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May 25, 2022

Federal Trade Commission
600 Pennsylvania Avenue NW
Washington, DC 20580

Re: Solicitation for Public Comments on the Impact of Pharmacy Benefit Managers' Business Practices and Their Impact on Independent Pharmacies and Consumers

Dear Chair Khan and Commissioners:

The Pharmaceutical Research and Manufacturers of America (PhRMA) appreciates the opportunity to provide this response to the Federal Trade Commission's Request for Information on the business practices of pharmacy benefit managers (PBMs) and their impact on independent pharmacies and consumers. 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. Since 2000, PhRMA member companies have invested nearly $1 trillion in the search for new treatments and cures, including $91.1 billion in 2020 alone.[1] Additionally, America's biopharmaceutical companies have successfully researched, developed, and delivered multiple vaccines and therapeutics to help halt the spread and mitigate the effects of COVID-19. The introduction of COVID-19 vaccines is estimated to have saved more than 2.2 million lives and averted up to 17 million hospitalizations in the United States.[2]

Our comments below discuss the growing influence of PBMs in the distribution and payment system for prescription medicines and the ways in which PBM business practices and PBM financial incentives may negatively impact patient access to medicines and patient out-of-pocket costs. 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 controlling prescription medicine access and affordability for hundreds of millions of Americans. Through horizontal and vertical integration, PBMs' role in the prescription drug supply chain has grown, as has their influence over which medicines patients have access to and whether they are affordable for patients. Moreover, the amount and proportion of value extracted out of the health care system by these vertically integrated intermediaries has risen dramatically.

Following review of the comments received in response to this RFI, PhRMA strongly encourages the FTC to undertake a broad and in-depth Section 6(b) study to understand PBMs' true nature: PBMs are gatekeepers with extraordinary bargaining leverage which they use to maximize their profits, often in ways that harm patients and others. By creating formularies that govern which medicines insurers cover, their associated cost sharing, and any utilization management or other restrictions on their use, PBMs are powerful intermediaries that can exert enormous influence over the number of patients who may ultimately receive a particular treatment. PBMs may effectively control patient access to medicines through cost and clinical management techniques applied to their formularies. To properly evaluate the

impact PBMs have on health care markets, it is critical that the FTC fully understand the impact of PBMs on patients, as well as the interplay between PBMs' various lines of business. We urge the FTC to conduct a rigorous analysis of PBM practices to identify those that cause significant harm to patients and competition in the health care industry and to address any harmful practices.

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PBMs Have Increased Their Influence in the Pharmaceutical Supply Chain through Horizontal and Vertical Consolidation

PBMs act as intermediaries between pharmaceutical manufacturers and payers to facilitate coverage and reimbursement arrangements for prescription medicines. Following their emergence in the 1960s, PBMs' initial role was to negotiate payment rates with pharmacies and manage prescription claims. The advent of electronic claims processing in the 1980s enabled PBMs to adjudicate pharmacy transactions in real time, creating administrative efficiencies and providing incentives for health plans and employers to contract for PBM services.[3] In subsequent decades, payers increasingly delegated the administration of their pharmacy benefits, expanding PBMs' scope of authority from adjudicating prescription claims to setting up pharmacy networks; designing formularies; conducting drug utilization reviews; operating mail order, retail, and specialty pharmacies; and negotiating rebates with pharmaceutical manufacturers.

After nearly two decades of horizontal consolidation, the PBM industry has become increasingly dominated by a small number of large companies.[4] Significant mergers and acquisitions have included Caremark's acquisition of AdvancePCS in 2004, CVS Health's acquisition of Caremark in 2007, Express Scripts' acquisition of Medco Health Solutions in 2012, and UnitedHealth's acquisition of Catamaran in 2015.[5,6] The combined market share of the three largest PBMs has grown significantly, from 48 percent in 2010 to 80 percent in 2021.[7,8] Today, just six companies control 96 percent of the PBM market.[9]

In recent years, the three largest PBMs – CVS Caremark, Express Scripts, and OptumRx – 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. They also comprise some of the largest companies in the U.S. Each is ranked among the top 15 companies on the Fortune 500 list for 2021, and their combined average annual revenues are nearly four times greater than the combined average for the three largest pharmaceutical manufacturers.[10]

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

Source: Fein, AJ. The 2022 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers, Drug Channels Institute. March 2022.

<u>PBM Contracting Entities and Business Arrangements Between Large and Small PBMs Further Consolidate the Market</u>

Despite the already considerable market power of their respective PBMs, each of these vertically integrated organizations has recently created a separate "rebate contracting entity" that is responsible for negotiating, collecting, and disbursing manufacturer rebates for their commercial book of business. Rebate contracting entities combine the purchasing power of large PBMs, smaller PBMs, and health insurers, significantly increasing their leverage in negotiations with manufacturers.[11] To date, very limited information about these rebate contracting entities, including their financial relationships with PBMs and insurers, has been made publicly available. The three entities and their associated PBMs / health insurers are:

- Ascent Health Services: Express Scripts / Cigna, launched in 2019
- Zinc: CVS Health / Aetna, launched in 2020
- Emisar Pharma Services: OptumRx / UnitedHealthcare, launched in 2021

In addition to increased negotiating leverage, market analysts and industry experts suggest that rebate contracting entities may create other advantages for PBMs. First, two of the three rebate contracting entities of these U.S.-based corporations are headquartered overseas (Ascent Health Solutions in Switzerland and Emisar Pharma Services in Ireland), allowing them to take advantage of lower foreign corporate tax rates and more restrictive privacy laws. Second, PBMs are consolidating market power through these entities to create new revenue streams via additional administrative service fees charged to manufacturers.[12] Growth of administrative service fees is consistent with research showing that PBMs are increasingly shifting away from a compensation model based on retained commercial rebates –

perhaps in response to increased public and employer scrutiny – in favor of revenues collected from spread pricing and administrative service fees assessed on manufacturers, payers, and pharmacies.[13] Some industry analysts have noted that rebate contracting entities are increasingly pressuring manufacturers to pay fees on all prescription claims that flow through the PBM, not just on claims that are actually rebate eligible.[14]

Changes in corporate structures are at the sole discretion of the PBMs, and other market players are generally left to respond to the market that the PBM presents to them. Higher administrative fees and new types of fees – based on service arrangements that are largely dictated by the PBM – are generally retained by contracting entities and their affiliates and do not appear to provide any direct benefits for patients.

In recent years, 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.[15,16,17] Lacking the negotiating clout of their larger competitors, smaller entities have thus far been unsuccessful in reducing the overall market share of the three largest PBMs.[18] In many instances, smaller PBMs contract or partner with larger PBMs to leverage their claims management systems 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.[19,20] For example, in 2021 Express Scripts managed the pharmacy network contracting and rebate negotiations for approximately 40 percent of prescriptions covered by Prime Therapeutics, a smaller PBM.[21] Such arrangements further contribute to the overall consolidation of the PBM market.[22]

Recommendation for the FTC: Examine the role played by rebate contracting entities in negotiating, collecting, and disbursing manufacturer rebates and the growth in service fees charged to manufacturers. What is the corporate relationship between these rebate contracting entities and the PBMs or insurers who own them?

PBMs Leverage Their Concentrated Market Power to Extract Large and Growing Payments from Manufacturers, Typically Without Direct Benefits for Patients

Patients Rarely Benefit Directly from the Significant Price Negotiations Happening in the Market Today

PBMs administer prescription drug benefits for more than 266 million publicly and privately insured Americans.[23] Negotiating on behalf of health plans, employers, and other payers, PBMs extract billions of dollars from pharmaceutical manufacturers each year.[24] These payments are comprised largely of rebates and fees set with reference to a medicine's wholesale acquisition cost (WAC), also known as the list price. The PBM industry is highly consolidated, with 80 percent of the market controlled by just three large companies: CVS Caremark, Express Scripts, and OptumRx.[25] The sheer volume of prescription claims managed by the three largest PBMs provides them with significant leverage in negotiations, often to the detriment of patients and competition.

