Statement for the Record

House Committee on the Judiciary

Subcommittee on Regulatory Reform, Commercial and Antitrust Law

The State of the Competition in the Pharmacy Benefit Manager and Pharmacy Marketplaces

November 17, 2015

Chairman Marino, Ranking Member Johnson, and Members of the Committee, thank you for the invitation to offer this Statement for the Record and for holding this important hearing. As a career pharmacist with over 30 years of experience, I have witnessed and participated in the creation and evolution of pharmacy benefit managers (PBMs). Since the 1980s, PBMs have evolved from fiscal intermediaries who adjudicate prescription drug claims to companies that manage pharmacy benefits, negotiate drug discounts with pharmaceutical companies, and require patients to use preferred providers and products to treat medical conditions. Over time, this evolution by PBMs has resulted in fewer choices in care for patients and an ever-restricting access to community pharmacists. Action must be taken to ensure that consumers and independent health care providers, alike, do not suffer from the consolidation of an under-regulated market that has continued to funnel consumers into a system that leaves Americans with no choice of service or care.

I believe there are three essential elements that must exist for the creation of a competitive market. These are transparency, choice, and level playing field for patients and providers alike that is devoid of conflicts of interest. Without these three elements, patients will see fewer choices and higher costs as providers are not forced to compete by offering fair prices and better services. Without transparency, consumers would not be able to evaluate products, make informed choices, and participate in the full range of services the market could offer. The lack of transparency of PBMs continues to make it difficult for consumers and pharmacists to take part in the benefits they deserve. According to the Pharmaceutical Care Management Association, PBMs manage over 250 million Americans' pharmacy benefits. The three largest PBMs alone cover more than 180 million patients in the United States, roughly 78% of all Americans who have pharmacy benefits.

Evidence to the lack of transparency was made apparent with the recent case involving Meridian Health Systems. In 2008, Meridian Health Systems (Meridian) was experiencing surging medication costs for its employees. In turn, they hired a PBM to help reduce their costs. In the beginning, the PBM projected that they would save Meridian at least $763,000. However, just three months into the contract with the PBM, Meridian was on pace to spend an additional $1.3

million than previously spent before hiring the PBM. On the brink of the largest medication bill Meridian had ever experienced, the officer in charge of Meridian's medication spending began to investigate where all the money was going. After review of Meridian's employee prescription data, he was shocked to find that the PBM was inflating their bills to play "the spread" (billing the company for larger amounts than what it costs to actually fill the prescription). Rather than the PBM acting a fiduciary for Meridian, like they were supposed to, the PBM padded its profits by taking advantage of a complicated and opaque system.

PBMs are supposed to be "honest brokers." They are supposed to act as a fiduciary to the plans they serve, bargaining to secure the lowest price for prescription drugs and dispensing services. I ask the committee: When a company owns the "independent" arbitrator, how can any action by the arbitrator be independent? When a PBM owns a drug company or has a mail order pharmacy, how can the PBM be an honest broker while serving two masters?

As a practicing pharmacist, I consistently helped by customers navigate their pharmacy benefits. I had to do this because PBMs create barriers for consumers and the only way for my patients to receive the care they needed was for me to help them understand what the PBM allowed and didn't allow. The majority of consumers never deal with the PBM or their insurance company to negotiate benefits. Most of the time, pharmacists are the professional who help consumers with the vast array of complex rules and agreements that define prescription drug benefits. Pharmacists are ultimately advocates and I did everything I could to provide my patients with the information to make informed decisions and receive the medications they needed for the highest possible health care.

Due to its lack of transparency and under-regulated market, PBMs have grown substantially since 2003. In just over ten years, the two largest PBMs have increased their profit margins by almost 600%. This increase alone is impressive without considering within those 10 years that the U.S. suffered the worst financial crisis since the Great Depression. A 600% increase in profits during some of the slowest overall economic growth this country has seen in a century only suggests the PBM market is not competitive and consumers are being footed with the bill.

While there are bad actors in any profession or field, the lack of transparency in PBMs limits our ability to respond and enact much needed reforms. Some PBMs have frequently faced a wide range of claims concerning deceptive business practices and anticompetitive conduct that has been shown to harm consumers and deny medication benefits. These acts can range from receiving kickbacks or rebates in exchange for exclusive arrangements to keep cheaper medications off the market to diverting patients to more expensive medications to take advantage of rebated that PBMs receive from drug manufacturers. From the pharmacy perspective, pharmacists are consistently squeezed out of the market when PBMs manipulate drug reimbursement rates or Maximum Allowable Cost (MAC) pricing, as a method of increasing their profits.

Moving forward, greater attention should be paid to legislative action that brings transparency and competitiveness back into the PBM market. I encourage the Committee to look at every possible angle to address these issues and bring transparency and choice back into the market while eliminating the existence of conflicts of interest.

I ran for Congress to serve the people of the First Congressional District of Georgia and my country. I serve to help and protect consumers, providing them with an environment where they can decide for themselves how they wish to live their lives. As a lifelong medical professional, I know that addressing the corrupt practices of PBMs would be a step to ensuring that Americans are provided the best possible quality of care in an affordable and accessible manner. Importantly, this would be achieved by allowing the free market to perform in the way it was intended.

I want to again thank Chairman Marino, Ranking Member Johnson, and the members of this Subcommittee for holding this hearing today. This is a perfect opportunity to show the American people that we care about them and are working towards patient-centered solutions for health care.

Earl L. 'Buddy' Carter
Member of Congress
First District of Georgia

Statement from Congressman Blum
for the
November 17th, 2015
Subcommittee on Regulatory Reform, Commercial and Antitrust Law
Hearing On
The State of Competition in the Pharmacy Benefit Manager and Pharmacy Marketplaces

I wish to thank the House Committee on the Judiciary, particularly, Chairman Goodlatte and Ranking Member Conyers, as well as the Subcommittee on Regulatory Reform, Commercial and Antitrust Law, especially Chairman Marino and Ranking Member Johnson, for permitting me the opportunity to submit these remarks and express my support for independent community pharmacists and their ability to provide quality health care to patients.

Community pharmacies are the most likely place of interaction between patients and knowledgeable medical professionals about drug and health related concerns, particularly in rural communities and smaller localities, and often the only professional they see outside of their family physician.

It is concerning that competition is concentrated in only a few entities that control the bulk of the industry, approximately 80% of the market, which adversely affects smaller, independent community pharmacies by reducing their access to information and their bargaining power compared to larger pharmaceutical networks.

Unfortunately, pharmacy benefit managers (PBMs) have great effects on the profitability, and therefore, sustainability of independent community pharmacies. The PBMs often reimburse at rates below the cost to acquire and dispense generic prescription drugs. Additionally, because of their inability to update reimbursement benchmarks in a timely fashion to better reflect market realities and leaving the pharmacy bearing the costs, the PBMs jeopardize the pharmacists' ability to continue to serve their patients in their communities.

