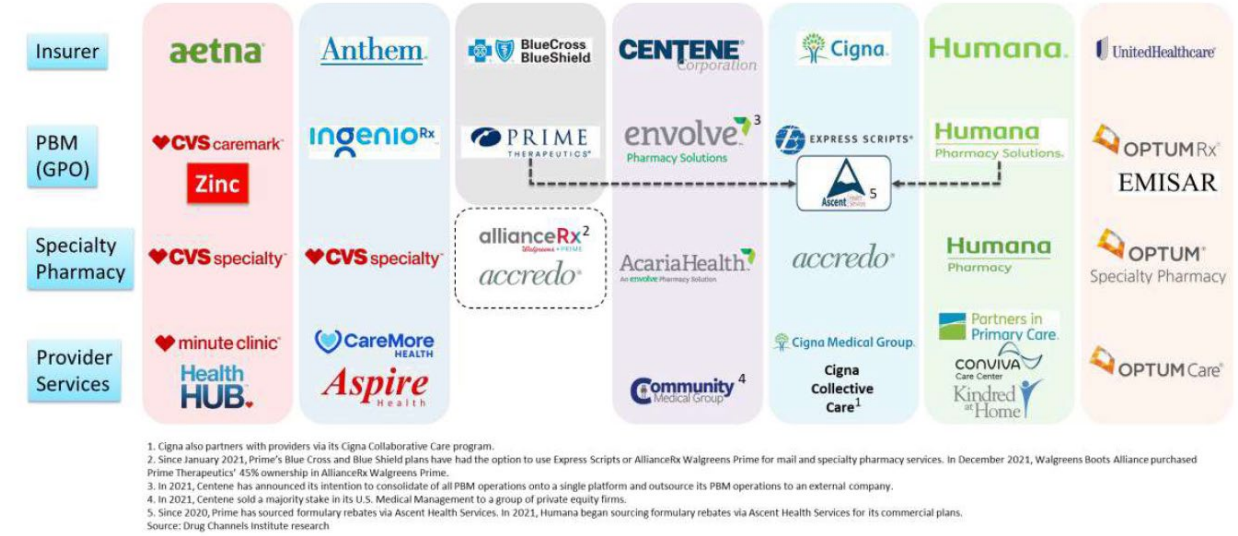
In other words, as public and government scrutiny of PBM practices has increased, PBMs have responded by adjusting their business models to exploit legal protections never intended for their benefit and by moving their operations offshore, thereby avoiding legislative and regulatory efforts to limit abusive practices. In one case – Emisar – UnitedHealth Group owns Emisar through its Optum subsidiary and also owns OptumRx, the only member of the "group" for which Emisar negotiates "group purchasing" contracts for its "members," through the same subsidiary. Essentially, UnitedHealth Group has used its subsidiary, Optum, to create another company based in Ireland to negotiate contracts on behalf of OptumRx, and only OptumRx. Necessarily, therefore,

[39] In 2020, Cigna rebranded its health care business, including Express Scripts, as Evernorth. Fein, 2022 Economic Report at 381, fn. 313.
[40] Fein, 2022 Economic Report at 152-53 (emphasis in original).

Emisar is negotiating contracts on behalf of OptumRx that OptumRx previously negotiated directly. The only possible business purposes for such an arrangement are to allow UnitedHealth Group and Optum to shield negotiations from scrutiny by the American public and the federal government and to shift revenues related to abusive PBM fees and business practices from OptumRx or the insurance plans it administers (including many plans offered by UnitedHealth Group) to an offshore company less amenable to public scrutiny and government oversight.

The following chart partially describes the nature of the interlocking relationships of PBM-centered health care conglomerates across adjoining markets:

Exhibit 212: Vertical Business Relationships Among Insurers, PBMs, Specialty Pharmacies, and Providers, 2022



1. Cigna also partners with providers via its Cigna Collaborative Care program.
2. Since January 2021, Prime's Blue Cross and Blue Shield plans have had the option to use Express Scripts or AllianceRx Walgreens Prime for mail and specialty pharmacy services. In December 2021, Walgreens Boots Alliance purchased Prime Therapeutics' 45% ownership in AllianceRx Walgreens Prime.
3. In 2021, Centene has announced its intention to consolidate of all PBM operations onto a single platform and outsource its PBM operations to an external company.
4. In 2021, Centene sold a majority stake in its U.S. Medical Management to a group of private equity firms.
5. Since 2020, Prime has sourced formulary rebates via Ascent Health Services. In 2021, Humana began sourcing formulary rebates via Ascent Health Services for its commercial plans.
Source: Drug Channels Institute research

Source: Drug Channels Institute, The 2022 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers at 340.

PBMs have additional relationships relevant to the FTC's antitrust and consumer protection analysis:

- CVS Health also owns the largest retail pharmacy chain, the second-largest mail order pharmacy, and the largest LTC pharmacy;
- UnitedHealth Group also owns the third-largest mail order pharmacy; and
- Cigna also owns the largest mail order pharmacy.

Effectively, therefore, PBMs operate at the hub of companies that:

- Control the providers who prescribe drugs for consumers.
- Provide health insurance and prescription drug coverage for consumers.

- Design drug formularies that determine the drugs to which consumers will have access and the out-of-pocket costs the consumer will have to pay for various drugs.
- Negotiate rebates from drug manufacturers, increasingly through PBM-owned GPOs, which also provide "services" to manufacturers in exchange for additional fees.
- Negotiate formulary placement and preferred formulary placement for drugs, which are driven primarily by manufacturer rebates.
- Design pharmacy networks and preferred pharmacy networks that determine the degree to which beneficiaries use particular pharmacies.
- Negotiate "pharmacy price concessions" and administrative fees from pharmacies, largely to determine whether pharmacies may, and the terms and conditions under which they may, participate in pharmacy networks or preferred pharmacy networks.
- Own market-dominant retail pharmacy chains, specialty pharmacies, mail order pharmacies, and LTC pharmacies.
- Establish limits on consumer access to drugs.
- Determine the out-of-pocket costs that consumers will pay for drugs.

Scope of SCPC Comments

The FTC's February 24 solicitation of public comments[41] included eight topics for which the agency requested comments. Our comments focus on those topics most relevant to LTC pharmacy interactions with PBMs. Despite this focus, however, SCPC urges the Commission to consider more broadly the impact that the vertical and horizontal integration has had on consumers and competition not only with regard to PBMs and prescription drugs, but also the manner in which PBMs have become the hubs of market-dominant health care conglomerates with substantial presence in adjacent markets. It is essential that the FTC evaluate PBMs, their corporate parents, and the businesses those parents operate in adjacent markets to determine the degree to which their collective business practices result in unfair, deceptive, or anticompetitive trade practices detrimental to consumers and to competition. Analysis and examples relevant to this conclusion appear throughout the following discussion.

Question: Do PBMs force patients to substitute different prescription drugs to maximize PBM rebates and fees.

Answer: Yes.

PBMs routinely misuse their formularies to require pharmacies to dispense higher cost brand name drugs rather than lower cost generic equivalents, resulting in higher consumer co-payments and higher revenue to the PBMs. For example, earlier this year Express Scripts announced its "brand-for-generic" substitution program, in which Express Scripts requires that pharmacies substitute

[41] https://www.ftc.gov/news-events/news/press-releases/2022/02/ftc-requests-public-comments-impact-pharmacy-benefit-managers-practices.

more expensive brand name drugs for less expensive generics. As part of this program, Express Scripts provides clear instructions to network pharmacies to use the Dispense as Written (DAW) code that allows pharmacies to dispense brands rather than generics when the physician does not require use of brands, which effectively overrides state generic substitution laws. The following information is a screenshot of an email communication from Express Scripts to its clients, which includes network pharmacies:

Restasis® added to the DAW 9 program

Effective March 22, 2022, Express Scripts will add Restasis® to the DAW 9 Brand-for-Generic Substitution Program. Clients that participate in the program will require Restasis® to be dispensed over the more expensive A/B rated generic alternative, cyclosporine. For participating clients, the appropriate brand name drug and a Dispense as Written (DAW) code of 9 (Substitution Allowed By Prescriber But Plan Requests Brand – Patient's Plan Requested Brand Product To Be Dispensed) will be needed on the claim submission.

The chart below contains the current list of brand medications included in this program, as well as the excluded higher net-cost generic equivalents. Members will share in these savings via a generic copay/coinsurance instead of a brand copay/coinsurance.

Covered brand drug	Excluded generic drug
Advair Diskus®	Wixela™ Inhub™, fluticasone/salmeterol DISKUS
Apriso®	mesalamine capsules
Absorica®	isotretinoin capsules
Carafate® Suspension	sucralfate suspension
Diclegis®	doxylamine succinate and pyridoxine hydrochloride tab
Duexis®	ibuprofen/famotidine tab
Epiduo Forte®	adapalene-benzoyl peroxide 0.3-2.5%
Restasis®	cyclosporine blister pack
Soolantra®	ivermectin 1% cream
Taclonex® Suspension	calcipotriene-betamethasone dipropionate sus
Uceris®	budesonide tab
Zomig 5 mg Nasal Spray®	zolmitriptan nasal spray

Although the Express Scripts notice asserts that the brands identified are less expensive than generic alternatives, we note that one of the "les expensive" branded drugs listed, Uceris, has a wholesale acquisition cost (WAC) of $1,792.83, while its generic is priced at less than $500.00.

There is substantial reason to believe both that other PBMs routinely require brand-for-generic substitution to maximize revenues from manufacturer rebates. We have received extensive anecdotal evidence from SCPC members for PBMs other than Express Scripts, particularly Caremark, and for many brand drugs, including without limitation Relpax, Zyprexa, Seroquel, Prevacid, Abilify, Invega, Pulmicort, Vimpat, and Advair. The Relpax example is instructive. The WAC for six Relpax pills is $431, while the most expensive generic is only $30.

PBMs claim that such substitutions drive such substantial rebates that the insurer's overall drug costs are lower than they otherwise would be. For example, the PBM managing Minnesota's Medicaid program claims that this practice lowers overall that the rebates it drives on branded products are so substantial that it is less costly for the state to use more expensive branded drugs rather than lower cost generics. It may be the case that a brand-for-generic substitution program reaps benefits for state Medicaid expenditures, but Medicaid requires that all manufacturer rebates be given to the Medicaid program itself. For commercial insurance and Part D plans, however, there is no requirement that either the federal government or Part D beneficiaries reap any benefit from the manufacturer rebates PBMs earn and share with the insurers.

In fact, use of these substitution programs for Part D beneficiaries who reside in SNFs and NFs actually increases overall federal expenditures. As discussed above, most residents in these facilities are dually eligible for Medicare and Medicaid, which means they automatically are enrolled in Medicare Part D. It also means that they pay no Part D premiums and no co-pays in most situations. However, the Part D Low Income Subsidy (LIS) program subsidizes premiums and co-pays for duals. When PBMs systematically substitute brands for generics, they increase the subsidies the federal government pays on behalf of beneficiaries, and also generate excess profits from manufacturer rebates for themselves and the PDPs they represent.

Question: Do PBMS use potentially unfair, deceptive, or anticompetitive contract terms and all related practices when calculating pharmacy reimbursements and disbursements, including the use of Average Wholesale Price, Wholesale Acquisition Cost, Maximum Allowable Cost, and Usual and Customary Pricing as well as all types of claw backs, fees, discounts, and performance metrics, such as Direct and Indirect Renumeration, Generic Effective Rate, Brand Effective Rate, Dispense Fee Effective Rate and all other similar provisions?

Answer: Yes. PBMs routinely use unfair, deceptive, and anticompetitive contract terms and related practices when calculating LTC pharmacy reimbursements and disbursements.

PBMs unquestionably use unfair, deceptive, and anticompetitive contract terms and related practices when calculating reimbursements and disbursements for LTC pharmacies. For at least the past fifteen years, since the implementation of the Part D program, PBMs have leveraged their growing market power to foist a series of unfair and anticompetitive contract terms and practices on pharmacies generally, and LTC pharmacies particularly. PBMs offer "take it or leave it" contract provisions that violate fundamental contracting principles and that would be unacceptable

in any other industry. These practices do not benefit consumers, and there is reason to believe that they do not demand the same terms and conditions of affiliated pharmacies that they demand of independent pharmacies.

We highlight six such practices in detail: contractual pricing terms; unilateral price change provisions; so-called "application fees" and purposeful untimely processing of network contracting arrangements; willful violation of contracting terms; Maximum Allowable Price (MAC) terms; and most significantly the improper, and we contend illegal, use of Direct and Indirect Renumeration (DIR) fees. Each of these topics is addressed below.

Contractual Pricing Terms. There are two components to payments pharmacies receive from plans administered by PBMs: cost of goods which generally seeks to compensate pharmacies for their costs in acquiring the drug; and a dispensing fee, which generally seeks to compensate pharmacies for the pharmacy and specialized services associated with dispensing the drug. PBMs consistently demand contract terms that allow them to routinely set drug payment prices below pharmacy acquisition cost. 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 that their businesses would face existential risk. This is especially true for LTC pharmacies serving Part D beneficiaries in SNFs and NFs. If a LTC pharmacy cannot serve all residents in a facility, the facility may have no choice but to replace the LTC pharmacy for all residents, not only the residents who have Part D coverage through a PDP managed by the PBM with which the pharmacy does not contract.

For pharmacies, and especially independent and LTC pharmacies, their acquisition costs are determined by the prices the wholesalers charge. Pharmacies have little ability to lower the prices they must pay for drugs, such that they cannot adjust their cost structures to accommodate PBM payments below acquisition costs. As a result, pharmacies may be forced to close or compelled to sell to large retail chains at suboptimal prices. They often must sell to retail chains that share common ownership with market dominant PBMs, an aspect of the PBM market discussed more fully below.

This threat is not speculative. In a 2019 survey conducted by the National Community Pharmacists Association (NCPA), 58 percent of independent pharmacy owners reported that they would have to close their doors by 2021 due to PBM practices, with an additional 19 percent reporting similar concerns about closure. [42] Based on independent analyses, NCPA reports that from June 2018 to June 2019, almost 2,000 retail pharmacies closed, such that 10 million consumers lost access to the pharmacy of their choice.[43] Perhaps most insidiously, there is evidence that PBMs treat pharmacies that are part of the same health care conglomerate differently, that PBM practices are

[42] https://ncpa.org/newsroom/news-releases/2019/10/16/local-pharmacies-pushed-to-brink-by-pharmacy-benefit-monopolies. Of course, this survey was conducted before the COVID-19 pandemic, but the overall anticompetitive impact PBM practices have had on pharmacies and the adverse implications for consumers continue unabated.
[43] https://ncpa.org/sites/default/files/pdf/survey-health-cp.pdf.

in part designed to force competing pharmacies either to sell to affiliated pharmacies at sub-market prices or go out of business altogether and that, as a result, affiliated pharmacies both increase market share and reduce access to consumers, particularly in rural areas. [44]

And of course, the pandemic had a devastating effect, accelerating the ability of the vertically and horizontally integrated PBM/pharmacy/health plan conglomerates to acquire independent pharmacies at artificially suppressed prices. One of these conglomerates, CVS Health, does not hide its intentions – its website openly invites such discussions.[45] PBMs' predatory pricing practices are crucial to this anticompetitive cycle since these practices place independent pharmacies in such economic straits that they cannot survive.

SCPC appreciates that hard bargaining is not a violation of the antitrust laws, and that competition between competitors on price is not an antitrust violation. But PBMs and pharmacies are not competitors, and unilaterally pricing drugs below the cost at which any pharmacy could possibly acquire the product is surely a reflection of inordinate market power and a slow but methodical predatory pricing strategy designed to force independent and LTC pharmacies out of the market, to the benefit of affiliated pharmacies and common corporate parents, but to the eventual detriment of consumers.[46]

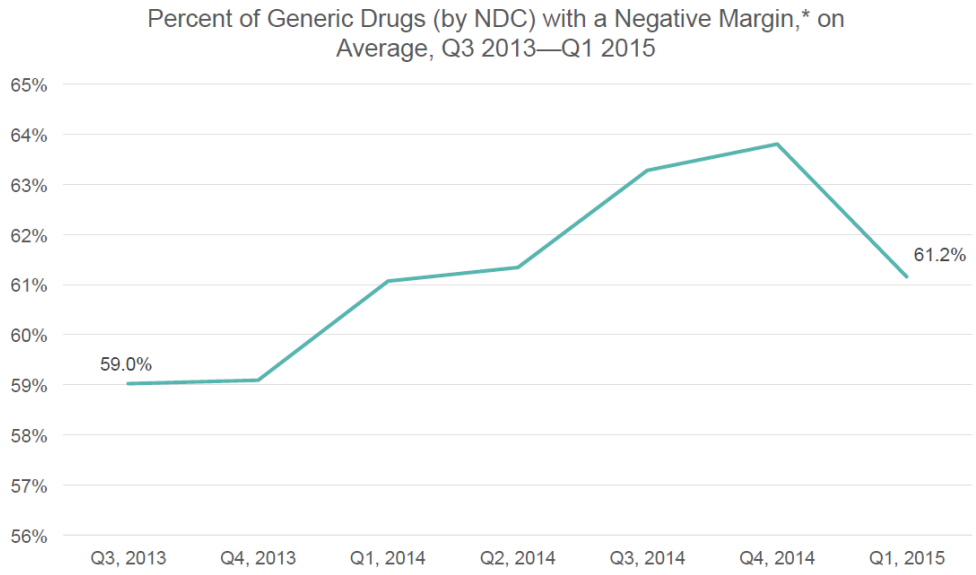
Avalere conducted an LTC pharmacy industry study using claims data between 2013-2015 to determine PBM reimbursement trends,[47] particularly with regard to generic drugs (which are approximately 90% of all drugs dispensed by LTC pharmacies). Among its conclusions, Avalere found that 61.2% claims for dispensing generic drugs were reimbursed below the pharmacy's acquisition cost of the drug:

[44]Columbus Dispatch, CVS Allegedly Squeezing Retailers (March 20, 2018), available at https://www.dispatch.com/story/lifestyle/health-fitness/2018/03/13/cvs-allegedly-squeezing-retailers/12933533007/; Kaiser Health News, How Rural America Is Losing its Pharmacies (Nov. 15, 2021), available at https://khn.org/news/article/last-drugstore-how-rural-communities-lose-independent-pharmacies/.

[45] https://cvsbuysellpharmacy.com/

[46] *See Eastman Kodak v. Image Technology Services,* 504 U.S. 451, 477-78 (1992).

