SENIOR CARE PHARMACY COALITION

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THE SENIOR CARE PHARMACY COALITION

STATEMENT FOR THE RECORD

BEFORE THE UNITED STATES HOUSE OF REPRESENTATIVES ENERGY AND COMMERCE COMMITTEE, HEALTH SUBCOMMITTEE

"EXAMINING THE DRUG SUPPLY CHAIN"

DECEMBER 13, 2017

The Senior Care Pharmacy Coalition (SCPC) welcomes the opportunity to present this statement for the record before the United States House of Representatives Energy and Commerce Committee, Health Subcommittee, as part of its hearing, "Examining the Drug Supply Chain." SCPC commends the Chairman and Ranking Member for their focus on the pharmaceutical pricing and supply chain. As the only Washington-based organization exclusively representing the interests of long-term care (LTC) pharmacies, we suggest that the LTC pharmacy sector is a meaningful ecosystem through which to understand the pharmaceutical distribution chain, and particularly the invidious efforts of Pharmacy Benefit Managers (PBMs) to siphon billions of dollars out of that system at a cost to consumers and the federal government alike.

There are many actors in the prescription drug markets – brand manufacturers, generic manufacturers, PBMs, wholesalers, group purchasing organizations (GPOs), Pharmacy Services Administrative Organizations (PSAOs), chain pharmacies, independent pharmacies, specialty pharmacies, home infusion pharmacies, LTC pharmacies, mail order pharmacies, 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, play a negative and damaging role in the 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 ways in which the three largest PBMs in the market today have created an "oligopoly" that harms patients, pharmacies and the federal government. Section III, focuses in more detail on how PBM pricing and contracting policies impact both consumers and independent LTC pharmacies. Finally, in Section IV, we conclude with recommendations for further Committee and legislative actions.

Before addressing the details, we share with the Committee the findings of the Pacific Research Institute (PRI), which earlier this year conducted a comprehensive review of the literature surrounding PBMs and their business practices.[1] PRI concluded that PBMs "[c]reate pricing uncertainty by incentivizing higher list prices for medicines that enable large rebates and discounts (which are particularly valuable for PBMs)," and which result in:

- The large discrepancy between list prices and transaction prices caus[ing] higher patient co-pays than necessary (co-pays typically depend on list prices);
- For Medicare Part D beneficiaries, the higher list prices and higher co-pays … push[ing some] patients into the coverage gap ("donut hole") faster;
- Impos[ing] large, and often unknown, fees that creat[ing] substantial revenue uncertainty and volatility, which are particularly problematic for small, LTC and specialty pharmacies;
- Increas[ing] PBMs' share of the gross expenditures at the expense of pharmacies and manufacturers; and

[1]Dr. Wayne Winegarden, The Economic Costs of Pharmacy Benefit Managers: A Review of the Literature, Pacific Research Institute (March 2017), available at www.pacificresearchinstitute.org

- Through control of the drug formularies, impos[ing] undue influence on the medicines patients can access.

We address these issues in detail below, and urge the Committee to explore these issues as it investigates the drug distribution chain.

I. LTC Pharmacy Context

The SCPC and its Members: SCPC's members serve about 700,000 residents daily in skilled nursing and assisted living facilities across the country. Our members represent 75% of all independent LTC pharmacy companies.[2] As described below, given the utilization of drugs in LTC settings, LTC pharmacy represents between six and eight percent of the prescription medication spend in the country.

The LTC Sector: 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, but 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.[3] To meet legal requirements and to ensure the safe dispensing of medications to the patients that they

[2] 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. The largest LTC pharmacy company, Omnicare (which is not an SCPC member), 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* 6-7.

[3] It is noteworthy that yet another example of the undue and adverse impact of PBMs and the corporate conglomerates of which they are a part, overall corporate strategy pushes consumers in the community away from retail pharmacies

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 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.[4]

4. Retail pharmacies receive payment before patients receive prescriptions; LTC pharmacies often provide medications before payers have confirmed payment. In retail, the pharmacy confirms payment from insurers and receives 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/PBM'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 who takes 13 prescription medications each month.[5] 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

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and toward mail-order pharmacies because mail-order pharmacies are less expensive to operate and have higher profit margins than retail pharmacies. For example, as the *New York Times* reported only four days ago, Caremark, the largest PBM in the country and a subsidiary of CVS Health, charges consumers more for a prescription dispensed in a CVS retail pharmacy (another subsidiary of CVS Health and the largest retail pharmacy chain in the country) than the same prescription dispensed by CVS' mail-order pharmacy (yet another subsidiary of CVS Health and the second-largest mail-order pharmacy in America). "Prescription Drugs May Cost More With Insurance than Without It," *New York Times* (December 9, 2017), available at https://www.nytimes.com/2017/12/09/health/drug-prices-generics-insurance.html.

