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Chairman Comer, Ranking Member Raskin, and Members of the Committee, thank you for inviting me to participate in today's hearing to discuss the role of pharmacy benefit managers in the market for prescription medicines. Understanding pharmacy benefit managers' growing influence over which medicines patients receive, where they can fill their prescriptions, and how much they pay out-of-pocket is a critical part of the discussion about what can be done to improve patient access and affordability and I appreciate the opportunity to explore this topic with you.

PhRMA represents the country's leading innovative biopharmaceutical research companies, which are devoted to discovering and developing medicines that enable patients to live longer, healthier, and more productive lives. The biopharmaceutical sector is one of the most research-intensive industries in the U.S.: over the last decade, PhRMA member companies have more than doubled their annual investment in the search for new treatments and cures, including nearly $101 billion in 2022 alone.

PBMs' Problematic Business Practices Threaten to Upend the Balance of Innovation, Access, and Cost Containment Achieved by the Competitive Market for Prescription Medicines

The U.S. competitive market is the engine that drives the innovative biopharmaceutical research and development ecosystem. Since 2000, biopharmaceutical companies have brought more than 750 new medicines to the U.S. market, resulting in significant progress against some of the most costly and challenging diseases.[1] Yet, as a result of robust negotiation and competition in the marketplace, retail and physician-administered medicines continue to represent just 14 percent of overall health care spending.[2] Less than half of this spending goes to brand biopharmaceutical companies, with the remainder going to pharmacy benefit managers (PBMs), health plans, the government, hospitals, pharmacies, generic manufacturers, and others.[3,4]

The private market-based system in the U.S. is designed to promote incentives for continued innovation and patient access to needed medicines while leveraging competition to achieve cost containment. Brand medicines face robust competition from generic drugs, biosimilars, and other brand medicines, which PBMs and insurers have historically leveraged to drive down prices. For example, less than a year after market entry of the first breakthrough treatment for hepatitis C, multiple other products entered the market, some offering improved cure rates for patients. The resulting competition was so fierce that the average net daily cost for this class today is nearly 80

percent lower than the first product's launch price.[5] Similarly, a recent Health Affairs study found that new brand medicines launched between 2013 and 2017 led to an immediate decrease in the average net price of competitors already on the market, generating more than $10 billion in savings across just twelve therapeutic classes.[6]

The U.S. biopharmaceutical marketplace is also designed to promote innovation and affordability through cost containment that is built into the prescription drug lifecycle. Government data showing that the average price of a medicine has fallen over the past decade illustrate the lifecycle in action. The Congressional Budget Office (CBO) examined nationwide trends in medicine prices and found that the average net price per prescription in Medicare Part D and Medicaid declined between 2009 and 2018, even though this period saw the introduction of many new treatments and cures.[7] These savings result from a unique system of cost containment: over time, new medicines help to improve patient outcomes and reduce overall health care costs while paving the way for lower-cost generics and biosimilars that bring long-term value to patients and the health care system.[8] Similar cost containment mechanisms do not exist for other health care services.[9]

Public debate about the cost of medicines often focuses on list prices, which do not account for the significant rebates and discounts PBMs receive from manufacturers. Many medicines, including those used to treat or prevent conditions like diabetes, asthma/COPD, hepatitis C and strokes, have average rebates of 40 percent or more and, for some medicines, list price reductions can exceed 80 percent.[10,11,12] Omitting manufacturer rebates and discounts from discussions about the cost of medicines can lead to fundamentally misleading conclusions. For example, despite PBMs' claims about skyrocketing prices,[13] net prices for brand medicines have grown more slowly than inflation for each of the last five years and did not grow at all in 2022.[14] Going forward, net prices for brand medicines are projected to decline by up to 5 percent annually through 2027, highlighting the important role of the competitive market in containing future prescription medicine spending growth.[15]

For decades, the competitive dynamics in the market for prescription medicines have worked successfully to balance innovation, patient access, and cost containment. But that balance is increasingly threatened by the misaligned financial incentives and conflicts of interest that characterize the PBM market today. Years of continuous horizontal and vertical integration have resulted in a market dominated by just a handful of large PBMs, whose business models often work to the detriment of patients and competition. A growing share of PBM compensation is now tied to the list price of medicines,[16] which experts note can distort the market by incentivizing PBMs to prefer medicines with higher list prices and large rebates over lower cost alternatives.[17] Rather than ensuring patients have rapid access to generics, biosimilars, and lower price therapies, we see PBMs denying or restricting coverage for these medicines.[18] Instead of using the rebates they negotiate with manufacturers to lower patient cost sharing, we see PBMs

requiring patients to pay their deductibles and coinsurance based on a medicine's undiscounted list price. We discuss the ramifications of these practices, as well as other actions PBMs may take to maximize their revenue at the expense of patient affordability, access, and adherence, in detail below.