[47] Avalere, MAC Pricing Analysis, (November 2015)(Prepared for the Senior Care Pharmacy Coalition). A copy of this analysis is attached as Exhibit 1.



Source: Avalere, MAC Pricing Analysis 21 (November 2015)(prepared for the Senior Care Pharmacy Coalition).

This trend has not diminished, and in fact is as prevalent today as it was nearly a decade ago. Once again, the trend reflects the overwhelming market power that PBMs and the oligopolies of which they are a part hold the market today.

Unilateral price change provisions. Most remarkably, PBMs typically demand contractual provisions allowing them to unilaterally change drug reimbursement formulas (e.g., WAC, MAC, AWP) and reimbursement rates at any time by simply notifying pharmacies and providing pharmacies an option for pharmacies to leave the pharmacy network if they are unwilling to accept the new payment rates. However, this is a false choice for LTC pharmacies serving residents in SNFs and NFs. LTC pharmacies have legal, contractual, and professional obligations to serve all residents in these facilities, particularly since these facilities contract with one LTC pharmacy to serve all their residents. If a LTC pharmacy chose to exit one prescription drug plan network because the administering PBM unilaterally changed reimbursement rates, then the pharmacy would be forced to sacrifice its contracts to serve all patients insured residing in the facility, not only the residents who were enrolled in the plan for which the PBM reduced reimbursement rates. Such unilateral rate reductions, moreover, do not yield any benefits to consumers, and may limit consumer access or undermine consumer quality.

This also is not a theoretical concern. For example, in 2016, Aetna and Humana considered a merger. In the summer of that year, Humana, through its owned PBM on behalf of its Part D plans, notified all LTC pharmacies in its network that all reimbursement rates to all LTC pharmacies would be reduced by 22% for the remainder of the plan year (also the calendar year), effective August 1, 2016. Despite the arbitrary nature of this decision, which certainly appeared as a step designed to make Humana a more attractive merger partner, LTC pharmacies could not exit the

Humana LTC pharmacy network because it would prevent them from serving all residents in a SNF or NF, which in turn would compel the facility to replace the LTC pharmacy with a competitor. This 22% reduction in payments to the LTC pharmacies yielded no benefit for consumers, but did threaten disruptions to their care – as well as the care of other residents in the LTC facilities in which the Humana beneficiaries resided – because transitions from one pharmacy to another risk precipitating patient adherence, medication error, and other quality of care issues. Ironically, Aetna and Humana terminated the deal in April 2017 after the United States District Court for the District of Columbia ruled that the proposed merger would have a substantial anticompetitive effect on the health insurance market.[48] Of course, CVS Health subsequently acquired Aetna, creating different anticompetitive concerns relevant to the FTC's current inquiry, which are discussed more fully below.

So-called "application fees" and related delaying tactics in processing of network contracting arrangements. As PBM DIR fees have become an increasing focus (more on that issue below), PBMs have shifted their revenue strategies, including growing use of tother pernicious and hidden fees, frequently employed in tandem with other abusive and manipulative practices. For example, pharmacies that wish to enroll in a PBM pharmacy network must pay substantial and ever increasing "application fees" simply for the privilege of applying to be in network. (PBMs also are charging health Plans "network access" fees for building the networks, allowing the PBMs to collect revenue on both sides of the transaction.) If a PBM has any questions about an application, it typically rejects the entire application, thereby obligating the pharmacy to submit a new application for which it must pay a new application fee. These hidden fees may accumulate rapidly to material amounts for small and independent LTC pharmacies.

Even after PBMs accept applications, they regularly and arbitrarily keep pharmacies out of the very networks into which the pharmacies were enrolled, falsely claiming that PBMs can only admit pharmacies into networks at specified times of the year. There is no legitimate business or regulatory reason that a PBM cannot allow a pharmacy into a specified network at any time of the year. Yet, due to their market power, PBMs arbitrarily restrict pharmacy access to networks. By arbitrarily excluding or delaying new pharmacies from participating in networks, PBMs intentionally restrict competition.

Such tactics may become even more insidious. For example, in 2016, Caremark refused to allow LTC pharmacy companies that contracted with Part D Plans administered by Caremark through a LTC pharmacy PSAO from adding new pharmacies to the network in the then-current plan year unless the pharmacy agreed to accept sub-market contractual rates for the 2017 plan year and agreed to negotiate directly with Caremark rather than allowing the PSAO to negotiate terms for its members which individual LTC pharmacies then could accept or reject. CMS compelled Caremark to abandon this practice as contrary to Medicare Part D requirements, but the behavior is nonetheless notable on its face and evidence of the deceptive and anticompetitive practices in which PBMs routinely engage.

[48] U.S. v. Aetna, Civil Action No. 16-1494(JDB), Memorandum Opinion filed 01/23/17.

Willful violation of contracting terms. PBMs also simply ignore contract terms, effectively in full knowledge that pharmacies are comparatively ill-equipped to pursue protracted and costly litigation to enforce abstruse contractual terms and therefore are unlikely to do so. For example, in 2019 Express Scripts (ESI) and Prime Therapeutics announced a "collaboration" to provide "more affordable care."[49] In fact, the arrangement required ESI to adjudicate the Prime contracts, at the existing Prime contractual rates.

In January 2021, ESI began adjudicating LTC pharmacy claims submitted pursuant to contracts negotiated by Prime. Under these contracts, Prime agreed to pay LTC pharmacies LTC pharmacy dispensing fees for Medicare Part D beneficiaries residing in nursing homes and ALFs. Rather than honoring these contractual terms, however, ESI simply refused to pay the negotiated contracted dispensing fee based on instructions from Prime. Prime had unilaterally declared that all contracted LTC pharmacy rates would be paid at lower retail rates, even though the LTC pharmacies performed significantly enhanced patient care and specialized services consistent with Part D LTC network adequacy requirements.

Indeed, Prime has misinterpreted applicable CMS guidance to prevent LTC pharmacies from submitting claims in a manner that would make those claims eligible for higher LTC pharmacy dispensing fees under their existing contracts with LTC pharmacies. This misinterpretation seems more than inadvertent, since it ignores plain language clearly stated in the CMS guidance. This misinterpretation allows Prime to reject a claim that would qualify for the LTC pharmacy dispensing fee because the submitting LTC pharmacy "miscoded" the beneficiary's residential setting as LTC, forcing LTC pharmacies to submit claims that improperly classify patient location according to CMS guidelines but that allow both Prime and ESI to pay lower retail dispensing fees. The choice for LTC pharmacies is to receive no payment or receive a payment lower than the contract requires Prime to pay.

Today, 17 months later, ESI and Prime continue to ignore contract terms, intentionally misconstrue CMS guidance, refuse to pay agreed-upon LTC pharmacy rates and reject LTC claims, notwithstanding the fact that the claims are coded accurately based on CMS guidance concerning use of codes designating SNFs and ALFs as service locations. It is only by dint of its size and unfair and disproportionate market power, that ESI and Prime continue to ignore contractual terms to pay LTC pharmacies substantially less than the contracts warrant.

We highlight this example as but one of many such situations. The point is not to emphasize a particular contractual dispute affecting a substantial portion of the LTC pharmacy market, but rather to underscore a pattern of unfair and deceptive trade practices that PBMs employ for their own financial benefit and to the detriment of the pharmacies that provide services directly to consumers. Such practices adversely impact consumers, who are at risk of losing their LTC pharmacy services, and harm independent pharmacies who face the Hobson's choice of inadequate

[49] https://www.express-scripts.com/corporate/articles/express-scripts-and-prime-therapeutics-collaborate-deliver-more-affordable-care-more-100.

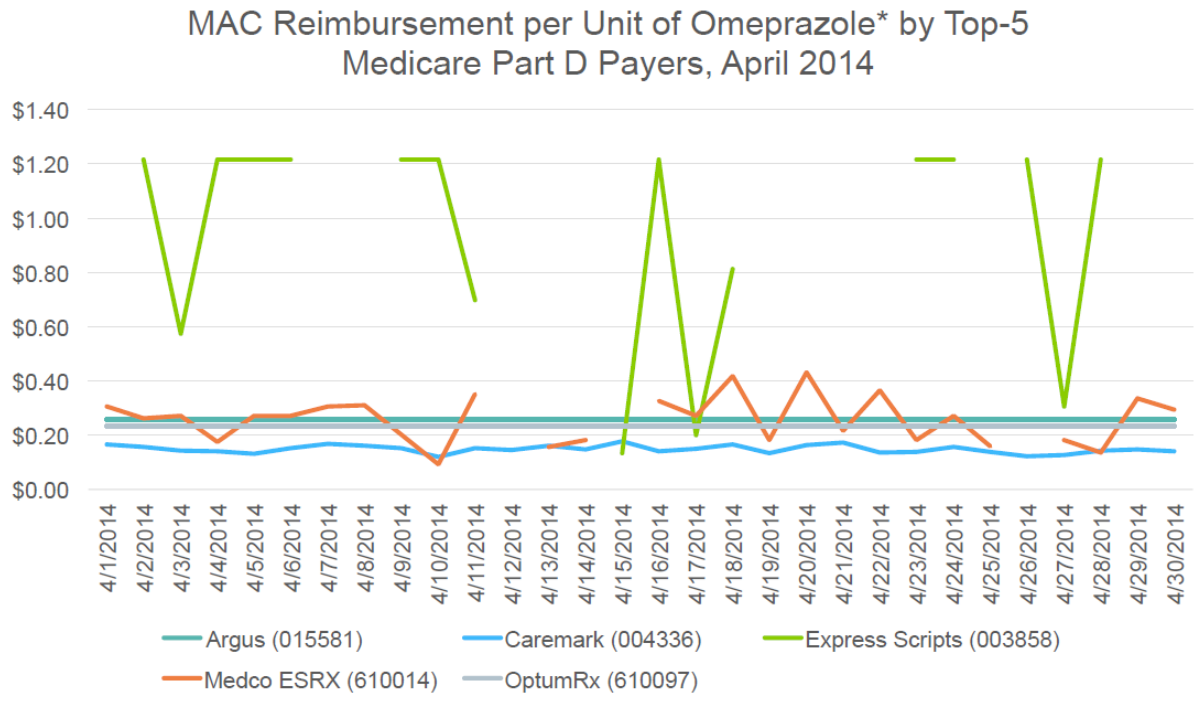
reimbursement in derogation of binding contractual terms or expensive and protracted contract litigation against deep-pocket opponents who have demonstrated their unwillingness to engage in good faith implementation of clear contractual provisions and CMS guidance.

MAC pricing terms. SCPC previously has provided the FTC with an analysis of how PBMs unfairly and deceptively manipulate so-called "Maximum Allowable Cost" (MAC) reimbursement.[50] In that analysis, we describe an analysis Avalere performed in 2015 that examined more than 24 million Medicare Part D claims for the eight-quarter period ending March 31, 2015, in part to determine whether any relationship existed between PBM rate changes for commonly prescribed generics and identifiable marketplace changes on which MAC pricing purportedly is based. The results remain deeply troubling. The Avalere report, issued in November 2015, demonstrates there is no apparent relationship between changes in the amount a PBM pays for a medication and actual changes in the marketplace.[51]

For example, in April 2014, Omeprazole was the most commonly prescribed medication in America's nursing homes. On April 2, ExpressScripts paid about $1.22 for the cost of the medication. The next day, April 3, ExpressScripts paid about $0.58 for the cost of the same medication. Two weeks later, on April 15, ExpressScripts paid about $0.14 for the cost of the same medication. By contrast, for the entire month of April 2014, Caremark's payment for the same medication varied from $0.14 to $0.18. Optum paid a consistent $0.22 for Omeprazole every day of the month.

[50] *See* SCPC Comments to FTC, November 8, 2017 Pharmaceutical Pricing Workshop (December 8, 2017). A copy of these comments is attached as Exhibit 2.
[51] The Avalere analysis is attached as Exhibit 1.

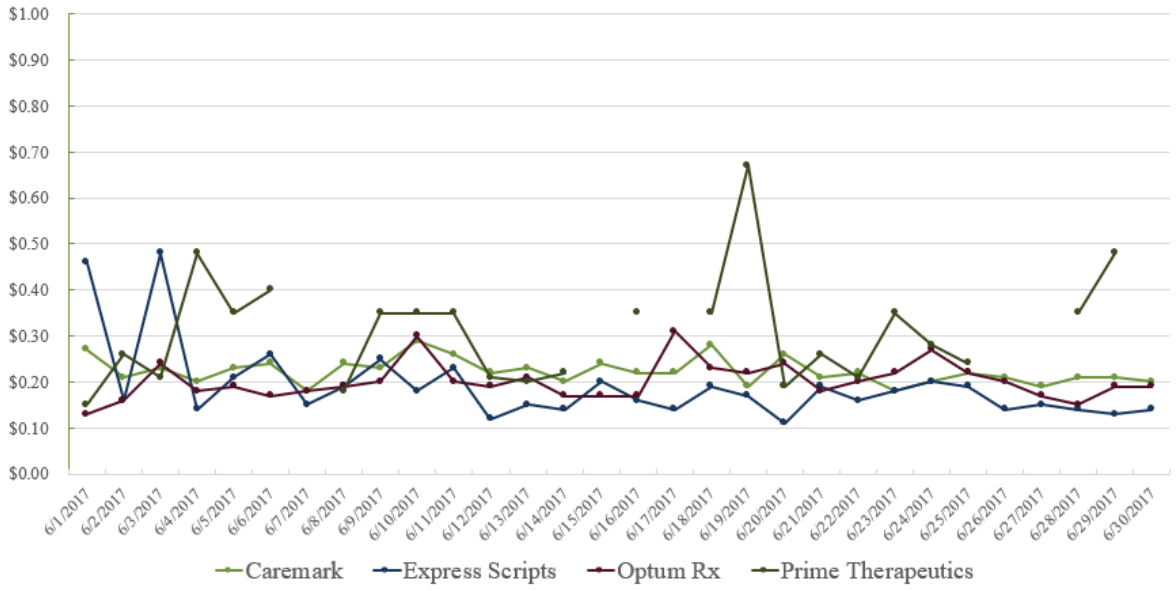
MAC Variability for Omeprazole



Source: Avalere, MAC Pricing Analysis __ (November 2015)(prepared for the Senior Care Pharmacy Coalition).

A similar study conducted in 2018 shows the same results for a different MAC-priced medication.

MAC Price Variability: Furosemide*
Per Unit Reimbursement by Top-4 Medicare Part D Payers



MAC: Maximum Allowable Cost; NDC: National Drug Code
* NDC 00378020810 :
Notes: Top-4 payers identified based on total days supply dispensed, and listed alphabetically. Weighted average daily MAC price by PBM payer. Discontinuities in average daily price indicate that there were no dispenses for that drug paid by that payer on that day.

Source: Proprietary analysis of SCPC member Medicare claims data.

It is evident that considerations other than marketplace prices are driving day-to-day payment changes. When confronted by Congress during a hearing of the Regulatory Reform, Commercial and Antitrust Subcommittee of the House Judiciary Committee, witnesses from Caremark and Express Scripts were unable to provide any explanation for, much less identify specific marketplace changes to justify, these day-to-day variations within an individual PBM or between PBMs.[52] They did acknowledge, however, that PBMs managed multiple formularies with differing prices for the same medication on the same day, with all payment rates calculated using the MAC pricing methodology.

If MAC pricing truly were based on identifiable marketplace changes, then differing prices for the same medication on the same day by the same PBM simply due to different formularies logically could not occur. The most obvious explanation is unilateral price manipulation, a hallmark of an

[52] The subcommittee hearing occurred on November 17, 2015 and was the third in a series of hearings on the state of competition in the health care marketplace. This specific hearing concerned "[t]he State of Competition in the Pharmacy Benefit Manager and Pharmacy Marketplaces." Https://judiciary.house.gov/press-release/regulatory-reform-subcommittee-to-hold-third-hearing-on-the-state-of-competition-in-the-health-care-marketplace/.

oligopolistic marketplace. As such, we urge the Commission to investigate how PBMs set MAC prices, why such prices vary so radically between PBMs and from day to day even within the same PBM, and how such predatory pricing practices can be eliminated.

Direct and Indirect Remuneration (DIR) Fees. Historically, certain payment adjustments PBMs made to payments made to pharmacies in exchange for dispensing medications to insureds were classified as DIR fees. Over time, an expanding array of fees PBMs charge pharmacies have been classified as DIR fees. Pursuant to regulations which CMS finalized earlier this year, the Part D program has adopted a definition of DIR fees that now encompasses all post-point-of-sale fees that PBMs charge to pharmacies, including various administrative fees (e.g., claims processing fees and switching fees) and quality or performance-based payment adjustments. DIR fees – also known as "pharmacy price concessions" - offer one of the most egregious examples of opaque and anticompetitive PBM contracting practices that harm consumers.

DIR fees do not reflect fair market value for services PBMs or PDPs render to the pharmacies that pay them. Indeed, DIR fees are nothing more than extortionate "pay to play" fees that PBMs demand of pharmacies to participate in pharmacy networks. PBMs may do so because they wield disproportionate market power that has grown ever more pronounced and unfair as the PBM market has become more concentrated and as PBMs have become more integrated into health care conglomerates that own not only PBMs but also health insurers, prescription drug plans, retail, mail order, specialty, and LTC pharmacies, and direct primary care health care provider organizations. It is no coincidence that the period from 2010 to 2020 witnessed substantial consolidation among PBMs, substantial vertical and horizontal integration of healthcare conglomerates organized around the market power of PBMs, and exponential growth in the use of DIR fees, which we note occurred without any change in the "services" PBMs rendered to pharmacies in exchange for those fees.

SCPC has raised the DIR fee issue with both the FTC and CMS previously. We have described the degree to which the PBM market has become oligopolistic and the manner in which the three-market dominant PBMs have become the center of health care conglomerates that also dominate adjacent markets. Wayne Winegarden, Ph.D., of the Pacific Research Institute, has explained how PBMs use undue market power to extract fees from pharmacies without providing any commensurate services:

> PBMs have been able to establish undue market power over other industry participants. The increasing consolidation and integration of PBMs has enabled these companies [to use] their immense market share to design a variety of business tactics aimed at gaining additional profits, reducing amounts paid to pharmacy providers, and driving prescription volume to the PBMs' wholly-owned pharmacies. These include mandatory mail order for maintenance medications (in which patients are denied a choice of pharmacy and forced to receive drugs from the PBM's wholly-owned mail order pharmacy), arbitrary exclusion of specialty pharmacies from PBM networks, and below-acquisition cost reimbursement.

