

**THE PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION’S PUBLIC COMMENTS IN
RESPONSE TO THE FEDERAL TRADE COMMISSION’S SOLICITATION FOR PUBLIC COMMENTS
ON THE BUSINESS PRACTICES OF PHARMACY BENEFIT MANAGERS AND THEIR IMPACT ON
INDEPENDENT PHARMACIES AND CONSUMERS ISSUED ON FEBRUARY 24, 2022.**

The Pharmaceutical Care Management Association (PCMA) thanks the Federal Trade Commission (FTC) for this opportunity to address the critically important role served by Pharmacy Benefit Managers (PBMs), and their pro-competitive impact on patients, physicians, employers, independent and chain pharmacies, and other businesses across the pharmaceutical distribution and payment system. PBMs are the only entities in the pharmaceutical supply and payment chain whose mission is to help health plans and consumers reduce their prescription drug costs. PBMs are incentivized and committed to reducing drug costs for all consumers.

PCMA recognizes that there may be many misunderstandings or misperceptions regarding PBMs’ business practices and hopes that the comments provided below are clarifying and informative to the FTC and the general public. On multiple prior occasions, the FTC has examined the PBM industry, whether at the request of Congress, in reviewing mergers or when commenting on proposed state laws that would have restrained competition, and, in each instance, the FTC has determined that PBMs have a pro-competitive influence and their services provide a significant and measurable benefit to consumers. PCMA expects that this solicitation for public comments is once again a fair opportunity for the industry to provide data and information that will update the FTC’s and other stakeholders’ understandings of the role that PBMs play in driving down prescription drug costs. PCMA looks forward to having a

conversation about the benefits that PBMs provide consumers and hopes that this will be the beginning of a larger process designed to identify and evaluate the root causes and impacts of rising drug prices.

PCMA is the national association representing America's PBMs. PCMA's members include PBMs that administer prescription drug plans for more than 266 million Americans who have health insurance through a variety of sponsors, including Medicare Part D plans, the Federal Employees Health Benefits Program (FEHBP), state government employee plans, managed Medicaid plans, self-insured employer plans, union plans, commercial health plans, and others. Nearly all health plans (both government-funded and commercial) and employer and union sponsors choose to utilize PBM services to control drug spend and to facilitate prescription drug coverage and access for the plan members. However, each PBM is unique both in terms of corporate structure and business strategy, and PCMA's comments should not be misunderstood to indicate that all PBM practices are uniform. PCMA can only provide a generalized explanation of PBMs that may not accurately describe all possible activities and marketplaces.

1. What is the role of PBMs in minimizing costs in the supply chain for prescription drugs?

PBMs exist in large part to bring drug prices down to provide affordable access for the drugs patients need at the lowest net cost. Without PBMs in the marketplace, consumers, health plans and plan sponsors would be left to negotiate prices on their own or pay the full costs of these drugs.

Many efficiencies benefiting consumers are achieved by PBMs performing essential functions related to managing prescription drug benefits, including negotiating drug prices with

pharmaceutical manufacturers and retail pharmacies, establishing a network of pharmacies to fill prescriptions, developing clinically appropriate formularies, and processing and paying claims for prescriptions. PBMs can achieve economies of scale that benefit consumers, and PBM services allow health plans and plan sponsors to avoid expending the significant resources needed to manage prescription drug benefits reliably and efficiently. By one independent estimate, PBMs help health plans and consumers save 40%-50% on their annual drug and related medical costs compared to what they would have spent without PBMs.¹

PBMs offer health plans and plan sponsors a variety of services and programs in addition to handling claims processing for prescription drug benefits to contain and lower costs to both the health plans and the consumers they serve, including, amongst others:

- a. *Encouraging Generics and Less Expensive Brands.* PBMs incentivize dispensing of generics and less expensive brand-name medications, including through formularies, which are lists of prescription drugs that are clinically reviewed and approved by the PBM's pharmacy and therapeutics (P&T) committee and are covered by a health plan. PBMs also incentivize cost-effective prescribing of prescription drugs, including through tiered cost sharing, prior authorization and step therapy protocols, generic incentive programs, consumer education, and physician outreach, all designed to drive down pharmaceutical costs for consumers.

¹ *The Return on Investment (ROI) on PBM Services*, VISANTE (Feb. 2020), https://www.pcmanet.org/wp-content/uploads/2020/02/ROI-on-PBM-Services-FINAL_.pdf (last visited Mar. 24, 2022).

- b. *Implementing Programs to Improve Adherence.* Many PBMs implement patient adherence programs to assist patients in complying with their prescription regimens. PBMs also conduct drug utilization reviews to reduce waste and encourage appropriate medication use. Both programs improve clinical outcomes, which helps lower overall health care expenditures.
- c. *Alternative Options for Delivering Drug Therapy to Patients.* In coordination with drug utilization reviews and patient adherence programs, PBMs also provide innovative, alternative ways to ensure that prescription drugs make it into the hands of patients. Through the increased use of mail-order pharmacies and specialty pharmacy management programs, PBMs are able to reduce costs and increase accessibility.
- d. *Improving Quality and Safety.* PBMs promote the use of technology and infometrics to improve quality and safety by monitoring for, and preventing, adverse drug events, drug duplication and possible toxic interactions between drugs.
- e. *Designing Alternative Compensation Structures.* In response to the varied needs and incentives of health plans and plan sponsors, PBMs have sought to distinguish themselves by offering a variety of different compensation structures. While some health plans and plan sponsors may prefer to compensate PBMs on a per-claim or per-enrollee basis, others prefer to compensate PBMs by allowing them to retain a portion of the cost savings they achieve. Competition amongst

PBMs has led them to offer health plans and plan sponsors the flexibility to choose the model that best fits the plans' or the sponsors' own needs.

A. Typical Prescription Drug Payment Structure

In a typical transaction, a wholesaler acquires a drug from the manufacturer at the list price, possibly with a discount negotiated between the wholesaler and the manufacturer. The wholesaler then sells the drug to the pharmacy at a rate negotiated between the wholesaler and the pharmacy, which may include a discount off the wholesaler's list price. A pharmacy services administrative organization (or PSAO), which provides back-office support for pharmacies, including remittance collection and reconciliation, may also be involved in the negotiation or sourcing of a wholesaler. A recent study found that at least four out of five independent pharmacies are represented in their negotiations with PBMs by PSAOs, which leverage their scale to negotiate contracts on behalf of independent pharmacies.² Over 75% of independent and small chain pharmacies contract with PSAOs owned by the "Big Three" wholesalers (Amerisource Bergen, Cardinal Health, and McKesson).³

When a consumer with health insurance that includes a pharmacy benefit uses that insurance and purchases a prescription drug from the pharmacy, the pharmacy dispenses the drug pursuant to the terms of a contract between the pharmacy and the consumer's PBM, at a rate negotiated in advance and typically tied to the manufacturer's list price. The pharmacy collects the consumer's deductible, co-pay (a set dollar amount) or co-insurance (a percentage of the

² *Pharmacy Services Administrative Organizations (PSAOs) and Their Little-Known Connections to Independent Pharmacies*, HEALTH EVALUATIONS (Jan. 2021), <https://www.pcmnet.org/research-pharmacy-services-administrative-organizations-psaos-and-their-little-known-connections-to-independent-pharmacies/> (last visited May 19, 2022).

³ *Id.*

pharmacy's negotiated rate for the drug) from the consumer and the PBM reimburses the pharmacy according to the terms of the contract between the PBM and the pharmacy. Finally, the health plan reimburses the PBM for the drug pursuant to its contract with the PBM. PBMs thus facilitate and help manage the pharmacy benefit, ensuring network pharmacies are paid for drugs dispensed to consumers on their behalf.