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

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

programs. The Medicare and Medicaid Requirements of Participation for skilled nursing facilities (SNFs) and nursing facilities (NFs) contain detailed Pharmacy Services requirements.[6] 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 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.[7]

II. The PBM Marketplace: A Classic Oligopoly Harming Patients, Pharmacies, and the Federal Fisc

Who are the PBMs?: 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.[8] Moreover, each of the three major PBMs is part of a corporate conglomerate that has gained significant control over multiple, interdependent markets in the drug distribution chain – 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.

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[6] 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.

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

[8] *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) (market share of 75-80% was "more than adequate to establish a prima facie case" of market power.").

1. UnitedHealth Group owns Optum Health, the country's third-largest PBM. UnitedHealth is the largest health insurer, largest Medicare Advantage (Part C) Plan sponsor, largest Medicare Part D Plan sponsor and largest Medi-Gap insurer in America. Within the last ten days, UnitedHealth Group agreed to buy the DaVita Medical Group unit, continuing the accelerating trend of vertical and horizontal integration of health care businesses. Optum will take control of DaVita Medical Group's nearly 300 clinics and half-dozen outpatient surgical centers.

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.[9]

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 pharmacies. It operates walk-in medical clinics co-located with CVS retail pharmacies inside 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 insures 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.[10]

Such arrangements have created inherent incentives for these large PBMs to favor their own corporate affiliates and exclude competitors, and allow them the power to extract significant sums from today's diffracted drug distribution system.

At a recent hearing before the Federal Trade Commission, Dr. Neeraj Sood of the University of Southern California (USC) Schaeffer School presented a thorough analysis of the PBM sector, and how PBMs are achieving excessive profits.[11] Dr. Sood's analysis effectively demonstrates the adverse impact of the PBM sector on patients, unaffiliated payers, pharmacies and free market competition. However, his analysis ***understates the impact on the LTC pharmacy sector.***

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

[9] 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)); *see also* National Academy of Sciences Report at 55.
[10] *Id.*
[11] Neera Sood, Ph.D., Professor and Vice Dean for Research, Sol Price School of Public Policy, University of Southern California, presentation to joint FTC-FDA Workshop, "Follow the money: The flow of funds in the pharmaceutical distribution system," (Nov. 8, 2017), available at https://www.ftc.gov/system/files/documents/public_events/1255653/understanding_competition_in_prescription_drug_markets_workshop_slides_11-8-17.pdf (Slide 74-105).

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.[12]

Rebates, DIR Fees, and PBM Profits: PBM representatives claim that their role in the drug distribution chain is one of negotiating drug discounts on behalf of purchasers (large employers, health plans, and others) to drive efficiency into the drug distribution system.[13] While that claim may have been true 10 or 20 years ago, it is no longer the case. Rather, PBMs today are a destructive force in the drug distribution system, taking profits for themselves at a cost to patients, pharmacies, and the federal government. PBMs do this through two principle practices: first, they negotiate "rebates" from drug manufacturers, but rather than passing those rebates on to consumers (as they claim they do), they retain the vast majority of those rebates for themselves.[14] Second, PBMs have developed a series of opaque and unjustified "fees" that they charge pharmacies (which in turn effectively are required to "pay to be paid"). The Medicare program defines some of these fees as "Direct and Indirect Remuneration" or "DIR," which we address below.

PBMs Harm Competition: PBMs today are exacting billions of dollars from the drug supply chain without providing any value for consumers or the federal government.[15] Moreover, their consolidation and vertical integration exacerbate the harm to consumers, government payment programs, pharmacies and free market competition. Examples of anticompetitive practices by PBMs abound, especially in the LTC pharmacy space.

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[12] 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.

[13] *See generally* http://www.pcmanet.org/policy-issues; *see also* Merritt, Testimony before the Senate HELP Committee, October 17, 2017 at 1, available at https://www.help.senate.gov/imo/media/doc/Merritt.pdf.

[14] *See* National Academy of Sciences, Making Medicines Affordable (Dec, 2017) at 16, available at http://nap.edu/24946 ("The most prominent of these intermediaries are the pharmacy benefit managers (PBMs), who interact with prescription drug insurers—and sometimes directly with employers offering health insurance plans—to negotiate prices both with manufacturers and with retail pharmacies. Adding further to the complexity, drug manufacturers very commonly offer price rebates to PBMs, but no meaningful information exists to determine the size of those rebates, what portion of the rebates eventually results in lower prices for patients, or the portion that the PBMs retain as profit"). While the National Academy has been unable to quantify the portion that PBMs retain as profit, CMS has better data related to the Part D program and should be able to provide that estimate to Congress upon request.