In addition to the significant payments provided to PBMs, brand manufacturers are also required by statute to provide sizable rebates and discounts to government programs. Combined, total rebates, discounts, and other payments from brand manufacturers to PBMs, payers, providers, government, and others have tripled since 2012, reaching $236 billion in 2021.[26,27] Manufacturer price concessions can significantly lower the net prices of brand medicines, which were 49 percent lower, on average, than wholesale acquisition costs (i.e., list prices) in 2021.[28] Net prices for brand medicines have increased at or below the rate of inflation for the past five years and are projected to remain flat or decline by up to 3 percent annually through 2025.[29]

Net prices reflect the final prices paid by PBMs and health plans. Yet in the majority of cases, the net price is not the price available to patients with insurance at the pharmacy counter. Instead, patients with deductibles and coinsurance – who pay a percentage of the cost of their medicine rather than a fixed copayment – are typically required to pay based on the undiscounted list price, rather than the net price that reflects the rebates and discounts paid to the PBM by the manufacturer. 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 negotiated rates.

Health plans and employers often use some portion of the rebates paid by manufacturers 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 expenditures to pay more out of pocket, while rebate savings are spread out among all health plan enrollees in the form of lower premiums.[30] 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.

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.[31,32] 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, nearly half (49 percent) of commercial and 92 percent of Part D total patient out-of-pocket spending for brand medicines is based on list price.[33,34]

Requiring patients to pay cost sharing based on list prices can result in a health plan or PBM realizing a net gain when a prescription is filled. As an example, imagine a patient enrolled in a high deductible health plan who takes a medication with a list price of $400. The patient's PBM has negotiated a 55 percent rebate on this medicine, equal to $220. However, because the patient has not yet met her deductible, her bill at the pharmacy counter reflects the medication's full list price of $400. Despite paying nothing for this patient's medicine, the PBM still collects the rebate, receiving a payment of $220 from the manufacturer. Furthermore, the out-of-pocket cost to the patient ($400) in the deductible exceeds the net price that the PBM will pay ($400 - $220 = $180) once the patient has met her deductible.

While there is clear credible evidence that net prices and spending for brand medicines are growing more slowly than inflation,[35] that is not the case for patients because such a large – and growing – share of the rebates paid by manufacturers are not being used to reduce patient costs at the pharmacy counter. Today, more than 50 percent of spending on brand medicines goes to others in the supply chain, including PBMs, health plans, employers, government, hospitals and other stakeholders – that do not research, develop, and manufacture novel medicines.[36] In fact, in recent years more of the increase in spending on brand medicines has gone to payers, including PBMs and health plans, than to pharmaceutical manufacturers.[37,38] As noted above, rebate dollars do not translate into lower prices for medicines; they may be used by PBMs and plans any way they wish, including dividends to shareholders.

Indeed, while rebates have grown and net prices continue to fall, patient out-of-pocket costs are increasing. To illustrate, despite a 62 percent decrease in the net price of a leading insulin since 2012, the average out-of-pocket costs for commercially insured and Medicare Part D patients taking this insulin increased by 60 percent over this period.[39] This dynamic negatively impacts patient affordability, access, and adherence to prescribed medicines, which ultimately drives greater costs to the health care system.

Recommendation for the FTC: Undertake a rigorous analysis of whether and how PBMs and payers use rebates paid by manufacturers to directly benefit patients who utilize prescription medicines.

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

According to a recent 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."[40] Historically, PBMs often retained a portion of the rebates they negotiated on behalf of their commercial health plan and employer clients, denominated as a portion of a medicine's wholesale acquisition cost (i.e., list price), as compensation for their services.[41,42] In addition, the administrative fees that PBMs charge to plan sponsors and pharmaceutical manufacturers are commonly based on a percentage of list price and are usually retained in total by the PBM. Because rebates and administrative fees paid to PBMs are typically calculated as a percentage of a medicine's list price, government agencies, economists, and other experts have noted that PBMs may favor medicines with high list prices and larger rebates to maximize their revenue.[43,44,45]

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.[46,47] Despite public statements by PBMs that they support reforms to lower the price of medicines for patients and encourage manufacturers to lower list prices,[48,49] at least one PBM has introduced contract terms that discourage list price reductions.[50] This PBM requires significant advance notice (in some cases nearly two years) in order for a manufacturer to reduce a product's price. Moreover, if such notice is not provided, it penalizes the manufacturer by requiring the manufacturer to continue to pay rebates to the PBM based on the higher list price.[51] 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.[52]

PBMs leverage their control over the market to demand favorable contracts with manufacturers at the expense of patients. According to the Senate Finance Committee, "[m]anufacturers have a strong financial incentive to gain access to a plan sponsor's formulary, particularly national formularies administered by the three largest PBMs on behalf of hundreds or thousands of health plan clients."[53] PBMs' tremendous bargaining power often allows them to dictate terms of contracts with manufacturers. Manufacturers may have very little or no opportunity to edit these template adhesion contracts created by PBMs, which may contain terms that penalize manufacturers for price reductions.

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.[54,55] 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."[56]

In addition, 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.[57,58] Although such arrangements may insulate the PBM and plan from changes in list price, patients with deductibles and coinsurance – whose cost sharing is 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.

<u>PBMs May Exclude Lower List Price Versions of Brand Medicines from their Formularies in Favor of Higher List Price Versions</u>

"Authorized Generics" is a term commonly used to describe approved prescription medicines that are marketed under the relevant New Drug Application but do not have the brand name. Innovator pharmaceutical manufacturers may make Authorized Generics available at lower list prices to lower patient out-of-pocket costs. Manufacturers have done this with insulins, which as biologics are not technically authorized generics, but may similarly be authorized by their manufacturer. Despite the availability of authorized generic versions of certain brand 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.[59] For example, in 2022, two of the three largest PBMs excluded one or more lower list price authorized insulins in favor of a higher list price alternative.[60,61] Coverage of lower list price options 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.[62] PBMs' exclusion of lower list price options in favor of medicines with higher list prices and large rebates has financial implications for patients with deductibles or coinsurance. For some patients, having these medicines on the PBM's formulary could reduce their out-of-pocket costs by hundreds or thousands of dollars per prescription.[63]

The three largest PBMs have also been reluctant to encourage utilization of the first interchangeable biosimilar long-acting insulin, which became available in 2021.[64] Industry analysts have noted that market dynamics – whereby PBMs prefer high list price products with larger rebates – prompted the manufacturer of the 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.[65] Not one of the three largest PBMs includes the lower list price version as a preferred option on their 2022 standard 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 dramatically lower out-of-pocket costs for insulin for many patients.

Recommendation for the FTC: Evaluate whether PBM contracts and downstream agreements with their clients (e.g., rebate guarantees) demonstrate a preference by PBMs to cover brand medicines with higher list prices over lower list price options.

PBM Formulary Decisions and Utilization Management Restrictions Can Influence Which Medicines Patients Can Access, and When

PBMs Increasingly Impose Utilization Management Restrictions and Formulary Exclusions

The formularies that PBMs establish for their clients govern which medicines are covered, the associated patient cost sharing, and any utilization management or other restrictions on their prescribing or use. PBMs may use a variety of utilization management techniques to direct patients and providers towards their preferred medicines, including:

- Prior authorization – the PBM requires the provider to seek approval to prescribe a medicine by submitting documentation to prove that a particular medicine is being prescribed consistent with the PBM's own established clinical criteria or is medically necessary for an individual patient.
- Step therapy – patients must fail on one or multiple alternative drugs before the PBM will cover the medicine originally prescribed by the provider.
- Formulary exclusions – a medicine is not included on the list of drugs covered by a PBM.