Separate from the process described above, PBMs are able to negotiate lower net costs for brand prescription drugs through rebates from manufacturers. Rebates have been a part of the prescription drug supply chain in some form or another for about 30 years. In the past, most manufacturers offered upfront discounts on their products in exchange for promises of greater volume and formulary access. However, this paradigm began to shift in the 1990s. A legal settlement from a 1994 lawsuit between pharmacies and many of the largest drug wholesalers and manufacturers ensured that manufacturers could no longer refuse to provide discounts on products based solely on the buying entity, and that pharmacies are entitled to the same types of discounts made available to other entities. As a result of this settlement, as well as the Anti-Kickback Statute safe harbor amendments and regulations, manufacturers began imposing the current system of retrospective rebates pursuant to which rebate amounts are conditioned on demonstrated volume.

In practice today, manufacturers pay negotiated rebates to PBMs on a periodic, predetermined basis—for the branded drugs that were dispensed to the consumers covered by the PBMs based on an agreement negotiated in advance between the manufacturer and the PBM. PBM-health plan contracts specify how the health plan will share in any rebates or discounts the PBM obtains from pharmaceutical manufacturers, but typically, the PBMs pass the manufacturer

rebates on to the health plans. PBMs do not dictate to health plans or plan sponsors which drugs are covered or how passed-through rebates are used. In certain contexts, health plans and plan sponsors may allow PBMs to retain a portion of rebates, as negotiated by contract with the plan, to compensate for the PBM's services, or plans may alternatively choose to pay PBMs fees separately on a per-claim or per-enrollee basis.

Manufacturers only offer rebates on branded drugs and are typically compelled to offer larger rebates on drugs that face competition from other therapeutically similar or equivalent products. In the absence of competing drug alternatives, manufacturers often offer only minimal rebates, if any at all. Consistent with treatment protocols, PBMs bargain with manufacturers for larger rebates on a drug in exchange for preferred placement of that drug in a plan's formulary (or list of covered drugs). These negotiations may also include stronger restrictions on—or exclusion of—competing therapeutic alternatives as well as “price protection” rebates that protect consumers, health plans and PBMs against price increases. For drugs in the preferred tier of a plan's formulary, plan enrollees typically have a lower copayment or coinsurance rate.⁴

The availability of therapeutic alternatives or substitutes (including alternative branded drugs, generics, and biosimilars) provides PBMs with the ability to negotiate lower prices on behalf of their clients' plans and their members. When alternatives are limited, such as when a new drug is the first to treat a particular condition or manufacturers have used patent law to extend their exclusivity periods, then PBMs have limited ability to negotiate lower prices. As competing drugs enter the market, PBMs gain the flexibility to prefer a lower-cost alternative to

⁴ *Prescription Drugs: Spending, Use, and Prices*, CONG. BUDGET OFF. at 7 (Jan. 19, 2020), <https://www.cbo.gov/system/files/2022-01/57050-Rx-Spending.pdf> (last visited Mar. 24, 2022).

a given drug or to manage utilization of competing drugs through utilization management tools designed to increase use of alternatives that may be associated with lower costs, higher efficacy, or better safety profiles.⁵

2. How do PBMs design formularies on behalf of health plans?

Many health plans, such as those sponsored by employers or labor unions, commercial insurers, Medicare Part D plans, and Medicaid Managed Care plans, outsource the management of their pharmacy benefits to PBMs, but the sponsors ultimately retain authority over the benefits with respect to the services for which PBMs are contracted. Often, plan sponsors elect to use a PBM's standard formulary, which has been developed under the guidance of their P&T committee, to use clinically driven prescription drug cost-management programs designed to deliver high-quality drug benefits while targeting unnecessary costs.⁶ PBMs offer various design models and compensation terms, depending on plan sponsors' specific needs. PCMA can only provide a generalized explanation of the process that may not accurately describe all of the possible structures.

PBMs offer two key functions that are essential to sustainable drug costs for health plans: formulary management programs and clinical utilization management. Together, these programs ensure patient access to clinically appropriate medications while managing utilization to reduce wasteful spending. It is, however, ultimately the health plan's decision about how it wants to design its drug benefit plan, and health plans can choose how and whether to use these tools.

⁵ *Id.*

⁶ *2017 Trends in Specialty Drug Benefits*, PHARM. BENEFIT MGMT. INST. (2017), www.pbmi.com/research; *2016 Trends in Drug Benefit Design*, PHARM. BENEFIT MGMT. INST. (2016), www.pbmi.com/research.

A. *Formulary Management Programs*

A formulary is a regularly updated list of prescription drugs approved for reimbursement by the PBM's clients. PBMs typically develop one or more basic formularies and recommend appropriate formularies to health plans and plan sponsors, who often customize their formulary or develop their own.⁷ The purpose of drug formularies is to encourage the use of safe, effective, and the most affordable medications. Drug formularies are not static. Rather, they are developed and regularly reviewed and updated by a team of healthcare specialists known as the P&T committee, and then by the PBM itself.⁸ The first and most important component is clinical safety and efficacy, and choosing drugs with evidence of highest comparative effectiveness, which is the primary responsibility of the P&T committee.⁹

PBMs rely on P&T committees, which are panels of experts typically made up of independent physicians, pharmacists, and individuals with other appropriate clinical expertise from multiple key disciplines, to determine the most clinically appropriate drugs for a given illness or condition. While PBMs manage their formulary development process independently, it is generally the case that the majority of P&T committee members are independent of the PBM and the P&T committees work independently. The PBMs also exclude from the committees

⁷ *The Management of Specialty Drugs*, sPCMA at 9 (June 2016), https://www.spcma.org/wp-content/uploads/2016/06/sPCMA_The_Management_of_Specialty_Drugs.pdf (last visited Mar. 24, 2022).

⁸ *Formulary Manufacturer Contracting*, ACAD. OF MANAGED CARE PHARM. (Feb. 2015) <https://www.amcp.org/sites/default/files/2019-06/Formulary%20Manufacturer%20Contracting%20-%202015%20%281%29.ppt> (last visited Mar. 24, 2022). Academy of Managed Care Pharmacy (AMCP). *Formulary Manufacturer Contracting*. February 2015.

⁹ Richard Alan Brook, et al., RA, Carlisle JA, Mehr SR, Sneeding JE. *The US Payor Landscape: Results from a Survey of Medical Directors and Pharmacy Directors on Comparative-Effectiveness Research*, J. OF PHARM. & PHARMACOLOGY 2, 432 (2014), https://www.researchgate.net/publication/267923794_The_US_Payor_Landscape_Results_from_a_Survey_of_Medical_Directors_and_Pharmacy_Directors_on_Comparative-Effectiveness_Research (last visited Mar. 24, 2022).

those with close ties to manufacturers to shield the deliberations from undue outside influence. The P&T committees help create formularies that include the most clinically sound prescription drugs by evaluating the latest and most authoritative clinical and medical literature and other evidence, and then determine whether each medication under review “must be,” “must not be,” or “may be” added to a formulary.¹⁰ Typically, P&T committees consider only clinical factors in their recommendations to PBMs and cost or business considerations are handled outside the P&T committee process.¹¹

While PBMs automatically accept the P&T committees’ “must include” or “must not include” recommendations, “may be included” drugs are typically drugs that are therapeutically equivalent to others, which enables PBMs to then use competition to negotiate greater price concessions from manufacturers.