Through Horizontal and Vertical Integration, PBMs Have Increased Their Influence Throughout the Prescription Drug Supply Chain

PBMs act as intermediaries between pharmaceutical manufacturers and payers to facilitate coverage and reimbursement arrangements for prescription medicines. Situated between the biopharmaceutical companies that research and develop innovative medicines and the patients likely to benefit from those treatments, PBMs play a central role in determining which medicines patients will have access to and at what cost for hundreds of millions of Americans.

After nearly two decades of horizontal consolidation, the PBM industry is now dominated by three large companies: CVS Caremark, Express Scripts, and OptumRx.[19] The combined market share of the three largest PBMs has grown significantly, from 48 percent in 2010 to 79 percent in 2022.[20,21] Today, just six companies control 96 percent of the PBM market.[22]

In recent years, the three largest PBMs have also combined with health insurers, specialty and mail order pharmacies, and provider groups to form large vertically integrated organizations (see Figure 1). These vertically integrated organizations have enormous influence over which medicines patients have access to, the circumstances under which those medicines are covered, when and where they can be dispensed or administered to patients, and the amount paid out of pocket by patients. The three largest PBMs have become key drivers of revenues and profits for their respective vertically integrated organizations.[23]

Figure 1: Vertical Business Relationships Between PBMs, Insurers, Specialty and Mail Order Pharmacies, and Provider Services, 2023

Source: Drug Channels. Mapping the Vertical Integration of Insurers, PBMs, Specialty Pharmacies, and Providers: A May 2023 Update. May 10, 2023. https://www.drugchannels.net/2023/05/mapping-vertical-integration-of.html

Despite the already considerable market power of their respective PBMs, each of these vertically integrated organizations has also created a separate "rebate contracting entity" – referred to by PBMs themselves as a Group Purchasing Organization,[24] or PBM GPO – that is responsible for negotiating, collecting, and disbursing manufacturer rebates for their commercial book of business. The three rebate contracting entities and their associated PBMs and health insurers are Ascent Health Services (Express Scripts and Cigna, launched in 2019), Zinc (CVS Health and Aetna, launched in 2020), and Emisar Pharma Services (OptumRx and UnitedHealthcare, launched in 2021).

Industry experts suggest that rebate contracting entities may create several advantages for PBMs. First, at least one of these rebate contracting entities is headquartered overseas (Ascent Health Solutions in Switzerland), allowing it to take advantage of lower foreign corporate tax rates and more restrictive privacy laws.[25] Second, PBMs are using these entities to create new revenue streams via additional fees charged to manufacturers. Compared to rebates, these new fees are less transparent to employers and plan sponsors and can be more difficult for PBM clients to audit.[26] Third, rebate contracting entities may represent an attempt by PBMs to sidestep ongoing legislative and regulatory reform initiatives, including efforts to increase PBM transparency.[27]

PBM rebate contracting entities introduce an additional non-transparent middleman to an already complex system, and experts have raised concerns that these entities are likely to increase costs

without providing any direct benefits for patients.[28] The Ohio Attorney General recently filed a lawsuit against Ascent Health Services, alleging that it enabled certain PBMs and health insurers to engage in anticompetitive behavior and fix prices, causing negative consequences for patients, employers, pharmacies, health insurers, manufacturers, and competitive pharmaceutical markets in the state of Ohio.[29]

While a number of smaller PBMs have attempted to break into the market and disrupt the dominant PBM model by offering their clients greater transparency and accountability,[30,31,32] they have thus far been unsuccessful in reducing the overall market share of the three largest PBMs.[33] In many instances, smaller PBMs contract or partner with larger PBMs to leverage their infrastructure and negotiating power, with the larger entities acting as rebate aggregators for the smaller entities and generating revenue by retaining a portion of the rebate or "spread" between their rates and the lower rates passed through to the smaller PBMs.[34,35] For example, in 2022 Express Scripts managed the pharmacy network contracting and rebate negotiations for approximately half of all business handled by Prime Therapeutics, a smaller PBM.[36] Such arrangements further contribute to the overall consolidation of the PBM market.[37]