The number of medicines subject to utilization management in the commercial market and Medicare Part D has grown over time. In the commercial market, a recent study by Avalere Health found that prior authorization and step therapy for single-source brand medicines increased for all therapeutic areas in

the analysis, including conditions such as cancer, depression, rheumatoid arthritis (RA) and diabetes, between 2014 and 2020.[66] Similar trends have been observed in the Medicare Part D market, where the average number of medicines covered by Part D plans that were subject to utilization management restrictions increased from 27 percent in 2010 to 47 percent in 2021.[67]

PBMs commonly apply utilization management restrictions to innovative medicines, including treatments for cancer, RA, multiple sclerosis (MS), hepatitis C, and high cholesterol.[68] Often, PBMs have a narrower allowed usage for medicines than what the FDA has approved in the labeling, and they use prior authorization and step therapy to limit the circumstances in which patients can access these medicines. One recent study found that more than 80 percent of commercial health plans' step therapy policies for specialty medicines were more restrictive than the FDA labeling and more than half were more restrictive than recommended clinical guidelines.[69]

The past decade has also seen a proliferation in the number of medicines excluded from PBM formularies. Formulary exclusions significantly increase PBMs' negotiating leverage with manufacturers.[70] According to the Senate Finance Committee, "[p]harmaceutical companies are sensitive to the sheer size of PBMs and the resulting product volumes they can affect, which allows the middlemen to extract higher rebates from manufacturers through the use of formulary exclusion tactics."[71] The practice of formulary exclusions began in 2012, when CVS Caremark became the first PBM to exclude a subset of medicines from its standard commercial formulary. Express Scripts and OptumRx followed in 2014 and 2016, respectively.[72] In 2020, nearly 850 unique medicines were excluded from at least one of the three largest PBMs' standard formularies, a 676 percent increase since 2014.[73]

Medicines to treat common chronic conditions like diabetes, cardiovascular disease, and depression are frequently excluded from PBM formularies.[74] PBMs also increasingly exclude medications to treat complex conditions like cancer, autoimmune disorders, and HIV, even though variation in patient response to treatment for these conditions is well-documented.[75] Nearly one in five PBM formulary exclusions target single-source brand medicines for which generic equivalents or biosimilar alternatives are not yet available.[76]

Patients who require treatment with a medicine excluded from a PBM's formulary may be forced to pay the full price for the medicine out of pocket or undertake a burdensome appeals or exceptions process, which may delay onset of treatment. Patients who change health plans (or employers) can unknowingly lose access to medicines they have been taking for months or years. Although plan sponsors are not required to use their PBM's standard formulary, adopting a custom formulary may result in additional costs through fees or a reduction in rebates the plan sponsor receives from the PBM.[77] According to a survey of PBMs, 85 to 90 percent of large employers use their PBM's standard formulary.[78]

Physician and patient organizations have protested PBM formulary exclusions on the grounds that they force stable patients to change therapies without clinical justification, a practice known as non-medical switching (this practice is discussed in more detail below).[79,80] For example, in a recent letter to CVS Caremark, the Partnership to Advance Cardiovascular Health denounced the PBM's unilateral decision to remove all but one direct oral anticoagulant from its 2022 commercial formulary, calling it

"dangerously disruptive for patients currently on therapy." The letter also claimed that CVS Caremark's action would "disproportionately affect historically disadvantaged patients" and "unquestionably exacerbate health equity concerns that exist in cardiovascular care."[81]

Recommendation for the FTC: Study the impact on consumer prices, out-of-pocket spending, and experiences when PBMs deny formulary placement, limit coverage of a medicine, or encourage non-medical switching.

Utilization Management Restrictions May Interfere with Patient Access to Medicines

Onerous utilization management restrictions may interfere with the patient-physician decision making process and blur the lines between benefits administration and the practice of medicine. PBMs claim that utilization management tools simultaneously lower costs and promote clinically appropriate medication use. However, research shows that these tools can have the unintended consequence of keeping patients from accessing the medicines they need.[82] Numerous studies have found that utilization management restrictions may be associated with therapy delays, gaps in care, and lower medication adherence, which can lead to increased use of expensive hospital and emergency care and higher overall health care costs.[83] Utilization management restrictions have also been shown to disproportionately burden communities of color, with Black Americans and Hispanic Americans nearly 1.5 times and nearly twice as likely, respectively, to report being subject to utilization management for prescription medicines relative to white Americans.[84]

Step therapy requirements – also known as "fail first" – can be particularly burdensome for patients.[85] Recent research highlights the frequency with which PBMs and health plans use step therapy, finding that large commercial payers apply these restrictions to nearly 40 percent of their coverage policies for specialty medicines.[86] This study also found that use of step therapy protocols was inconsistent across payers, both in terms of the particular medicines subject to step therapy and the number of therapies required to demonstrate treatment failure (i.e., step therapy may involve failing on two or three different medicines prior to receiving the medicine prescribed by the patient's physician).[87]

In a survey of patients with cancer, 1 in 7 respondents reported that they had encountered step therapy during the prior 12 months of treatment, which required them to first try an alternative cancer medication before receiving the medication originally prescribed by their physician.[88] Cancer patients may also be subject to commercial policies that require them to fail on older, less effective therapies before administering new IV treatments to treat iron-deficiency anemia,[89,90] which can result in patients incurring additional copayments as well as added transportation and other expenses. First-hand patient accounts also indicate that upon switching insurance providers, payers may require patients to repeat step therapy protocols, even when it means taking medicines that they have previously tried without success,[91] which can be challenging for patients experiencing complex or terminal conditions.

PBM Formulary and Utilization Management Decisions Lack Transparency

The clinical and economic rationale for PBM formulary and utilization management decisions is decidedly opaque.[92,93] This lack of transparency is particularly concerning in light of the PBMs' distorted financial incentives, discussed above, and the exacerbation of those incentives through increased consolidation and vertical integration with payers.

PBM formulary and utilization management decisions are made by Pharmacy and Therapeutics (P&T) committees comprised of physicians, pharmacists, and other health care professionals not otherwise employed by PBMs. The three largest PBMs contend that P&T committee decisions are based solely on clinical efficacy and do not take the cost of a medicine into consideration.[94,95,96] However, in addition to a P&T committee, each of the three largest PBMs also maintains a separate internal formulary review committee, made up of the PBM's employees, that may explicitly consider the cost of a medicine when making recommendations about the coverage status of certain medicines.[97,98,99]

PBM P&T committees are not required to publicly disclose the sources or types of evidence used to inform their decision making, nor how they weighed each piece of evidence.[100] The degree to which the P&T committee may have relied on controversial measurements of value or whether they considered important patient-centric factors such as heterogeneity in treatment response (i.e., the likelihood that a treatment may have different effects for different patients), improvements in quality of life or other patient-reported outcomes, and the potential for reducing health disparities for communities of color is generally unknown.

Very Little Research Has Explored the Clinical Justification and Basis for PBM Coverage Decisions

One recent effort by the Institute for Clinical and Economic Review (ICER) – which typically adopts a pro-payer perspective – to determine whether medicines are covered "fairly" was largely stymied by a lack of available data.[101] Many of the fair access criteria pre-specified by the researchers could not be ascertained from payers' publicly available cost sharing and prior authorization documentation. For example, ICER was unable to determine the "[e]fficiency of process for requesting and adjudicating medical exceptions for individual patients," whether payers had "[s]ought input from clinical experts on whether there are distinctive benefits and harms of treatment that may arise for biological, cultural, or social reasons across different communities," or whether payers' clinical eligibility criteria "[c]onsidered limitations of evidence due to systemic under-representation of minority populations."

The ICER report concluded that greater transparency regarding the framing and implementation of payer coverage policies is needed. In some instances, the report noted, "[c]overage policies and tiering have been treated by some companies as competitive assets, held in confidence, and used to seek advantages against rivals." For example, while many payers openly publish information about their utilization management requirements for specific medicines, one of the three largest PBMs, OptumRx, only makes information about its prior authorization policies available to providers, with no opportunity for review by patients, researchers, or the public.[102] This lack of transparency about coverage limitations

and cost sharing requirements can be especially burdensome for patients, resulting in confusion, delays in accessing necessary medicines, and difficulty adhering to treatment regimens.