> Altogether, PBM business tactics make it nearly impossible for pharmacy providers to stay viable.[53]

Earlier this year CMS issued a Final Rule that will require PDPs to "pass through" DIR fees to Part D beneficiaries at point of sale, effective January 1, 2024. this change will have dubious impact on overall costs for consumers, may incentivize greater use of DIR fees, and may incentivize more aggressive PBM and PDP business practices designed to recoup any losses they may sustain from the pharmacies with which they contract. We briefly review the history of CMS' consideration of DIR fees in the Medicare Part D program because it is instructive regarding PBM use of unfair, deceptive, and anticompetitive business practices and in understanding the likely market responses to the new DIR fee pass through requirement.

Despite concerns CMS expressed in Part D regulations finalized in 2014, PBMs radically expanded use of DIR fees without restraint from 2014 to the present, while disingenuously claiming that new fees were designed to incent higher quality or better performance. In 2017, CMS requested stakeholder input regarding the concept of passing DIR fees through to beneficiaries at point of sale, and in 2018 proposed but did not finalize a rule to do so.[54] In both instances, SCPC commented that CMS should eliminate such fees because pharmacies "do not receive anything of value for such … fees other than the ability to participate in the Part D plan's pharmacy network," 87 Fed. Reg. at 1917. We note that CMS policy guarantees all LTC pharmacies the ability to participate in Part D LTC pharmacy networks, such that paying any fees at all should be unnecessary to guarantee such access.[55]

Despite increasing scrutiny from CMS, Congress, and the general public, the impunity with which PBMs increased DIR fees in recent years has been astonishing. For the Part D program alone, aggregate DIR fees ***increased from $9 million in the aggregate in 2010 to $9.5 billion in the aggregate in 2020, a 100,400 percent increase in 10 years.***[56] Not only do PBMs offer no services in return for these fees, but no legitimate reason exists to charge these fees at all. Rather, by contract with the PDPs, the pharmacy provides a set of services to beneficiaries for which they should be reimbursed at a negotiated rate. [57] Other than reasonable fees negotiated at fair market rates paid in exchange for legitimate services rendered, the lion's share of payments should flow from the purchaser of services – in this case the PBM on behalf of the PDP – to the provider of services – in this case the pharmacy. As the claims administrator, it is reasonable for the PBM to charge

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[53] *See* https://www.pacificresearch.org/wp-content/uploads/2017/06/PBM_Lit_Final.pdf.
See also https://www.pacificresearch.org/wp-content/uploads/2020/01/DrugAffordability_F.pdf.
[54] 82 Fed. Reg. 56419 (Nov. 28, 2017); 83 Fed Reg. 62174 (Nov. 30, 2018).
[55] Part D sponsors "must offer standard LTC pharmacy network contracts to all LTC pharmacies operating in their service area that request such contracts." Part D Manual at § 50.
[56] Medicare Program: Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefits Programs;" Agency Docket Number CMS-4192-P, 87 Fed. Reg. 1842 (Jan. 13, 2022), available at https://www.federalregister.gov/documents/2022/01/12/2022-00117/medicare-program-contract-year-2023-policy-and-technical-changes-to-the-medicare-advantage-and.
[57] For the Part D program, this formulation is defined in regulation at 42 C.F.R. § 423.100 et seq.

reasonable services fees (e.g., claims processing fees), provided that these charges are set at fair market value. However, there is no legitimate business purpose that could justify a ***100,000 percent increase*** in fees over 10 years in exchange for nothing.

Although CMS has termed DIR fees "pharmacy price concessions,"[58] they are not price concessions at all. Unlike drug manufacturers, pharmacies have no product for which to discount or rebate a "price." Instead, these fees represent an unjustified abuse of market power through which PBMs, and the PDPs they represent, extract excess sums from pharmacies with no market leverage for no purpose other than to enrich PBMs and the PDPs they represent.

DIR fees, moreover, do not benefit consumers. CMS attempted to address this aspect of the DIR fee problem in this year's Final Rule, but it is far from certain that the result will be a net benefit for consumers. Consumer out-of-pocket costs regarding prescription drugs include both Part D premiums and co-pays. Under Part D, co-pays are determined based on the "negotiated price" of a drug at point-of-sale. Since DIR fees are post-point-of-sale "price concessions," they historically have not reduced the negotiated price on which beneficiary co-pays were calculated. Thus, consumers reaped no benefit from ever increasing DIR fees. The Final Rule will require PDPs, through the PBMs that administer their plans, to pass through DIR fees to consumers at point-of-sale, which will reduce co-pays.

Lower co-pays, however, do not necessarily translate into a net benefit for consumers in the aggregate. Due to the design of the Part D program, passing through DIR fees to consumers at point-of-sale will reduce out-of-pocket costs for consumers, but also will increase Part D premiums for all enrollees. On an individual basis, some consumers will be net winners – the combination of lower out-of-pocket costs and insurance premiums will be lower with the pass through than without it – while other consumers will be net losers – higher total costs with the pass through than without it. On an aggregate basis, we simply do not know whether consumers will have lower overall costs or higher overall costs.[59]

It is important to note that the pass through does not eliminate the incentive for PDPs and PBMs to charge DIR fees. Since consumers pay only a portion of drug costs as out-of-pocket co-pays, they would receive only a portion of DIR fees on a pass through basis. The PBMs and PDPs would retain the remaining portion of the DIR fees. Thus, even with the pass through, PBMs and PDPs still will have significant incentives to continue imposing DIR fees on pharmacies. Not only does the pass through fail to disincentivize DIR fees, but it actually incents higher DIR fees in two ways.

First, PDPs and PBMs could increase DIR fees to recoup the portion of revenues lost due to consumer pass throughs. Second, PDPs and PBMs could increase DIR fees to gain consumer

[58] 87 Fed. Reg. at 1909.

[59] In the narrative accompanying the Final Rule, CMS asserts without evidence that the aggregate impact will be beneficial for consumers. 87 Fed. Reg. 27702, 27706 & 27839 (May 9, 2022). Absent evidence, this assertion is pure speculation.

market share. Given the marketing advantage a PDP would have in claiming that its plan has lower consumer out-of-pocket copays than its competitors, the pass through easily could spark a competitive war among PDPs to lower out-of-pocket co-pays by increasing DIR fees over time. Of course, beneficiaries for whom the offsetting premium increases would be greater than the additional savings on out-of-pocket co-pays would be net losers, and the aggregate impact would remain unknown.

In any case, pharmacies are likely to be losers as well. Existing contracts between PDPs and pharmacies effectively require PDPs to hold pharmacies harmless if beneficiaries' co-pays decrease. However, such hold harmless provisions are not required under the Part D program. Given the disproportionate market power that PBMs wield in negotiations with pharmacies, it is predictable that they will change the contract terms unilaterally such that pharmacies no longer will be held harmless. Alternatively, PBMs likely would create other charges not considered DIR fees to recoup their losses from the pass through from pharmacies. Given the long history of unfair, deceptive, and anticompetitive PBM practices discussed earlier, it is clear that PBMs have both the will and the capacity to do so.

Absent any free market-based justification for DIR fees and the obviously anticompetitive impact they have, these fees should not be redirected or accounted for at the point-of-sale but should be prohibited outright. As such, we call upon the FTC to eliminate DIR fees altogether. They are unfair and deceptive, they undermine competition, and they may adversely impact consumers.

Question: Do PBMs' use other potentially unfair, deceptive, or anticompetitive practices, including audit provisions; pharmacy network design and exclusions; use of gag clauses, confidentiality clauses, and non-disparagement clauses; and other potentially unfair provisions.

Answer: Yes. PBMs have used and continue to use other unfair, deceptive, and anticompetitive practices to the detriment of consumers and competition.

PBMs historically have used various contractual provisions such as gag clauses and confidentiality clauses to impede competition, harm consumers, and damage pharmacies. In fact, until 2018 when Congress banned their use, PBMs routinely included "gag clauses" in contracts that prevented pharmacies from informing consumers when the cash price for a drug would be less than the out-of-pocket co-pay required by a consumer's drug coverage. PBMs demanded such gag clauses because they and the insurers whose plans they administered earned manufacturer rebates that artificially increased the price of the drug and therefore the consumer co-pay. Of course, if the consumer paid the cash price, the purchase would not help to drive manufacturer rebates for the PBM or the insurer. [60]

[60] *See* S. 2553 and S. 2554 (115th Cong.), https://khn.org/news/no-more-secrets-congress-bans-pharmacist-gag-orders-on-drug-prices/.

Unfortunately, government attempts to curb PBM excesses merely causes PBMs to shift tactics. Even as Congress pursued legislation to eliminate gag clauses, PBMs were reducing their use while increasing the use of other unfair, deceptive, and anticompetitive practices. For example, PBMs expanded use of so-called "narrow networks" for their plans and make unavailable certain types of pharmacy services that consumers need. The Prime-ESI situation discussed above is but one example of ESI refusing to recognize consumers' need for LTC pharmacy services and forcing LTC pharmacies to continue to provide such services without payment or reduce the level of services provided despite patient needs.

CVS/Caremark recently implemented narrow network requirements for the Federal Employee Benefits (FEHB) plans which it administers. CVS/Caremark announced a new narrow pharmacy network that similarly rejected recognition that insureds may require LTC and therefore would benefit from LTC pharmacy services, such that the PBM will not reimburse pharmacies for LTC pharmacy services.[61] The new Caremark program automatically moved its LTC network pharmacies into its new retail network (allowing limited time for LTC pharmacies to opt out) and eliminated any reimbursement for LTC pharmacy services. The Caremark plan refused to recognize that the FEHB members or retirees have LTC needs similar to Medicare members. As a result, LTC pharmacies are no longer reimbursed for providing the services that consumers need, and consumers are at risk of losing key needed pharmacy services. This new narrow network also excludes two large chain retail pharmacies, Walgreens and Duane Reade, and effectively has forced many community pharmacies to opt out due to the low reimbursement offered.[62]
SCPC members have analyzed the impact of the Caremark elimination of its LTC reimbursement on pharmacy economics, concluding that continued participation in the hew narrow network would require LTC pharmacies to operate at a loss. The following chart analyzes the financial impact of these changes on the one LTC pharmacy's revenues:[63]

[61] https://www.opm.gov/healthcare-insurance/healthcare/plan-information/plan-codes/2022/brochures/71-017.pdf.
[62] Id. at 95.
[63] This chart was prepared by an SCPC member based on proprietary information.

Caremark FEP Trend

Caremark FEP LTC Claims Summary*

Values	2021	2022 Annualized	Change
LTC Patient Count	2,800	2,800	-
LTC Rx Count #	240,000	250,000	10,000
LTC Revenue Per Rx $	$40.00	$33.50	($6.50)
Product Margin Per Rx $**	$13.50	$6.90	($6.60)
Margin %	33.7%	20.6%	-13.10%
Brand Rate %	13.3%	19.8%	-6.50%

*2022 data YTD February annualized; Figures rounded

**Excludes cost to fill; In 2021 was below Medicaid FFS and nearly 50% reduction in margin in 2022.

Notes
- Caremark automatically switched FEP LTC network to retail network and rates effective 1/1/22
- Rate only impact -$1.6M in 2022
- Barely profitable business is now well below cost to fill

The Caremark change is unsustainable for LTC pharmacies, which likely will leave the network. Since retail and mail order pharmacies generally do not provide the enhanced clinical and specialized services LTC pharmacies provide, FEHB beneficiaries who need LTC will not have access to pharmacy services that would improve their health outcomes and lower their overall health care costs, including their out-of-pocket health care costs. It is consumers, including FTC staff and their families who need LTC pharmacy services, who will suffer.

This practice is not unique to Caremark – Express Scripts implemented similar changes to its administration of the TriCare program, which provides health insurance and prescription drug coverage for veterans. Given the timing, it seems likely that Caremark's change in FEHB prompted Express Scripts decided to follow Caremark's lead with respect to TriCare. The impact on consumers and LTC pharmacies will be the same as well – beneficiaries will be denied access to needed LTC pharmacy services and LTC pharmacies will be denied access to consumers who need and would benefit from their services. The following chart analyzes the financial impact of these changes on the one LTC pharmacy's revenues:[64]

[64] This chart was prepared by an SCPC member based on proprietary information.

ESI TriCare Trend

ESI TriCare LTC Claims Summary*

Values	2021	2022 Annualized	Change
LTC Patient Count	4,000	4,000	-
LTC Rx Count #	325,000	337,000	12,000
LTC Revenue Per Rx $	$43.00	$37.50	($5.50)
Product Margin Per Rx $ **	$12.75	$6.60	($6.15)
Product Margin %	29.60%	17.60%	-12.00%
Generic MAC Rate %	84.64%	91.14%	-6.50%

*2022 data YTD February annualized; Figures rounded

**Excludes cost to fill; In 2021 was below Medicaid FFS and nearly 50% reduction in margin in 2022.

Notes
- ESI MAC adjustments moved -650bps
- Rate only impact - $2M in 2022
- Slightly unprofitable business now well below cost to fill
- Not a coincidence that this happened at the same time as Caremark FEP

Question: Do PBMs adopt policies and practices related to specialty drugs and pharmacies, including criteria for designating specialty drugs, reimbursements to specialty pharmacies, practices for encouraging the use of PBM-affiliated specialty pharmacies, and practices relating to dispensing high-cost specialty drugs over alternatives, which are unfair, deceptive, or anticompetitive?

Answer: Yes, PBMs routinely adopt unfair, deceptive, and anticompetitive policies and practices, and through corporate affiliates exert unfair and anticompetitive influence on adjacent markets for health insurance, prescription drug coverage, and pharmacies, in ways that benefit affiliated specialty pharmacies to the detriment of LTC pharmacies and the patients they serve that is

Specialty drugs represent a growing segment of the market for manufacturers, insurers, PBMs, and pharmacies. Since PBMs operate at the nexus of these market actors, they are driving the specialty drug market in ways that benefit a handful of so-called specialty pharmacies, the largest of which are "payer-aligned" such that they are owned by the same health care conglomerates that own the market-dominant PBMs. This occurs to the detriment of unaffiliated LTC pharmacies and consumers who need specialty drugs.

The percentage of pharmacy revenues represented by specialty drugs has grown from 24% in 2013 to 38% in 2021.[65] Dispensing revenues for specialty drugs were $191.6 billion in 2021, an 8.7% increase from 2020.[66] From 2012 to 2021, the number of specialty drugs also has increased

[65] Fein, 2022 Economic Report at 73.
[66] Id.

dramatically. Specialty drugs account for roughly 50% of all PBM benefit spending,[67] an increase from 30% in 2012.[68]

PBMs, in collaboration with manufacturers and so-called "payer-aligned specialty pharmacies," systematically exclude LTC pharmacies from access to specialty drugs. Ironically, however, the PBMs rely on LTC pharmacies to assist in administering specialty drugs to LTC facility residents and complete all necessary clinical and specialized services required for these residents without any payment for services from the PBM or the prescription drug plans they administer.

There is no clear and consistent definition of "specialty drug" and no consensus definition of "specialty pharmacy." These ambiguities have allowed PBMs, in partnership with manufacturers, insurers and so-called payer-aligned specialty pharmacies to determine which drugs are designated as specialty drugs and which pharmacies have access to drugs so designated. The primary purpose of these machinations is to capture revenues, particularly manufacturer rebates and reimbursement for very expensive drugs, for PBMs and their affiliated "payer-aligned specialty pharmacies" and the corporate conglomerates of which PBM, the "payer-aligned specialty pharmacy," and the health insurer are subsidiaries or affiliates. These arrangements work to the detriment of consumer access and to competition from unaffiliated pharmacies.

As described by the Pharmaceutical Care Management Association (PCMA), the trade group that represents PBMs, specialty drugs exhibit at least one of the following attributes:[69]

- Drugs prescribed for a person with complex or chronic medical conditions
- Drugs used to treat rare or orphan diseases
- Drugs that require advanced patient education, adherence, and support
- Drugs that are oral, injectable, inhalable, or infusible
- Drugs that have high monthly cost
- Drugs that have unique storage or shipment requirements
- Drugs that are not stocked at a majority of retail pharmacies

Most of these attributes are of questionable value in distinguishing specialty drugs from other drugs. For example, individuals with LTC needs suffer from multiple chronic and often complex conditions yet most of the prescription drugs they receive are not classified as "specialty drugs." PCMA describes some conditions to illustrate this attribute, including blood disorders, cancer, Crohn's disease, HIV/AIDs, infertility, multiple sclerosis, and rheumatoid arthritis. However, the most prevalent chronic conditions are depression, heart disease, lung disease, high blood pressure, and diabetes, conditions generally treated by non-specialty drugs.[70] Unlike the more prevalent chronic conditions which PCMA does not identify, many of the drugs used to treat the conditions

[67] Id. at 74.
[68] Pharmaceutical Care Management Association, "PBM's Management of Specialty Drugs" (undated).
[69] Id.
[70]

PCMA identifies disproportionately are expensive brand name drugs, and are conditions manufacturer research and development is targeting, such that more new and likely very expensive drugs to treat these conditions likely will emerge soon. This attribute seems nothing more than another way to identify high-cost drugs rather than a unique attribute of specialty drugs. We underscore that PCMA separately identifies high cost as a distinct attribute of specialty drugs.

While there are drugs that require advanced patient education, enhanced adherence services, coordination among pharmacies, physicians, and other caregivers, and other types of support, LTC pharmacies routinely provide these all of services, and for residents in federally defined LTC facilities LTC pharmacies are required by law to provide them. By contrast, for residents in LTC facilities neither PBMs nor their payer-affiliated specialty pharmacies provide or may legally provide these services, yet PBMs require that specialty pharmacies dispense specialty drugs to LTC facility residents. In this context, specialty pharmacies cannot be distinguished from LTC pharmacies based on comparative ability to provide these services.

The" attribute" that specialty drugs could be oral, injectable, inhalable, or infusible is true of ***all drugs.*** It therefore is irrelevant as a criterion on which to distinguish specialty drugs from other drugs.

The PCMA claim that only specialty pharmacies can meet unique storage and special handling requirements also is misleading and seems intended to create market barriers to patient access and fair competition. Generally, such requirements pertain to cold chain storage and distribution. To the extent these storage and special handling requirements suggested that drug distribution should be limited to "specialty pharmacies," distribution of COVID-19 vaccines undermines the claim. Several COVID-19 vaccines require "super cold chain" distribution, yet most retail and LTC pharmacies were able to manage storage, distribution, and administration of these vaccines safely and effectively.