PBMs May Have Financial Incentives to Prefer Medicines with Higher List Prices and Large Rebates and May Discourage Manufacturer Efforts to Reduce List Prices

According to a Senate Finance Committee report, "PBMs have an incentive for manufacturers to keep list prices high, since the rebates, discounts, and fees PBMs negotiate are based on a percentage of a drug's list price—and PBMs may retain at least a portion of what they negotiate."[38] Historically, PBMs often retained a portion of the rebates they negotiated on behalf of their commercial health plan and employer clients, calculated as a percentage of a medicine's wholesale acquisition cost (i.e., list price), as compensation for their services.[39,40] The fees that PBMs and their rebate contracting entities charge to pharmaceutical manufacturers are also typically calculated as a percentage of list price.[41] Government agencies, economists, and other experts have noted that basing rebates and fees on list prices may incentivize PBMs to favor medicines with higher list prices to maximize their revenues.[42,43,44]

Public sources have also noted that manufacturer efforts to reduce list prices have been met with significant headwinds, including demand letters from PBMs requiring additional payments in the event of list price decreases.[45,46] Despite public statements by PBMs that they support reforms to lower the price of medicines for patients and encourage manufacturers to lower list prices,[47] at least one PBM has introduced contract terms that discourage list price reductions.[48] The Health and Human Services (HHS) Office of Inspector General (OIG) has also indicated that PBMs may have incentives to penalize manufacturers for reducing list prices, including removing medicines from the formulary or placing them on a less-preferred cost sharing tier, both of which may result in higher costs for patients.[49] In a recent survey, more than 2/3 of biopharmaceutical

company respondents indicated that they perceived list-price based fees charged by PBMs as a barrier to lowering list prices.[50]

Industry analysts have observed that PBM and plan sponsor contracts often guarantee that the plan sponsor will receive a minimum dollar amount of rebates from the PBM and have suggested that these guaranteed minimum rebate payments from PBMs to plan sponsors may provide additional incentives for PBMs to prefer medicines with large rebates.[51,52] According to one industry expert, PBM rebate guarantees may also limit manufacturers' ability to reduce list prices, since "these guarantees dissolve when a manufacturer cuts its list price to be closer to that of the drug's net price. The removal of rebate dollars creates a contract dilemma. A PBM no longer has rebate funds to pay out, yet their customers still expect the guaranteed payments."[53]

Large PBMs often require price protection clauses stipulating that if a medicine's list price increases by more than a certain percentage, the manufacturer must provide an additional price protection rebate reimbursing the PBM for increases above the pre-specified threshold.[54,55] Although such arrangements may insulate the PBM and plan from changes in list price, patients with deductibles and coinsurance – who are typically required to pay their cost sharing based on the list price – are not protected from experiencing higher out-of-pocket costs, as a result of benefit designs implemented by vertically integrated PBMs and their affiliated health plans.

PBMs May Increase Out-of-Pocket Costs for Patients by Excluding Lower Price Medicines from Their Formularies

"Authorized generic" is a term commonly used to describe an approved prescription medicine that is marketed under the brand name drug's New Drug Application (NDA) but does not use the brand name on the label. Biopharmaceutical manufacturers may make authorized generics available at lower list prices to lower patient out-of-pocket costs, as some manufacturers have done for hepatitis C and insulins (as biologics, insulins are not technically authorized generics, but may similarly be authorized by their manufacturer). Despite the availability of authorized generic versions of these medicines – which may have considerably lower list prices than their otherwise therapeutically equivalent brand name counterparts – PBMs do not uniformly include these medicines on their standard commercial formularies.[56]

The three largest PBMs have also been reluctant to encourage utilization of the first interchangeable biosimilar long-acting insulin, which has been available since 2021.[57] Most state laws enable interchangeable biosimilars to be substituted by the pharmacist without having to first contact the prescribing physician, but the pharmacist cannot substitute an interchangeable biosimilar if a patient's PBM does not cover the product. A PBM's decision to exclude these products from formulary can impose a significant barrier to uptake and limit patient access to medicines that could lower their out-of-pocket costs at the pharmacy counter.[58]