Although the same clinical data are available to each PBM's P&T committee, there is often considerable variation in which medicines are excluded from the standard formularies of the three largest PBMs.[103,104] Furthermore, it is not uncommon for medicines previously on a PBM's formulary to be later excluded, and in some cases subsequently added back, even with no change to available therapeutic alternatives or clinical guidelines.[105] Using cost-effectiveness as a proxy for a medicine's clinical value, researchers reviewed the formulary exclusion lists of two of the three largest PBMs and failed to find an association between cost-effectiveness and a medicine's exclusion status.[106] They concluded that as a result of PBMs' exclusion policies, some patients "will be asked to switch from an excluded to a recommended drug in spite of the fact that in some instances the excluded drug is clinically superior."[107] Although cost-effectiveness metrics often provide an incomplete and imperfect picture of value,[108,109,110] these findings suggest that the observed variation in the exclusion lists of PBMs is frequently unrelated to a medicine's clinical benefits, contrary to claims commonly made by PBMs.[111,112] As previously noted, this is difficult to ascertain due a lack of transparency into payer use of evidence and decision making.

Payer Access Restrictions May Override Physicians' Authority to Make Independent Clinical Decisions

The practice of requiring patients to change therapies for reasons other than suboptimal clinical efficacy, side effects, or poor adherence is known as non-medical switching. Based on a systematic review of the literature, non-medical switching is commonly associated with negative clinical and economic outcomes for patients, particularly when patients' conditions are already well managed by their existing treatment regimen.[113] These negative outcomes may include discontinuation of treatment, disease exacerbation, hospitalizations and emergency department visits, higher medical costs, and premature mortality.

Non-medical switching may occur when a PBM makes a change to the formulary mid-year. PBMs may add utilization management restrictions, assign medicines to higher cost sharing tiers, or drop medicines from the formulary at any time, often with as little as 30- or 60-days' notice to patients.[114] As a result, patients may find that the medicines they've been taking for months or years – which they understood to be on formulary at the time they enrolled in their health plan – suddenly have significantly higher out-of-pocket costs or are no longer covered. Recognizing that formulary stability is important for beneficiaries to maintain access to needed therapy, the Centers for Medicare & Medicaid Services (CMS) has established robust protections against mid-year formulary changes in the Medicare Part D program. Part D plan sponsors may not remove a medicine from their formulary, increase the cost sharing, or impose new or more restrictive utilization management requirements mid-year without seeking prior approval from CMS and must exempt beneficiaries taking the affected medicine for the remainder of the year.[115] However, similar protections are limited in the commercial market.

While non-medical switches frequently occur as a result of PBM formulary exclusions or patient cost sharing changes, at least one payer has also offered certain patients a direct financial incentive to encourage them to switch therapies. In 2021, Cigna (owner of the nation's second largest PBM, Express Scripts, which makes formulary decisions on behalf of most plans offered by Cigna) began offering

patients taking a certain autoimmune medicine a $500 debit card to incentivize them to have their physicians switch them to an alternative medicine preferred by the payer.[116] Patients who chose to remain on their existing therapy would be required to pay a higher out-of-pocket cost.[117] The American Medical Association House of Delegates subsequently passed a resolution opposing this action, noting that "using money to persuade patients to make a choice against their own health raises ethical concerns" and "will disproportionately affect patients of lower socio-economic status, who may have less ability to refuse such a payment despite their health interests."

HHS OIG Has Identified Potential for Conflicts of Interest Among P&T Committees in Medicare Part D

Conflicts of interest may compromise the objectivity of the P&T committee process. To this end, federal regulations and guidance issued by CMS require that P&T committees employed by Medicare Part D plan sponsors have at least one practicing physician and one practicing pharmacist who are independent of, and free of conflict with, the Part D plan sponsor and pharmaceutical manufacturers.[118] However, CMS has not extended these conflict-of-interest requirements to include the PBMs that manage benefits on behalf of Part D plan sponsors. Nor are there such requirements on PBMs' commercial market business for large and self-insured group health plans.

The HHS OIG has raised concerns about whether existing CMS regulations are sufficient to ensure that Part D P&T committee members are free from potential financial conflicts of interest. An investigation by the OIG revealed that two-thirds of Part D P&T committees maintained by PBMs did not include having a financial stake in the PBM in their definition of conflict of interest.[119] Despite a recommendation by the OIG that CMS require P&T committee members to be independent and free of conflict from PBMs, CMS did not accept this recommendation and accordingly has not issued regulations or guidance to this effect.

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

PBMs Use Narrow Pharmacy Networks to Steer Patients Towards Affiliated or Preferred Retail Pharmacies

Traditionally, health plans offered unrestricted access to retail pharmacies and patient cost sharing did not vary based on the pharmacy that filled the prescription. Over the past decade, PBMs have implemented narrow networks that incentivize or require patients to fill prescriptions at specific pharmacies that are either affiliated with the PBM or that agree to accept lower reimbursement rebates as a condition of network participation.[120] There are two types of narrow pharmacy networks:

- *Preferred pharmacy networks*, where patient cost sharing is lower at in-network pharmacies compared to out-of-network pharmacies.
- *Closed pharmacy networks*, where patients are required to use in-network pharmacies or preferred distribution formats (e.g., mail order pharmacy for maintenance or specialty medicines) for their treatment to be covered by insurance.

Pharmacy networks limit patient choice of pharmacies while enabling PBMs to capture larger margins on each prescription filled. Pharmacies that reject low reimbursement rates or other PBM contract terms face exclusion from networks that serve a large share of the market. Currently, 90 percent of Medicare Part D prescription drug plans (PDPs), 66 percent of Medicare Advantage prescription drug plans (MA-PDs), and 35 percent of large commercial plans have adopted a preferred pharmacy network.[121]

PBMs Leverage Their Market Power to Craft Favorable Contracts at the Expense of Pharmacies, Employers, and Patients

PBMs heavily influence the net revenue a pharmacy will realize for each prescription filled.[122] Market power allows PBMs to craft extraordinarily favorable agreements with pharmacies to capture a significant share of pharmacies' would-be dispensing margins. For example, PBM and pharmacy contracts often include "performance" clauses so that a pharmacy receives an additional payment for exceeding a pre-specified metric or is required to return a portion of their payment to the PBM if they underperform. In practice, however, the payments *from* pharmacies to PBMs have far exceeded the payments *to* pharmacies from PBMs.[123] This suggests PBMs are able to compel pharmacies to agree to unrealistic performance metrics, which provide PBMs another avenue to collect additional revenue from pharmacies.

Pharmacy fees have become an increasingly important source of revenue for PBMs. Data from CMS show that retrospective pharmacy price concessions in Medicare Part D, also known as direct and indirect remuneration (DIR) fees, increased by more than 107,400 percent from 2010 to 2020.[124] As observed in a recent report commissioned by the Community Oncology Alliance, "As employers and plan sponsors are demanding a greater share of the PBM rebates, and as those rebates have been threatened with regulation by state and federal lawmakers, PBMs have gone 'downstream' to make up for any rebate revenue shortfalls by assessing [Direct and Indirect Renumeration (DIR)] fees on pharmacy providers."[125] Net of all pharmacy incentive payments, pharmacy DIR fees increased nearly 170 percent per year, on average, between 2012 and 2020 and now comprise the second largest category of DIR received by PBMs and plan sponsors, with manufacturer rebates being the largest.[126]

Skyrocketing growth in pharmacy DIR fees has not translated into lower out-of-pocket costs for patients. Like manufacturer rebates, DIR fees lower costs for PBMs and plan sponsors, but these savings historically have not been directly passed on to Part D beneficiaries at the pharmacy counter (a final rule recently issued by CMS will require that pharmacy price concessions be applied to reduce the prices available to beneficiaries at the point-of-sale beginning on January 1, 2024).[127] Additionally, DIR fees on medicines are often calculated as a percentage of the list price, further contributing to the misaligned incentives that may lead PBMs to prefer medicines with higher list prices.[128]