P&T committees also serve very important medication safety functions such as reviews of new drugs that uncover any safety concerns, and periodic literature reviews for potential safety or efficacy issues with existing drugs. These reviews are critical. One recent study found that 32% of novel drugs approved by the Food and Drug Administration (FDA) had safety risks only discovered after the drug was approved and on the market.¹²

¹⁰ Martha Runmore, et al., Rumore MM, Vogenberg FR. *PBM P&T Practices: The HEAT Initiative Is Gaining Momentum*, 42 PHARM. & THERAPEUTICS 5, 330 (May 2017), http://www.pbmwatch.com/uploads/8/2/7/8/8278205/pbms_heat_article.pdf (last visited Mar. 24, 2022).

¹¹ *P&T Committee*, ACAD. OF MANAGED CARE PHARM. (Feb. 1, 2016), <https://www.amcp.org/Resource-Center/formulary-utilization-management/pt-committee>. Academy of Managed Care Pharmacy (AMCP). (2016, Feb 1). P & T Committee. February 2016. <https://www.amcp.org/Resource-Center/formulary-utilization-management/ptcommittee>.

¹² Nicholas Downing, et al., Downing NS, Shah ND, Aminawung JA, Pease AM, Zeitoun J, Krumholz HM, Ross JS. *Postmarket Safety Events Among Novel Therapeutics Approved by the US Food and Drug Administration Between 2001 and 2010*, 317 J. OF THE AM. MED. ASS’N 18, 1854, 1863 (May 9, 2017), <https://jamanetwork.com/journals/jama/fullarticle/2625319> (last visited Mar. 24, 2022).

Drug formularies are an important tool used by PBMs, health plans and health plan sponsors not just to manage specialty and other high-cost drugs, but also to give patients financial incentives to use generic drugs when therapeutically appropriate and available. It is ultimately up to the PBMs' clients to decide, based on the needs of their enrollees, the exact formulary that will be used in conjunction with their benefit plans, as well as the specific techniques that will be applied to encourage formulary compliance. The most effective tool for achieving formulary compliance is a benefit structure or plan design where preferred drugs, including generics, have lower enrollee cost sharing.¹³ Drugs that do not provide sufficient clinical efficacy or value are not given preference on formularies. Typically, in categories with multiple clinically equivalent therapies, PBMs recommend that drugs with the lowest net cost (final cost after all discounts and rebates) be placed on a formulary tier with lower cost-sharing than those with a higher net cost. PBM-recommended tiered formularies, combined with health plan-determined tiered cost-sharing, have resulted in 90% of prescriptions being filled with generics.¹⁴

B. Clinical Utilization Management Programs

To ensure that patients and plan sponsors receive value from brand, specialty and other high-cost drugs, PBMs work with P&T committees and specialty pharmacies to create programs that provide prescribers and patients with evidence-based care, efficient medication delivery, clinical outcomes monitoring, and reduced costs.

¹³ *What is a formulary?*, sPCMA. (2016), Retrieved: <http://spcma.org/component/knowledge/?stack=188>.

¹⁴ Murray Aitken & Michael Kleinrock, *Medicine Use and Spending in the U.S.: A Review of 2018 and Outlook to 2032*, IQVIA INST. at 12 (May 2019), <https://www.mass.gov/doc/medicine-use-and-spending-in-the-us-a-review-of-2018-and-outlook-to-2023/download#:~:text=The%20base%20case%20scenario%20for,over%20the%20past%20five%20years> (last visited Mar. 24, 2022).

PBM clinical utilization management program tools have been used over the last two decades to control traditional and specialty drug trends and assure safe and efficient medication utilization. These tools include drug utilization review, prior authorization, step therapy, pharmacy network design, and site-of-care management programs. Innovative strategies such as the use of genomic and other advanced molecular diagnostics are also enabling PBMs to facilitate targeted and cost-effective drug therapies for patients.¹⁵

Prescription drug utilization management programs, such as step therapy and prior authorization, are important clinical tools to help ensure that patients receive medication that is safe and effective for their condition, limit off-label use of medications, promote adherence to guidelines when they are available, and reduce costs.¹⁶ In a review of available literature, the Government Accountability Office (GAO) found that utilization management tools were associated with improved health indicators and financial savings.¹⁷

Prior authorization is an administrative requirement that a physician must obtain from the insurer when prescribing certain drugs to ensure that the cost will be reimbursed. Prior authorization may require documentation, as recognized in peer-reviewed literature, that the patient has the FDA-approved indication and possibly meets narrower requirements. Often used

¹⁵ *PBMs Provide Clinical Value to Patients, Doctors and Other Healthcare Providers*, PHARM. CARE MGMT. ASS'N at 4 (Apr. 2017), https://www.pcmagnet.org/wp-content/uploads/2017/04/PBMs-Provide-Clinical-Value-to-Patients-Doctors-and-Other-Healthcare-Providers_whitepaper_final-1.pdf (last visited Mar. 24, 2022).

¹⁶ C.I. Starmer et al., *Rosiglitazone Prior Authorization Safety Policy: A Cohort Study*. J MANAG CARE SPEC PHARM. (2012), 18(3):25-233; S. Jacob et al., *Economic Outcomes Associated with Safety Interventions by a Pharmacist-Adjudicated Prior Authorization Consult Service*. J. MANAG CARE SPEC PHARM. (2019), 25(3):411-416; P.P. Gleason et al., *Dalfampridine Prior Authorization Program: A Cohort Study*. J MANAG SPEC PHARM. (2013), 19(1):18-25.

¹⁷ *Medicare Part D: Use of Pharmacy Benefit Managers and Efforts to Manage Drug Expenditures and Utilization (GAO-19-498)*, U.S. GOV'T ACCT. OFF. at 26 (July 2019), <https://www.gao.gov/assets/gao-19-498.pdf> (last visited Mar. 24, 2022).

in conjunction with prior authorization, step therapy is used to control costs and improve patient safety by requiring them to try one or more first-line therapies for a given condition (*i.e.*, “steps”), and only move to a higher-line therapeutic alternative if the patient does not respond or experiences side effects.¹⁸

3. How do PBMs help consumers minimize drug prices?

PBMs are at the table on behalf of plan sponsors and consumers to negotiate lower prescription drug prices. PBMs have served as innovators by using a variety of sophisticated tools and strategies to drive down drug costs. This includes negotiating for manufacturer rebates and pharmacy discounts, working with plans to encourage consumers to use lower-cost branded drugs, generics, and biosimilars when available, reducing inappropriate or over-utilization, avoiding duplicative or contraindicated prescriptions pharmacies might not detect, and improving patient adherence to prescriptions.¹⁹ For every dollar health plan sponsors and consumers spend on PBMs for these purposes, the PBMs return \$10 in savings.²⁰

PBMs’ savings directly benefit consumers. On average, each American fills more than 12 prescriptions per year and PBMs, on behalf of the consumers they serve, are able to lower the costs of those prescription drugs by \$962 annually.²¹ The overall health system (*i.e.*, health plans, employer sponsored plans, and consumers) currently pays approximately \$1,315 per

¹⁸ M.A. Fischer & J. Avorn, *Step therapy – clinical algorithms, legislation, and optimal prescribing*. JAMA. (2017), 317(8):801-802.

¹⁹ *The Return on Investment (ROI) on PBM Services*, VISANTE at 4 (Feb. 2020), https://www.pcmamet.org/wp-content/uploads/2020/02/ROI-on-PBM-Services-FINAL_.pdf (last visited Mar. 24, 2022).

²⁰ *Id.* at 9.