Because of their control of the market and the lack of negotiating power of the community pharmacies, the PBMs have little incentive to respond to these important participants in the U.S. healthcare system and these pharmacies are slowly disappearing from the communities they serve due to these costly burdens.

I commend the Committee for conducting this hearing in order to positively address these concerns before the negative impacts affect independent pharmacies in my district and across the country. I remain hopeful Congress, along with consultation from the Centers for Medicare and Medicaid Services, will work to ensure a robust U.S. healthcare ecosystem with the inclusion of independent pharmacies.

The Value Provided by Pharmacy Benefit Managers

Submitted to the
House Judiciary Committee
Subcommittee on Regulatory Reform, Commercial and Antitrust Law

November 17, 2015

America's Health Insurance Plans (AHIP) is the national association representing health insurance plans. Our members provide health and supplemental benefits to the American people through employer-sponsored coverage, the individual insurance market, and public programs such as Medicare and Medicaid. AHIP advocates for public policies that expand access to affordable health care coverage to all Americans through a competitive marketplace that fosters choice, quality, and innovation.

Our members are strongly committed to providing high quality, affordable prescription drug benefits to their customers through a variety of products offered both in the commercial market and in public programs. To accomplish this important goal, our member plans contract with pharmacy benefit managers (PBMs) to administer their prescription drug benefits or, in other cases, they have established their own PBMs as subsidiaries. We appreciate this opportunity to comment on PBMs and the role they play in providing cost-effective prescription drug benefits to health care consumers.

Health plans work with PBMs to establish Pharmacy & Therapeutics Committees consisting of physicians, pharmacists, and other health care professionals who evaluate the efficacy and safety of prescription drugs and determine when clinically appropriate therapeutic alternatives and generics are available. In addition to processing claims for pharmaceutical benefits, PBMs also are engaged in several other key activities: negotiating contracts with pharmacies that promote value for enrollees and often include quality-based incentives to support the delivery of the most appropriate, cost-effective medications; negotiating, on behalf of their consumers, discounts and rebates from pharmaceutical manufacturers on medications included in the PBM's formulary; and supporting innovative programs that health plans have implemented to improve patient care for their enrollees.

Research findings demonstrate that these activities are providing value to consumers:

- An October 2013 study[1] by Milliman concluded that preferred pharmacy network plans will reduce federal Medicare spending by an estimated $7.9 billion to $9.3 billion over ten years. This study also found that the rapid adoption of preferred pharmacy networks and improvements in generic dispensing rates were "critical factors" in reducing the per beneficiary cost of Medicare Part D subsidies.

- A December 2014 study[2] by Visante found that the average Medicare Part D enrollee in urban and suburban areas can save $20-$40 on monthly cost sharing by traveling one additional mile to use a preferred retail pharmacy. This study also concluded that the average Medicare beneficiary in rural areas can save $20-$40 per month on copays by traveling an additional four miles to use a preferred pharmacy.

Medicare Part D plans also work with their PBMs to negotiate rebates that significantly reduce costs for taxpayers. According to the 2015 Medicare Trustees Report, "In the 2015 plan bids, plans significantly increased the projected rebates." The trustees further stated: "Many brand-name prescription drugs carry substantial rebates."[3]

Additionally, a recent AHIP issue brief[4] outlines plan-specific examples of the strategies health plans are using to improve patient care, while also holding down costs, for enrollees who can benefit from specialty drugs. One example involves an AHIP member, AmeriHealth Caritas, that works with a PBM to manage the drug component of its health plans. AmeriHealth Caritas has achieved positive results through a drug therapy management program that serves diabetes patients who are taking multiple medications. Participants in this innovative program have experienced a 10 percent *decrease* in the rate of inpatient admissions – compared to a 66 percent *increase* for non-participants.

Our issue brief also highlights the experiences of other health plans that are working with PBMs to provide patients with tools and support to help them successfully manage their specialty medications, promote collaborative arrangements with physicians and pharmacists, and use specialty pharmacies to manage the distribution of specialty medications.

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[1] The Impact of Preferred Pharmacy Networks on Federal Medicare Part D Costs, 2014-2023, Milliman, prepared for Pharmaceutical Care Management Association, October 2013
[2] Medicare Part D Plans Provide the Average Beneficiary Convenient Access to Preferred Pharmacies with Significant Savings. Visante, prepared for Pharmaceutical Care Management Association, December 2014
[3] 2015 Medicare Trustees Report, page 144
[4] Specialty Drugs: Issues and Challenges, Health Plan Examples, AHIP, July 2015

The tools and techniques used by health plans and PBMs are more important than ever as consumers face the consequences, which are sometimes devastating, of escalating pharmaceutical prices. Whether consumers are confronted with the six-figure cost of new specialty medications or huge overnight increases in the prices of existing medications, current developments in the pharmaceutical markets are alarming. Health plans and PBMs are both strongly focused on helping to mitigate the impact of such developments on consumers, as part of their ongoing commitment to ensuring that consumers receive medications that are not only effective, but also affordable.

We thank the committee for considering our perspectives on the positive contributions made by PBMs to support our members in offering high quality, affordable prescription drug benefits.

American Pharmacists Association®
Improving medication use. Advancing patient care.
APhA

November 17, 2015

REGULATORY REFORM, COMMERCIAL, AND ANTITRUST LAW SUBCOMMITTEE OF HOUSE JUDICIARY COMMITTEE HEARING:
"THE STATE OF COMPETITION IN THE PHARMACY BENEFITS MANAGER AND PHARMACY MARKETPLACES"

Statement of the American Pharmacists Association

The American Pharmacists Association thanks Chairman Marino for the opportunity to submit the following statement for the record regarding the interplay of pharmacy benefits managers ("PBMs"), pharmacies, and other health care stakeholders within our health care system.

APhA, founded in 1852 as the American Pharmaceutical Association, represents more than 62,000 pharmacists, pharmaceutical scientists, student pharmacists, pharmacy technicians, and others interested in improving medication use and advancing patient care. APhA members provide care in all practice settings, including community pharmacies, hospitals, long-term care facilities, community health centers, physician office practices, ambulatory care clinics, managed care organizations, hospice settings, and the uniformed services.

As Congress considers competition in the marketplace, APhA urges legislators to focus on patients—particularly on how transparency and accountability deficits can translate to access barriers and increased costs for patients. Without a level playing field for pharmacies, in terms of networks and reimbursement structure, patient access and choice will suffer. To ensure efficient use of resources (meaning both dollars and clinicians), APhA suggests several reforms that will safeguard patient access while improving transparency and competition in the pharmacy marketplace.

I. Imposition of an "Any Willing Pharmacy" Requirement.

PBMs create closed networks of pharmacies (or "preferred networks") where plan beneficiaries receive discounts on medications. Some PBMs limit pharmacy participation in these networks, with certain PBMs limiting pharmacies' participation even when pharmacies are willing to meet network terms and conditions. APhA's community pharmacist members have repeatedly voiced concern about the substantial adverse impact of preferred networks on their businesses, patient access, and continuity of care. In some cases, pharmacists are forced to close pharmacy locations because they are shut out of the preferred network in a service area. When pharmacies close, patients lose access to health care through pharmacists and pharmacist-provided services. To ensure adequate patient access, PBMs should have to contract with any pharmacy willing to accept the PBM's contractual terms and conditions for network participation (referred to as the "any willing pharmacy" requirement).