The PCMA claim that a specialty drug is a drug not stocked at a majority of retail pharmacies is yet another disingenuous statement intended to reduce competition. The primary reason retail pharmacies do not stock "specialty drugs" is that they are prevented from acquiring these drugs because PBMs influence manufacturers to restrict distribution of high-cost brand name drugs to a handful of specialty pharmacies, led by so-called "payer-aligned specialty pharmacies" – the specialty pharmacies that are part of the same health care conglomerates as the market-dominant PBMs. Not surprisingly, such payer-affiliated specialty pharmacies dominate the market for prescriptions of "specialty drugs."[71] If the entity claiming that specialty drugs are drugs not stocked by most retail pharmacies is also the entity that prevents most retail and LTC pharmacies from acquiring the drug, and that entity also is commonly owned by the same company that owns the "payer-aligned specialty pharmacy" that has unfettered access to those same drugs, the criterion itself is at best suspect and at worst cynically misleading.

[71] As noted infra at 38, the specialty pharmacies owned by CVS Health, UnitedHealth Group, and Cigna/Evernorth control 65% of the specialty prescriptions dispensed in the U.S. Fein, 2022 Economic Report at 77.

There also is no universal definition of "specialty pharmacy." Various organizations offer varying definitions of specialty pharmacy that share common focus on the health conditions for which drugs are dispensed or the services that pharmacies provide to patients.[72] CMS has declined repeatedly to define specialty pharmacy.[73]
PCMA distinguishes specialty pharmacies from other pharmacies based on provision of key services, including:

- 24/7 access to specially trained pharmacists and clinicians
- Physician consultations to address side effects, adherence reactions, and non-adherence
- Patient care management services to ensure patient safety
- Data analytics that drive better patient outcome

Importantly, the ability to provide these services is not unique to so-called specialty pharmacies. LTC pharmacies provide all these services and, in for residents in federally defined LTC facilities, are required to do so by law. LTC pharmacies must provide not only access to specially trained pharmacists, but must also have the capacity to deliver medications to patients 24/7, such that on this criterion LTC pharmacies provide a greater level of service than specialty pharmacies. LTC pharmacies must provide consultation to patients and their families concerning side effects and adverse reactions. LTC pharmacies must provide various services to assure medication adherence such that, for residents in LTC facilities, adherence rates routinely approach 100%. LTC pharmacies are required to manage medications to ensure patient safety. LTC pharmacies and the pharmacists they employ are required to participate on the care planning teams for residents such that they routinely have access to physicians and other clinicians as well. Consequently, there are no reasonable criteria on which to distinguish specialty pharmacies from LTC pharmacies.

Nonetheless, LTC pharmacies generally cannot obtain specialty drugs because distribution is limited. Manufacturers generally determine which drugs are classified as specialty drugs and subject to limited distribution, but it is hard to believe that decisions within the control of PBMs do not influence their decisions. While manufacturers decide the pharmacies that may obtain shipments of specialty drugs, we believe the PBMs play a significant role in determining whether a drug will be classified as a specialty drug. The three largest specialty pharmacies by prescription revenues are owned by the same parent organizations that own the three largest PBMs, CVS Health, Cigna, and United. The combined market share for these three specialty pharmacies is 65%:

[72] Id. at 67-68.
[73] CMS most recently reiterated this position in 2018. https://www.federalregister.gov/documents/2018/04/16/2018-07179/medicare-program-contract-year-2019-policy-and-technical-changes-to-the-medicare-advantage-medicare.

Exhibit 48: Prescription Revenues and Market Share from Specialty Pharmaceuticals, By Company, 2021

Pharmacy Name	Parent Organization	Estimated 2021 U.S. Prescription Revenues from Specialty Drugs ($ billions)	Change in Revenues vs. 2020	Share of Prescription Revenues from Specialty Drugs
CVS Specialty[1]	CVS Health	$52.9	+11%	28%
Accredo / Freedom Fertility	Cigna (Evernorth/Express Scripts)	$43.5	+15%	23%
Optum Specialty Pharmacy[2]	UnitedHealth Group (OptumRx)	$25.8	+8%	14%
AllianceRx Walgreens Prime / Walgreens stores	Walgreens Boots Alliance	$19.2	-14%	10%
Humana Specialty Pharmacy	Humana	$4.9	+14%	3%
Acaria Health[3]	Centene (Envolve Health)	$4.7	+3%	2%
Kroger Specialty Pharmacy / Kroger stores	Kroger	$4.0	+4%	2%
CarePathRx[4]	n/a	$2.0	+33%	1%
Specialty Pharmacy Solutions[5]	McKesson	$1.8	+5%	1%
AHF Pharmacy[6]	AIDS Healthcare Foundation	$1.7	+12%	1%
US Bioservices	AmerisourceBergen	$1.6	+5%	1%
SenderraRx	n/a	$1.3	+18%	1%
Walmart Specialty Pharmacy / Walmart stores	Walmart	$1.1	+6%	1%
Elixir Specialty / Rite Aid stores	Rita Aid	$0.8	+6%	0%
Amber Pharmacy / Hy-Vee stores	Hy-Vee	$0.6	+21%	0%
All other retail, mail, long-term care, and specialty pharmacies	n/a	$25.7	n.a.	13%
Total		$191.6	+9%	100%

Source: Drug Channels Institute research and estimates. Includes revenues from retail, specialty, and mail pharmacies. Includes specialty revenues from retail locations, where relevant. Excludes revenues from network pharmacies of PBM-owned specialty pharmacies and infusion services covered by medical benefit. Totals may not sum due to rounding.
1. Includes CVS Caremark specialty pharmacies and CVS retail pharmacies.
2. Formerly known as BriovaRx.
3. Includes Drug Channels Institute estimated revenues from AcariaHealth, Exactus Pharmacy Solutions, Foundation Care, and PANTHERx Rare Pharmacy.
4. Includes Drug Channels Institute estimated revenues from BioPlus Specialty Pharmacy, ExactCare Pharmacy, and the management services organization of Chartwell Pennsylvania.
5. Includes Biologics by McKesson and the Patient Assistance Pharmacy (formerly known as Care Advantage).
6. Growth rate based on revised figure for 2020.

Source: Drug Channels Institute, The 2022 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers, at 77.

These same parent organizations also own major health and prescription drug insurance companies. PBMs, therefore, have the ability to negotiate rebates from manufacturers, drive market share for drugs by formulary placement, and direct revenues to "payer affiliated" specialty pharmacies to the detriment of competition, in that unaffiliated pharmacies are denied access to specialty drugs. LTC pharmacies, for example, simply cannot access specialty drugs because distribution is limited and excludes LTC pharmacies. Such exclusion occurs despite the fact that LTC pharmacies – often due to legal requirements – must provide the same services that purportedly make specialty pharmacies unique.

The result of PBMs excluding LTC pharmacies from receiving specialty drugs is that LTC facility residents often cannot timely access these needed medications. If the LTC pharmacy that contracts with a LTC facility cannot obtain a specialty drug, then the beneficiary must arrange with the PBM administering his or her Part D Plan to obtain the necessary drug from an authorized specialty pharmacy. Unfortunately, a high percentage of LTC facility residents suffer from cognitive impairments which may prevent them from making such arrangements. They often may lack family or informal caregivers capable of making such arrangements on their behalf. In such cases, they simply will not receive the prescription drugs they need. In other situations, consumers will receive the drugs either because the specialty pharmacy ships them directly to the facility or the

specialty pharmacy ships them to the consumer's family members who then transport the drugs to the facility.[74] The patient safety risks of delays and possible mishandling inherent in such a haphazard approach are obvious.

Adding insult to injury, specialty pharmacies do not provide and in many cases cannot legally provide the services to LTC facility residents the PBMs claim distinguish specialty pharmacies from other pharmacies.[75] Since federal law requires that all facility residents receive these pharmacy services, the LTC pharmacy with which the facility contracts must provide them regardless of payment, and therefore must fill the service gap left by specialty pharmacies. However, neither PBMs nor the specialty pharmacies shipping the drugs will pay LTC pharmacies for these services, such that the LTC pharmacy typically provides the services without payment, despite the fact that the LTC pharmacy likely has a contract with the relevant Part D plan administered by the relevant PBM.

Finally, residents in LTC facilities – and consumers generally – do not understand that medications their insurer or the PBM administering their prescription drug plan might 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. As described earlier, this process restricts patient access to specialty drugs and threatens patient safety. For most residents in LTC facilities, moreover, there is no potential for any offsetting reduction in out-of-pocket costs. Most residents in SNFs and NFs are dually eligible for Medicare and Medicaid because they are low-income. Dual eligible enrollees do not pay Part D premiums and have low or no co-pays. Therefore, to the extent that restricting distribution of specialty drugs and other limitations on dispensing of specialty drugs imposed by PBMs reduces out-of-pocket costs for consumers generally, these limitations do not reduce out-of-pocket costs for most LTC facility residents.

In sum, PBMs exist at the heart of a system that classifies drugs as specialty drugs based on criteria that fail to distinguish drugs on any consistent basis other than high-cost (and therefore high revenues and high profitability), that restricts distribution of specialty drugs to pharmacies based on service criteria indistinguishable from services LTC pharmacies provide, and that undermines both access and patient safety for residents in LTC facilities with no offsetting consumer benefit. If nothing else, the Commission should investigate these arrangements and prevent PBMs, their "payer-affiliated" "specialty" pharmacies, their "pharmacy-affiliated" health and prescription drug

[74] Once the specialty drug is delivered to the facility, it must be handled and administered independent of the system of specialized packaging and delivery the LTC pharmacy provides to the facility for all residents and for all other drugs. These systematic processes and protocols are designed specifically to optimize patient safety and adherence. Thus, by denying LTC pharmacies access to specialty medications, PBMs undermine access to needed medications and threaten patient safety.

[75] Under federal law and Medicare Part D payment policy, only LTC pharmacies that contract with LTC facilities may perform patient care and specialized services as required by the Medicare and Medicaid pharmacy services requirements of participation discussed supra at 5.

insurers, and the parent companies that own these vertically and horizontally integrated health care conglomerates from continuing their collective stranglehold on high-cost prescription drugs.

Question: are there potential conflicts of interest and anticompetitive effects arising from horizontal and vertical consolidation of PBMs with insurance companies, specialty pharmacies, and providers?

Answer: Yes. There are existing conflicts of interest and anticompetitive effects inherent in the horizontal and vertical consolidation of PBMs with insurers, specialty pharmacies, retail pharmacies, mail order pharmacies, LTC pharmacies, providers, and so-called "PBM-GPOs.

As the foregoing discussion demonstrates, the potential for conflicts of interest and anticompetitive effects resulting from the substantial vertical and horizontal integration of PBMs with insurance companies, specialty pharmacies and health care providers is vast. Indeed, it is even broader than the topic as described by the Commission suggests, since the resultant oligopolistic conglomerates also include common ownership of other pharmacy types – retail (CVS Health), mail order (CVS Health, United, and Cigna), and LTC (CVS Health). The recent addition of PBM-GPOs offers yet another example of the ways in which these conglomerates created tortured corporate structures to avoid public scrutiny and government oversight in the quest to protect revenues from unfair, deceptive, and anticompetitive practices.

While the examples detailed in the foregoing discussion amply demonstrate conflicts of interest and anticompetitive results, we offer one final example of the manner in which PBMs manipulate contractual provisions to the benefit of affiliated pharmacies and to the detriment of consumers and unaffiliated LTC pharmacies. PBMs increasingly have withheld or recouped payments from pharmacies based on quality or performance metrics. These metrics, in turn, often evaluate processes or outcomes outside the control of pharmacies and, in the case of LTC pharmacies, often are tied to metrics of little relevance to the LTC patient population. Purportedly holding pharmacies financially accountable for performance on metrics over which they have little control, and which largely are irrelevant to the patients they serve seems nothing more than anticompetitive seizure of otherwise legitimate payments for services rendered.

In some cases, moreover, the metrics imposed may affirmatively injure consumers. For example, in some contracts applicable to Part D beneficiaries residing in ALFs, contracts that Express Scripts negotiates with pharmacies withhold a portion of payments based on performance against a "quality" metric of the percentage of medications dispensed in 90-day supplies. The higher the percentage of 90-day dispenses, the better the "quality" provided by the pharmacy and the more of the withheld amount the pharmacy may "earn back."

The 90-day dispense metric undermines patient safety and quality of care for Medicare Part D beneficiaries living in ALFs. These residents have a high prevalence of cognitive impairment, take on average 12-14 prescription medications daily, and receive little assistance in self-administering

medications each day. They also are subject to frequent changes in prescription medications. For such individuals, the shorter the dispensing cycle, the better the medication adherence and the better the patient safety.

For these reasons, LTC pharmacies generally dispense medications on cycles of 30 days or less. LTC pharmacies, therefore, generally score poorly on the Express Scripts 90-day dispense metric and therefore earn back little or no quality or performance compensation. Mail order pharmacies, by contrast dispense most medications on 90-day cycles, and Cigna owns and operates the largest mail order pharmacy in the country, also known as Express Scripts. Since mail order pharmacies compete directly with LTC pharmacies for Part D business among Part D enrollees residing in ALFs and in private homes, Express Scripts use of the 90-day dispense metric shifts payments from unaffiliated LTC pharmacies from which payments are withheld to mail order pharmacies that necessarily include an affiliated pharmacy. Caremark uses a similar metric in contracts it negotiates for Part D residents in ALFs, with similar benefit to its affiliated mail order pharmacy and similar detriment to unaffiliated LTC pharmacies and consumers.

This example illustrates conflicts of interest – PBMs using metrics designed to benefit affiliated pharmacies at the expense of unaffiliated pharmacies. It also illustrates how vertical and horizontal integration undermines patient care and threatens competition.

Recommendations

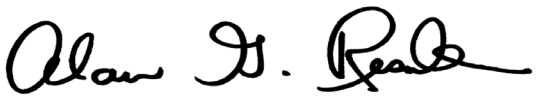
Any full and fair analysis of PBM practices and the vertically and horizontally integrated health care conglomerates organized around the market power of PBMs must conclude that these entities routinely engage in deceptive and anticompetitive trade practices that hurt individual consumers, damage unaffiliated pharmacies as consumers, and undermine competition across adjacent markets. We therefore urge the Commission to:

- Investigate PBM business practices both generally and specifically with respect to LTC pharmacies both as important intermediaries in providing prescription drugs and related LTC pharmacy services to patient who need LTC and as consumers of PBM services.
- Investigate PBMs and the vertically and horizontally integrated conglomerates of which they are a part to evaluate the anticompetitive impact of the resultant dominance across adjacent markets and the adverse impact on consumers that results.
- Based on the results of those investigations, act to prevent PBMs, and the conglomerates of which they are a part, from continuing to engage in unfair, deceptive, and anticompetitive practices that hurt consumers and undermine competition.

** * * * * * * * *

We appreciate the opportunity to submit these comments, and would be happy to address any questions you may have.

Respectfully submitted,



Alan G. Rosenbloom
President & CEO

Exhibits (2)

SCPC EXHIBIT 1

Avalere

MAC Pricing Analysis

Prepared for the Senior Care Pharmacy Coalition

November 2015
avalere.com

Analysis Overview

- Data Source:
  - Avalere created a data warehouse to store and aggregate transaction data from 18 independent LTC pharmacies* (6 parent companies)
  - The warehouse includes over 21.4 million individual drug transactions from January 2012 to March 2015**

- Analyses:
  1. Trends in Key Financial Indicators for Generic and Brand-Name Drugs (2013—2015)
  2. MAC Pricing Variability for Top Generic Drugs and Payers (April 2014)
  3. Percent of Drugs Dispensed that Are Generic vs. Brand-Name (2013—2015)
  4. Percent of Generic Drug NDCs with Negative Margin (2013—2015)

LTC: Long-Term Care; MAC: Maximum Allowable Cost; NDC: National Drug Code
* Independent LTC pharmacies refers to non-publicly traded LTC pharmacies.
** A significant percentage of transactions from 2012 and Q1-Q2 2013 are missing data on Cost of Goods Sold, so we have excluded these data from the analyses.