[15] National Academy of Sciences at 29 ("[t]he profits generated by PBMs…coupled with insurer's profits and the margins on reimbursement for drugs administered in the hospital or outpatient setting ultimately affect the patients and their ability to pay for therapies, and do not increase the incentives to develop new drugs"). *See also* testimony of Lori M. Reilly, Esq. Executive Vice President, Policy, Research & Membership, PhRMA, before the Senate Health, Education, Labor and Pensions Committee (October 17, 2017), available at https://www.help.senate.gov/imo/media/doc/Reilly2.pdf.

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 found that the ability of a firm to raise prices unilaterally constitutes direct evidence of market power.[16] LTC pharmacies must routinely accept contracts with payment formulas that allow PBMs to change prices daily and with no consideration of the prices competitors pay for the same medication and related services. 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 Committee to consult CMS' Part D Group to learn of examples CMS has had to address for the last decade, and particularly in the last three years during the PBM industry's period of rapid 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 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 for 2017. SCPC informed CMS of this predatory practice, and the agency instructed Caremark to honor its existing contracts.

MAC Pricing – Another PBM Abuse**.** 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.***[17]

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.[18]

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.

[16] 504 U.S. 451, 477-78 (1992).
[17] *See also* Forbes, Reform Pharmacy Benefit Managers (PBMs) To Improve Pharmaceutical Affordability (March 7, 2017) (noting inefficiency and impact of MAC prices).
[18] The Avalere report is available at: http://seniorcarepharmacies.org/wp-content/uploads/2015/11/20151116_SCPC-MAC-Pricing-Analyses_FINAL.pdf and was introduced by Rep. Collins during a Judiciary Committee hearing.

Either major PBMs have dramatically 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 PBMs 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.[19] 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, another hallmark of an oligopolistic marketplace.

The regulation in question requires that PDPs, through their respective PBMs, report price changes and identify the marketplace changes justifying such changes weekly, and that they provide the reports in formats that are user-friendly for pharmacies. 42 C.F.R. § 423.505. 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. We urge the Committee to examine this issue as well.

DIR – PBMs' 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.[20] 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.

[19] 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/.

[20] "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; not only are the fees pure profit for the PBMs and PDPs, but they actually and routinely misrepresent them to CMS: "[o]ur 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. Rather, they serve simply to drive up costs to the federal government, consumers and pharmacies to benefit PBMs' bottom lines.[21]

PBM's Unconvincing Effort to Mask DIR Fees as "Quality" Holdbacks: 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 particular, the Medicare program requires that brand name drugs be dispensed to nursing home patients in supplies no greater 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 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.

[21] In the retail context, a corollary to these "clawbacks" through DIR fees, consumers often would pay less for prescription medications if they paid out-of-pocket rather than if they rely on insurance coverage, because the co-pays the insurers charge (as negotiated and administered by PBMs on behalf of health plans) are greater than the out-of-pocket cost for the consumer. "Prescription Drugs May Cost More With Insurance Than Without It," note 3, *supra*. As a consumer quoted in the article states: "It just doesn't seem right…I just feel that the pharmaceutical industry and the health care industry are pulling these numbers out of thin air." The nexus between the pharmaceutical industry and the health care industry for consumers is the PBM industry, which of course is just a part of megalithic and oligopolistic conglomerates that are, in fact, pulling numbers out of thin air, a practice which Congress should stop immediately.

Summary: As clearly documented throughout the National Academy of Sciences Report,[22] 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.

The National Academy's first recommendation is that PBM transparency be mandated to understand the dollars that PBMs are retaining relative to their value:

> Potentially, this represents the largest opportunity among the committee's recommended actions. Transparency would help bring the margins of PBMs and 340B hospital and clinic plans toward a range that is more commensurate with the value they deliver. It might also lower prices from the biopharmaceutical companies. And transparency likely will reduce bad behavior and abuse in the market. Participants in the markets will perform better. If properly structured, this would pass savings on to patients. Importantly, it would not inhibit investments in research and development.[23]

We urge the Committee to pursue PBM transparency – for the benefit of consumers, for the Part D program, and for pharmacies as well.