Similarly, APhA supports the concept of reducing costs to patients through mechanisms as such preferred cost-sharing pharmacies ("PCSPs"). PBMs create sub-networks of PCSPs, whereby plans or PBMs contract with selected pharmacies to offer reduced or no cost-sharing for beneficiaries. While APhA supports the concept of reducing costs through PCSPs, we have concerns about this approach

when such arrangements are not offered to all pharmacies, or when the only PCSPs able to meet the terms and conditions for PCSP sub-network participation are pharmacies owned by the PBM.

II. Ensuring Patient Choice of Medication Delivery.

APhA understands the need to control health care and medication-related costs but believes that cost containment provisions, which may restrict patient choice or access, must be scrutinized to ensure they actually produce savings. For example, mail order delivery for prescriptions may be preferred for certain beneficiaries; however, such delivery may not be preferred or appropriate in all instances. And while prescription mail order delivery has been promoted and implemented to lower costs for patients and the system as a whole, in a recent report CMS noted that for certain plans and PBMs, mail order negotiated drug prices continue to outstrip the prices for the same drugs at retail pharmacies.[1] Again, APhA supports reasonable and appropriate cost-saving measures—provided such measures are data-driven and allow for patient choice.

It is important to note that some PBMs own their own mail order pharmacies, which may incentivize them to steer patients toward mail order delivery. CMS recently finalized a Part D requirement that allows plans and PBMs to automatically auto-ship new prescriptions without explicit beneficiary consent.[2] We have heard from members that many beneficiaries do not fully understand opt-out procedures for auto-ship programs (*e.g.*, that they can opt-out for one medication but continue to receive others via auto-ship), which effectively nullifies any ability to control delivery methods. This is particularly troubling for patients who prefer to have a face-to-face encounter with their pharmacists when receiving prescriptions, especially when receiving a new prescription. APhA is extremely supportive of identifying ways to provide convenient, cost-effective quality care to patients, but care and medication delivery method requirements and decisions should not be driven solely by business incentives.

III. Clarifying Pharmacy Costs for Participation in PBM Networks.

In addition to the restricted networks and delivery method issues discussed above, pharmacies also face rising, and often unpredictable, direct and indirect remuneration ("DIR") rates. PBMs set DIR fees, but are not required to provide detailed information to pharmacies regarding how the fees are calculated or how they will be imposed (and some are imposed retroactively on a monthly or quarterly basis, as "clawbacks," creating cash flow challenges). A number of our members are encountering increases in percentage fees for brand medications that result in the pharmacy returning more money to PBMs than the pharmacy actually receives for the medications. Pharmacies are seeing similar negative reimbursement for some generic medications as well. PBMs should be required to set reasonable thresholds for DIR fees so as not to limit pharmacy participation in PBM networks. Pharmacies simply do not have the margins to subsidize medications and despite a firm commitment to patient access, the financial realities associated with very high DIR may force many pharmacies to withdraw from networks, further constricting service accessibility in certain areas.

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[1] CMS, *Part D Claims Analysis*: *Negotiated Pricing Between General Mail Order and Retail Pharmacies* (Dec. 9, 2013) at p.2, *available at* https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/Downloads/Negotiated-Pricing-Between-General-Mail-Order-and-Retail-PharmaciesDec92013.pdf.

[2] CMS, *Announcement of Calendar Year (CY) 2016 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter* (Apr. 6, 2015), at p. 162, *available at* https://www.cms.gov/medicare/health-plans/medicareadvtgspecratestats/downloads/announcement2016.pdf.

As legislators are aware, changes continue to be made to health care in the United States, including incentivizing coordinated, patient-focused care delivery models and reimbursements tied to quality and outcomes. PBMs play an ever-increasing role in this new health care landscape, assuming responsibility for essential elements of care delivery systems including network creation and management, formulary decisions, and pricing. Because PBMs facilitate patients' access to medications as well as related education and counseling, healthy relationships between PBMs and pharmacies and other stakeholders are essential to effective care coordination—and to reaching quality, outcomes, and cost goals. Achieving these aims will require transparency and accountability from all stakeholders in the system. APhA believes that the reforms discussed above are important steps to appropriately integrating PBMs into value-based care models and effectively expending resources to benefit patients and the system as a whole.

Pharmacists hope to continue working closely with Congress, federal agencies, PBMs and other stakeholders to identify solutions that increase transparency and competition, while also enhancing patient outcomes and overall care quality. On behalf of pharmacists, we again thank the Committee for allowing us to comment on this important issue. As the Committee continues its work, we encourage you to use APhA as a resource.

Sincerely,

Thomas E. Menighan

Thomas E. Menighan, BSPharm, MBA, ScD (Hon), FAPhA
Executive Vice President and CEO

Testimony for the Record

Pharmaceutical Care Management Association

Before the

UNITED STATES HOUSE OF REPRESENTATIVES

JUDICIARY COMMITTEE

SUBCOMMITTEE ON REGULATORY REFORM, COMMERCIAL AND ANTITRUST LAW

"The State of Competition in the Pharmacy Benefit Manager and Pharmacy Marketplaces."

November 17, 2015

Introduction

The Pharmaceutical Care Management Association (PCMA) appreciates this opportunity to submit testimony for the record to the Subcommittee on Regulatory Reform, Commercial and Antitrust Law for this hearing examining the state of competition in the pharmacy benefit manager and pharmacy marketplaces. PCMA is the national association representing America's pharmacy benefit managers (PBMs), which administer prescription drug plans for more than 253 million Americans with health coverage provided through Fortune 500 employers, health insurers, labor unions, Medicare, Medicaid, the Federal Employees Health Benefits Program (FEHBP), and the Exchanges.

PBMs offer a wide variety of services aimed at making prescription drug benefit programs operate safely, efficiently, and affordably for their clients, including health plans, employers, unions and governments.

While many PBMs are independently owned and operated, some are subsidiaries of managed care plans, major chain drug stores or other retail outlets. PBMs compete to win business by offering their clients a range of sophisticated administrative and clinically based services, enabling them to manage drug spending by enhancing price competition and increasing the cost-effectiveness of medications.

All PBMs offer a core set of services to manage the cost and utilization of prescription drugs and improve the value of plan sponsors' drug benefits. Some offer additional tools, such as disease management, that can target specific clinical problems for intervention. It is up to the client of the PBM, however, to determine the extent to which these tools will be employed.

PBMs typically contract with retail pharmacies to form networks and bargain with the network pharmacies to set a rate at which the PBM will reimburse the pharmacy for each prescription that the pharmacy fills as a network provider. Most PBMs also operate, directly or through affiliates, their own mail-order, specialty drug and retail pharmacies, and negotiate directly with pharmaceutical manufacturers to purchase prescription drugs, which they use to fill prescriptions through these outlets. PBMs also take the lead role in helping patients adhere to their prescribed therapies to improve medical outcomes.