²¹ *Id.* at 6.

person per year for those prescriptions.²² Of the \$1,315 net cost per year, consumers pay \$180, or less than 14%, of the total.²³ Without PBMs and the savings they generate, costs could be as high as \$2,277 per person per year.²⁴

A. Rebates

One of the ways that PBMs are able to lower those costs is through negotiating rebates with drug manufacturers. Drug manufacturers set the launch prices of their own products and raise the prices on brand drugs regularly. But when drugs are therapeutically equivalent to—or otherwise competitive with—products already on the market, PBMs can use competition to combat high drug prices. When there is competition for drugs, PBMs can drive drug manufacturers to negotiate rebates from the list price they initially set to incentivize favorable formulary placement and utilization management rules by PBMs and plans.²⁵ As PCMA shared with the Office of Inspector General (OIG) in a 2018 comment letter, PBMs are able to harness competition to negotiate lower drug costs, and rebate levels are based on the current competitive market conditions, and are not correlated with launch prices or price increases.²⁶ PBMs, relying on the determinations of the P&T committees, are able to negotiate better pricing and rebates and

²² *Id.*

²³ *Id.*

²⁴ *Id.*

²⁵ Complaint at 16, *Pharmaceutical Care Management Association v. U.S. Department of Health and Human Services et al.*, No. 1:2021cv00095 (D.D.C. Jan. 11, 2021), <https://www.pcmnet.org/wp-content/uploads/2021/01/PCMA-Complaint-US-District-Court-for-the-District-of-Columbia.pdf> (last visited Mar. 24, 2022).

²⁶ *PCMA Comments on HHS OIG RFI on AKS Safe Harbors - October 23, 2018*, PHARM. CARE MGMT. ASS'N, at 3 (Oct. 23, 2018), https://downloads.regulations.gov/HHSIG-2018-0002-0120/attachment_1.pdf (last visited Mar. 24, 2022).

encourage use of more cost-effective medications, thereby increasing value by lowering costs with higher manufacturer rebates.²⁷

PBMs typically pass rebates onto health plans and plan sponsors, and it is up to the plans to decide how to use them, whether by offsetting the need for increased premiums or reducing members' out-of-pocket costs such as co-pays or co-insurance.²⁸ Despite the PBM-obtained savings being realized by the health plan's enrollees, PCMA has found (and shared with HHS OIG in 2019) that plan members are often unaware that the health plans and plan sponsors are using rebates to offset their total drug costs and reduce the need for increased premiums, especially when the point-of-sale (POS) prices at pharmacies are far more obvious.²⁹ To this point, a study by Oliver Wyman commissioned by PCMA found that Medicare Part D premiums would have been 52.4% higher in 2018 without rebates.³⁰ In addition to consumers saving on their prescription drug plan premiums, many plans use rebates to make it possible for consumers to pay low or no cost-sharing for generic or preferred brand drugs.³¹ This demonstrates PBMs' effectiveness in lowering the costs of prescription drugs for consumers and driving greater

²⁷ *Id.*

²⁸ *The Prescription Drug Landscape, Explored: A look at retail pharmaceutical spending from 2012 to 2016*, THE PEW CHARITABLE TRUSTS at 9 (Mar. 2019), https://www.pewtrusts.org/-/media/assets/2019/03/the_prescription_drug_landscape-explored.pdf (last visited Mar. 24, 2022).

²⁹ See *PCMA Comments on Safe Harbor Proposed Regulations - April 8, 2019*, PHARM. CARE MGMT. ASS'N at 30 (Apr. 8, 2019), https://downloads.regulations.gov/HHSIG-2019-0001-19773/attachment_2.pdf (last visited Mar. 24, 2022).

³⁰ Randall Fitzpatrick & Chris Carlson, *Premium Impact of Removing Manufacturer Rebates from the Medicare Part D Program*, OLIVER WYMAN at 4 (July 6, 2018), <https://www.pcmnet.org/wp-content/uploads/2018/07/OW-Part-D-Manufacturer-Rebate-Premium-Impact-FINAL.pdf> (last visited Mar. 24, 2022).

³¹ *PCMA Comments on Safe Harbor Proposed Regulations - April 8, 2019*, PHARM. CARE MGMT. ASS'N at 40 (Apr. 8, 2019), https://downloads.regulations.gov/HHSIG-2019-0001-19773/attachment_2.pdf (last visited Mar. 24, 2022).

competition in both the prescription drug space and various health plan and prescription drug spaces through multiple, potentially overlooked means.

PBMs have no control over the price the manufacturer sets for a drug—but through the use of rebates and other actions, PBMs have helped offset some of the rising drug costs. Rebates are an expected and beneficial component of value-based arrangements that bring savings to consumers. PCMA is not alone in supporting rebates. In 2019, PCMA found that academicians, drug manufacturers, health insurers, and employers generally understood that retrospective rebates are critical tools to promote value and the only proven and practical method to obtain pricing concessions from manufacturers.³²

Multiple reports from various federal agencies support the conclusion that PBMs successfully use rebates to minimize costs and blunt the impact of rising drug prices on consumers. According to a GAO report from 2019, based on PBM revenue reported to Centers for Medicare & Medicaid Services (CMS) by Part D plan sponsors in their rebates and other price concession data in 2016, the most recent data available at the time of the analysis, PBMs passed nearly all (99.6% of) rebates received from manufacturers through to Part D plan sponsors in 2016. Part D plan sponsors reported to CMS that, of the approximately \$18 billion in rebates that PBMs negotiated with pharmaceutical manufacturers on behalf of the Part D plan sponsors that year, PBMs retained only \$74.3 million, or about 0.4%, and passed through the

³² *Id.* at 25.

remaining 99.6% to Part D plan sponsors.³³ According to the report, PBM-negotiated rebates kept Part D spending 7% lower than it would have been without rebates.³⁴

An OIG report from 2019 found that total reimbursement had grown much more than rebate-adjusted reimbursement for brand-name drugs from 2011 to 2015. According to the OIG report, increases in rebates substantially reduced the percentage increase in reimbursement for brand-name drugs in Part D from 2011 to 2015.³⁵ Specifically, the OIG report found that total Part D reimbursement for brand-name drugs increased by 19% from 2011 to 2015, but only increased 4% in rebate-adjusted reimbursement for these drugs over those same five years. In addition, the OIG found that 10% of all branded drugs accounted for 60% of the rebate growth.³⁶ Unfortunately, the OIG report also found that reimbursement increased for nearly all brand-name drugs in Part D, regardless of whether the rebates for these drugs increased or decreased across the five years reviewed.³⁷ In other words, rebates saved money for Part D plan sponsors, but drug prices continued to rise.

According to a 2020 report from the U.S. Department of Health & Human Services (HHS), Office of the Assistant Secretary for Planning and Evaluation, Medicare Part D program spending increased an average of 6.0% per year between 2006 and 2018, but dropped by 4.8%

³³ *Medicare Part D: Use of Pharmacy Benefit Managers Efforts to Manage Drug Expenditures and Utilization*, GOVERNMENT ACCOUNTABILITY OFFICE (July 2019) at 16, <https://www.gao.gov/assets/gao-19-498.pdf>.

³⁴ *Id.*

³⁵ *Rebates for Brand-Name Drugs in Part D Substantially Reduced the Growth in Spending from 2011 to 2015 (OEI-03-19-00010)*, U.S. DEP'T OF HEALTH & HUM. SERV. OFF. OF THE INSPECTOR GEN. at 1 (Sept. 2019), <https://oig.hhs.gov/oei/reports/oei-03-19-00010.pdf> (last visited Mar. 24, 2022).

