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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 (FDA) 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 skilled 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

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 competitors⁹

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

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 Omeprazole 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.

¹⁵ See *Volmar Dists 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., <https://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

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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,



Alan G. Rosenbloom
President & CEO