Industry analysts have also noted that many PBM contracts lack uniform definitions, giving PBMs a great deal of flexibility to interpret contract terms in their favor and further contribute to the unequal bargaining power in contract negotiations between PBMs and pharmacies, as well as with employers and other payers.[129,130] PBMs appear to take advantage of this lax oversight and the absence of industry standards to modify and adjust contracts as needed to mitigate the effects of unfavorable restrictions or

reforms. For example, following the passage of state maximum allowable cost (MAC) laws, research shows that PBMs increased their use of effective rate guarantees, which enable PBMs to retroactively collect the spread between the amount paid to the pharmacy and the amount reported to the health plan, while still claiming to operate a pass-through pricing model.[131,132]

Lack of industry standards, limited transparency, and lax regulatory oversight are fundamental to PBMs' success, as neither payers nor patients can evaluate whether they are getting value from their pharmacy benefits.[133] In fact, industry analysts have noted that PBM contracts with employers have included clauses that prohibit the employer from conducting an independent audit.[134] According to the PBM Accountability Project, "PBMs' general lack of transparency is critical to their operations and allows them to buy a product or service from one stakeholder in the system and sell that product or service to another stakeholder at a higher price, without the payer understanding the true cost or inflationary nature of the services purchased — a practice known as 'arbitrage'."[135]

Information asymmetry may constrain the ability of employers and plan sponsors to evaluate 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.[136] 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.[137,138] Proposed federal legislation would require PBMs to disclose information on prescription drug utilization, costs, rebates, and fees to plan sponsors in the commercial market. According to the Congressional Budget Office, provisions in this bill would enable some employers and plan sponsors to better evaluate PBM contract provisions and obtain more favorable contracting terms, as well as increase competition among PBMs.[139]

PBM Policies May Disproportionately Harm Communities with Limited Access to Pharmacies

Unfavorable reimbursement terms have resulted in an unsustainable environment for many community pharmacies. The combination of these dynamics has resulted in pharmacy closures across the country. Pharmacy closures are associated with an immediate and sustained reduction in medication adherence, leading to poorer health outcomes for patients in impacted communities.[140,141] For example, community pharmacy closures were associated with a 50 percent increase in a patients' likelihood of abandoning their cardiovascular medicines.[142]

Pharmacy closures are twice as likely to occur in lower-income areas, further exacerbating existing access challenges for these communities.[143] Between 2009 and 2015, approximately one quarter of pharmacies serving low-income urban populations closed.[144] As a result, in 2015, one-third of all neighborhoods in the largest U.S. cities were considered pharmacy deserts, leading to poorer medication access for nearly fifteen million people in disproportionality Black and/or Hispanic/Latino neighborhoods.[145]

Narrow pharmacy networks further exacerbate these challenges by limiting the number of pharmacies where a patient can fill their prescription at the lowest possible out-of-pocket cost. This may force

patients to choose between paying more for their medicine or traveling farther to fill a prescription at a preferred pharmacy. Both options disproportionately affect populations who already experience health disparities, including those from lower-income communities, patients with mobility challenges, and patients who lack access to reliable transportation.

PBM-Owned Pharmacies Allow PBMs To Impose Non-Transparent and Harmful Policies on Patients, Like Accumulator Adjustment Programs and Copay Maximizers

Vertically integrated pharmacies provide PBMs with the necessary visibility and control to implement policies like accumulator adjustment programs (AAPs) and copay maximizers. AAPs exclude the value of manufacturer cost-sharing assistance given to eligible commercially insured patients from counting toward patients' deductibles and out-of-pocket maximums.[146] Copay maximizers adjust individual patient cost sharing upwards to match and exhaust the full value of the manufacturer-provided assistance.[147] PBMs often use these policies to undermine the intended impact of manufacturer cost-sharing assistance programs, which help eligible patients afford their out-of-pocket costs at the pharmacy counter and can significantly improve patient adherence to medicines. In 2019, the use of these cost-sharing assistance programs reduced patients' likelihood of abandoning their brand medicines at the pharmacy by an estimated 82 percent.[148]

While these programs are operated by payers outside the control of manufacturers and usually without their knowledge, analysts report that AAPs and copay maximizers have become more commonplace in the commercial market.[149] As use of these programs grows, their potential impact on certain patients – based solely on a patient's medical condition or need for a specific medicine – is concerning and could run afoul of nondiscrimination requirements.[150] PBMs and plans have been opaque about when they operate an AAP or copay maximizer and how it will impact patients.[151] Among Health Insurance Exchange plans, 42 percent did not disclose use of an AAP in materials made available prior to plan enrollment.[152]

Despite claims to the contrary from PBMs to justify the application of AAPs and copay maximizers, cost-sharing assistance does not bypass the PBM formulary process, undermine health insurance benefit design, or steer patients towards brand medicines. Additionally, use of AAPs and copay maximizer programs can slow patients' progress through the health insurance benefit and increase their out-of-pocket costs for other health care products and services. Meanwhile, there is wide consensus that AAPs shift costs to patients, leading to negative consequences. Many patients subject to an AAP experience an unexpectedly high out-of-pocket cost for their medicine mid-year when their cost-sharing assistance is exhausted. Patients experiencing this "copay surprise" have been observed to be more than 13 times as likely to discontinue therapy as patients who experience consistent copays.[153] CMS has also acknowledged that AAPs can expose patients to high out-of-pocket costs, which may cause them to stop taking their medicine, switch to an alternative, or pay more out-of-pocket, "none of which are patient-friendly, especially for those patients with rare and life-threatening conditions."[154] As noted above, "manufacturers have no control over (and sometimes no information concerning) those programs."[155]

PBMs also increasingly employ copay maximizer programs, which can fully exhaust manufacturer cost-sharing assistance in a plan year. Each large PBM implements copay maximizers directly or via partnerships with nontransparent, independent private companies.[156] These programs partly utilize a purported loophole in regulatory requirements for large and self-insured 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 annual limit on cost sharing. These programs may discriminate against enrollees who use cost-sharing assistance provided by manufacturers by offering more limited benefits – and higher cost sharing – to them as compared to other enrollees who have other forms of cost-sharing assistance, including family support. Copay maximizers can also 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.[157,158] When these pharmacies are not easily accessible, patients can face obstacles or delays in filling their prescriptions.

Manufacturers offer cost-sharing assistance directly to eligible patients; these programs are not intended to reduce costs for the patient's PBM or health plan. Any reduction in drug costs that the PBM or health plan unilaterally achieves through AAPs or copay maximizers occurs against the will of, and without the consent of, the manufacturer, and at the expense of patients. Public data from copay maximizer vendors including SaveonSP and PrudentRx indicate that health plans pay these vendors administrative fees of 25 percent or more of the total amount of cost-sharing assistance intended for patients and diverted through copay maximizer programs.[159] This payment structure comes with little transparency for patients enrolling through the manufacturer for assistance at the behest of these copay maximizer entities.