³⁶ *Id.*

³⁷ *Id.*

between 2017 and 2018, due partly to increased manufacturer rebates.³⁸ In addition, while Medicare Part D spending increased 6% annually between 2006 and 2018, Part D enrollees increased about 3.5%, but spending per enrollee increased on average 2.5% per year, again, largely due to PBMs successfully negotiating increased manufacturer rebates.³⁹

A 2018 study by the IQVIA Institute found that overall net spending on prescription drugs grew by 0.6% in 2017 including all off-invoice discounts and rebates. But this spending includes all types of prescription drugs, including institutional use for inpatients and outpatients. When the study looked at only retail and mail-order pharmacy distributions, net spending on prescription drugs declined by 2.1% in 2017.⁴⁰

The IQVIA Institute study also found that list prices at pharmacies rose by 58% over the five years between 2012 and 2017, but final out-of-pocket costs for consumers declined by 17%. Discounts, rebates, and other price concessions on brands reduced absolute invoice spending by an estimated 28%. These divergent trends reflect the complex dynamics involved with determining how much patients pay for their medicines at the point of sale (POS) and the influence those costs have on whether patients actually fill their prescriptions.

But it is not just government agencies who have identified specific benefits generated by PBMs. A 2018 report by Altarum, funded by the National Institute for Health Care Reform, also found that overall manufacturer rebates negotiated by PBMs benefit consumers. The report

³⁸ *Report to Congress: Prescription Drug Pricing*, US. DEP'T OF HEALTH & HUM. SERV. OFF. OF THE ASSISTANT SEC'Y FOR PLANNING AND EVALUATION at 7 (May 20, 2020), https://aspe.hhs.gov/sites/default/files/migrated_legacy_files/194881/2020-drug-pricing-report-congress-final.pdf (last visited Mar. 24, 2022).

³⁹ *Id.*

⁴⁰ Murray Aitken, et al., *Medicine Use and Spending in the U.S.: A Review of 2017 and Outlook to 2022*, IQVIA INST. at 2 (Apr. 19, 2018), <https://www.iqvia.com/insights/the-iqvia-institute/reports/medicine-use-and-spending-in-the-us-review-of-2017-outlook-to-2022> (last visited Mar. 24, 2022).

found that rebate payments have lowered government costs and contributed to lower premiums for consumers. In particular, the report estimated that \$89 billion in rebates were paid to health insurers in 2016, split across private health plans (\$23 billion), Medicare Part D plans (\$31 billion), Medicaid (\$32 billion), and other payers (\$3 billion), reducing total retail drug spending by 21%. In exchange for the rebates, health plans provided more favorable formulary placement, which reduced cost sharing for consumers at the point of purchase.⁴¹

A 2019 study by the Pew Charitable Trusts also found that the rise in branded drug list prices has been partially offset by the growth in manufacturer rebates.⁴² According to the study, rebates accounted for 15.8% of retail pharmacy benefit premiums in commercial plans in 2016, up from 9.2% in 2012. The study found that rebate growth reflected an increasingly competitive pharmaceutical marketplace allowing PBMs, health plans, and plan sponsors to negotiate more effectively in certain therapeutic categories (*e.g.*, diabetes, hepatitis C, cardiology, etc.). Health plans and plan sponsors may use manufacturer rebates to reduce patient out-of-pocket costs directly or to limit increases to premiums and lower overall plan costs for the employer or union sponsor.

B. Generic Substitution

Drug manufacturers do not provide rebates for the large majority of drugs (there are no rebates for generic drugs, which make up nearly 90% of prescriptions filled).⁴³ In these cases,

⁴¹ Charles Roehrig, *The Impact of Prescription Drug Rebates on Health Plans and Consumers*, ALTARUM at 2 (Apr. 2018), https://altarum.org/sites/default/files/Altarum-Prescription-Drug-Rebate-Report_April-2018.pdf (last visited Mar. 24, 2022).

⁴² *The Prescription Drug Landscape, Explored: A look at retail pharmaceutical spending from 2012 to 2016*, The PEW Charitable Trusts at 9 (Mar. 2019), https://www.pewtrusts.org/-/media/assets/2019/03/the_prescription_drug_landscape-explored.pdf (last visited Mar. 24, 2022).

⁴³ *PCMA Comments on Safe Harbor Proposed Regulations - April 8, 2019*, PHARM. CARE MGMT. ASS'N at 40 (Apr. 8, 2019), https://downloads.regulations.gov/HHSIG-2019-0001-19773/attachment_2.pdf (last visited Mar. 24,

PBMs reduce drug costs through incentivizing the use of lower-cost alternatives, including generics. PBMs' policies are designed to discourage a brand-name drug from being dispensed when there is an equivalent lower-cost generic drug available.⁴⁴

In an article published in 2020, researchers found that the conventional coverage pattern—generics preferred (that is, covered on lower cost-sharing tiers) to brand-name drugs—reflects the norm for Part D plans in 2019 and earlier years.⁴⁵ The researchers “found no evidence” of a widespread preference by plans or their PBMs for brand-name drugs (with rebates) over generics (without rebates).⁴⁶ In fact, the researchers found that 84% of all product-plan combinations covered the generic and excluded the brand-name drug in 2019, up from 69% in 2012.⁴⁷

The HHS OIG has been made aware that PBMs' negotiation for rebates and ability to substitute generic drugs enables them to help patients stay on their medications by making prescription drugs more affordable when many other health care costs and daily expenses are increasing faster than ever.⁴⁸ PBMs are the only advocate in the prescription drug and payment supply chain whose mission is to lower drug costs and they have a track record of doing so.

2022); Stacie B. Dusetzina, et al., *Medicare Part D Plans Rarely Cover Brand-Name Drugs When Generics Are Available*, 39: 8 HEALTH AFFAIRS 1326, 1326-1327 (2020), <https://doi.org/10.1377/hlthaff.2019.01694> (last visited Mar. 24, 2022).

⁴⁴ Stacie B. Dusetzina, et al., *Medicare Part D Plans Rarely Cover Brand-Name Drugs When Generics Are Available*, 39: 8 HEALTH AFFAIRS 1326, 1332 (2020), <https://doi.org/10.1377/hlthaff.2019.01694> (last visited Mar. 24, 2022).

⁴⁵ *Id.*

⁴⁶ *Id.*

⁴⁷ *Id.*

⁴⁸ *PCMA Comments on Safe Harbor Proposed Regulations - April 8, 2019*, PHARM. CARE MGMT. ASS'N at 1 (Apr. 8, 2019), https://downloads.regulations.gov/HHSIG-2019-0001-19773/attachment_2.pdf (last visited Mar. 24, 2022).

4. How do PBMs negotiate reimbursement rates with pharmacies?

A. Creating Pharmacy Networks to Establish Rates

To be competitive, PBMs make commitments to their health plans and plan sponsors that certain terms and conditions designed to increase quality and safety standards in the pharmacy will be included in contracts when designing pharmacy networks. When PBMs create pharmacy networks by contracting with independent pharmacies and pharmacy chains, the PBMs will negotiate for the inclusion of those terms and conditions in the contracts, but PBMs do not and cannot dictate contract terms to pharmacies.

To establish pharmacy networks, PBMs typically negotiate with pharmacies, or, in the case of independent pharmacies, with the PSAOs that negotiate on their behalf, to establish competitive rates at which the PBM will reimburse for each prescription that a pharmacy fills. Through these pharmacy negotiations, these networks allow PBMs to maximize accessibility, choice, and quality of service, as well as hold down costs for consumers enrolled in health plans and employer-sponsored plans.

When plan enrollees present a prescription to be filled, the pharmacies in a PBM's network dispense prescriptions for them using prescription drugs that pharmacies have purchased on their own directly from wholesalers or manufacturers. Before dispensing a drug, the pharmacy checks with the PBM to confirm the applicable plan benefit design for the consumer to determine eligibility, coverage, and cost-sharing information. After the prescription is filled, the PBM reimburses the pharmacy at a contractually agreed-upon rate minus any applicable cost-sharing collected by the pharmacy from the consumer. The PBM then separately bills the health plan for the prescription at the rate negotiated between the PBM and the health plan.