Industry analysts have noted that market dynamics – whereby PBMs may prefer high list price products with larger rebates – prompted the manufacturer of the first interchangeable biosimilar insulin to simultaneously introduce two identical versions – a branded version with a higher list price and rebates and an unbranded version with a lower list price, giving payers the option of which to cover.[59] Not one of the three largest PBMs includes the lower list price version as a preferred option on their 2023 standard commercial formulary. In fact, one of the three prefers the higher list price version and excludes coverage of the lower list price version altogether, even though coverage of the latter could lower out-of-pocket costs for insulin for many patients with deductibles and coinsurance.[60]

Coverage of lower list price options, including the interchangeable biosimilar insulin, has also been slow in Medicare Part D. According to a recent analysis by the Medicare Payment Advisory Commission (MedPAC), two lower list price insulins were either excluded from, or were not the preferred option on, many Part D formularies in 2019, resulting in respective market shares of just 2 percent and 17 percent.[61] As of October 2022, take up of the lower list price interchangeable insulin biosimilar in Part D remained negligible, accounting for just seven percent of new prescriptions.[62]

Similarly, the HHS OIG found that nearly half of Part D formularies excluded coverage of authorized generics for hepatitis C in 2020, even though the net cost of these options was significantly lower than the net cost of the highly rebated, higher list priced versions.[63] The OIG's findings directly contradict public statements by PBM executives that they prioritize medicines with the lowest net costs over medicines with large rebates.[64,65] PBMs' exclusion of lower list price options in favor of medicines with higher list prices and large rebates has direct financial implications for patients. For some, having these medicines on the PBM's formulary could reduce their out-of-pocket costs by hundreds or thousands of dollars per prescription.[66]

This year has also seen the launch of multiple biosimilars that compete against a widely used biologic for the treatment of autoimmune conditions, including one with an interchangeability designation. Several of these products launched with a dual-pricing strategy, offering payers two identical versions – one with a high list price and high rebate and one with low list price and low rebate. Two of the three largest PBMs have added several of the new autoimmune biosimilars – predominately the ones with higher list prices – to their standard commercial formularies, alongside and subject to the same cost sharing terms as the innovator biologic.[67] Covering higher list price biosimilars with large rebates may financially benefit the PBM, but it can leave patients paying significantly more out of pocket despite the high rebates. To date, uptake of the new autoimmune biosimilars remains very low, with the one biosimilar available in the first quarter of 2023 having captured just 4 percent of the market.[68]

While PBMs complain about the patent system being responsible for the price of medicines, this argument is a red herring, intended to distract lawmakers and stakeholders from PBMs'

egregious practices and negative impacts of PBM consolidation and vertical integration on patient access and market competition. Multiple patent law experts have noted that the patent system is not the cause of high medicine prices.[69] In fact, patents require the description of inventions to be disclosed, allowing society to understand and learn from the invention, fostering competition from other brand competitors while paving the way for generic and biosimilar versions at the end of the effective patent life. This long-standing policy framework balances incentives for continued innovation with timely entry of competitors and spurs robust brand-to-brand competition on price and clinical effects, increasing treatment options for patients and generating cost savings.

Patent laws apply the same in the pharmaceutical context as they do all other industries.[70] However, unlike in other industries, medicines must go through lengthy and costly clinical trials to confirm their safety and efficacy before potential U.S. Food and Drug Administration (FDA) approval. Only 12 percent of new molecular entities that enter clinical trials eventually receive FDA approval. Many medicines will reach the market with less than half of their original patent life remaining. Today, on average, generic competitors enter the market at around 13 years,[71] which is substantially less than the 20 years afforded other products by the patent system generally.

Furthermore, medicines are extremely complex and risky inventions that are often associated with multiple patents that cover other innovative aspects beyond the active ingredient, including the composition of dosage forms, methods of manufacturing, and use in a particular therapeutic indication. With an average of 10 to 15 years and $2.6 billion needed to develop one FDA-approved treatment,[72] companies would be unwilling to take the risk of investing in new medicines without these protections. As one expert has noted, "Trying to tackle pharma price growth, therefore, by fiddling with patent law seems to me like trying to steer the car away from an obstacle by sharply turning the volume knob on the radio."[73] Congress should not be tricked into fiddling with the patent laws, but should instead address the many problematic effects of extreme consolidation and vertical integration in the PBM industry.