This testimony will outline the valuable services that PBMs perform to provide patients, employers, and governments at all levels with the highest value and best quality for prescription drug benefits. These include:

- Managing benefits;
- Competing in their own regulated marketplace;

- Leveraging market competition among manufacturers;
- Negotiating through a robust retail pharmacy market;
- Using specialty pharmacies for specialty drugs;
- Providing savings and convenience with mail-service pharmacies;
- Bringing efficiency through maximum allowable cost reimbursement; and
- Improving outcomes and value through medication therapy management.

Managing Benefits

It is important to note that PBMs do not make patient coverage decisions; rather, they provide their clients with various options for savings on prescription drug costs. PBMs advise their clients on ways to structure drug benefits to encourage the use of lower cost drug alternatives — such as generics — when appropriate. The PBMs' role is advisory only; the client retains responsibility for establishing the plan design. Plan sponsors themselves guide how actively pharmacy benefits are managed. For example, they determine formulary coverage, copayment tiers, utilization management, and pharmacy channel options. In addition, PBMs use a variety of tools such as drug utilization review and medication management to encourage the best clinical outcomes for patients. In making these choices, the plan sponsors weigh a multitude of factors, including cost, quality, and their employee/enrollee needs, and member satisfaction.

Competing in Their Own Regulated Marketplace

Critics have contended that the PBM marketplace is controlled largely by three entities. While there has been some industry consolidation in recent years, as the Federal Trade Commission (FTC) noted with respect to the merger of Express Scripts and Medco,

> *"nearly every other consideration weighs against an enforcement action to block the transaction. Our investigation revealed a competitive market for PBM services characterized by numerous, vigorous competitors who are expanding and winning business from traditional market leaders"*[i]

In addition, PBM activities are highly regulated. The following entities all provide oversight in some capacity:

- The Centers for Medicare and Medicaid Services (CMS) at HHS highly regulates the Medicare Part D program (see later discussion of pharmacy networks), including formularies and coverage;
- The Center for Consumer Information and Insurance Oversight (CCIIO) within CMS also regulate health care benefits, access, and competition in the exchange marketplace;
- State boards of pharmacy regulate PBM-owned mail-service and specialty pharmacies;

- The Department of Labor (DoL) regulates employer group health plan benefits;
- The Federal Trade Commission regulates market activity with respect to PBMs as well as retail pharmacy, mail-service and specialty marketplaces;
- The Food and Drug Administration(FDA) regulates compounding pharmacy manufacturing activity and record keeping;
- State Medicaid agencies regulate Medicaid managed care organizations and benefits;
- URAC and other private entities accredit mail order and specialty pharmacies;
- State departments of insurance regulate licensure, claims payment, quality, access, appeal, and contracting; and
- Office of the Inspector General of Health and Human Services has investigatory oversight authority.

Leveraging Market Competition among Manufacturers

PBMs aggregate the buying clout of millions of enrollees through their client health plans, enabling plan sponsors and individuals to obtain lower prices for their prescription drugs through price discounts from retail pharmacies, rebates from pharmaceutical manufacturers, and the efficiencies of mail-service pharmacies.

PBMs are able to extract savings from manufacturers directly through rebating. Commercial clients negotiate the proportion of rebate savings returned to the plan and the proportion used by the PBM in lieu of other fees to pay for their services. When passed through to clients, rebates reduce the cost that they pay for their prescription drug benefit. In Medicare Part D, these rebates must largely be passed back to the beneficiary or federal government through reduced premiums or other means.

The rebate amount is generally based on the market share a PBM can demonstrate it moved, through formulary and drug benefit design, to that drug. In these cases, the end or "net" price of a product to the client cannot be determined until after the end of the time period for the agreement and the resulting total sales volume is known.

This successful market-based approach of the PBM industry has been well noted. Recent events show that competition in the marketplace can drive significant savings on expensive drugs. Earlier this year it was reported that PBMs were able to negotiate a 46 percent discount with the manufacturer of one new hepatitis C drug—saving billions—when a direct competitor drug was introduced into the market. Indeed, while some PBMs preferred this drug in their formulary, competing PBMs opted to prefer a competing manufacturer, realizing equally large discounts. Other PBMs chose to keep both on their formulary, and ultimately, the market competition has allowed for this steep discount as compared with when each drug was originally introduced.

As the FTC noted with respect to the Express Scripts – Medco Merger in 2012, "[a]s a general matter, transactions that allow firms to reduce the costs of input products have a high likelihood of benefitting consumers, since lower costs create incentives to lower prices."[iii]

Negotiating through a Robust Retail Pharmacy Market

Some have argued that our industry forces patients to use mail-service pharmacy and uses arcane business tactics and reimbursement policies to drive small-town independent pharmacies out of business. In fact, almost all empirical data points to the contrary. The very question at hand before this Committee—whether business tactics employed by PBMs are anticompetitive and hurt consumers—can be answered with an emphatic no.

Over the past five years, the overall number of pharmacies operating in the United States has increased. While mail-service pharmacy market penetration has remained relatively stable, the number of chain, mass merchant, and grocery store-based pharmacies have increased significantly – often as a result of an independent pharmacy selling its book of business to (or reopening under the banner of) that larger retailer. In fact, the most recent publicly reported data shows that, that independent pharmacy gross margins average 23 percent.[iv] In addition, just over one in four (26 percent) pharmacy owners have ownership in two or more pharmacies.[v]

Finally, far from being at a contract negotiating disadvantage, independent pharmacies can pool their collective purchasing power to increase leverage. More than 80 percent of independent pharmacies (18,103 of the 21,511 pharmacies identified by National Council for Prescription Drug Programs (NCPDP) data) use third-party organizations known as pharmacy services administrative organizations (PSAOs) or group purchasing organizations (GPOs) to increase their leverage in negotiating their payment terms and conditions with PBMs. [vi] Collectively PSAOs and GPOs can have larger buying power than the largest retail chains and are typically owned by drug wholesalers—entities far larger than PBMs.

According to a January 2013 report of the Government Accountability Office (GAO), between 20,275 and 28,343 pharmacies – most of which were independent – were represented by PSAOs. The GAO found that PSAOs represented the buying power ranging from 4,883 independent pharmacies to as many as 12,080 total retail pharmacies represented by wholesalers.[vii] The majority of PSAOs were owned by either drug wholesalers or independent pharmacy cooperatives. Others were either stand-alone, or owned by private entities.[viii]

The GAO reports that PSAOs contract primarily on behalf of independent pharmacies and offer a wide range of services, including those for which PBMs are most often criticized by independent drugstores – to their independent pharmacy clients. These services include: claims assistance, audit assistance, centralized payment, certification in specialized care programs, compliance

support, flat generics (the ability to operate a program that offered generics for a flat fee), front-of-store layout assistance, inventory management, marketing support, reconciliation, and retail cash cards.[ix] Contract terms may also include payment arrangements, including reimbursement amounts and schedules.