B. Reducing Pharmacy Costs in Networks

As noted above, PBMs negotiate lower pharmacy costs by forming a preferred or exclusive network of retail pharmacies. Retail pharmacies offer competitive discounts to PBMs depending on the type and number of health plans covered by the PBM and the narrowness of the pharmacy network — in general, the narrower the network, the higher the discount the pharmacy will offer to the health plans and consumers, as it expects more volume of business. Because consumers respond favorably to lower, competitive prices, pharmacies are incentivized to compete aggressively, thus reducing the prices that consumers pay for retail prescription drugs.

Pharmacies are willing to make substantial price concessions, some based on proven volume, to ensure they have access to the plans with the largest and fastest-growing membership bases. By creating preferred networks, PBMs are able to create savings that reduce premiums by \$63 per member per year. One study estimated preferred networks created by PBMs for Part D health plans save federal taxpayers at least \$870 million annually.⁴⁹

Consumers recognize these potential savings, and, as a result, they prefer plans with preferred networks. For plan year 2021, 99% of Part D beneficiaries chose Part D plans with preferred pharmacy networks—an increase from 92% in 2020. In a survey, 85% of Medicare Part D beneficiaries reported satisfaction with their Medicare preferred network prescription drug plan (PDP), and nearly 80% said they would be disappointed if their plan were

⁴⁹ *Putting into Appropriate Context the Growth of Pharmacy DIR*, PHARM. CARE MGMT. ASS'N at 1 (Mar. 2020), <https://612076-1984026-raikfcquaxqncofqfm.stackpathdns.com/wp-content/uploads/2020/03/Putting-into-Appropriate-Context-the-Growth-of-Pharmacy-DIR.pdf> (last visited Mar. 24, 2022).

eliminated.⁵⁰ These examples demonstrate that PBMs are delivering value to consumers through intense competition amongst pharmacies for access to their networks.

C. Inclusion of Independent Pharmacies

PBMs negotiate to include independent pharmacies in their networks, rather than only contracting with larger pharmacy chains. Often but not always, independent pharmacies participate in preferred networks through contracts negotiated and administered by their powerful PSAOs. As of 2019, all but one major PSAO chose to negotiate for the pharmacies they represent to participate in PBMs' preferred networks and fill prescriptions for consumers served by plans utilizing those networks.⁵¹

In addition to increasing consumer choice and convenience by including neighborhood pharmacies in plans' networks, PBMs' contracts with independent pharmacies promote healthy competition in the pharmacy marketplace. PBMs provide independent pharmacies opportunities for steady revenue in an ever-evolving healthcare industry, as well as access to resources and technologies to support their businesses and lighten the regulatory costs that serve to advantage chain pharmacies. Between 2011 and 2021, the number of independent pharmacies nationwide increased by approximately 13% (or by 2,645), whereas chains lost around 80 stores (0.2%) on average.⁵² This demonstrates that independent pharmacies continue to thrive.

⁵⁰ *Id.*

⁵¹ *Putting the Growth of Pharmacy DIR in Context*, PHARM. CARE MGMT. ASS'N at 2 (Mar. 2020); Adam Fein, *The Law of Holes: Some Independents Skip 2019 Part D Preferred Pharmacy Networks* (Oct. 23, 2018), DRUG CHANNELS, <https://www.drugchannels.net/2018/10/the-law-of-holes-some-independents-skip.html> (last visited Mar. 24, 2022).

⁵² *Id.* at 2.

Indeed, between 2016 and 2020, independent pharmacies' gross margin from prescriptions alone has been stable, ranging from 20.8% to 21.1%. The overall gross margin from prescription and non-prescription products for independent pharmacies has also varied little (at 21.8% to 22%) over those five years.⁵³ As shown in these historical statistics, PBMs have proven, and will continue, to be instrumental to ensuring that consumers have more options for where to fill their prescriptions at reasonable prices based on the stability provided to independent pharmacies.

5. How are contracts between PBMs and pharmacies designed to keep prescription drugs accessible and affordable?

Between 2010 and 2021, enrollment in Medicare Part D grew 75.3%, from 27.7 million to 48.7 million beneficiaries. Alongside increased beneficiary enrollment, other components of the program also grew, including total drug claims and spending, rebates, and pay-for-performance. The 2020 Medicare Trustees report found that all forms of Part D Direct and Indirect Remuneration (DIR), which encompasses PBM-negotiated manufacturer rebates as well as certain pharmacy price concessions ("pharmacy DIR"), also grew from 11.3% in 2010 to an estimated 28.4% in 2020 and resulted in significant negotiated savings for taxpayers and beneficiaries even as Part D grew.⁵⁴

⁵³ Adam Fein, *Five Things to Know About the State of Independent Pharmacy Economics* (Feb. 15, 2022), DRUG CHANNELS, <https://www.drugchannels.net/2022/02/five-things-to-know-about-state-of.html> (last visited Mar. 24, 2022).

⁵⁴ *The 2020 Annual Report of The Boards of Trustees of The, Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds*, THE 2020 Annual Report of the BOARDS OF TRUSTEES, of the FEDERAL HOSPITAL INSURANCE AND FEDERAL SUPPLEMENTARY MEDICAL INSURANCE TRUST FUNDS (April 22, 2020), CTRS. FOR MEDICARE & MEDICAID SERVS. at 140, <https://www.cms.gov/files/document/2020-medicare-trustees-report.pdf>. (last visited Mar. 24, 2022).

Pharmacy DIR is a Part D plan sponsor and PBM innovation, which introduced value-based pharmacy care, quality measures, and pay-for-performance incentives. Part D plan sponsors use performance-based pharmacy networks to advance high-quality pharmacy care, promote improvements in clinical outcomes for beneficiaries, and help contain costs—all in line with beneficiary preferences. Value-based contracting and pay-for-performance models, including preferred pharmacy networks, have grown from use in 22% of Medicare PDPs to 98% of PDPs since 2012. The 2019 Medicare Trustees report found that manufacturer rebates and pharmacy pay-for-performance are “a factor that has significantly slowed Part D spending growth.”⁵⁵ Average premiums are 17% to 57% lower for beneficiaries selecting Part D plans that use preferred pharmacy networks than those who do not.

Value-based contracts are designed to assess the performance of drugs in real-world situations, with the goal of obtaining better value, improved clinical outcomes, and lower costs. PBMs have led the industry in creating contracts that account for the value of specialty and high-cost medications.⁵⁶ Value-based arrangements are at the forefront of new drug payment designs and will be critical to managing costs of next-generation therapies like cell and gene therapies, orphan drugs, and ultra-expensive specialty drugs. To manage these high costs, health plans and plan sponsors will need broad flexibility to craft and employ value-based contracts with both manufacturers and pharmacies.

⁵⁵ *2019 Annual Report of The Boards of Trustees of The Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds*, THE BOARDS OF TRUSTEES, FEDERAL HOSPITAL INSURANCE AND FEDERAL SUPPLEMENTARY MEDICAL INSURANCE TRUST FUNDS (April 22, 2019), <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/Downloads/TR2019.pdf>.

⁵⁶ *Solving America’s High Drug Cost Problem: Prevent Drug Company Tactics that Increase Costs and Undermine Clinical Quality*, PHARMACY BENEFIT MANAGEMENT INSTITUTE at 3 (Jan. 2021), https://www.pcmagnet.org/wp-content/uploads/2021/01/Solving-America%E2%80%99s-High-Drug-Cost-Problem_whitepaper_FINAL2.pdf (last visited Mar. 24, 2022).

PBMs and Part D plan sponsors use pharmacy DIR to reward high-performing pharmacies, create high-quality pharmacy networks, promote quality access for beneficiaries, improve health outcomes, and reduce premiums. Benchmarks for pharmacy DIR reflect Star Ratings and other value-based, patient-centered quality measures. For the 2020 Medicare Part D Star Ratings, plan ratings include five Pharmacy Quality Alliance measures, including medication adherence and medication therapy management program completion. Pharmacies that improve adherence, increase generic dispensing, and improve overall patient access to care are rewarded through pharmacy DIR.