Executive Summary / Findings

- **Analysis #1 –** *Trends in Key Financial Indicators for Generic and Brand-Name Drugs*
  - Generic drugs reimbursed using MAC pricing have negative margins because revenue has remained flat even as total cost has increased
- **Analysis #2 –** *MAC Pricing Variability for Top Generic Drugs and Payers*
  - MAC prices paid for the same generic drug on the same day by different payers can vary considerably
- **Analysis #3 –** *Percent of Drugs Dispensed that Are Generic vs. Brand-Name*
  - The percent of prescriptions and total days supplied by generic drugs has increased
- **Analysis #4 –** *Percent of Generic Drug NDCs with Negative Margin*
  - The percent of generic drugs that, on average, have a negative margin has increased

MAC: Maximum Allowable Cost
COGS: Cost of Goods Sold
NDC: National Drug Code

SCPC EXHIBIT 1

Avalere

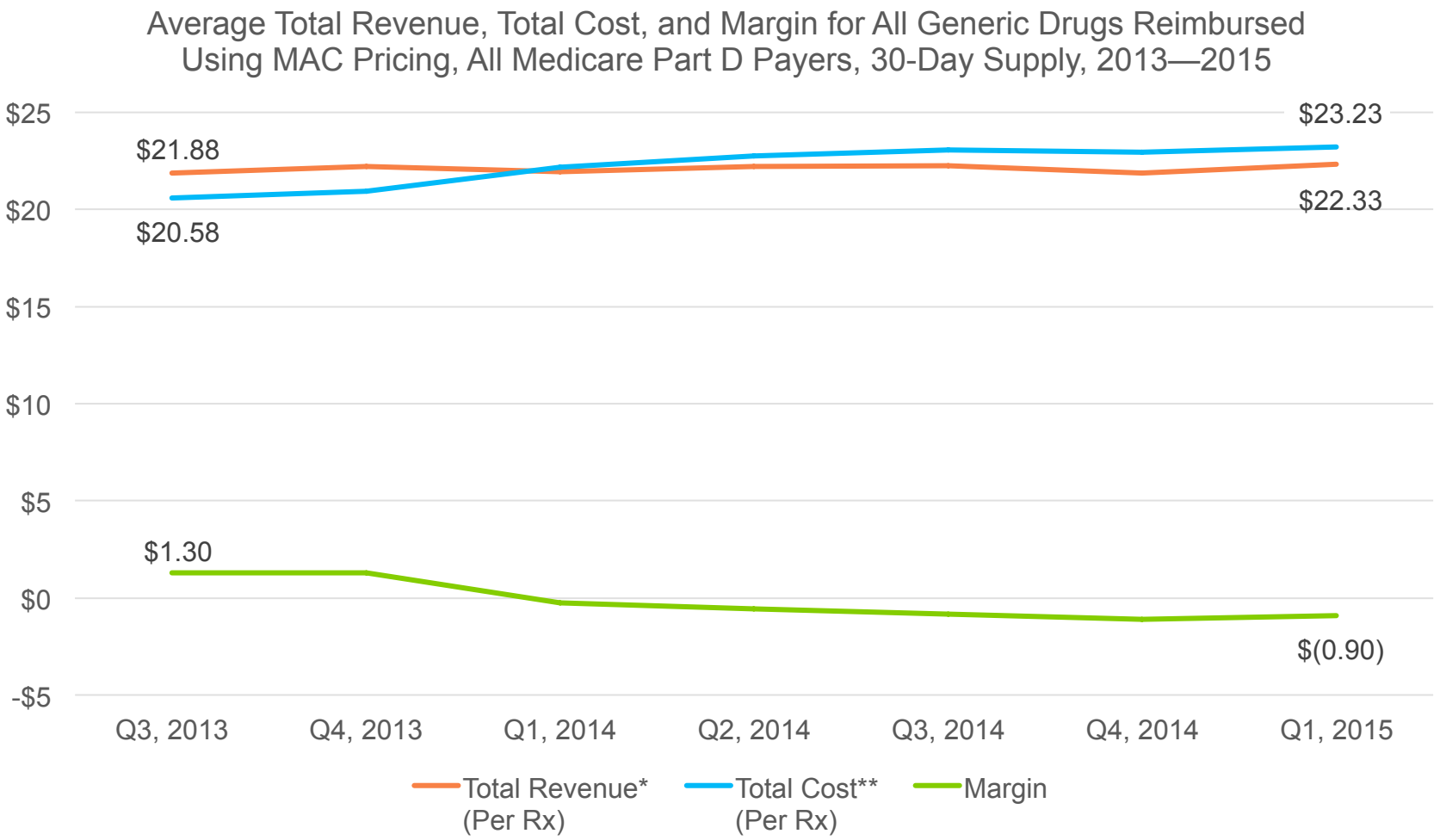
#1 – Trends in Key Financial Indicators for Generic and Brand-Name Drugs

Overview #1 – Trends in Key Financial Indicators for Generic and Brand-Name Drugs

- Objective: assess the trends of key financial indicators (revenue, cost, and margin) for generic and brand-name drugs
- Methodology:
  1. Determined average total revenue* and average COGS per 30-day supply for all generic and brand-name drugs, all Medicare Part D payers (Q3 2013 to Q1 2015)
  2. Calculated total cost by adding COGS to a fixed cost to dispense**
  3. Calculated the margin by subtracting total cost from total revenue
  4. Segmented the results for:
     a. Generic drugs reimbursed using MAC pricing
     b. Generic drugs reimbursed using a method other than MAC pricing
     c. Brand-name drugs reimbursed using all methods
     d. Generic and brand-name drugs reimbursed using all methods
- Finding:
  - Generic drugs reimbursed using MAC pricing have negative margins because revenue has remained flat even as total cost has increased

MAC: Maximum Allowable Cost; COGS: Cost of Goods Sold
* Total revenue includes reimbursement for ingredient costs plus dispensing fees, but does not include manufacturer rebates (if any).
** This analysis uses a fixed $13.54 for cost to dispense. The value is the median cost to dispense a 30-day supply of a prescription as determined by researchers with Virginia Commonwealth University and Midwestern University. Source: Carroll, N.V., Rupp, M.T. & Holdford, D.A. Analysis of costs to dispense prescriptions in independently owned, closed-door long-term care pharmacies. *J Manag Care Spec Pharm.* 20: 291-320, (2014).

Financial Indicators for Generic Drugs Reimbursed Using MAC Pricing

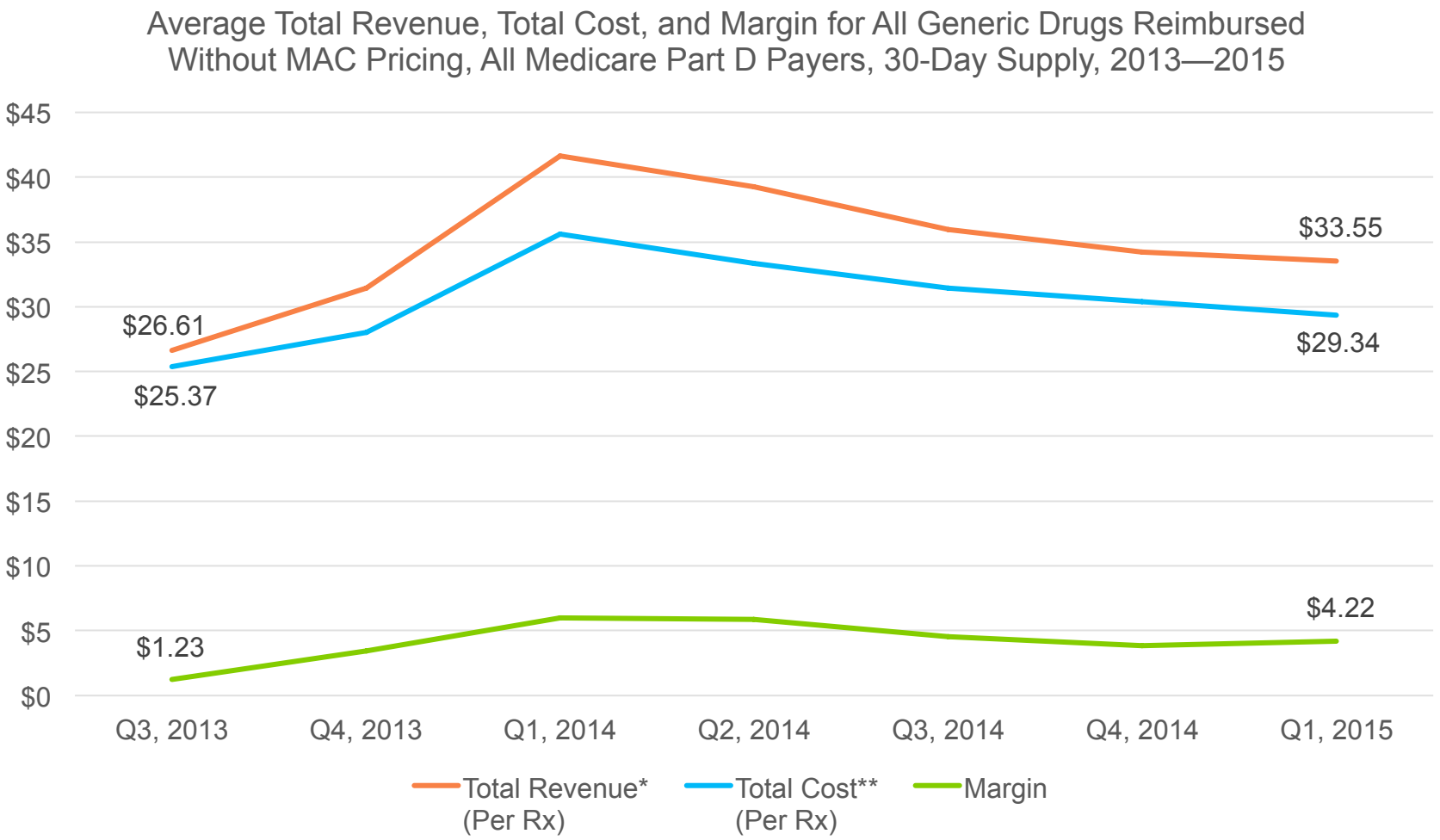


MAC: Maximum Allowable Cost

* Total revenue includes reimbursement for ingredient costs plus dispensing fees, but does not include manufacturer rebates (if any).

** Total cost is cost of goods sold plus cost to dispense. This analysis uses a fixed $13.54 for cost to dispense. The value is the median cost to dispense a 30-day supply of a prescription as determined by researchers with Virginia Commonwealth University and Midwestern University. Source: Carroll, N.V., Rupp, M.T. & Holdford, D.A. Analysis of costs to dispense prescriptions in independently owned, closed-door long-term care pharmacies. *J Manag Care Spec Pharm.* 20: 291-320, (2014).

Financial Indicators for Generic Drugs Reimbursed Using a Method Other Than MAC Pricing

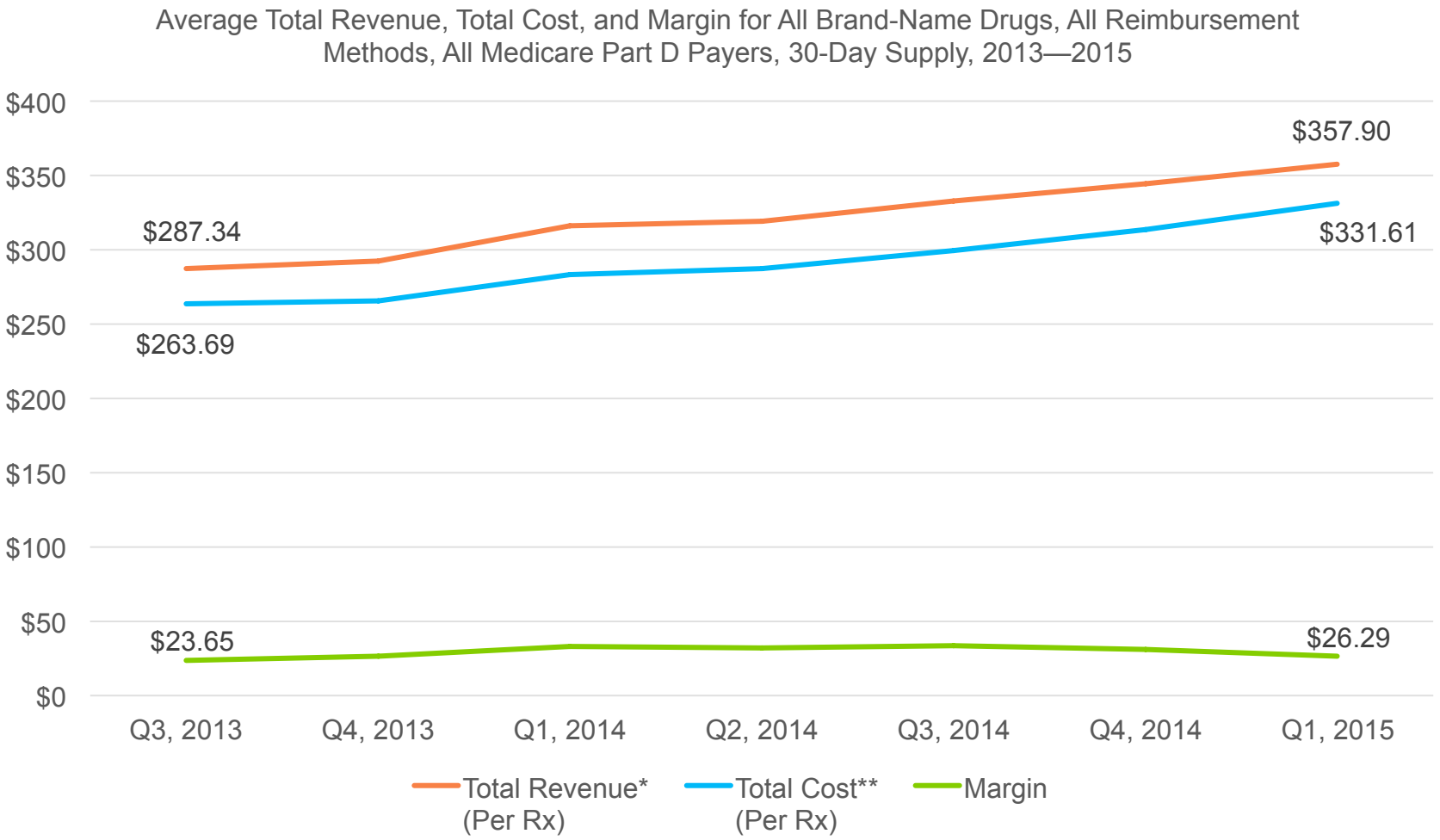


MAC: Maximum Allowable Cost

* Total revenue includes reimbursement for ingredient costs plus dispensing fees, but does not include manufacturer rebates (if any).

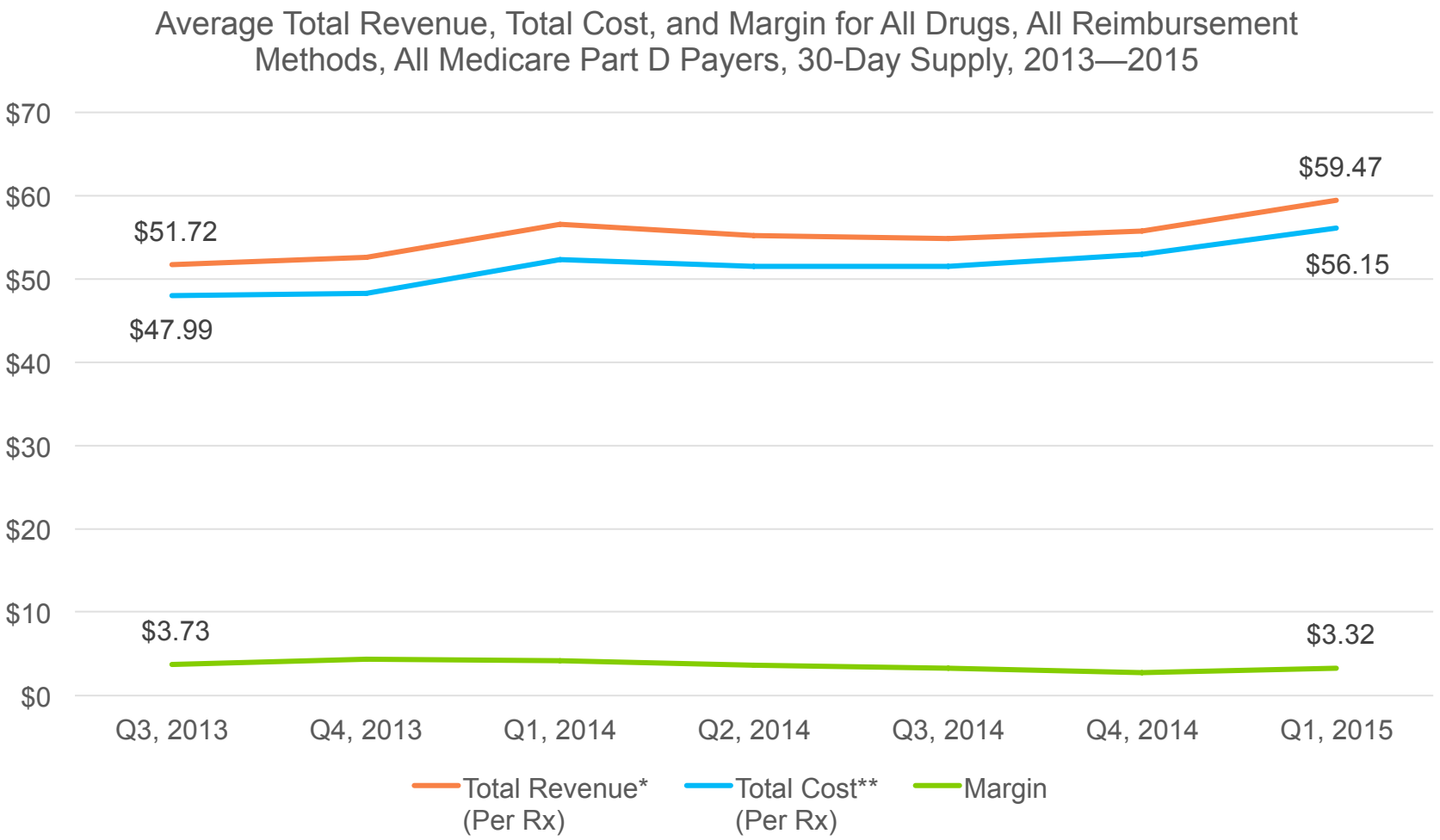
** Total cost is cost of goods sold plus cost to dispense. This analysis uses a fixed $13.54 for cost to dispense. The value is the median cost to dispense a 30-day supply of a prescription as determined by researchers with Virginia Commonwealth University and Midwestern University. Source: Carroll, N.V., Rupp, M.T. & Holdford, D.A. Analysis of costs to dispense prescriptions in independently owned, closed-door long-term care pharmacies. *J Manag Care Spec Pharm.* 20: 291-320, (2014).

Financial Indicators for Brand-Name Drugs



* Total revenue includes reimbursement for ingredient costs plus dispensing fees, but does not include manufacturer rebates (if any).
** Total cost is cost of goods sold plus cost to dispense. This analysis uses a fixed $13.54 for cost to dispense. The value is the median cost to dispense a 30-day supply of a prescription as determined by researchers with Virginia Commonwealth University and Midwestern University. Source: Carroll, N.V., Rupp, M.T. & Holdford, D.A. Analysis of costs to dispense prescriptions in independently owned, closed-door long-term care pharmacies. *J Manag Care Spec Pharm.* 20: 291-320, (2014).

Financial Indicators for All Drugs



* Total revenue includes reimbursement for ingredient costs plus dispensing fees, but does not include manufacturer rebates (if any).
** Total cost is cost of goods sold plus cost to dispense. This analysis uses a fixed $13.54 for cost to dispense. The value is the median cost to dispense a 30-day supply of a prescription as determined by researchers with Virginia Commonwealth University and Midwestern University. Source: Carroll, N.V., Rupp, M.T. & Holdford, D.A. Analysis of costs to dispense prescriptions in independently owned, closed-door long-term care pharmacies. *J Manag Care Spec Pharm.* 20: 291-320, (2014).