Competition Lowers Net Prices for Brand Medicines, But Patients Rarely Benefit Directly from the Significant Price Negotiations Happening in the Market Today

The net price of a medicine reflects the final price paid by the PBM and the plan sponsor. Yet in the majority of cases, the net price is not the price available to patients with insurance at the pharmacy counter. Instead, PBMs and insurers typically require patients with deductibles and coinsurance – who pay a percentage of the cost of their medicine rather than a fixed copayment – to pay based on the undiscounted list price, rather than the discounted net price paid by the PBM. In contrast, health plans typically base patient out-of-pocket spending for care received from doctors and hospitals within the plan's provider network on the discounted rates negotiated by the plan on patients' behalf.

The number of patients that face high out-of-pocket costs for their prescription medicines has grown significantly in recent years, largely due to increased enrollment in high deductible health plans and payers' increasing use of coinsurance for prescription medicines.[74,75] Benefit designs that incorporate high deductibles and coinsurance expose patients to high out-of-pocket costs based on undiscounted list prices, even though the net prices available to PBMs and health plans are often significantly lower. Today, two thirds (66 percent) of commercial and 92 percent of Part D total patient out-of-pocket spending for brand medicines is based on list price.[76,77]

Health plans and employers frequently use manufacturer rebates to reduce premiums for all enrollees, rather than to directly lower costs for patients facing high cost sharing for their medicines. According to one actuarial firm, this results in a system of "reverse insurance," whereby payers require patients with high prescription medicine costs to pay more out of pocket, while rebate savings are spread out among all health plan enrollees in the form of lower premiums.[78] Asking sicker patients with high medicine costs to subsidize premiums for healthier enrollees is the exact opposite of how health insurance is supposed to work.

While Congress moved aggressively – and in PhRMA's view misguidedly – to impose price-setting on pharmaceutical manufacturers in last year's Inflation Reduction Act (IRA), there is no denying that the IRA failed to hold PBMs accountable for their egregious business practices, such as charging patients more than they themselves pay for medicines. A recent analysis by the Government Accountability Office (GAO) illustrates the scope of this problematic practice. GAO found that for 79 of the top 100 highly rebated medicines in Medicare Part D, the total costs to beneficiaries exceeded the total net costs to plan sponsors by nearly 400 percent ($21 billion vs. $5.3 billion).[79] While the IRA was touted as an attempt to reduce beneficiary spending on prescription medicines, it did nothing to address the misaligned incentives created by the failure of PBMs and plan sponsors to use rebate savings to directly lower patient out-of-pocket costs at the pharmacy counter. PBMs and plan sponsors determine how much patients pay out-of-pocket and the decision to base patient cost sharing on a higher price than PBMs and plan sponsors actually pay for a medicine is their choice and theirs alone.

<u>The PBM Business Model Has Evolved Beyond Rebates, With Fees and Vertically Integrated Pharmacies Accounting for a Growing Share of PBM Profits</u>

New research confirms that the primary sources of PBM profits have changed significantly over the last decade. The PBM business model has largely shifted away from retention of commercial rebates – perhaps in response to increased public and employer scrutiny – in favor of fees charged to manufacturers, payers, and pharmacies and revenues generated by vertically integrated specialty and mail order pharmacies.[80,81] While the total amount of rebates obtained by PBMs has continued to increase each year, fees and specialty pharmacy are now the fastest growing components of PBM profits.

The fees PBMs obtain from manufacturers – which are predominately based on the list price of medicines – have more than doubled in the commercial market over the past five years, including rapid growth in new data and vendor fees charged by their rebate contracting entities.[82] Because these new fees, and the activities of PBM rebate contracting entities in general, are less transparent to employers and plan sponsors, employers and plan sponsors may not benefit from the additional revenues being collected by these entities.[83] PBMs' incentives to maximize list-price based fees in this highly consolidated, vertically integrated market raises concerns about the impact on patient access and affordability, as well as employer and health system costs.