In 2018, PCMA had an independent third party conduct a survey of its members to assess the potential impact on monthly premiums for Medicare PDPs if all drug manufacturer rebates and pharmacy DIR were required to be applied at the point of sale starting the following year. According to the survey, Medicare PDPs expected that 100% of PDP plans and virtually all PDP enrollees would be impacted if manufacturer rebates and pharmacy DIR were required to be applied at the POS. Medicare PDPs expected that monthly premiums would rise by 22% annually if all manufacturer rebates and all pharmacy DIR were required to be applied at POS.⁵⁷

A. Transparency

PCMA supports actionable transparency for consumers, including transparency that enables and encourages consumers to shop for coverage that best fits their health needs and pocketbook; and, once covered, use the most cost-effective, highest-value health care goods and services. PBMs provide consumers and prescribers with real-time benefit tools (RTBTs), which

⁵⁷ *PCMA Member Survey: The Impact of POS Rebates and POS Pharmacy DIR*, PHARM. CARE MGMT. ASS'N at 1 (Mar. 2018), <https://612076-1984026-raikfcquaxqncofqfm.stackpathdns.com/wp-content/uploads/2018/03/PCMA-Survey-on-the-Impact-of-POS-Rebates-and-POS-Pharmacy-DIR-L.pdf> (last visited Mar. 24, 2022).

provide real-time information on exactly where the patient is with respect to progressing through a deductible or another benefit phase, what drugs are on the patient’s formulary, and what cost sharing to expect for a given drug at the pharmacy. This enables prescribers and patients to avoid pharmacy-counter surprises and helps ensure that physicians can prescribe drugs that are affordable for patients. PBMs also provide consumers with information on in-network pharmacies, premiums, general cost sharing, and benefits for their prescription drug coverage.

Some health plans and employer-plan sponsors seek “transparent” PBM contracts. Most large health plans, including large-employer plan sponsors, and some states already require PBMs to pass through 100% of rebates. Health plans and plan sponsors typically put out requests for proposals, which include all their requirements for their PBMs, including transparency requirements. Additionally, health plans and plan sponsors typically require the contractual right to regularly audit their PBMs, including all of the PBMs’ contracts with drug manufacturers, to ensure compliance with their contract terms.

There are, however, limits to the benefits of transparency.⁵⁸ As the FTC itself explained in 2009 in its comments on the likely competitive effects of the PBM-related provisions of New York Senate Bill 58, there are two principal concerns with overly broad disclosure requirements:

- First, they may increase the cost of the PBM’s services because it will preclude health plans and PBMs from entering into efficient (*i.e.*, cost-effective) contracts for the administration of pharmacy benefits; and

⁵⁸ See Complaint at 15-18, *Pharmaceutical Care Management Association v. U.S. Department of Health and Human Services, et al.*, No. 1:2021cv02161 (D.D.C. Aug. 12, 2021), <https://www.pcmanet.org/wp-content/uploads/2021/08/2021-08-12-1-PCMA-v.-HHS-Complaint.pdf> (last visited May. 19, 2022).

- Second, they may have the unintended consequence of publicizing proprietary business information in a way that could foster collusion among third parties.⁵⁹

To the extent that transparency may increase the risk that sensitive business information becomes public, this could facilitate collusion among third parties and undermine competition to the detriment of consumers. PBMs provide health plans, plan sponsors, and consumers with a broad array of accurate, actionable information on price and quality to make efficient purchasing decisions. However, disclosure of proprietary business information and cost information that the PBMs use to achieve competitive outcomes would be beyond the scope of actionable information that is beneficial to a consumer's decision-making, and would instead interfere with a PBM's ability to negotiate lower prices on behalf of those very same consumers.⁶⁰

6. How have PBMs improved patient adherence, kept prescription drugs accessible and affordable, and reduced waste and adverse clinical outcomes?

Some PBMs are affiliated with pharmacies that conduct pharmacy operations, including mail-order pharmacies. The PBM-affiliated pharmacies provide a convenient, reliable, and affordable option for consumers to safely access prescription drugs, including through home delivery by mail or common carrier. By accessing drugs from PBM-affiliated pharmacies, consumers are able to realize significant cost savings captured by PBMs. The FTC has previously stated that “[r]etail prices tend to exceed mail order prices on prescription drugs” and

⁵⁹ See *FTC Staff Comment to the Honorable James L. Seward Concerning New York Senate Bill 58 on Pharmacy Benefit Managers (PBMs)*, FED. TRADE COMM'N (Mar. 2009), available at https://www.ftc.gov/sites/default/files/documents/advocacy_documents/ftc-staff-comment-honorable-james-l.seward-concerning-new-york-senate-bill-58-pharmacy-benefit-managers-pbms/v090006newyorkpbm.pdf (last visited Apr. 11, 2022).

⁶⁰ *Id.*

that “data indicate that retail prices exceed mail order prices even after adjusting for prescription size.”⁶¹ The FTC’s own study of mail-order pharmacies determined that concerns about potential conflicts of interest of “self-dealing” arrangements were “without merit.”⁶² In fact, the study found that “average total prices at owned mail-order pharmacies typically were lower than at mail-order pharmacies not owned by the large PBMs.”⁶³

Mail-order pharmacies in particular have proven invaluable during the COVID crises. The ability to deliver prescription drugs directly to consumers is not just convenient, but has increased access and adherence, particularly for elderly, immobile, or incapacitated populations, and has reduced costs. At a time when many people were unable or unwilling to leave their homes, mail-order pharmacies were able to continue safely and effectively dispensing prescription drugs without requiring a trip into a retail pharmacy.

Even in normal times, PBMs play a unique role in driving adherence, holding down costs, and increasing patient access to quality care. Increased drug prices, combined with high deductible insurance coverage, can create barriers for patients to access their medicines, causing them often to make life-altering decisions about whether to continue with their medication or not. PBMs seek to reduce those barriers and help patients stay on their prescription drugs to live healthier lives. For example, according to Visante, PBMs have worked to improve drug therapy

⁶¹ See *FTC Staff Comment to Hon. Terry G. Kilgore Concerning Virginia House Bill No. 945 to Regulate the Contractual Relationship Between Pharmacy Benefit Managers and Both Health Benefit Plans and Pharmacies*, FED. TRADE COMM’N (Oct. 2006), available at https://www.ftc.gov/sites/default/files/documents/advocacy_documents/ftc-staff-comment-hon.terry-g.kilgore-concerning-virginia-house-bill-no.945-regulate-contractual-relationship-between-pharmacy-benefit-managers-and-both-health-benefit/v060018.pdf (last visited Apr. 11, 2022).

⁶²*Pharmacy Benefit Managers: Ownership of Mail-Order Pharmacies*, FED. TRADE COMM’N (Aug. 2005), available at https://www.ftc.gov/sites/default/files/documents/reports/pharmacy-benefit-managers-ownership-mail-order-pharmacies-federal-trade-commission-report/050906pharmbenefitprt_0.pdf (last visited Apr. 11, 2022).

⁶³ *Id.*

and prescription adherence in diabetic patients. Diabetes is the most prevalent chronic disease in the U.S., affecting 30 million Americans, and the PBMs' efforts have resulted in the annual prevention of:

- 400,000 heart attacks;
- 250,000 strokes;
- 100,000 amputations;
- 50,000 end stage kidney disease diagnoses; and
- 450,000 emergency department visits related to hyper/hypoglycemia.⁶⁴

According to a GAO report from 2019, a review of 52 peer-reviewed studies indicated that PBMs' utilization management services were associated with improved beneficiary health indicators, as well as financial savings.⁶⁵

7. How have PBMs minimized the costs of expensive specialty drugs and used specialty pharmacies to provide more comprehensive healthcare management programs?