Vertical Integration with Pharmacies Can Generate Sizable and Growing Revenue Streams for PBMs

In-House Specialty and Mail Order Pharmacies Represent a Large and Growing Source of Profit for PBMs

Vertically integrated specialty and/or mail order pharmacies represent a significant and growing source of PBM revenue. Through vertical integration, PBMs may require patients to use an in-house pharmacy, a plan-owned 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 certain patients to use CVS' mail order or retail pharmacies if they wish to fill prescriptions for a 90-day supply of a medicine.[160] Similarly, a vertically integrated organization can require the providers it employs to direct patients to pharmacies or other provider groups owned by the organization and may reward physicians for prescribing in compliance with the PBM's formulary. Such arrangements would be more difficult for PBMs to enforce if the provider and pharmacy were part of different organizations.[161]

A recent study by the PBM Accountability Project estimates that total gross profit from PBM-affiliated specialty and mail order pharmacies increased from $8.9 billion in 2017 to $10.1 billion in 2019, accounting for 36 percent of PBMs' total gross profit.[162] By incentivizing or requiring the use of 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.[163,164] Nearly 60 percent of large commercial health plans financially incentivize enrollees to fill maintenance medications at PBM-affiliated mail order pharmacies and more than half (51 percent) use a restricted specialty pharmacy network.[165]

PBM-owned specialty pharmacies may also generate new sources of revenue by enabling PBMs to manage specialty medicines administered by providers in outpatient health care settings. These medicines have historically been purchased directly by providers and covered under a health plan's medical benefit, often without access restrictions like utilization management and formulary exclusions. In place of the traditional provider "buy and bill" system, PBMs increasingly require provider-administered medicines to be filled at their in-house specialty pharmacy 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). In both situations, providers continue to receive a fee for administering the medicine, but the cost of the medicine is reimbursed by the PBM directly to the specialty pharmacy.

PBM-mandated brown bagging and white bagging practices shift the profit margins on specialty medicines from providers to PBM-affiliated pharmacies. More importantly, they may limit patients' treatment options by allowing PBMs to apply utilization management tools like prior authorization and step therapy to medicines that historically have not been subject to such restrictions.[166] Despite warnings from the American Hospital Association that white and brown bagging practices may disrupt timely patient access to medicines and/or compromise patient safety and quality of care,[167] white and brown bagging have grown to account for more than one-third of hospital outpatient departments' sourcing of oncology medicines.[168]

Contract Pharmacy Relationships Give PBM-Owned Pharmacies an Outsized Role in the 340B Drug Discount Program

Although the 340B Drug Discount Program was originally limited to providers serving a predominately safety net patient population, the growing use of for-profit participants such as contract pharmacies has given for-profit and PBM-owned retail and specialty pharmacies a large, and growing, role in the program. "Contract pharmacies" originated in 1996 via guidance from the Health Resources and Services Administration (HRSA) allowing a health clinic or qualifying hospital without an in-house pharmacy to enter into an arrangement with one contract pharmacy to receive discounted 340B drugs and dispense them to the 340B patients on behalf of the covered entity.[169] In 2010, HRSA guidance dramatically expanded the use of contract pharmacies by allowing any covered entity (including covered entities with an in-house pharmacy) to contract with an *unlimited* number of contract pharmacies.[170]

In light of the 2010 policy change from HRSA, allowing for one entity to have multiple contract pharmacy arrangements, PBM-affiliated pharmacies are able to "leverage their market power to drive growth in the 340B program and capture profits related to 340B sales."[171] The concentrated power inherent in these vertically integrated companies with a PBM, health plan, and contract pharmacy under common ownership creates financial incentives for PBM-affiliated pharmacies to be aggressive about contracting with a broad set of covered entities, providing them the opportunity to steer greater utilization to their

own specialty and contract pharmacies. This means hundreds of 340B hospitals and clinics could be served through just one contract pharmacy location (via a mail order facility). Specifically, PBM-affiliated specialty pharmacies account for only 0.5 percent of 340B contract pharmacies (by distinct location) but represent 18 percent of 340B contract pharmacy arrangements (contractual relationships).[172]

This sizeable increase in contract pharmacies – fueled in part by policies not grounded in the governing statute – has not helped increase patient access to affordable medicines. Instead, PBM-affiliated contract pharmacies are exploiting the 340B program to earn outsized profits without any clear benefit to patients, despite the program's original focus to serve safety-net entities. For example, in 2018, 340B covered entities and their contract pharmacies generated an estimated $13 billion in gross profits on 340B purchased medicines.[173] Additionally, the average profit margin earned by contract pharmacies on commonly dispensed 340B medicines is an estimated 72 percent vs. a margin of 22 percent for non-340B medicines dispensed through independent pharmacies.[174]

The significantly higher margins on 340B medicines have incentivized greater vertical consolidation and rapid expansion of contract pharmacy relationships. 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.[175] 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).[176] Mail order pharmacies represent the fastest growing segment of the contract pharmacy dispensing channels. In 2020, mail order contract pharmacies grew by 56 percent from the previous year, at a rate two and a half times the growth rate of 340B retail contract pharmacies.[177]

The 340B revenue generated through contract pharmacies has become significant enough that market analysts are taking it into consideration when evaluating company performance. Recently, an analyst noted that reduced volume of highly profitable 340B prescriptions filled by retail pharmacies will limit CVS Health's ability to exceed its earnings guidance, leading the analyst to downgrade the company's stock.[178]

Steps the FTC Can Take Using Existing Tools to Study the PBM Industry

PhRMA supports the FTC studying PBMs to better understand their market power, identify the conflicts of interest they face, and eliminate the harm they cause. Such a study is consistent with the FTC's priorities to address dominant intermediaries and extractive business models. We, like the American public, want the U.S. health care system to ensure the best treatments get into the hands of providers and patients, and do not get sidelined by PBMs and their vertically integrated affiliates seeking to maximize their bottom lines. Current PBM practices are bad for competition, innovation, and patients. They cannot be changed until they are fully understood in the context of a broad Section 6(b) study.

Additionally, a broad Section 6(b) study may serve as a basis for federal and state lawmakers to take further measures to improve competition in the marketplace by addressing the problematic practices and incentives discussed above. We list some possible areas of legislative and regulatory focus below.

Federal and State Lawmakers Should Consider Market-Based Reforms to Strengthen PBM Incentives, Promote Transparency, and Improve Patient Access and Affordability

Below, we outline a range of potential approaches that federal and state lawmakers could take to improve competition in the marketplace by addressing the problematic – and misaligned – PBM incentives outlined above.

Require 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 would lower patient out-of-pocket costs and help realign payer incentives. In recent years, numerous legislative and regulatory proposals have sought to ensure that Medicare Part D beneficiaries benefit at the point-of-sale from negotiated rebates. For beneficiaries who do not receive low-income subsidies, fully sharing rebate savings at the point-of-sale could reduce cost sharing by 10 to 19 percent on average over the next ten years.[179] Beneficiaries taking brand medicines could see even higher savings. For example, a beneficiary taking a $400 brand medicine with a 30 percent manufacturer rebate could save $120 while in the deductible phase and could continue to save $30 per month if paying coinsurance while in the initial coverage phase.[180] Patients who take brand medicines with relatively large rebates, such as medicines for diabetes, asthma, and autoimmune disorders, would be likely to see larger than average reductions in out-of-pocket costs if the rebates were passed on to them.[181]

Lowering out-of-pocket costs for beneficiaries who need prescription medicines that carry rebates may lead to a small increase in Part D premiums. That is because patients who use these medicines would no longer be subsidizing 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 the healthy subsidizing the sick. For a few additional dollars a month in premium costs, healthier beneficiaries would also gain the security of knowing they have more meaningful drug coverage if their health status were to decline in the future. A recent survey found that a majority of patients (59 percent) prioritize lowering out-of-pocket costs over lowering premiums.[182]

In the commercial market, actuaries estimate that sharing negotiated rebates directly with patients at the point-of-sale would increase premiums by an average of 1 percent or less.[183] Recognizing that lower cost sharing can improve patient access to medicines, some PBMs have already adopted point-of-sale pass through programs for their commercial market customers. Within two months of implementing such a program for fully insured group health plans, OptumRx observed up to a 16 percent improvement in medication adherence.[184] Similarly, CVS Health recently noted that "Not only do [point-of-sale] rebates save employees money, they also make prescription purchases more transparent."[185] In 2021, West Virginia became the first state in the nation to require PBMs to pass through manufacturer rebates at the point-of-sale,[186] and 16 states are considering legislation this year to do the same to ensure that patients receive the benefit of manufacturer rebates at the pharmacy counter.