Vertically integrated pharmacies now account for more than half of PBM profits.[84] PBMs may require patients to use a PBM-owned retail, mail order, or specialty pharmacy or disincentivize the use of non-affiliated pharmacies by requiring patients to pay higher cost sharing. For example, CVS Health leverages its joint ownership of a PBM, a chain of retail pharmacies, and a mail order pharmacy to limit access by requiring some patients to use CVS' mail order or retail pharmacies if they wish to fill prescriptions for a 90-day supply of a medicine.[85] By steering patients towards their affiliated specialty and mail order pharmacies, PBMs capture greater margins on each transaction and reduce dispensing fees and other costs associated with patients filling prescriptions at non-affiliated pharmacies.[86,87] Steering, however, can happen without a patient's knowledge and can deny patients the benefits and convenience of visiting their local pharmacist. It can also result in unnecessary treatment delays, with patients potentially experiencing worse outcomes from not being able to fill prescriptions in a timely manner.[88]

Similarly, a vertically integrated entity like UnitedHealthGroup's Optum Health – the largest employer of physicians in the U.S.[89] – can require the providers it employs to direct patients to pharmacies or other provider groups affiliated with the organization and may reward physicians for prescribing medicines that provide the largest financial benefits for PBMs. Such arrangements would be more difficult for PBMs to enforce if the provider and pharmacy were part of different organizations.[90] PBMs may also generate new sources of revenue by enabling PBM-owned pharmacies to manage specialty medicines historically administered by providers in outpatient health care settings. PBMs increasingly require provider-administered medicines to be filled at their in-house specialty pharmacies and shipped directly to a provider's office for storage until the patient comes in for treatment (known as white bagging) or shipped to the patient to bring with them to their appointment (known as brown bagging). Research shows that brown and white bagging is associated with lower costs for PBMs and insurers but higher out-of-pocket costs for patients.[91]

PBMs and their vertically integrated pharmacies also profit from participation in the 340B Drug Pricing Program. Although the 340B Program was created to benefit safety net providers and the predominately low-income and uninsured patients they treat, the growing use of entities such as "contract pharmacies" – that capture a share of profits from the program – has given PBM-owned retail and specialty pharmacies a large, and growing, role. Overall, 40 percent of all

contract pharmacy relationships are between a 340B covered entity and a pharmacy associated with one of the three largest PBMs.[92] Over half of the 340B profits retained by contract pharmacies are concentrated in just four for-profit corporations, two of which are vertically integrated with two of the three largest PBMs (CVS Health and Express Scripts).[93] The ability of PBM-affiliated pharmacies to earn significantly higher margins on 340B medicines has incentivized greater vertical integration and rapid expansion of contract pharmacy relationships.

Vertically integrated pharmacies also provide PBMs with the necessary visibility and control to implement copay maximizers, which adjust individual patient cost sharing upwards to match and exhaust the full value of cost-sharing assistance provided by pharmaceutical manufacturers.[94] These programs partly utilize a purported loophole under the Affordable Care Act for large employer group health plans, which these plans rely on to deem certain prescription medicines as not "essential health benefits" and therefore not subject to the Affordable Care Act's maximum annual limitation on cost sharing. Copay maximizers may discriminate against patients taking certain medicines for which manufacturer cost-sharing assistance is available by offering them more limited benefits – and higher cost sharing – as compared to other patients who receive other forms of cost-sharing assistance, such as family support. A recent study shows that non-white patients are 27 percent more likely to be exposed to copay maximizers than white patients.[95] PBMs that use copay maximizers can require patients to obtain medicines exclusively from PBM-owned or affiliated pharmacies, allowing these entities to gain additional revenue in the form of dispensing fees and spread pricing.[96,97] When these pharmacies are not easily accessible, patients can face obstacles or delays in filling their prescriptions.

Vertically Integrated PBMs and Pharmacies Can Profit by Marking Up the Price of Medicines, Exposing Some Patients to Higher Out-of-Pocket Costs

Generic drugs are a central part of the cost containment mechanism built into the prescription medicine lifecycle. Once a brand medicine's patent protection ends and multiple generics enter the market, it is not unusual for the cost of treatment to decline by upwards of 90 percent.[98] However, a recent investigation by the Wall Street Journal (WSJ) revealed that generic drugs dispensed by PBM-owned pharmacies can cost thousands of dollars more than the very same generic drugs dispensed at independent pharmacies.[99] PBMs' conflict of interest is clear: instead of working on behalf of patients, employers, and plan sponsors to lower costs, vertically integrated PBMs and pharmacies can maximize their profits by significantly marking up the prices of low-cost generic drugs.