Given the collective negotiating leverage that PSAOs bring to bear, it is difficult to argue that independent pharmacies lack the ability to negotiate with PBMs, or that they are faced with so-called "take-it-or-leave-it" contracts by PBMs.

Pharmacy Network Formation: PBMs harness competition among pharmacies to lower costs and encourage quality care by developing broad networks of pharmacies willing to accept discounted pricing in exchange for access to plan members. Retail pharmacies must compete to be part of the retail pharmacy network for a particular PBM or risk losing access to the consumer. Pharmacies enter into contracts with a PBM – either directly or through an aforementioned PSAO – to participate in the PBM's retail network and provide prescriptions to a plan's beneficiaries. A GAO study confirmed that PBMs reimburse pharmacies at levels below cash-paying customers, but above the pharmacies' estimated drug acquisition costs.[x]

For consumers with set copayments, their out-of-pocket costs and copayments are the same regardless of which pharmacy in the network dispenses the prescription. Therefore, network pharmacies compete on service, convenience, and quality to attract consumers within a particular plan.

However, PBMs are increasingly offering their clients and consumers a choice of more selective networks as a way to reduce costs further. PBMs use competition to get pharmacies to offer bigger discounts or a lower dispensing fee, and often higher quality, in exchange for an even higher volume of potential customers as a result of a more selective network. Plan sponsors must balance the access and availability of pharmacies against deeper discounts and more affordable coverage achieved by a smaller network.

Regardless whether they are preferred networks or the broader, widely inclusive pharmacy networks, PBMs use pharmacy networks not only to reduce costs through negotiation of lower rates and fees, but also to help guard against fraud, waste, and abuse. Approximately one percent of prescription drug costs result from fraud, waste, and abuse, including problems such as improper quantity, improper days' supply, improper coding, duplicative claims, irregular information, suspicious patterns over time, and other irregularities.

Part D Pharmacy Networks: Pharmacy network formation has been of considerable interest to policymakers recently in the Medicare Part D program. Starting in 2011, Medicare Part D plans started offering preferred cost sharing pharmacy options. According to the most recent CMS

data, the average Medicare Part D pharmacy network consists of 66,986 total pharmacies, and nationally, most PBMs contract with even more. Further, within Part D pharmacy networks, 14,380 pharmacies—20 percent of those in a Part D network—offered further discounts, or what CMS calls "preferred cost sharing."[xi]

CMS regulates the cost-sharing differentials in and beneficiary access to these plans with preferred cost sharing networks. Guidance in the Part D Pharmacy Benefit Manual explicitly states,

> *"A Part D sponsor may not establish a differential between cost-sharing at preferred versus non-preferred pharmacies that is so significant as to discourage enrollees in certain areas (rural areas or inner cities, for example) from enrolling in that Part D plan – even if it otherwise meets the retail access standards...A pharmacy network that effectively limits access in portions of a Part D sponsor's service areas in this manner would be discriminatory and disallowed..."*[xii]

Moreover, CMS's own data bear out that Part D sponsors and their PBM partners have saved beneficiaries and the Medicare program alike significant sums. CMS analyzed negotiated prices between preferred and non-preferred pharmacy networks in April of 2013. CMS's findings were that costs were in fact lower in preferred networks for the majority of sponsors with these networks, with savings ranging from 0.1 percent to as much as 24.3 percent lower. Specifically, CMS found:

- "Negotiated pricing for the top 25 brands and 25 generics in the Part D program at preferred retail pharmacies is lower than at non-preferred network pharmacies, according to CMS."
- Forty-nine out of 50 of the drugs examined by CMS had lower average negotiated prices at preferred pharmacies, with Lipitor—a unique case—being the one exception.
- On average, negotiated prices at preferred pharmacies, including mail-service pharmacies, were 3percent lower for brands and 11 percent lower for generics, according to CMS.[xiii]

The CMS analysis confirmed that negotiated prices at preferred pharmacies were lower on average than at non-preferred pharmacies. Indeed, government and beneficiary savings from preferred pharmacy network plans are likely even greater, as the government's analysis takes into account only part of the savings from these plans.

Medicare beneficiaries have overwhelmingly chosen to enroll in these typically lower-premium PDPs and are overwhelmingly satisfied. During this benefit year (2015), 81 percent of all beneficiaries enrolled in PDPs with preferred costs sharing options.

In 2014, the top five Medicare PDPs with the lowest average premiums all included preferred pharmacy networks. In addition, of all Part D plans with national or near-national status, seven of the top 10 with the lowest average premiums had preferred pharmacy networks.[xiv]

In addition, seniors are satisfied with their Part D coverage. A national poll conducted by Hart Research Associates shows that seniors in plans with preferred pharmacy networks are overwhelmingly satisfied, citing lower costs and convenient access to pharmacies, among other benefits. The survey revealed that 80 percent of those in preferred pharmacy plans—which translates to over 7 million seniors—would be very upset if their plan was no longer available.[xv]

Preventing Harmful Legislation Governing Part D Pharmacy Networks: One proposal before Congress, H.R. 793, would require that any Medicare Part D prescription drug plan that has preferred cost sharing pharmacies allow any pharmacy in a medically underserved area to be a preferred cost sharing pharmacy under the terms and conditions comparable to those the plan has agreed upon with other pharmacies located in the area. This would all but destroy any ability plans have to create a preferred cost sharing pharmacy network. If the existing preferred pharmacies could not rely on extra customers because the network included virtually every pharmacy, they will have no reason to agree to the extra discount to join the narrow preferred network.

H.R.793 would impose this pharmacy contracting policy in an area designated as a Health Professional Shortage Area (HPSA), which designates geographic areas facing shortages of many types of medical professionals – none of which are related to pharmacy. Nearly 95 percent of all Medicare Part D enrollees reside in counties meeting at least one of the "underserved area" criteria established in this legislation.

Much like provisions in the controversial proposed Medicare Part D Rule that was ultimately withdrawn by the Administration in March of 2014, H.R. 793 would effectively end Part D plans' ability to create preferred cost sharing pharmacies, threatening to eliminate popular Medicare Part D Plans for millions of Americans.