Increase PBM Transparency for Plan Sponsors and Patients

Policies that would require all rebates, fees, and other payments received by a PBM (and/or their affiliates) to be fully disclosed to plan sponsors, along with plan sponsor audit rights, would help ensure accountability to PBM customers.[187] 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. Smaller employers and health plans especially may not benefit from the price concessions negotiated by PBMs, particularly if a PBM decides not to classify certain fees or other concessions as "rebates."[188,189] In recent years, a growing chorus of plan sponsors have begun questioning PBM practices.[190] A 2017 survey by the National Pharmaceutical Council found that only about one-third of employers found their PBMs trustworthy and only 19 percent of employers understand how PBMs make money from the services they provide.[191] Half of employers also strongly agreed that PBMs' coverage and formulary exclusion decisions lack transparency.[192]

Although the Consolidated Appropriations Act of 2021 requires health plans to report certain information on prescription medicine spending to the federal government, stakeholders like the American Benefits Council have raised concerns that, despite these requirements, plan sponsors may lack the commercial bargaining position to gain access to the necessary plan-level detail on rebates and other prescription drug spending data held by their PBM, even for a fee.[193] Implementing PBM transparency requirements, including audit rights and access to claim data, would provide information necessary for plan sponsors to properly evaluate whether PBMs are effective at managing the pharmaceutical benefit and lowering costs for the payer.

Patients would also benefit from policies requiring additional PBM transparency. Providing patients with real-time, comprehensive information in an easily accessible and understood format about anticipated out-of-pocket costs, utilization management requirements, and the exceptions and appeals process would enable patients to make better choices based on their individual needs. Requiring prior authorization and appeals determinations for state-regulated plans to be made in a timely manner (e.g., 24 to 72 hours), as several states have done, would cut down on the negative impacts that abuse of utilization management restrictions can have on patients.[194,195] There is growing evidence that informed and empowered patients who are engaged in collaborative dialogue and decision-making with their clinicians have the potential to drive better health outcomes, improve care quality, make our health care system more efficient, and cut costs across the entire system.[196]

Require that PBM Compensation is Based on the Value of Services, Not the Price of Medicines

To the extent that PBMs provide valuable services to their clients, they should be entitled to compensation based on that value. However, PBM compensation should not be permitted to be tied to the price of a medicine. Several states have considered legislation that would achieve this goal. Notably, legislation introduced in Nevada would require PBM compensation from health plans to be derived from administrative fees only and prohibits such fees from being based on savings generated by rebates.[197] A bill considered in New York would mandate a pricing model for PBM and health plan contracts that allows for ingredient costs plus an administrative fee. At the federal level, 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.[198] Unfortunately, Congress has chosen to delay the implementation of that rule until 2026 and is considering further delaying it or withdrawing it entirely.[199]

Require PBMs to Be Fiduciaries to Their Clients or Patients

As discussed in this letter, PBMs exercise an enormous amount of influence in the prescription drug market, from negotiating rebates with manufacturers, setting up pharmacy networks, administering the pharmacy benefit on behalf of plan sponsors, crafting utilization management protocols, setting up formularies, and operating mail order, specialty, and/or retail pharmacies. The evolution and growing scope of PBMs' influence on plan sponsors' choices in the market, as well as patients' ability to afford and access their prescriptions, requires a commensurate regulatory structure to ensure that patients are protected. In short, PBMs should be committed to putting patients' and their clients' best interests ahead of their own bottom line when executing their contractual duties.

Expressly imposing a fiduciary duty, a legal concept articulated within the ERISA statute,[200] on PBMs and requiring these companies to act in the best interest of patients would be an important step for Congress to take to ensure that PBMs act in a transparent manner and place their duties to patients and their clients before their own financial interests at all times.

In fighting back state-level fiduciary legislation, the PBM industry has relied on U.S. Department of Labor sub-regulatory guidance, which has said that third party administrators such as PBMs "who have no power to make any decisions as to plan policy, interpretations, practices or procedures, but who perform [certain] administrative functions for an employee benefit plan…are not fiduciaries of the plan."[201] However, as discussed previously in this letter, PBMs *can* exercise these functions with respect to certain plans, and because of vertical integration, PBMs can have significant influence on plan policies at many levels. Recognizing the influential role PBMs have when managing a critical benefit for patients, several states have taken or considered action to require greater PBM accountability to their clients, patients, and providers. For example, New York recently enacted a law that imposes upon PBMs an explicit duty of good faith and fair dealing with all parties, including but not limited to individuals and pharmacies, with whom a PBM interacts in the performance of pharmacy benefit management services. The law also provides that the duty owed to a covered individual shall be the same as that owed to the health plan.[202]

Prohibit Spread Pricing Contracts in All Markets

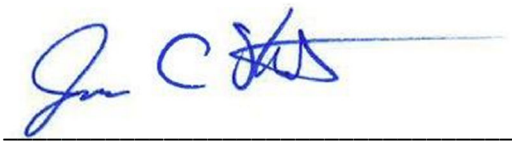
Spread pricing enables PBMs to profit from the difference between the amount they reimburse pharmacies for a medicine and the amount they charge their clients. Famously, Ohio policymakers launched an investigation into PBM practices and found that in addition to costing taxpayers an extra $150 million to $186 million per year by charging above average rates, PBMs had used spread pricing to make over $200 million more per year from the state than they reimbursed pharmacies.[203] After the investigation, Ohio policymakers prohibited spread pricing contracts in Medicaid managed care plans. Subsequently, at least 21 states and CMS took action to limit spread pricing.[204,205] Congress has

considered banning spread pricing,[206] but legislation has never advanced. Similar prohibitions could also be applied to health insurance issuers and group health plans.

* * *

PhRMA appreciates the FTC's effort to solicit input on how the business practices of PBMs impact patients and stakeholders in the prescription medicine supply chain. We hope these comments will help to inform your deliberations. If you have any questions, please contact us.

Sincerely,



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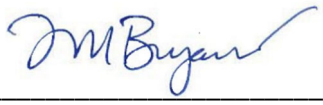