Across a selection of generic drugs analyzed by the WSJ, the prices that CVS Health and Cigna (i.e., Express Scripts) charged to plan sponsors were 24 and 27 times higher, respectively, than the prices charged by the generic manufacturers themselves.[100] For one generic cancer drug, CVS Health and Cigna reimbursed their own specialty pharmacies between $6,600 and $7,000 per prescription, while the same generic drug cost just $54 at a non-affiliated pharmacy. The

potential to earn high profits on otherwise low-cost generic drugs further incentivizes PBMs to steer patients to their own specialty and mail order pharmacies.

Marking up the prices of generic drugs eliminates an important source of cost savings in the competitive market for prescription medicines. It can also result in significantly higher out-of-pocket costs for patients, particularly those with coinsurance or deductibles, whose payments are calculated based on the price the PBM pays to the pharmacy. In the case of the aforementioned generic cancer drug, a CVS Health patient with 25 percent coinsurance would be responsible for paying $1,750 out of pocket if they filled their prescription at CVS Health's vertically integrated specialty pharmacy vs. $13.50 at an independent pharmacy. According to one health policy expert, "Someone in the middle of that transaction is making a lot of money, and they're doing it at the detriment of the consumers."[101]

PBMs Leverage Their Market Power to Compel Employers to Accept Unfavorable Terms that May Limit Access and Choice and Shift Costs to Patients

Industry analysts have noted that contracts between PBMs and their employer and plan sponsor clients often lack uniform definitions, and that PBMs can leverage their market power to interpret this ambiguity in their favor.[102,103] PBMs also appear to take advantage of lax oversight and the absence of industry standards to modify and adjust contracts as needed to mitigate the effects of restrictions or reforms intended to increase transparency or patient access.[104]

PBMs have historically retained a portion of the rebates they negotiate on behalf of their health plan and employer clients. While the remainder of the rebates are generally passed on to plan sponsors, smaller employers and health plans may not benefit from all of the price concessions the PBM has negotiated with manufacturers, particularly if the PBM decides not to define certain fees or other concessions as "rebates."[105] Lack of transparency in contracts between employers and PBMs has led many plan sponsors to question the share of rebate savings being passed through, how much the PBM is retaining in the form of fees charged to manufacturers, and whether the PBM is disclosing and passing on other price concessions, such as savings from price protection rebates.[106]

Lack of transparency may also prevent employers and plan sponsors from evaluating potential PBM financial conflicts of interest, such as whether the PBM's formulary or preferred pharmacy network has been chosen based on the lowest cost to the plan sponsor vs. the highest financial returns for the PBM.[107] In addition, many employers lack in-house capabilities for evaluating pharmacy benefit options and more than three-quarters rely on consultants or brokers – which may themselves be compensated by PBMs, for advice.[108] A recent investigation revealed that "a largely hidden flow of money" between benefits consultants and PBMs can undermine consultants' ability to provide impartial advice, prompting consultants to recommend contract terms that favor PBMs at the expense of employers and enrollees.[109]

Congress Should Pass Market-Based Reforms to Strengthen PBM Incentives, Improve Patient Access and Affordability, and Promote Transparency

Overwhelming support has emerged in this Congress for reforms to a slew of PBM practices that can increase costs for patients, employers, and the health care system. PBM reform is one of the few issues that garners bicameral and bipartisan support and PhRMA implores Congress to not forgo this opportunity to hold PBMs accountable. Reforms that would have the highest impact on addressing PBMs' misaligned incentives, lowering patient out-of-pocket costs, and leveling the playing field for employers and plan sponsors include:

Basing PBM Compensation on the Services Provided, Not the Price of Medicines

The fees PBMs receive from manufacturers, pharmacies, health insurers, and employers account for a rapidly growing share of PBM profits.[110] To the extent that PBMs provide valuable services to stakeholders in the pharmaceutical supply chain, they should be entitled to compensation based on that value. However, PBM compensation should not be tied to the price of a medicine. According to experts, basing PBM compensation on the price of medicines can create incentives for PBMs to prefer medicines with higher list prices over lower cost alternatives.[111] Ending price-based PBM compensation in favor of flat fees is expected to reduce PBM incentives to prefer higher price medicines, thereby generating savings for employers and plan sponsors.[112] Patients with deductibles and coinsurance could also benefit from expanded coverage of lower price medicines in the form of lower out-of-pocket costs. Although a rule finalized by the HHS OIG in 2020 created a new safe harbor to the federal Anti-Kickback Statute to protect flat fees to PBMs that are not based on percentage of sales,[113] the IRA has delayed implementation of that rule until 2032.