Eliminating preferred cost sharing pharmacies would raise beneficiary premiums and cost billions. According to the actuarial firm Oliver Wyman, eliminating preferred pharmacy networks in Part D would, over 10 years, result in an added $990 in premiums per affected enrollee, and an added cost to the government of approximately $24 billion.[xvi] Further, a Moran Company estimate of similar legislation, as introduced in the 113th Congress, would have increased federal mandatory spending by more than $21 billion over the next 10 years.[xvii]

A separate analysis conducted by Milliman finds that preferred pharmacy network plans were estimated to reduce federal Medicare spending by approximately $870 million in 2014, and by $7.9 billion to $9.3 billion in the subsequent 10 years.[xviii]

According to the Federal Trade Commission, under any willing pharmacy provisions, "beneficiaries who are willing to accept coverage under a plan with a narrow network of preferred pharmacies in exchange for lower costs may be deprived of that option." The commission went on to state that any willing pharmacy provisions "may threaten to harm competition and Medicare beneficiaries."[xix] That FTC analysis explains that "any willing provider and [freedom of choice (FOC)] laws can make it more difficult for health insurers, plans, or PBMs to negotiate discounts from providers, resulting in higher costs." The Commission has also expressed its concern that any willing provider and FOC provisions "may also reduce incentives for plans to invest in plan designs and complex negotiations with pharmacies and manufacturers." They conclude,

- Selective contracting with pharmacies and other health care providers can lower prices paid by plans and their beneficiaries; and
- Any willing provider and FOC laws tend to raise prices or spending because they impair the ability of Part D plan providers to engage in selective contracting.[xx]

Thus, the use of selective networking has proven to be one of the most important tools that PBMs have brought to bear to keep costs down. The value to employers and governments is clear, and the savings, access and choice provided to patients proven. Policymakers should encourage, not thwart, the formation of such networks.

Using Specialty Pharmacies for Specialty Drugs

The number and range of specialty drug and biologic products available to patients has increased dramatically in recent years. As a general rule, specialty drugs: treat more complex conditions requiring greater clinical oversight; may have more side effects requiring active clinical management; and involve more intense patient education. They are also typically very expensive—the highest priced specialty drugs can cost over $400,000 per patient per year. Thus, it is critical to help patients comply with their treatment regimens and ensure they are receiving the greatest value from their medications.

Payers are increasingly relying on specialty pharmacies to dispense these medications. Specialty pharmacies are distinct from retail pharmacies in that they coordinate the many aspects of care for people with complex and chronic conditions and provide robust offerings of clinical and operational specialty pharmacy services. These entities manage drug regimens for those with a complex, chronic condition, such as multiple sclerosis, hepatitis C, and rheumatoid arthritis; or a

rare medical condition, such as cystic fibrosis, hemophilia, or multiple myeloma. Using dedicated, specialized personnel, specialty pharmacy provides patient education and clinical support beyond traditional dispensing activities. Specialty pharmacies typically manage therapies where the drug is an oral, injectable, inhalable or infusible drug product with unique storage or shipment requirements, such as refrigeration.

Due to the high cost and rigorous storage, handling, and tracking requirements, traditional retail pharmacies are often not able to keep specialty drugs on hand in their inventory to dispense. Specialty pharmacies typically, upon conveyance of a prescription, contact the patient and provide the choice of delivery to their local pharmacy, physician's office, or home.

Specialty pharmacies offer a wide array of clinical services that a traditional brick-and-mortar pharmacy may not be able to offer. These include:

- Providing round-the-clock access to pharmacists, nurses and clinicians dedicated to and specially trained with respect to the disease state treated by the drug, the specialty drug, and the drug's potential side effects.
- Offering physician consultations to address patient side effects, adverse drug reactions, non-compliance, and other patient concerns.
- Performing disease-specific and drug-specific patient care management services that meet the unique needs of each patient and that incorporate multiple safeguards when dispensing and delivering the drug to ensure patient safety.
- Collecting data and tracking outcomes for specific patients as required.
- Managing compliance and persistency of drug regimens for patients.
- Managing care within manufacturer risk evaluation and mitigation strategies (REMS) program requirements, including REMS reporting, Phase IV trials, the dispensing of FDA trial drugs under strict protocols, and related clinical and cognitive counseling.

In addition, specialty pharmacies offer various operational services not typically associated with neighborhood pharmacies, including:

- Adhering to rigorous storage, shipping and handling standards to meet product label shipping requirements, such as temperature control, and timely deliveries of the product in optimal condition.
- Offering related services that may include coordinating services with other service providers, such as those providing skilled nursing or custodial care, delivery of infusion therapies, and direct-to-physician distribution.
- Expediting access to therapy by enrolling patients and resolving benefits questions and utilization management requirements, such as prior authorizations.

- Facilitating eligible patients' enrollment in patient assistance programs and access to charitable resources.
- Aligning economic incentives across medical and pharmacy benefits while helping patients navigate the complexity of sometimes siloed benefit structures.

Thus, specialty pharmacies have an advantage over traditional pharmacies by helping manage prescription drug costs and improving quality of care. Three key advantages are:[xxi]

- **Better Patient Outcomes**: Specialty pharmacies employ highly trained teams of patient care coordinators, pharmacists, nurses, and insurance specialists, all working toward helping patients take complex medications safely and effectively. Specialty pharmacy services significantly improve the quality of patient care relative to other distribution channels.
- **Lower Drug Costs**: Specialty pharmacies and coordinated benefit management strategies provide a savings advantage of seven to 12 percent relative to other distribution channels such as retail pharmacies and physician offices.
- **Lower Non-Drug Medical Costs**: Specialty pharmacy services reduce expenditures on hospitalizations and other medical costs through a range of patient-centered services that enhance patient adherence to drug therapies, including patient education, training and monitoring, nursing and supportive care, case management, and 24/7 pharmacy support.

Taken together, these advantages of specialty pharmacies will save an estimated $13.5 billion for consumers, employers, and other payers in 2015, and $251.5 billion over the 10-year period 2015-24, according to recent research.[xxii]

Such cost-saving innovations in the delivery of pharmacy benefits have become increasingly necessary in the face of current spending trends for specialty prescription drugs. Since 2006, the annual increase in spending for specialty drugs has been above 13 percent every year.[xxiii] Additionally, current projections show that drug spending is poised to increase dramatically, driven by the use of high-cost drugs[xxiv] Where specialty drug spending in the U.S. in pharmacy and medical benefits combined in 2014 was estimated to be $127 billion, it is projected to almost double to $235 billion in less than three years.[xxv] Moreover, by 2024, all health spending in the U.S. is expected to increase to 19.6 percent of GDP, driven in part by, "the sharp rise in prescription drug spending growth."[xxvi] We believe these projected trends will be difficult to sustain in the long term without PBMs continuing to use proven techniques and making advances in payment systems to continue to deliver the drugs Americans need.

Providing Savings and Convenience with Mail-Service Pharmacies

Mail-service pharmacies typically provide 90-day prescriptions for medications that consumers need on an ongoing basis. Local drugstores are used for new therapy starts and acute-care prescriptions. Consumers use mail-service pharmacies once they are stabilized on a medication, after having finished several 30-day prescriptions from their local drugstores.