Avalere

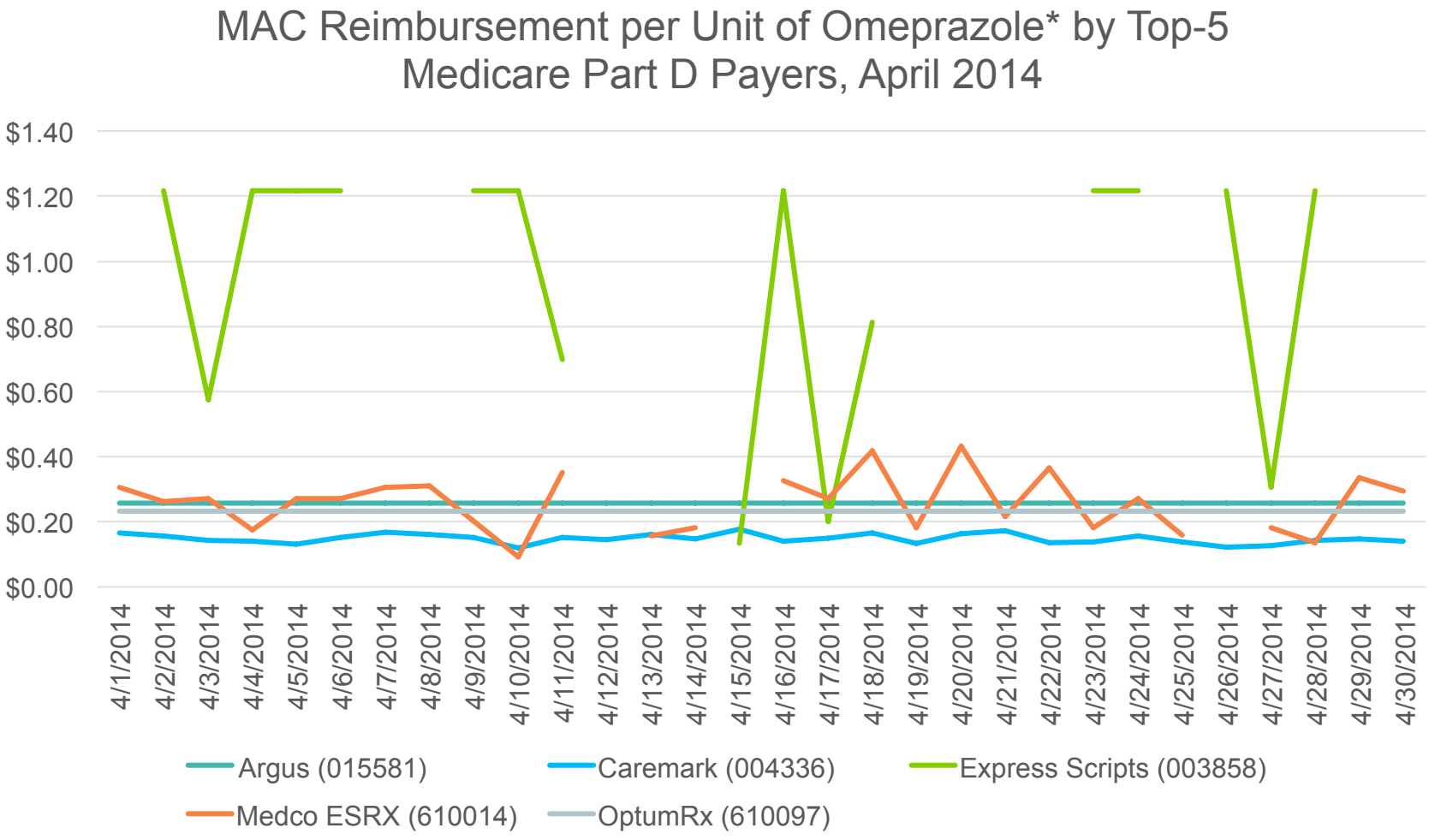
#2 – MAC Pricing Variability for Top Generic Drugs and Payers

Overview #2 - MAC Pricing Variability for Top Generic Drugs and Payers

- Objective: evaluate the change in MAC pricing over the course of a month for a single drug and individual payers
- Methodology:
  1. Determined the top-5 Medicare Part D payers by total volume*
  2. Determined the top-3 generic drugs by total volume,* all Medicare Part D payers
  3. Calculated the daily average MAC reimbursement per unit** of each drug by each payer in April 2014
  4. Calculated the daily average COGS per unit of each drug for the top-5 payers in April 2014
- Finding:
  - MAC prices paid for the same generic drug on the same day by different payers can vary considerably

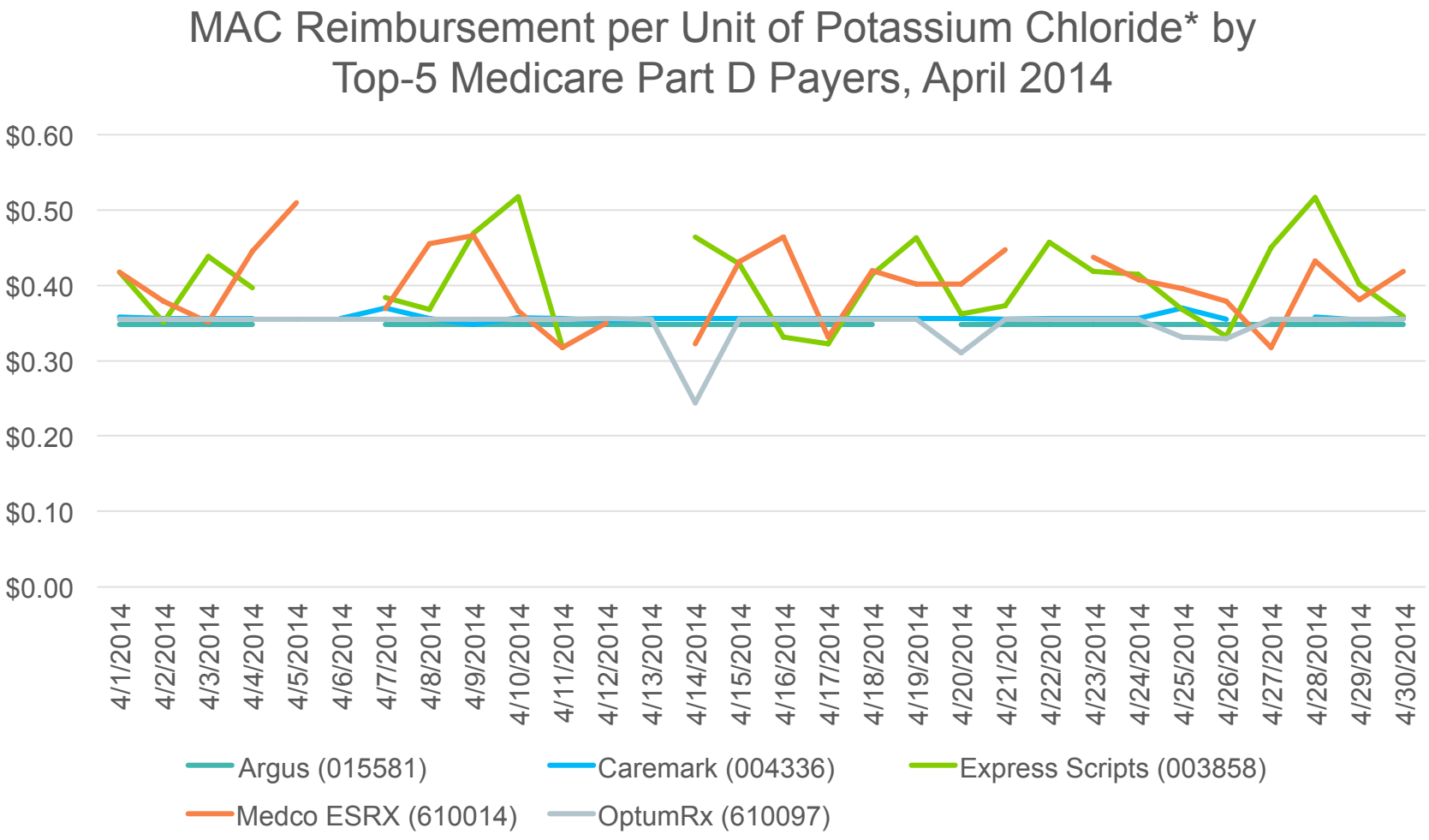
* Volume defined as total days supply dispensed
** For example, the MAC reimbursement for a single pill of the particular drug.
MAC: Maximum Allowable Cost; COGS: Cost of Goods Sold

MAC Variability for Omeprazole



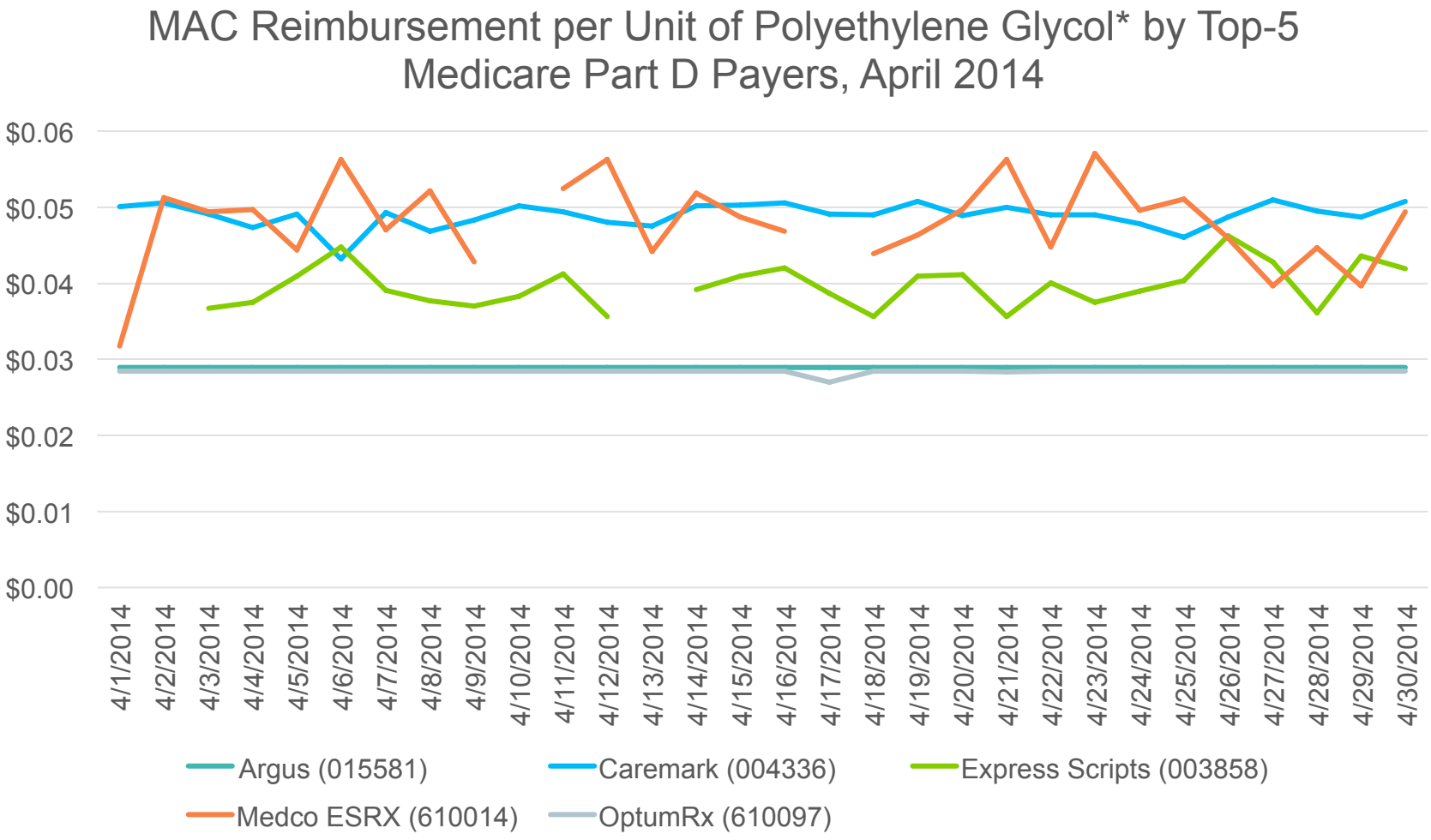
* NDC = 60505006501
MAC: Maximum Allowable Cost; COGS: Cost of Goods Sold; NDC: National Drug Code
Notes: top-5 payers identified based on total days supply dispensed, listed alphabetically. Weighted average MAC reimbursement provided for each payer daily. COGS is the weighted average for all payers, daily. Gaps in the trend line indicate that no data is available for that payer for this drug on that day.

MAC Variability for Potassium Chloride



* NDC = 62037099910
MAC: Maximum Allowable Cost; COGS: Cost of Goods Sold; NDC: National Drug Code
Notes: top-5 payers identified based on total days supply dispensed, listed alphabetically. Weighted average MAC reimbursement provided for each payer daily. COGS is the weighted average for all payers, daily. Gaps in the trend line indicate that no data is available for that payer for this drug on that day.

MAC Variability for Polyethylene Glycol



* NDC = 51991045757
MAC: Maximum Allowable Cost; COGS: Cost of Goods Sold; NDC: National Drug Code
Notes: top-5 payers identified based on total days supply dispensed, listed alphabetically. Weighted average MAC reimbursement provided for each payer daily. COGS is the weighted average for all payers, daily. Gaps in the trend line indicate that no data is available for that payer for this drug on that day.

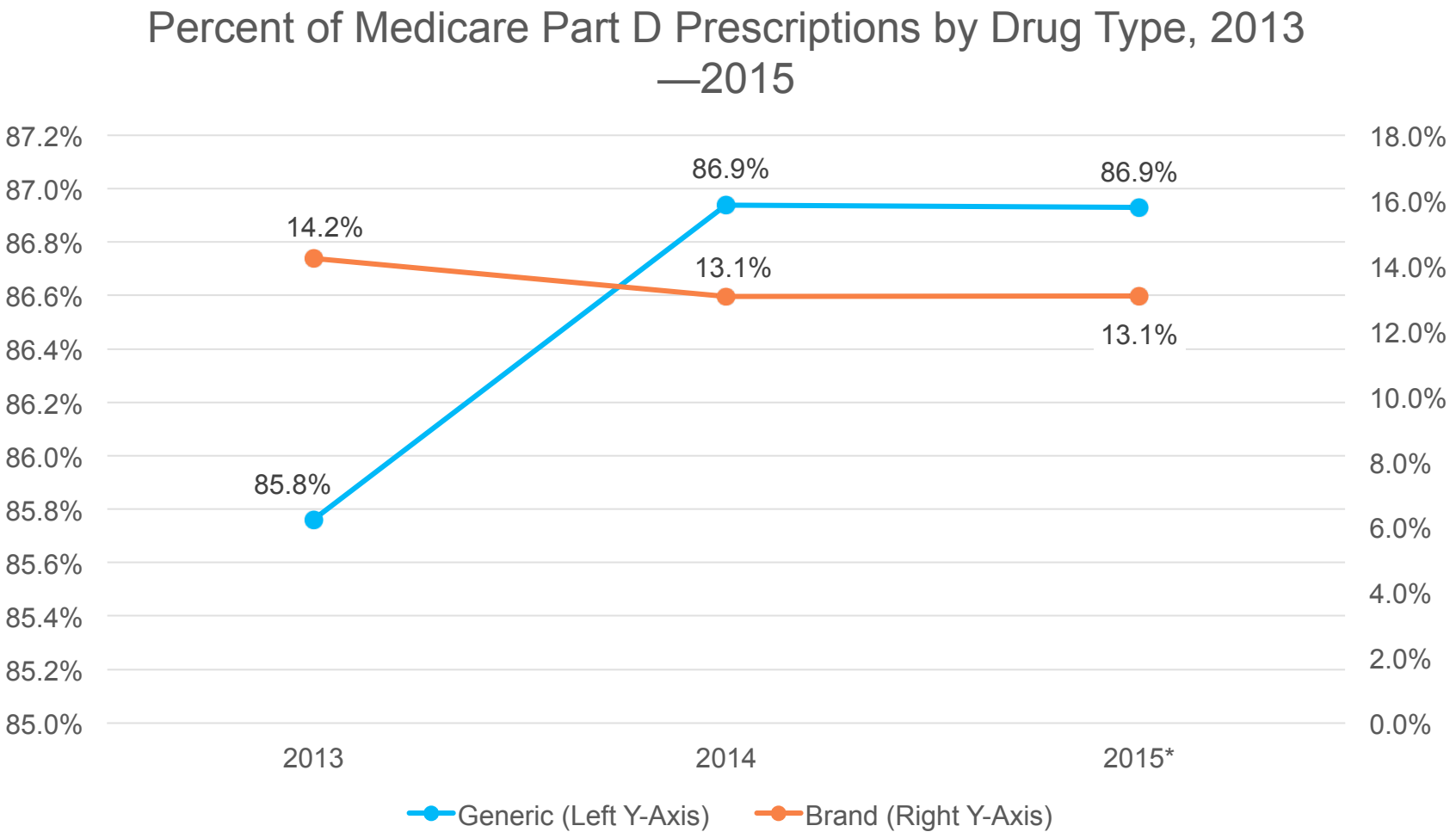
Avalere

#3 – Percent of Drugs Dispensed that Are Generic vs. Brand-Name

Overview #3 – Percent of Drugs Dispensed that Are Generic vs. Brand-Name

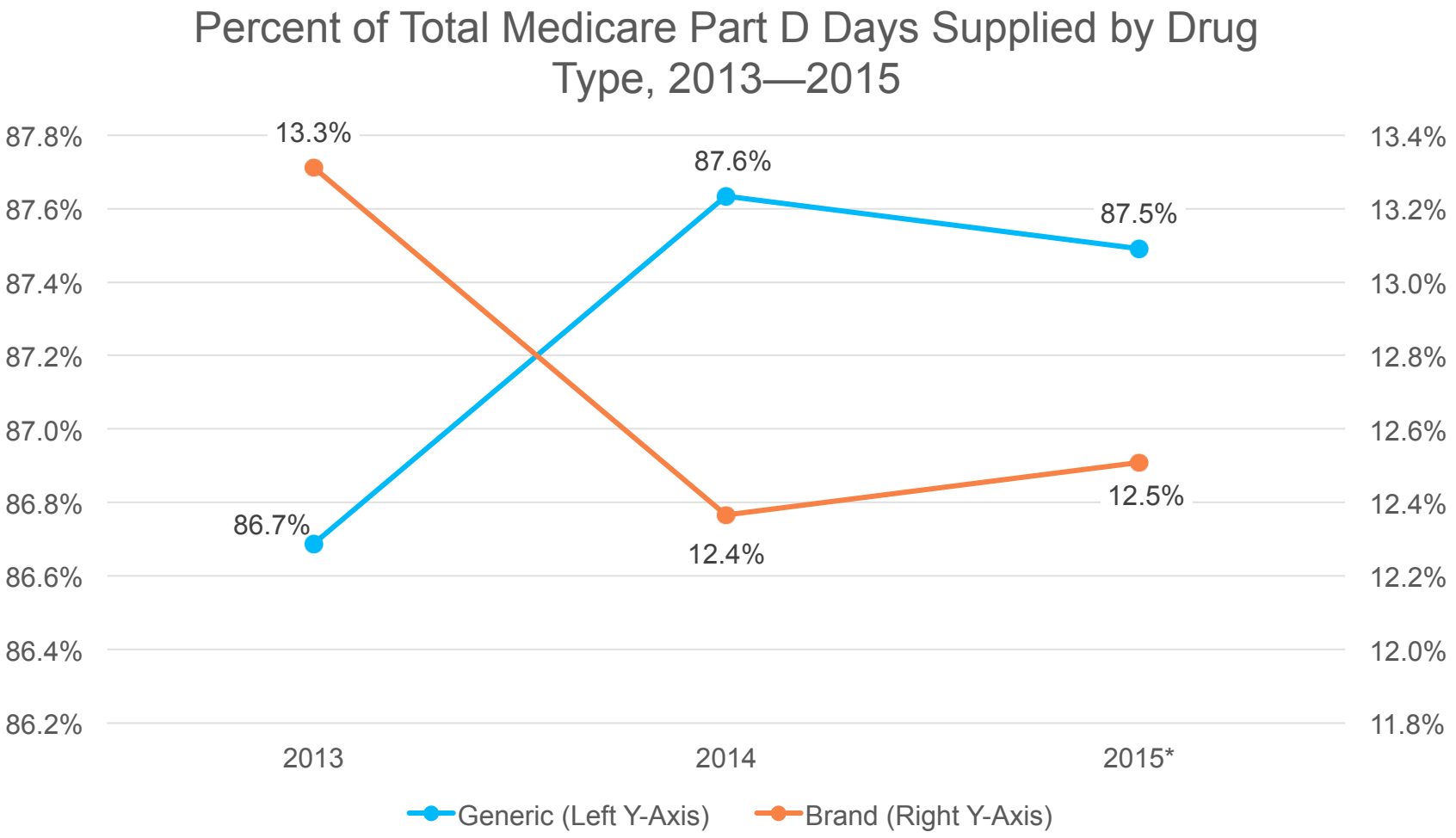
- Objective: assess whether generic drugs represent an increasing share of total drugs dispensed
- Methodology:
  1. Determined the percent of Medicare Part D drugs dispensed that are generic versus brand-name from 2013—2015. Segmented the results by:
     a. Number of prescriptions
     b. Number of days supplied
- Finding:
  - The percent of prescriptions and total days supplied by generic drugs has increased

Prescriptions for Generics vs. Brands



* Includes data from Q1.