The increasing utilization and high cost of specialty pharmaceuticals, which CMS has defined as those for which the monthly cost is at least \$830 a month and may also be defined as drugs for complex conditions and that require special handling, education or clinical care, have required health plans and plan sponsors to employ cost-management techniques.⁶⁶ One of these techniques is volume purchasing, often through centralized distribution systems. Combining bulk purchasing economies of scale with sophisticated clinical patient management services can lead

⁶⁴ *The Return on Investment (ROI) on PBM Services*, VISANTE (Feb. 2020), https://www.pcmanet.org/wp-content/uploads/2020/02/ROI-on-PBM-Services-FINAL_.pdf (last visited Mar. 24, 2022).

⁶⁵ *Medicare Part D: Use of Pharmacy Benefit Managers Efforts to Manage Drug Expenditures and Utilization*, GOVERNMENT ACCOUNTABILITY OFFICE (July 2019) at 26, <https://www.gao.gov/assets/gao-19-498.pdf>.

⁶⁶ Amy Larrick Chavez-Valdez, *Contract Year (CY) 2023 Final Part D Bidding Instructions*, CTR. FOR MEDICARE & MEDICAID SERVS, at 4 (Feb. 3, 2022), <https://www.cms.gov/files/document/2023partdbiddinginstructions.pdf> (last visited Apr. 6, 2022).

to less product waste, identification of adverse events and better achievement of therapeutic effect, potentially lowering overall health costs.⁶⁷

PBMs do not push consumers towards high-cost specialty drugs over more cost-effective alternatives. In fact, the opposite is true. PBMs do contract with specialty pharmacies to offer their expertise so that the pharmacies can engage patients to make better health decisions, maximize the use of their benefits, and assist physicians in managing increasingly complex medication regimens and patient populations.⁶⁸ But PBMs have also partnered with specialty pharmacies (as well as other pharmacies) to reduce prescription drug costs, increase patient choice, improve quality for patients by offering lower-cost pharmacy plans that offer convenient access and extra discounts at certain pharmacies, and provide lower-cost options for home delivery of medications for patients with chronic conditions.⁶⁹

These steps have a significant effect on the lives of the patients. Specialty pharmacy management offered by PBMs (*e.g.*, patient education and adherence programs; individual patient monitoring, care management and care coordination; physician consultation and care coordination; sophisticated data analytics) will add more than 1 million Quality Adjusted Life

⁶⁷ *Concept Series Paper on Specialty Pharmaceuticals*, ACAD. OF MANAGED CARE PHARM. at 3 (Nov. 2006), <https://www.amcp.org/sites/default/files/2019-03/Specialty%20Pharmaceuticals.pdf> (last visited Mar. 24, 2022).

⁶⁸ *PBM Specialty Pharmacies Improve Patient Outcomes and Reduce Costs*, PHARM. CARE MGMT. ASS'N at 1 (Apr. 2017), https://www.pcmnet.org/wp-content/uploads/2017/04/PBM-Specialty-Pharmacies-Improve-Patient-Outcomes-and-Reduced-Costs_whitepaper_final.pdf (last visited Mar. 24, 2022).

⁶⁹ *PBM Specialty Pharmacies Improve Patient Outcomes and Reduce Costs*, PHARM. CARE MGMT. ASS'N at 3 (Apr. 2017), https://www.pcmnet.org/wp-content/uploads/2017/04/PBM-Specialty-Pharmacies-Improve-Patient-Outcomes-and-Reduced-Costs_whitepaper_final.pdf (last visited Mar. 24, 2022).

Years (QALYs)⁷⁰ for patients with multiple sclerosis and rheumatoid arthritis over ten years (2020-29).⁷¹

Few independent specialty pharmacies are able to provide such high-touch patient care services while simultaneously delivering cost savings on their own. When specialty pharmacies apply PBM drug benefit design tools to patient care, they have the ability to increase medication adherence rates, reduce hospitalizations, lower patient medical expenses, and save on overall healthcare costs. PBM-affiliated specialty pharmacies develop highly customizable programs and services that result in up to a 50% difference in cost trends.⁷²

Since other pharmacies have limited capabilities to synthesize and incorporate health plan-generated data, health plans and plan sponsors increasingly rely on PBMs and these specialty pharmacies to provide high-quality, data-driven interventions while managing short- and long-term costs. PBMs work with specialty pharmacies to create integrated models that employ clinical solutions to support patients across the continuum of care. Simplifying complex drug treatment regimens for patients through outreach from specialty pharmacists can halve the number of patients who are readmitted to the hospital — improving care and significantly lowering costs to the healthcare system. Over the next ten years, PBMs' expertise, which is being utilized by specialty pharmacies, will save health plans, plan sponsors and consumers an

⁷⁰ A QALY is a relative measure of the ability of alternative treatments to extend life and enable people to maintain normal daily activities when living with chronic illness.

⁷¹ *The Return on Investment (ROI) on PBM Services*, VISANTE at 2 (Feb. 2020), https://www.pcmamet.org/wp-content/uploads/2020/02/ROI-on-PBM-Services-FINAL_.pdf (last visited Mar. 24, 2022).

⁷² *PBM Specialty Pharmacies Improve Patient Outcomes and Reduce Costs*, PHARM. CARE MGMT. ASS'N at 9 (Apr. 2017), https://www.pcmamet.org/wp-content/uploads/2017/04/PBM-Specialty-Pharmacies-Improve-Patient-Outcomes-and-Reduced-Costs_whitepaper_final.pdf (last visited Mar. 24, 2022).

estimated \$250 billion on the cost of specialty medications and related non-drug medical costs when compared to what expenditures would be with limited use of PBMs.⁷³

8. Conclusion

The fundamental role of a PBM is to negotiate lower drug prices for health plans, plan sponsors and the consumers they serve. PBMs are the only entities in the pharmaceutical supply and payment chain whose mission and incentive is to lower drug costs. Rising drug prices is a problem that needs to be addressed. Making drugs more affordable means consumers not only can pay for their medications, but they keep taking their medications. The PBMs' role in making drugs more affordable for consumers, combined with PBM programs and PBM-affiliated pharmacies, leads to better health outcomes and lower overall health costs. Without PBMs negotiating on their behalf, consumers would be paying list prices on medications – more than \$530 billion in 2020 alone. While PBMs are using all available tools to help drive down drug costs and more consumers are benefiting from PBM-negotiated savings than ever before, it is simply not enough. PBMs and health plans have no control over the prices manufacturers set for drugs or the prices pharmacies pay for drugs.

Public policies need to address the root causes of increasing drug prices and not restrict market-based tools that drive competition. These policies include restructuring Medicare Part D to reduce manufacturer incentives to increase prices; changing Part D rules that protect manufacturers from competition in certain drug classes, preventing pay-for-delay settlements by manufacturers that delay generic entry into the market; codifying definitions of patent thickets,

⁷³ *Id.*

evergreening, product hopping and secondary patent to better enable challenges to those manufacturer practices; and eliminating barriers to development, approval, launch and availability of biosimilars.

The FTC has an important role to play in ensuring a fair and competitive market, but PBMs and other market-based tools have and should continue to play their part in that effort. PCMA appreciates the opportunity to submit these comments as part of the FTC's renewed interest in the critical role of PBMs in helping to drive down drug costs and looks forward to further discussions with the FTC and the broader public policy community on how PBMs can continue to make prescription drugs affordable and accessible to consumers.