Mail-service pharmacies are able to generate savings for consumers and payers by being vastly more efficient than brick-and-mortar drugstores. Through the use of computer-controlled quality processes, robotic dispensing machinery, and advanced workflow practices, mail-service pharmacies are able to fill large quantities of prescriptions while enhancing quality and reducing costs. This technology allows pharmacists to focus on clinical and cost management functions, rather than counting pills, printing instructions, and assembling prescriptions by hand as is done in drugstores. In addition, mail-service pharmacies offer patients private counseling over the phone from trained pharmacists seven days a week, 24-hours a day. According to a recent study, mail-service pharmacies will save an estimated $5.1 billion for consumers, employers, and other payers in 2015, and $59.6 billion over the 10-year period 2015-24.[xxvii]

Technologically advanced mail-service pharmacies achieve dispensing accuracy rates up to 23 times better than drugstores. Studies have found an error rate of nearly one in every 50 prescriptions (1.72 percent) filled at drugstores, compared to less than one in every 1,000 prescriptions (0.075 percent) at mail-service pharmacies.[xxviii] By being more accurate, mail-service pharmacies help ensure that patients get the correct drugs, dosages, and dosage forms, and thus avoid costly adverse drug events that can result in hospitalization.

Research has shown that use of mail-order pharmacies results in better adherence by patients. This improves health outcomes and often reduces non-drug medical costs, such as hospitalizations. Part of the reason mail-service pharmacy improves adherence is that patients receive their prescriptions in 90-day supplies, rather than 30-day supplies, which tends to reduce adherence problems.[xxix] Even after accounting for 90-day prescriptions, however, evidence suggests that mail-service pharmacy users achieve higher adherence rates than drugstore users.[xxx] Lower copays, home delivery, and refill reminder programs all likely play roles.

Research has also shown that use of mail-order pharmacies results in less waste. To minimize waste, mail-service pharmacies are typically used only once a patient is stable on a medication after having finished several 30-day prescriptions from their local drugstores. A 2011 study of patients taking statin medications found that on a yearly basis, four 90-day drug prescriptions through drugstores were associated with 4.04 days of waste, while four 90-day mail-service prescriptions were associated with 3.08 days of waste.[xxxi]

Moreover, the innovations in the PBM marketplace with respect to mail-service pharmacy have created consumer friendly innovations across pharmacy channels. For example, many retail

outlets – both chain and independent – now offer 90-day fills of chronic medications, and plans offer beneficiaries the option of having prescriptions filled at either mail or retail.

Mail-Service Pharmacy Value in Medicare Part D: PBMs' use of mail-order pharmacy also brings savings and convenience to Medicare Part D. In 2013, CMS examined the negotiated pricing between mail-service and retail pharmacies in Part D. In its analysis, CMS identified 57 plan sponsors offering prescription drug plans (PDPs) with mail-order benefits and examined claims data for the top 25 brand and top 25 generic drugs dispensed at both mail order and retail pharmacies.

CMS' data confirm that mail-service pharmacies offer a better deal than drugstores in Medicare Part D. Key points from the CMS analysis include:

- Overall costs at mail-service pharmacies were 16 percent less than retail pharmacies ($1.26 per pill at mail vs. $1.50 at retail) across all drugs.
- For generic drugs only, mail-service pharmacies were 13 percent less expensive than retail pharmacies ($0.21 per pill at mail vs. $0.24 at retail).[xxxii]

While it's clear in the data, the report summary fails to note the central point: because they are most efficient, mail-service pharmacies typically charge lower drug prices than drugstores. Regulators should remove barriers in Medicare that keep seniors from accessing home delivery. Removing Medicare's restrictions on home delivery and encouraging beneficiaries to get refills of maintenance medications by mail would also reduce hospital and physician costs by improving adherence to chronic medications.

Other detailed research on mail-service pharmacy conducted by federal agencies is equally compelling.

- At the request of Congress, the Federal Trade Commission was asked in 2002 to conduct a comprehensive inquiry into whether or not PBM ownership of mail-service pharmacies could result in a conflict of interest between the plan's interest and the PBM's incentive to dispense through their mail-service pharmacy in order to generate additional profits. The FTC resoundingly concluded that there was "strong evidence that in 2002 and 2003, PBMs' ownership of mail-order pharmacies generally did not disadvantage plan sponsors."[xxxiii]
- In January 2003, the GAO examined the value provide by PBMs participating in the federal employees' health plan. For prescription drugs dispensed through mail-service pharmacies, the average mail-order price was about 27 percent below the average cash price paid by consumers for brand name at a retail pharmacy and 53 percent below the average cash price paid for generic drugs.

- In July of 2013, the Department of Defense Inspector General audited the TRICARE Mail Order Pharmacy (TMOP) program at the request of congress to determine the efficiency and effectiveness of selected aspects of the TMOP program. The report concluded that "it was generally more cost efficient for beneficiaries to obtain pharmaceuticals through the TMOP program than through retail pharmacies. In addition, adequate controls in the TMOP program over dispensing pharmaceutical were in place." [xxxiv] The report found that for the third quarter FY 2012 alone, the $398.9 million spent on mail-order prescriptions would have cost $465.7 million through retail pharmacies – a result of 16.7 percent savings.

Thus, we believe it is clear that mail-service pharmacy is an important tool that saves money and provides tremendous convenience for those taking chronic and maintenance drugs. Its use should be encouraged—not discouraged—wherever possible and feasible.

Bringing Efficiency through Maximum Allowable Cost Reimbursement

Maximum allowable cost (MAC) is one of the most common methodologies used in paying pharmacies for dispensing generic drugs. By definition, MAC is the maximum allowable reimbursement by a PBM for a particular generic drug that is available from multiple manufacturers and sold at different prices. Each manufacturer has its own price for a particular generic drug and these prices can differ extensively by manufacturer. The use of MAC encourages competition: the purpose of MAC pricing is to encourage pharmacies to obtain the lowest-cost generic from among identical products from various manufacturers.

A MAC list is a common cost management tool that is developed from a survey of wholesale prices existing in the marketplace, taking into account market share, existing inventory, expected inventories, reasonable profits margins and other factors. Each PBM develops and maintains its own confidential MAC list derived from its specific proprietary methodology. Again, the purpose of a MAC list is to incentivize pharmacies to negotiate more competitive rates for generic drugs with manufacturers and wholesalers in order to keep overall prices down.

PBMs use MAC lists to balance providing fair compensation to pharmacies with being able to provide a cost-effective drug benefit plan to their health plan and employer clients. MAC pricing has become the industry standard—it is used by 79 percent of private employer prescription drug plans for retail generic prescriptions. In addition, 45 state Medicaid programs now use MAC lists. States adopted MAC lists after government audits showed that Medicaid reimbursements based on cost-plus reimbursement for generic drugs far exceeded a pharmacy's acquisition costs.

The reason MAC lists are such effective tools is that generic drugs often have a wide range of manufacturer list prices, including variations by strength and dose, and the MAC prices reconcile

the differences between an inflated list price and the price the pharmacy actually pays for the drug. A MAC list standardizes the reimbursement amount for identical products, regardless of each manufacturer's list price. It prevents pharmacies from earning extraordinary profits from dispensing generics. Without the MAC list, pharmacies could negotiate to acquire the drugs at a substantial discount from a manufacturer's list price but be reimbursed based on the manufacturer-published price. With the MAC lists, the pharmacies are always motivated to seek and purchase generic drugs at the lowest price in the marketplace. Thus, MAC lists are intended to prohibit pharmacies from inflating drug prices.