Days Supplied by Generics vs. Brands



* Includes data from Q1.

SCPC EXHIBIT 1

Avalere

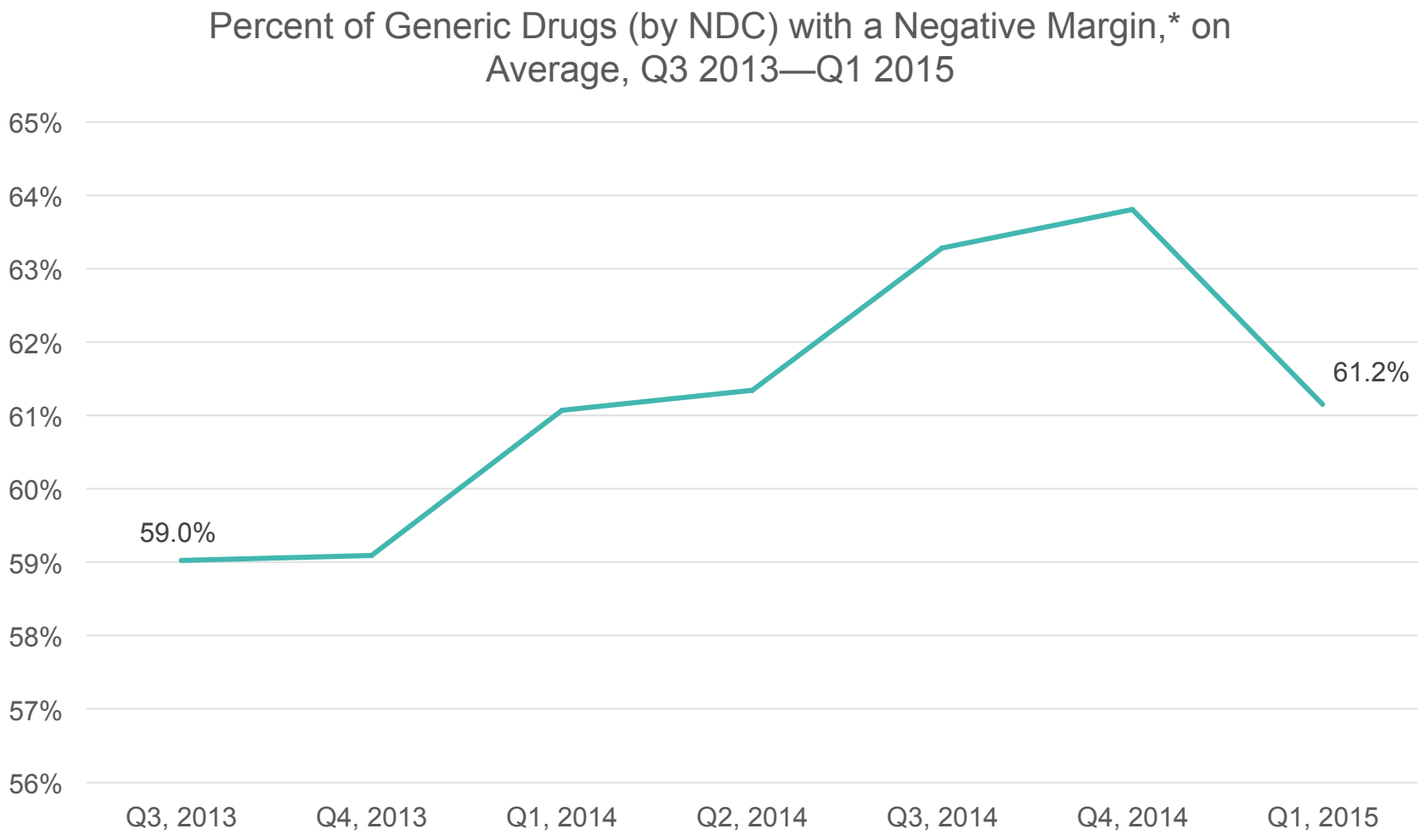
#4 – Percent of Generic Drug NDCs with Negative Margins

Overview #4 - Percent of Generic Drug NDCs with Negative Margins

- Objective: estimate the percentage of generic drugs that have a negative margin, and determine whether that percentage has increased
- Methodology:
  1. Calculated the percent of Medicare Part D generic drugs with a negative margin: Average Revenue – (Average COGS + Cost to Dispense) < 0
     a. Average revenue is equal to average ingredient cost plus average dispensing fee*
     b. Cost-to-dispense is fixed for a 30-day supply of a drug**
  2. Segmented the results for each quarter from Q3 2013 to Q1 2015
- Finding:
  - The percent of generic drugs that, on average, have a negative margin has increased

COGS: Cost of Goods Sold; NDC: National Drug Code
* Revenue does not include manufacturer rebates (if any).
** This analysis uses $13.54 for cost to dispense. The value is the median cost to dispense a 30-day supply of a prescription as determined by researchers with Virginia Commonwealth University and Midwestern University. Source: Carroll, N.V., Rupp, M.T. & Holdford, D.A. Analysis of costs to dispense prescriptions in independently owned, closed-door long-term care pharmacies. *J Manag Care Spec Pharm.* 20: 291-320, (2014).

Percent of Generic Drug NDCs with Negative Margins



NDC: National Drug Code

* Defined as: *Average Revenue – (Average COGS + Cost to Dispense) < 0.* Revenue includes reimbursement for ingredient costs plus dispensing fees, but does not include manufacturer rebates (if any). This analysis uses $13.54 for cost to dispense. The value is the median cost to dispense a 30-day supply of a prescription as determined by researchers with Virginia Commonwealth University and Midwestern University. Source: Carroll, N.V., Rupp, M.T. & Holdford, D.A. Analysis of costs to dispense prescriptions in independently owned, closed-door long-term care pharmacies. *J Manag Care Spec Pharm.* 20: 291-320, (2014).

SENIOR CARE PHARMACY COALITION

1700 PENNSYLVANIA AVENUE, NW, SUITE 200, WASHINGTON, DC 20006

December 8, 2017

Via upload to: https://ftcpublic.commentworks.com/ftc/pharmaworkshop/

Federal Trade Commission
600 Pennsylvania Avenue, NW
Washington, DC 20580

Re: Comments on November 8, 2017 Pharmaceutical Workshop

Dear Commissioners:

Introduction. The Senior Care Pharmacy Coalition (SCPC) commends the Federal Trade Commission (FTC) and Food and Drug Administration (FTC) for their focus on the pharmaceutical pricing and supply chain, particularly their recent workshop, "Understanding Competition in Prescription Drug Markets: Entry and Supply Chain Dynamics." SCPC also appreciates the opportunity to comment on matters relevant to the issues raised during the workshop.

SCPC is the only organization in Washington that exclusively represents the interests of long-term care (LTC) pharmacies. SCPC's LTC pharmacy members serve about 700,000 residents daily in skilling nursing and assisted living facilities across the country. SCPC's members constitute 75% of all independent LTC pharmacy companies.[1] Given that LTC pharmacy represents between six and eight percent of the medication spend in the country, the LTC pharmacy sector is a meaningful ecosystem against which to measure competition in the pharmaceutical distribution chain.

[1] SCPC defines "independent LTC pharmacies" as those LTC pharmacies that are not part of a corporate family that includes a pharmacy benefits manager (PBM). SCPC believes that there are inherent conflicts of interest between pharmacies and PBMs, such that common ownership necessarily results in anticompetitive behavior. As the Centers for Medicare and Medicaid Services (CMS) recently noted in the context of the Medicare Prescription Drug (Part D) program (referring to PBMs as "sponsors"): "only a handful of plans have passed through a small share of price concessions to beneficiaries at the point of sale. Instead, because of the advantages that accrue to sponsors in terms of premiums…the shifting of costs, and plan revenues, from the way rebates and other price concessions applied as DIR at the end of the coverage are treated under the Part D payment methodology, sponsors may have distorted incentives, 82 Fed. Reg. 56336, 56419 (Nov. 28, 2017). The largest LTC pharmacy company, Omnicare, controls roughly 50% of the LTC pharmacy market, with more than 1,000 independent LTC pharmacy companies serving the remainder the market. Omnicare is a wholly owned subsidiary of CVS Health, which also owns Caremark, the largest PBM in the country, as well as Coram, the largest home infusion company, and CVS specialty, the largest specialty pharmacy. For a more extensive discussion of the anticompetitive market impact CVS Health has on drug prices, Medicare Part D beneficiaries, Medicare program costs and LTC pharmacies, *see infra at 4-5.*

There are many actors in the prescription drug markets – brand manufacturers, generic manufacturers, pharmacy benefit managers (PBMs), wholesalers, group purchasing organizations (GPOs), Pharmacy Services Administrative Organizations (PSAOs), chain pharmacies, independent pharmacies, specialty pharmacies, home infusion pharmacies, LTC pharmacies, mail order pharmacy, Medicare, Medicaid, private insurers and of course consumers (including Medicare and Medicaid beneficiaries). Given that its members are active participants in the distribution chain, and based upon years of analysis, SCPC believes that PBMs, together with their corporate siblings in horizontally and vertically integrated conglomerates, are anticompetitive actors in a highly consolidated, increasingly integrated and unjustifiably opaque supply and payment chain. For that reason, our remarks focus on PBM conglomerates.

In Section I we provide important context concerning the LTC pharmacy sector. Section II describes the PBM industry, and the classic oligopoly that the three largest PBMs in the market today have created. Section III, addresses how PBM pricing and contracting policies impact both consumers and independent LTC pharmacies. Finally, in Section IV, we conclude with recommendations for further FTC actions.

I. LTC Pharmacy Context

LTC pharmacies serve nursing homes, assisted living facilities, and other group and residential settings. LTC pharmacy differs substantially from retail pharmacy. LTC pharmacies are "institutional" or "closed door" pharmacies, which means they are not open to the public and do not sell convenience items as do retail pharmacies. Rather, they contract with LTC facilities and congregate care settings or payer intermediaries to provide pharmacy services to residents in those facilities or settings.

There are four fundamental differences between retail and LTC pharmacy:

1. Retail pharmacies sell myriad products beyond medications to consumers, yet as "closed door" operations, LTC pharmacies do not face consumers. For many retail pharmacies, dispensing medications is a "loss leader," with financial success based on sale of convenience items. LTC pharmacies do not have this option. They succeed or fail based entirely on dispensing medications and providing a wide array of services required by statute, regulation and professional responsibility.

2. The clinical responsibility of retail pharmacies ends when the patient leaves the pharmacy with a prescription. The clinical responsibility of LTC pharmacies is continuous and extended, from the time the pharmacy receives a prescription until the patient's transition from a LTC facility to home or another setting is complete.

3. Retail pharmacies dispense the vast majority of medications in 30-day bottles. To meet legal requirements and to ensure the safe dispensing of medications to the patients that they serve, LTC pharmacies dispense prescriptions in specialized, "single unit dose" packages. In other words, the LTC pharmacy dispenses medications by individual dose specific to each patient for each medication administration (or "med pass") at the facility. LTC pharmacies also employ sophisticated dispensing technology at both the pharmacy and the

LTC facility to improve efficiency and reduce medication errors. LTC pharmacies also dispense and deliver prescriptions to patients 24-hours per day, 7 days a week, 365 days per year. LTC pharmacies pre-position "emergency kits" in nursing homes and other care facilities. LTC pharmacies reconcile prescriptions for opioids and other controlled substances at least daily and often by med pass. Finally, at least monthly and usually more frequently, LTC pharmacies review every patient chart (called Drug Utilization Review) and otherwise manage each care setting transition to ensure medication continuity between sites of care.[2]

4. Retail pharmacies receive payment before patients receive prescriptions; LTC pharmacies often provide medications before payers have confirmed payment. In retail, the pharmacy has confirmed payment from insurers and has received patient co-payments before giving patients medications. For LTC pharmacies, requirements that medications be delivered to patients within as little as two hours following receipt of a prescription or chart order, coupled with the insurance company's requirements to assure that prescribed medications are "on formulary" and professional and legal obligations to assure that patients receive clinically appropriate medications, often requires that LTC pharmacies release prescriptions for delivery to facilities before confirming payment. In some cases, as many as 30% of prescriptions leave the pharmacy before payment is confirmed.

The complexity of LTC patient conditions also distinguishes LTC pharmacy from retail pharmacy, and underscores the value LTC pharmacies deliver through their services to patients. The average resident in a skilled nursing facility (SNF) is a woman in her mid-80s suffering from multiple chronic conditions, has mild to moderate dementia and takes 13 prescription medications each month.[3] In assisted living facilities, the average number of prescriptions per patient is even higher. As a result, pharmacy services – not simply dispensing medications – are crucial to the quality of care for patients and increasingly important in preventing adverse events like re-hospitalizations, patient falls, polypharmacy complications, medication-induced dementia and other adverse drug reactions, thereby improving the quality of care and reducing Medicare expenditures.

The Department of Health and Human Services (HHS), through the Centers for Medicare and Medicaid Services (CMS), heavily regulates LTC pharmacies under the Medicare and Medicaid programs. The Medicare and Medicaid Requirements of Participation for skilled nursing facilities (SNFs) and nursing facilities (NFs) contain detailed Pharmacy Services requirements.[4] LTC facilities that participate in Medicare and Medicaid contract with independent LTC pharmacies to satisfy those requirements, which include specialized packaging, unit dose packaging, and delivery

[2] These activities are listed in and required by the Medicare Prescription Drug Program Manual (the Part D Manual), Chapter 5, Section 50.5.2.

[3] Managed Health Care Associates, Inc., MHA Independent Long Term Care Member Study at 27 (2017).

[4] The Part D Manual, Chapter 5, Section 50.5.2.; 42 C.F.R. § 483.5 and .60 (requirement that nursing homes provide specialized medication services); *See* Centers for Medicare and Medicaid Services, State Operations Manual (Publication No. 100-07), available at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs-Items/CMS1201984.html. The major pharmacy-related bases for violation citations (F-Tags) include: F-Tag 309: Quality of Care; F-Tag 329: Unnecessary Drugs; F-Tag 332-333: Medication Errors; F-Tag 425: Pharmacy Services; F-Tag 428: Medication Regimen Review; and F-Tag 431: Storage, Labeling, and Controlled Medications. Note that the term "long-term care facilities" does not, under federal law, include assisted living facilities.

within specified time periods depending on the medication and the urgency of a particular prescription.

Most importantly, LTC pharmacies must provide consulting pharmacy services on an ongoing basis. They are part of the care management team for every patient in a facility, and must conduct periodic drug regimen reviews of patients, participate with facility staff in medication reconciliation and be on-site at every facility at least once every month. In addition, the Medicare Part D Manual lays out specific requirements for pharmacies to qualify as LTC pharmacies eligible for participation in Part D networks. LTC pharmacies must comply with a far more extensive array of statutory and regulatory requirements than retail pharmacies.

Part D is the largest single payer for patient medications in LTC facilities. Medicare Part A is the second-largest payer, with Medicaid Part B and a small amount of Medicaid the other primary payers. In 2015, SCPC sponsored a report which Avalere prepared describing the LTC pharmacy marketplace and major policy challenges the sector faces.[5]

II. The PBM Marketplace: A Classic Oligopoly

As several panelists noted during the November 8 workshop, three PBMs – Caremark, ExpressScripts and Optum – process nearly 75% of all prescriptions dispensed in America. For LTC pharmacies, these three PBMs process more than 90% of all prescriptions. Such a high degree of market concentration is the very definition of an oligopolistic marketplace.[6]

Market concentration among PBMs is just the tip of the oligopolistic iceberg. Each of the three major PBMs is part of a corporate conglomerate that has gained significant control over multiple, interdependent markets – not just the PBM market, but also the health insurance, wholesale and pharmacy (retail, LTC, specialty, home infusion and mail order) markets - through acquisitions both horizontal and vertical and through exclusionary conduct, all of which has accelerated dramatically over the past three years.

1. United Health owns Optum Health, the country's third-largest PBM. United Health, the largest health insurer, largest Medicare Advantage (Part C) Plan sponsor, the largest Medicare Part D Plan sponsor and the largest Medi-Gap insurer in America.