PhRMA supports efforts in the Senate to "delink" PBM compensation from the price of a medicine. For example, the Senate Finance Committee advanced a bill with near unanimity in July – the Modernizing and Ensuring PBM Accountability (MEPA) Act – that would prohibit price-based PBM compensation in Medicare Part D. PBM compensation would instead be limited to flat dollar amount bona fide service fees, based on the fair market value of services rendered.[114] The Senate Finance Committee's bipartisan legislation, the Patients Before Middlemen Act also includes this delinking prohibition.[115] Notably, CBO has projected that Section 2 of the MEPA Act, which includes the delinking provisions and additional PBM transparency and disclosure requirements, would save the federal government more than $700 million dollars over 10 years.[116] Congress should move forward to enact this policy.

While PhRMA believes that the PBM reforms advanced by the Senate Finance Committee are a positive first step toward reigning in misaligned PBM incentives, it is imperative that these reforms extend beyond Medicare Part D and into the commercial market, where list price-based fees paid to PBMs have increased exponentially.[117] Congress must address the commercial

market failures caused by PBMs in order for the private market to work as intended. In the absence of such action, PBMs will continue to erode competition and undermine free market incentives, while patients and other stakeholders continue to shoulder the burden.

Requiring PBMs to Pass Through Manufacturer Rebates at the Point-of-Sale

Requiring PBMs and health plans to share the savings they receive on medicines directly with patients at the pharmacy counter in the commercial market and Medicare Part D would lower patient out-of-pocket costs and help realign payer incentives. Patients who take brand medicines with large rebates, such as medicines for chronic conditions like diabetes and asthma/COPD, could see sizable reductions in out-of-pocket costs if the rebates were passed on to them at the pharmacy counter.[118]

Actuaries estimate that sharing negotiated rebates directly with commercially insured patients at the point-of-sale would increase premiums by an average of one percent or less.[119] The substantial savings for patients at the pharmacy counter would outweigh those premium increases and provide patients with increased access and affordability for often lifesaving medicines. Notably, policies that would require PBMs to pass through 100 percent of rebates to commercial plan sponsors (rather than directly to patients) are unlikely to lower patient cost sharing. Actuarial analysis shows that on average, employers use 70 percent of the rebates they receive to reduce the employer's premium contribution and 30 percent to reduce the employee's premium contribution. None of the rebates they receive are used to directly lower patients' out-of-pocket costs for prescriptions.[120]

PhRMA applauds lawmakers' efforts to establish patient protections, such as ensuring that post-deductible cost sharing for Part D beneficiaries does not exceed the net price paid by the plan sponsor. These types of reforms would outlaw an egregious practice, but they are insufficient to provide seniors with the full benefits of price negotiation. The lack of true progress in sharing rebate savings directly with patients only furthers PBMs' increasingly misaligned incentives. While using rebates to directly lower out-of-pocket costs for Part D beneficiaries could lead to a small increase in Part D premiums, patients who use these medicines would no longer be forced to subsidize the premiums of healthier enrollees by paying higher cost sharing. In other words, Part D would once again work like insurance is supposed to work, with everyone paying in and insurance providing financial protection for patients when they get sick. Premium increases could be mitigated in a number of ways, including requiring the pass through of rebates only for certain therapeutic classes or phasing in the requirements over several years. A recent survey found that a majority of patients (59 percent) prioritize lowering out-of-pocket costs over lowering premiums.[121]

Increasing PBM Transparency

Calls to increase PBM transparency have been a prominent theme in Congressional hearings and markups this Congress. Policies to establish transparency surrounding PBM practices and to delink PBM compensation from the price of medicines enjoy broad support from stakeholders, including Medicare beneficiary advocates.[122]

Lack of transparency and the complexity of rebates and fees can make it difficult for plan sponsors to assess whether they are fully benefiting from all price concessions that PBMs negotiate on their behalf. Requiring PBMs (and their affiliates) to report aggregate information on prescription drug utilization, costs, rebates, and fees would provide information necessary for employers and plan sponsors to properly evaluate whether PBMs are effectively managing the pharmaceutical benefit and would help ensure accountability to PBM customers.[123] According to CBO, proposed federal legislation that would require PBMs to disclose detailed aggregate information on prescription medicine spending and utilization to plan sponsors could enable employers and plan sponsors to better evaluate PBM contract provisions and obtain more favorable contracting terms, as well as increase competition among PBMs.[124]

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