Because manufacturer list prices for generics change frequently, the MAC lists need to be updated frequently. How often this happens is determined by the contracts between the PBM and its client and the PBM and the pharmacy, or it is regulated for government programs such as Medicare Part D, which requires updates at least every seven days. Typically, prices for generics fall over time, so MAC prices are updated to reflect the falling prices and ensure that consumers are not overpaying for generics. They are also adjusted when manufacturers raise prices so that pharmacies are fairly paid.

Government findings confirm the effectiveness of MAC pricing. An August 2013 report of the HHS Office of the Inspector General looked at the effectiveness of MAC in containing Medicaid drug costs. The report stated,

> *"Our findings demonstrate the significant value MAC programs have in containing Medicaid drug costs. To maximize Medicaid drug cost-containment strategies, we recommend that CMS encourage states to reevaluate their MAC programs to identify additional cost-saving opportunities....CMS concurred with (the OIG) recommendations. CMS plans to release an informational bulletin that encourages states to reevaluate their MAC programs for cost-saving opportunities in the near future."*[xxxv]

In fact, the OIG found that the State of Wyoming's Medicaid MAC program produced the greatest savings, and that "39 of 45 States would have saved $483 million in the first half of 2011 had they used Wyoming's MAC program."[xxxvi]

Preventing Harmful Legislation on MAC Pricing: The MAC Transparency Act" (H.R. 244) would increase costs for government and Medicare Part D, TRICARE, and FEHBP enrollees alike, by tying the hands of plan sponsors trying to restrain the costs of prescription drugs. Specifically, the legislation would require that plans disclose their pricing methodologies and reward inefficient pharmacies by removing incentives for them to operate and purchase more effectively for patients enrolled in Federal programs. The bill would increase the cost of drugs solely to benefit pharmacies.

The legislation also stands in direct conflict with existing Medicare law. By statute, "to promote competition" in Part D, the government "may not interfere with the negotiations between drug manufacturers and pharmacies and PDP sponsors...." H.R. 244 would require CMS to enforce provisions governing the private negotiations between sponsors and pharmacies, including the widely used MAC pricing tool.

A January 2015 report by Visante, found that legislation prohibiting the use of MAC pricing in both the public and private sector could increase costs of affected generic prescriptions by 31 percent to 56 percent, resulting in expenditures on generic prescriptions increasing by up to $6.2 billion annually.[xxxvii]

In addition, concerns that supporters of the legislation may express over inadequate notifying of pharmacies of MAC lists are misplaced. Federal law requires disclosure of updated MAC prices to pharmacies in the Part D program. The law states that,

> *"[i]f the PDP sponsor of a prescription drug plan uses a standard for reimbursement of pharmacies based on the cost of a drug, each contract entered into with such sponsor under this part with respect to the plan shall provide that the sponsor shall update such standard not less frequently than once every 7 days, beginning with an initial update on January 1 of each year, to accurately reflect the market price of acquiring the drug."*[xxxviii]

CMS issued guidance implementing this part of the statute, which will take effect on January 1, 2016.

It is also important to note that the prescription drug reimbursement in a MAC system is a two-way street for both pharmacies and PBMs. Just as acquisition prices may increase before a plan has the opportunity to increase its reimbursement, when a drug price falls, that same lag also can apply to a higher pharmacy reimbursement. The frequency of MAC price updating may also be among the terms and conditions included among the contract terms between a pharmacy and individual PBMs.

Improving Outcomes through Medication Therapy Management (MTM)

Drug therapy is critical to helping patients manage their chronic conditions. However, many patients need help to remember to take their medications or can benefit from better coordination of their drug therapy. Plan sponsors and others are increasingly employing MTM in an attempt to improve enrollee outcomes by targeting interventions for enrollees with specific conditions whom evidence shows can benefit from drug therapy. In fact, PBMs today are focusing much of their innovative efforts on ways to drive adherence to prescribed therapies. When well targeted

to appropriate enrollees, these services provide the opportunity to improve medication use and to reduce the risk of adverse events, at an overall savings to the health system.

Our companies find that MTM works best when used with predictive analytics to identify individual patients who are most at risk for overuse or underuse of drugs, or whose drug therapy regimens could otherwise be improved. In particular, studies suggest that MTM is most effective for patients with targeted needs (for example, patients recently discharged from hospitals or long-term care facilities), where services are designed for the specific needs of the patients, and the focus is on MTM outcomes rather than process documentation.

PCMA strongly supports CMS' recently announced Medicare Part D Enhanced Medication Therapy Management Model Test. We strongly support its implementation and urge Congress to do the same. This Part D Enhanced MTM Model (Model) is designed to test changes to the Part D program that would achieve better alignment of PDP sponsor and government financial interests, while also creating incentives for robust investment and innovation in better MTM targeting and interventions. CMS anticipates the Model will begin on January 1, 2017. The proposed duration of the initial Model test performance period is five years, from CY 2017 through CY 2021.

As we understand it, the Model was carefully constructed by experts at CMS over a multi-year period and incorporates input from myriad stakeholders who have been performing Part D MTM activities. For our own part, PCMA has encouraged CMS for several years to test MTM models that would:

- Target MTM services on high-risk beneficiaries most likely to benefit from such interventions;
- Provide financial incentives for plans to offer and beneficiaries to participate in expanded MTM services;
- Recognize expenditures for expanded MTM services as quality improving activities for purposes of medical loss ratio (MLR) reporting requirements;
- Offer greater flexibility in MTM benefit design and the range of services;
- Focus on clinical outcomes rather than process measures such as medication counts or completed CMRs;
- Provide access to Parts A and B beneficiary data, including alignment with ACOs, for stand-alone PDPs; and
- Allow sufficient time for a range of MTM projects to be assessed before concluding a MTM Model program.

We believe the Model as proposed by CMS meets these principles and we look forward to its implementation. In time, we think the Model and similar initiatives that target patients who may

be at risk for poor outcomes resulting from complications, contraindications, or non-adherence will provide evidence of the best ways to improve drug therapy to help patients manage their conditions. As this evidence is disseminated across the health system, PBMs will work with pharmacists, physicians, patients, clinicians, plan sponsors, and other stakeholders to incorporate what is learned into best practices for MTM with the aim of increasing adherence, improving health outcomes, and lowering costs.

Conclusion

PBMs exist because they increase the value of prescription drug benefits, They rely on market forces and competition to deliver high-quality benefits and services to their health plan clients and enrollees. We urge the Subcommittee to pursue policies that foster and encourage competition to keep prescription drug costs and pharmacy benefits more affordable for employers, enrollees, taxpayers and government programs. By contracting with PBMs who use proven prescription drug management strategies, benefit sponsors realize significant savings and their enrollees are provided wide access to medications and pharmacies at more affordable prices.

PCMA looks forward to working with the Congress to find additional ways to promote savings while continuing to deliver the highest quality, highest value prescription drug benefits for all.

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