2. ESI, Inc., owns Express Scripts, the country's second-largest PBM. It also owns the largest mail-order pharmacy in America. Through Econodisc Contacting Services, ExpressScripts is a co-owner of one of the three GPOs that purchase 91% of all generic medications purchased in the United States.[7]

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[5] Available at http://seniorcarepharmacies.org/wp-content/uploads/2015/10/Avalere_LTC_Pharmacy-the-Evolving-Marketplace-and-Emerging-Policy-Issues.pdf.

[6] *See FTC v. H.J. Heinz Co.*, 246 F.3d 708, 724 (D.C. Cir. 2001) (recognizing that "[i]t is a central object of merger policy to obstruct the creation or reinforcement by merger of such oligopolistic market structures."). *Cf. United States v. Densply Int'l*, 399 F.3d 181, 187 (3d Cir. 2005) (holding that market share of 75-80% was "more than adequate to establish a prima facie case" of market power.").

[7] Chester (Chip) Davis, Jr., Association for Accessible Medicines, presentation to FTC & FDA workshop, "Understanding Competition in Prescription Drug Markets: Entry and Supply Chain Dynamics" (Nov. 8, 2017).

3. CVS Health owns Caremark, the country's largest PBM. CVS Health is the largest interlocking horizontally and vertically integrated health care insurance/PBM/provider/pharmacy conglomerate in the United States. The company owns the nation's largest retail, LTC and specialty pharmacy chains. The company also owns among the nation's largest mail order and home infusion pharmacy. It operates walk-in medical clinics co-located with CVS retail stores in Target department stores. CVS Health currently offers its own Part D plans under the brand name "SilverScript." CVS Health will be providing PBM services to Anthem, which provides health insurance to 19 million Americans, as soon as 2019. CVS Health recently announced its intention to acquire Aetna, the country's third-largest health insurer. CVS Health also is a co-owner of Red Oak, another of the three GPOs that together purchase 91% of all generic medications sold in America.[8]

These arrangements have created inherent incentives for these large PBMs to favor their own corporate affiliates and exclude competitors[9]

Dr. Sood's conclusions ***understate*** the impact in the LTC pharmacy space. His analysis is based on the three largest publicly traded companies in each channel of the drug distribution chain – manufacturers, wholesalers, GPOs, PBMs and pharmacies. None of the three largest pharmacy chains operates a LTC pharmacy. Dr. Sood notes that the three major PBMs control 75% of all prescriptions; for LTC pharmacy companies, these three companies control a significantly higher 90%+ of all prescriptions. Finally, since nearly half of the LTC pharmacy market is composed of smaller, independent LTC pharmacies, the disproportionate market power these PBMs wield in other markets becomes both overwhelming and necessarily anticompetitive in the LTC pharmacy arena.[10]

Examples of PBM anticompetitive practices abound, especially in the LTC pharmacy space.

Contract "Negotiations." PBMs' ability to secure anti-competitive and one-sided contract terms from LTC pharmacies convincingly demonstrates the anticompetitive impact that PBM market consolidation and vertical/horizontal integration. In *Eastman Kodak Co. v. Image Technology Services*, the Supreme Court held that the ability of a firm to raise prices unilaterally constitutes direct evidence of market power.[11] LTC pharmacies must routinely accept contracts with payment formulas that allow PBMs to change prices daily.[12] SCPC's members are routinely forced to accept "take it or leave it" contracts which reflect the inordinate market power that PBMs wield in the LTC pharmacy market. (SCPC urges the FTC to consult with CMS Part D Group to learn of

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[8] *Id.*

[9] *See, e.g.*, Fed. Trade Comm'n Complaint, Merck & Co., FTC File No. C3853, available at: https://www.ftc.gov/sites/default/files/documents/cases/1999/02/9510097merckcmp.htm.

[10] By contrast, for example, retail pharmacy is dominated by chain pharmacies like CVS and Walgreens, which affords them greater comparative market power than LTC pharmacies. In addition, these chain pharmacies also participate in the same purchasing groups that purchase 91% of generic medications, underscoring not only their comparatively greater market power than LTC pharmacies, but also the opaque business relationships that create inherent conflicts of interest and strong incentives for conglomerates that own PBMs to use PBMs as a tool to leverage their overall corporate interests at the expense of patients, pharmacies and government payment programs.

[11] 504 U.S. 451, 477-78 (1992).

[12] *See* discussion of Maximum Allowable Cost pricing *infra* at 6-7.

examples its sister Agency has had to address for the last decade, and particularly the last two years during the PBM industry's consolidation.) In 2016, Caremark attempted to increase its already disproportionate market power by refusing to negotiate with the largest PSAO representing LTC pharmacies in negotiations with PBMs like Caremark for its 2017 contracts on behalf of Part D PDPs. Caremark improperly tried to influence LTC pharmacies to accept its unilateral, pharmacy-by-pharmacy contracts by refusing to honor key provisions of its existing contracts in 2016 unless the pharmacy accepted the unilateral contract. SCPC informed CMS of this predatory practice, and the agency instructed Caremark to honor its existing contracts.

Part D Pricing for Generics. The Medicare Part D statute allows PDPs/PBMs to use a methodology known as Maximum Allowable Cost (MAC) pricing to establish payment rates for most generics. Under this methodology, the pharmacy does not know the payment rate for any medications at the time a contract is signed because MAC pricing allows the PDPs/PBMs to change payments on a day-to-day basis, ***provided that those changes are based on actual and identifiable changes in the marketplace.***

In 2015, SCPC asked Avalere to examine 24 million Part D claims for the eight-quarter period ending March 31, 2015 and, in part, to determine whether there is any relationship between PBM rate changes for commonly prescribed generics and identifiable marketplace changes. The results are deeply troubling. The resultant report, issued in November 2015, demonstrates there is no apparent relationship between changes in the amount a PBM pays for a medication and actual changes in the marketplace.[13]

For example, in April 2014, Omeprazole was the most commonly prescribed medication in America's nursing homes. On April 2, ExpressScripts paid about $1.22 for the cost of the medication. The next day, April 3, ExpressScripts paid about $0.58 for the cost of the same medication. Two weeks later, on April 15, ExpressScripts paid about $0.14 for the cost of the same medication. By contrast, for the entire month of April 2014, Caremark's payment for the same medication varied from $0.14 to $0.18. Optum paid a consistent $0.22 for Omeprezole every day of the month.

Either major PBMs have such disparate access to market information or something other than marketplace changes are driving day-to-day payment changes. The latter seems far more plausible, particularly given PBMs' desultory compliance with a CMS regulation requiring that PDMs report information about payment rate changes under MAC pricing and the marketplace changes justifying each rate change. When confronted by Rep. Doug Collins (R-GA) during a hearing of the Regulatory Reform, Commercial and Antitrust Subcommittee of the House Judiciary Committee, witnesses from Caremark and ExpressScripts were unable to provide any explanation for, much less identify specific marketplace changes to justify, these day-to-day variations within an individual PBM or between PBMs.[14] They did acknowledge, however, that PBMs managed

[13] The Avalere report is available at: http://seniorcarepharmacies.org/wp-content/uploads/2015/11/20151116_SCPC-MAC-Pricing-Analyses_FINAL.pdf.

[14] The subcommittee hearing occurred on November 17, 2015, and was the third in a series of hearings on the state of competition in the health care marketplace. This specific hearing concerned "[t]he State of Competition in the Pharmacy Benefit Manager and Pharmacy Marketplaces." Https://judiciary.house.gov/press-release/regulatory-reform-subcommittee-to-hold-third-hearing-on-the-state-of-competition-in-the-health-care-marketplace/

multiple formularies with differing prices for the same medication on the same day, with all payment rates calculated using the MAC pricing methodology. If MAC pricing truly were based on identifiable marketplace changes, then differing prices for the same medication on the same day by the same PBM simply due to different formularies logically could not occur. The most obvious explanation is unilateral price manipulation, another hallmark of an oligopolistic marketplace.

The regulation requires that PDPs, through their respective PBMs, report this information weekly and do so in a manner that is user-friendly for pharmacies. PBMs have honored this regulation in the breach, such that no useful or user-friendly data has been reported to CMS since the regulation became effective in January 2016. 42 C.F.R. § 423.505.

Predatory Pricing to Reduce Competition. SCPC is aware that the corporate conglomerates of which the dominant PBMs are unfairly advantage their corporate affiliates at the expense of consumers, competitors and competition itself. [15] For example, term sheets that Omnicare, the LTC pharmacy company owned by CVS Health, is offering to nursing homes appear to offer below-cost pricing and which no competing LTC pharmacy could offer. [16] This is a classic example of oligopolistic behavior – use market power to force competitors out of the market as a predicate to establishing monopoly pricing. Absent likely concessions from Caremark not available to competing LTC pharmacies, it is unlikely that Omnicare could sustain below-market pricing to force competitors out of the market.

Creating Unjustifiable Fees. PBMs process LTC pharmacy claims under Part D. In recent years, PBMs have imposed and continue to impose a surprising and growing array of fees on LTC pharmacies. These fees have little market-based justification; rather, they represent yet another example of PBMs wielding undue oligopolistic power to the detriment of consumers, government payers, LTC pharmacies and free market competition.

PBM fees fall primarily into three categories: claims processing (or "point-of-sale" fees), "Direct and Indirect Remuneration" or "DIR" fees (post-point-of-sale clawbacks) and "quality" or "performance" fees (also post-point-of-sale). PBMs also regularly create and impose new fees without prior notice or explanation to LTC pharmacies, and no recourse for the LTC pharmacies but to "pay" the fees. [17] . PBMs charge LTC pharmacies a claims processing fee ranging from $0.25 to $1.00 per claim. A substantial majority of claims are processed on a computer-to-computer basis, and LTC pharmacies submit hundreds of millions of Part D claims annually. There simply is no market-based justification for such exorbitant fees, and policy analysts often overlook point-of-sale fees like claims processing fees in discussing the impact PBM practices have on the marketplace.

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[15] *See Volmar Distrs v. New York Post Co.*, 825 F. Supp. 1153, 1160 (S.D.N.Y. 1993) ("The ultimate goal of the predatory firm is to recoup its losses by raising prices after competition is diminished.").

[16] SCPC would welcome the opportunity to provide detailed information to the FTC at the agency's convenience.

[17] "Payment" of these fees is a misnomer, since PBMs typically subtract fees from future payments, making it even harder for LTC pharmacies to contest or even obtain explanations of fees before PBMs take monies from LTC pharmacies.

With respect to DIR fees, CMS recently concluded that PBMs ***do not*** pass these fees on to consumers or reduce Medicare expenditures on Part D; rather, the fees result in pure profit for the PBMs and PDPs. "Our analysis of the Part D plan payment and cost data indicates that in recent years DIR amounts Part D sponsors and their PBMs actually received have consistently exceeded bid-projected amounts." 82 Fed. Reg. 56240 (November 15, 2017). DIR fees have no clear market justification.

With respect to "quality" fees, one example illustrates how PBMs and their corporate parents manipulate the system to impose fees on LTC pharmacies that not only increase profits for the PBMs but also increase profits for their corporate siblings. LTC pharmacies contract with assisted living facilities ("ALFs") to provide prescription medications and pharmacy services to facility residents.

In some of its contracts with LTC pharmacies that serve ALFs, ExpressScripts imposes a post-point-of-sale "quality fee." The quality fee is calculated such that the higher the percentage of 90-day prescriptions dispensed, the higher the score on this "quality" metric and the lower the fee imposed on LTC pharmacies. LTC pharmacies generally do not dispense in quantities greater than 30-day supplies, and various payment programs strongly encourage - and in some cases require – that the dispensing cycle be shorter – in the case of brand name drugs dispensed in nursing homes no more than 14 days.

More importantly, the longer the dispensing period, the greater the likelihood of patient non-compliance, particularly in environments like ALFs where residents are responsible to administer their own medications. The ExpressScripts "quality" metric in fact is inversely related to quality. It is directly related, however, to the percentage of mail order prescriptions dispensed because mail order pharmacies typically do dispense for 90 days. With ESI owning not only the ExpressScripts the PBM but also the largest mail order pharmacy in America, and with mail order a realistic alternative for ALF residents to obtain prescription medications, this quality fee seems to be nothing more than naked exploitation by the PBM to benefit its affiliated mail order business. It appears that Caremark may have created a new fee imposed on LTC pharmacies beginning in 2017 that is based on the same principle and, of course, Caremark's corporate parent, CVS Health, also owns one of the nation's largest mail order pharmacies.

All of these fees are opaque to consumers, LTC pharmacies and even the Medicare program itself. CMS' recent report underscores the need for transparency with respect to all of the fees and charges PBMs impose seemingly at whim on LTC pharmacies, particularly given the demonstrable and adverse impact on consumers, government payment programs and free market competition.

Refusing Sensible Application of Contractual Provisions. Historically, when natural disasters that could dislocate patients in LTC facilities loom, PBMs automatically override codes that reject prescription refills because they would be "filled too soon." This waiver protects patients by assuring that they have continuous access to needed medications despite relocation precipitated by natural disaster. In 2016, when Hurricane Matthew hit the southeastern states, Optum refused to override these codes, putting patients at risk. In September 2017, Caremark informed LTC pharmacies throughout Florida that, when Hurricane Irma was expected to batter the state, the PBM would not override the "fill too soon" codes. CMS finally had to compel Caremark to

override the codes in the interest of patient safety and quality, but only after three days of Caremark's failure to implement corrective actions it has represented to CMS had been completed. Adding injury to insult, in recent weeks Caremark apparently has begun systematic efforts to audit LTC pharmacies, presumably on the theory that, since the hurricane did not cause the degree of relocation feared as the storm approached Florida, Caremark is entitled to claw back payments for those prescriptions filled as a result of the code overrides.

These practices are not aberrations, they are examples of ongoing "sharp practices" which are the produce of an oligopolistic, rather than a free, market.

III. The Impact of PBM Oligopoly

Standard microeconomic theory would predict that, in an oligopolistic market, costs would be higher than necessary, oligopolistic actors would earn "excess profit" as defined by standard microeconomic theory, consumers would have fewer choices and competitors would face unfair and anticompetitive practices threatening their business survival. These anticipated outcomes are occurring right now.

Dr. Sood concluded both that PBMs earn excess profit and that PBMs contribute to higher drug costs.[18] Recent analysis by the Wakely Group evaluated the budgetary impact of legislation pending in Congress to eliminate DIR fees under Part D contracts. The Wakely Group analysis concluded that the legislation would save the Medicare program more than $3 billion over 10 years.[19] The necessary corollary to this conclusion is that DIR fees currently cost the Medicare program money, thereby increasing the cost to the federal government for prescription drugs under Part D.

For Part D beneficiaries who pay co-pays and deductibles (i.e., Part D beneficiaries who are not dually eligible for both Medicare and Medicaid), CMS analysis conclusively demonstrates that PBM practices result in higher out-of-pocket costs for beneficiaries. The analysis also establishes that PBMs approve certain medications in part to force Part D beneficiaries through the "donut hole" in Part D coverage. There are two reasons for this: (1) the more, and more expensive, the medications a beneficiary takes, the greater the revenue and profit for the PBM; and (2) the sooner the beneficiary reaches the donut hole, the greater the revenue and profit for the PBM and PDP because the federal government's share of overall payment for prescription medication increases to 85% once a patient enters the catastrophic layer of Part D coverage.[20]

PBMS also restrict consumer choice, although few consumers are aware of these restrictions. PBMs negotiate formularies based primarily on the rebates (for brands) and discounts (for generics) they and the plans they represent will earn. Thus, financial incentives for PBMs and PDPs determine the medications to which insureds will have access, rather than clinical considerations and the medical needs of an individual patient. needs of patients, but rather on the

[18] *See discussion supra at 4-5.*
[19] Available at http://www.ncpa.co/pdf/wakely-report.pdf.
[20] *See, e.g.,* htpps://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2017-Fact-Sheet-items/2017-01-19-2.html.

Essentially, PBM and PDP profit, not patient quality or out-of-pocket cost, determines the medications to which enrollees have access.

The result is twofold. Some consumers will receive less than optimal medications to treat their clinical conditions. Others will face higher prices for clinically optimal medications. In either case, consumers are adversely effected – either with inferior quality of care or higher out-of-pocket costs.

Finally, LTC pharmacies clearly suffer from the unfair exploitation of market power detailed in Section II. This is not merely a threat to competitors, it is a threat to competition itself because, as independent LTC pharmacies are forced out of the market by predatory pricing and practices, market concentration increases and prices inevitably increase as well.

IV. Recommendations

The issues and concerns raised at the workshop and in our comments are squarely within the statutory and regulatory ambit of the FTC and the Department of Justice. SCPC strongly encourages the FTC and, where appropriate, the Justice Department, to:

1. Regularly exchange information with CMS Part D representatives concerning PBM pricing and practices.

2. Investigate whether PBMs and the corporate conglomerates of which they are a part exploit undue market power in violation of antitrust law and regulation.

3. Closely scrutinize the proposed CVS Health acquisition of Aetna in the context of the market power and leverage the corporate conglomerates – particularly CVS Health – have been able to develop. We respectfully submit that the appropriate markets to consider vis-à-vis this proposed transaction occur at the nexus of health insurance, the prescription drug supply chain, chain pharmacies of all stripes and PBMs. Considering this proposed transaction simply as vertical integration without appreciation of all the hidden relationships and implications across markets does a disservice to competition and consumers.

4. Issue clear guidance on the limits of vertical and horizontal integration of pharmacies, health plans, PBMs and other major actors in the LTC pharmacy market.

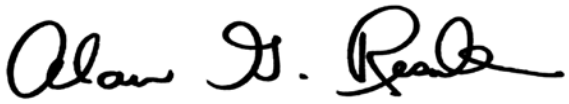
5. Issue recommendations to Congress regarding ways the Part D statute could be modernized to limit the negative impact PBMs and the corporate conglomerates of which they are a part have on costs and quality for consumers, federal health care expenditures and competition.

Conclusion

SCPC once again commends the FTC for bringing greater focus to the myriad issues surrounding prescription drug pricing and the drivers of higher prices and higher out-of-pocket costs. The FTC, working with CMS, would do well to continue investigating the marketplace not only to identify the true reasons for higher costs, but also to compel the corporate conglomerates that now dominate the marketplace to comply with relevant legal and regulatory obligations. The market should be

free and fair, which includes larger players legitimately benefitting from greater market power. When opacity, consolidation, corporate integration across markets and related improper behaviors drive the market, however, it is not free. It therefore is appropriate for the FTC, the FDA and the Justice Department to investigate and act so we return to the free market principles that underlie the nation's antitrust laws and the Part D program.

Sincerely,



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