III. The PBMs' Trifecta: Excess Profits for PBMs, Harm to Consumers, Medicare & Pharmacies, and Damage to the Free Market

In its' January 19, 2017 analysis, CMS clearly demonstrated how PBM practices increase costs to consumers and the federal government. More specifically, 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 confirmed 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.[24] For PBMs, this is the trifecta – they retain the rebates and DIR fees which go directly to the bottom line, consumers are pulled through coverage layers of the Part D program quicker without PBMs having to share savings, and beneficiaries hit the Part D "catastrophic" coverage level sooner, reducing PBMs payment for beneficiaries and increasing federal costs to offset the PBM savings.

[22] Report at 16, 50, 160.
[23] Report at 160.
[24] *See, e.g.*, htpps://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2017-Fact-Sheet-items/2017-01-19-2.html.

PBMs also unduly and improperly harm pharmacies in the process by exacting unjustified DIR fees, which also go directly to the bottom line. Indeed, CMS's January findings were further sharpened in its recent Part D Proposed Rule, where CMS (referring to PBMs as "sponsors") more deeply analyzed how PBMs (mis)manage DIR fees and demonstrated how the PBMs keep these fees as profit, rather than use them for any legitimate purposes. In the Proposed Rule, CMS noted: "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).

CMS is not the only entity to reach this conclusion; Dr. Sood concluded both that PBMs earn excess profit and that PBMs contribute to higher drug costs.[25] Further, a 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.[26] 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.

Consumer choice is also restricted by PBMs, 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. 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 affected – 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, but it will increase costs to both consumers and the Part D program. 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 Committee's hearing and in this written statement justify Congress taking a hard look at the PBM sector, and revisiting some of the assumptions that Congress has made over the past decades when enacting Medicaid reforms and the Part D program.

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[25] https://www.ftc.gov/system/files/documents/public_events/1255653/understanding_competition_in_prescription_drug_markets_workshop_slides_11-8-17.pdf (Slides 91-96)

[26] Available at http://www.ncpa.co/pdf/wakely-report.pdf.

The Part D program began as a free market exercise, but has become an oligopolistic market benefitting only PBMs and the corporate conglomerates of which they are a part. Legislation is needed to enact PBM reforms, and require that PBMs not abuse their market position to the detriment of consumers, pharmacies or the federal fisc.[27]

First, Congress should consider legislation requiring PBMs to pass through all rebates. On November 16, 2017, CMS issued a Proposed Rule that sought public input on several suggested approaches to compelling PBMs to pass all rebates on to Part D beneficiaries. The Subcommittee could accelerate development and consideration of such legislation by holding a hearing specifically focused on these issues.

Second, Congress should enact pending legislation designed to eliminate or severely restrict the use of DIR fees and to require greater transparency regarding PDP and PBM pricing and practices. *See, e.g.* H.R. 1038 (addressing DIR fees); H.R. 1316 (addressing PBM transparency).[28] Once again, the Subcommittee could accelerate consideration of pending legislation with a hearing focused specifically on these concerns.

Third, the Subcommittee should hold a follow up hearing to evaluate how PBMs and the corporate conglomerates of which they are a part exploit undue market power in to the detriment of consumers (including Part D beneficiaries), the Medicare program and the free market. As part of that hearing, we recommend the Committee 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.

Finally, the Subcommittee should refer related issues to the House Judiciary Committee for further investigation and evaluation from the perspective of the adverse impact on competition and the shocking degree to which the Medicare Part D program, and America's health care system, has become a creature of ever-larger oligopolistic corporate conglomerates rather than a free and fair marketplace.

Conclusion

SCPC thanks the Subcommittee for its focus on the drug distribution chain, and how PBMs drive higher prices and higher out-of-pocket costs. We welcome the opportunity to work with the Subcommittee in the future, and applaud further efforts by the Subcommittee to investigate and

[27] *See also* Forbes, To Improve Pharmaceutical Pricing, Reform PBMs And Fix Health Care's Systemic Problems (April 4, 2017).

[28] CMS has also sought comments in its recent Part D Proposed Rule on ways in which PBMs could be required to share rebates and DIR fees with consumers at the point of sale, rather than keep rebates and DIR fees as PBM profits. 82 Fed. Reg. 56336, 56419 (Nov. 28, 2017). We encourage the Committee to work with the Agency to expand upon the Agency's ideas and to require PBMs to pass through the rebates, as Congress and CMS originally intended when the Part D Program was created. Unfortunately, the CMS approach to pharmacy fees is misguided. As explained more fully in the statement, PBM pharmacy fees are nothing more than exploitation of undue oligopolistic market power to the detriment of pharmacies more so than consumers. The appropriate market correction regarding pharmacy fees is eliminating them altogether, as various bills pending in both the House and Senate propose.

legislate in this area so we can return to the free market principles that underlie the nation's laws and the Part D program.

Alan Rosenbloom
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