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[1] PhRMA. "2021 PhRMA Annual Membership Survey," July 2021. https://phrma.org/research-and-development/2021-phrma-annual-membership-survey
[2] Schneider EC, Shah A, Sah P, et al. Impact of U.S. COVID-19 Vaccination Efforts: An Update on Averted Deaths, Hospitalizations, and Health Care Costs Through March 2022. The Commonwealth Fund. April 8, 2022. https://www.commonwealthfund.org/blog/2022/impact-us-covid-19-vaccination-efforts-march-update#:~:text=Through%20March%202022%2C%20we%20estimate,in%20the%20absence%20of%20vaccination.
[3] Motheral BR, Fairman KA. Changes in PBM Business Practices in 2019: True Innovation or More of the Same? Journal of Managed Care & Specialty Pharmacy. 2016;26(10):1325-1333. https://doi.org/10.18553/jmcp.2020.20213
[4] Herman B. "FTC may probe pharmacy benefit managers," Axios. February 14, 2022. https://www.axios.com/ftc-study-pharmacy-benefit-managers-drug-prices-3078116f-382a-4b05-ac62-da5bc1d1b892.html
[5] "Caremark Completes Acquisition of AdvancePCS," *The Pink Sheet Daily*. March 24, 2004. https://pink.pharmaintelligence.informa.com/PS058931/Caremark-Completes-Acquisition-Of-AdvancePCS
[6] Sweeney E. "Lawmakers ask FTC for retrospective review of PBM mergers," *Fierce Healthcare.* July 2018. fiercehealthcare.com/payer/house-energy-and-commerce-ftc-pbm-mergers-healthcare-costs
[7] "Top 50 PBM Companies and Market Share by Annual Prescription Volume (Second Quarter 2010)." *Drug Benefit News*. April 16, 2010.
[8] Fein AJ. "The Top Pharmacy Benefit Managers of 2021: The Big Get Even Bigger." Drug Channels. April 5, 2022. https://www.drugchannels.net/2022/04/the-top-pharmacy-benefit-managers-of.html
[9] *Ibid*.
[10] The Fortune 500 – 2021 Fortune 500 Company List. https://fortune.com/fortune500/
[11] Nephron. "Optum Launches 'Emisar' Contracting Entity; Navtius Aligns with Ascent via Prime." July 26, 2021.
[12] *Ibid*.
[13] PBM Accountability Project. "Understanding the Evolving Business Models and Revenues of Pharmacy Benefit Managers," December 2021. https://www.pbmaccountability.org/_files/ugd/b11210_264612f6b98e47b3a8502054f66bb2a1.pdf?index=true
[14] Nephron. "Optum Launches 'Emisar' Contracting Entity; Navtius Aligns with Ascent via Prime." July 26, 2021.
[15] Cohen J. "Capital Rx Aims to Disrupt the PBM Market." *Forbes*. February 2, 2022. https://www.forbes.com/sites/joshuacohen/2022/02/02/capital-rx-aims-to-disrupt-the-pbm-market/?sh=3da9135e319a
[16] "Disrupting Pharmacy Benefit Management: RxParadigm Launches to Restore Drug Industry Competitiveness and Reduce the Costs of Prescription Drugs for Americans." *BusinessWire*. February 9, 2021. https://www.businesswire.com/news/home/20210209005355/en/Disrupting-Pharmacy-Benefit-Management-RxParadigm-Launches-to-Restore-Drug-Industry-Competitiveness-and-Reduce-the-Costs-of-Prescription-Drugs-for-Americans
[17] Gliadkovskaya A. "Startup aims to be a 'no-compromises' PBM, but the market may need convincing." *Fierce Healthcare*. October 6, 2021. https://www.fiercehealthcare.com/payer/startup-aims-to-be-a-no-compromises-pbm-but-market-may-take-convincing
[18] Herman B. "The biggest PBMs are handling more and more of the country's drug price negotiations." *STAT+.* March 22, 2022. https://www.statnews.com/2022/03/22/pharmacy-benefit-managers-revenue-contracts/
[19] Fein AJ. "The 2022 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers." Drug Channels Institute. March 2022.
[20] Levitt JE, Lee DY. "Cautionary tale: Plan sponsors losing manufacturer rebate dollars to PBMs through rebate aggregators." BenefitsPRO. April 15, 2021. https://www.benefitspro.com/2021/04/15/cautionary-tale-plan-sponsors-losing-manufacturer-rebate-dollars-to-pbms-through-rebate-aggregators/
[21] Fein AJ. "The 2022 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers." Drug Channels Institute. March 2022.
[22] PBM Accountability Project. "Understanding the Evolving Business Models and Revenues of Pharmacy Benefit Managers," December 2021. https://www.pbmaccountability.org/_files/ugd/b11210_264612f6b98e47b3a8502054f66bb2a1.pdf?index=true
[23] Pharmaceutical Care Management Association (PCMA). About PCMA. 2022. https://www.pcmanet.org/about/
[24] Fein AJ. "Warped Incentives Update: The Gross-to-Net Bubble Exceeded $200 Billion in 2021." Drug Channels. March 22, 2022. https://www.drugchannels.net/2022/03/warped-incentives-update-gross-to-net.html
[25] Fein AJ. "The Top Pharmacy Benefit Managers of 2021: The Big Get Even Bigger." Drug Channels. April 5, 2022. https://www.drugchannels.net/2022/04/the-top-pharmacy-benefit-managers-of.html
[26] Fein AJ. The 2017 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers. Drug Channels Institute. February 2017.

[27] Fein AJ. "Warped Incentives Update: The Gross-to-Net Bubble Exceeded $200 Billion in 2021." Drug Channels. March 22, 2022. https://www.drugchannels.net/2022/03/warped-incentives-update-gross-to-net.html
[28] IQVIA. "The Use of Medicines in the U.S.: Spending and Usage Trends and Outlook to 2026," April 2022. https://www.iqvia.com/insights/the-iqvia-institute/reports/the-use-of-medicines-in-the-us-2022
[29] *Ibid*.
[30] Girod CS, Hart SK, Weltz S. "2017 Milliman Medical Index." Milliman. May 2017. http://www.milliman.com/uploadedFiles/insight/Periodicals/mmi/2017-milliman-medical-index.pdf.
[31] Kaiser Family Foundation. Employer Health Benefits: 2020 Annual Survey. https://files.kff.org/attachment/Report-Employer-Health-Benefits-2020-Annual-Survey.pdf ;
[32] IQVIA. "Medicine Spending and Affordability in the U.S.," August 2020. https://www.iqvia.com/insights/the-iqvia-institute/reports/medicine-spending-and-affordability-in-the-us
[33] *Ibid*.
[34] PhRMA. "Trends in Out-of-Pocket Spending for Brand Medicines in Medicare Part D." https://www.phrma.org/Report/Trends-in-Out-of-Pocket-Spending-for-Brand-Medicines-in-Medicare-Part-D
[35] Over this period, inflation was 1.7 percent for health insurance, 3.6 percent for hospital services, and 2.6 percent for physicians' services; BLS. "Table 2. Consumer Price Index for All Urban Consumers (CPI-U): U. S. city average, by detailed expenditure category," January 2022. https://www.bls.gov/news.release/cpi.t02.htm
[36] Brownlee A. "The Pharmaceutical Supply Chain, 2013-2020," Berkeley Research Group, January 2022. https://www.thinkbrg.com/insights/publications/pharmaceutical-supply-chain-2013-2020/
[37] *Ibid*.
[38] Van Nuys K, Ribero R, Ryan M. Estimation of the Share of Net Expenditures on Insulin Captured by US Manufacturers, Wholesalers, Pharmacy Benefit Managers, Pharmacies, and Health Plans From 2014 to 2018. *JAMA Health Forum*. 2021;2(11): e213409. https://doi.org/10.1001/jamahealthforum.2021.3409
[39] Sanofi. "Sanofi 2022 Pricing Principles Report: Advancing Responsible Leadership." March 2022. https://www.sanofi.us/dam/jcr:e9d0bb41-e295-4d90-b23c-9b1b9df5116d/Sanofi_2022_Pricing_Principles_Report.pdf
[40] Senate Finance Committee. "Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug," 2021. https://www.finance.senate.gov/imo/media/doc/Grassley-Wyden%20Insulin%20Report%20(FINAL%201).pdf
[41] PBM Accountability Project. "Understanding the Evolving Business Models and Revenues of Pharmacy Benefit Managers," December 2021. https://www.pbmaccountability.org/_files/ugd/b11210_264612f6b98e47b3a8502054f66bb2a1.pdf?index=true
[41] *Ibid*.
[42] Any retention of rebates by PBMs would occur after the rebate is provided by the manufacturer at the sole discretion of PBMs and payers. Such arrangements typically are not transparent to manufacturers.
[43] 84 Fed. Reg. at 2341.
[44] Medicare Payment Advisory Commission. "Report to the Congress: Medicare Payment Policy. Chapter 13: The Medicare Prescription Drug Program (Part D): Status Report." March 2021. https://www.medpac.gov/document/chapter-13-the-medicare-prescription-drug-program-part-d-status-report-march-2021-report/
[45] Sood N, Ribero R, Van Nuys K. The Association Between Drug Rebates and List Prices. USC Schaeffer White Paper. February 11, 2020. https://healthpolicy.usc.edu/research/the-association-between-drug-rebates-and-list-prices/
[46] Sagonowsky E. "UnitedHealthcare demands drug rebates even if pharma cuts list prices: analyst," February 2019. https://www.fiercepharma.com/pharma/letter-to-pharmas-unitedhealthcare-seeks-to-protect-drug-rebates-from-price-reductions
[47] Gal A, Wilkes L, Chen A, et al. "Biopharma and managed care: UNH reaches out to pharma to manage rebate change, but change is hard and pain will spread." Bernstein Research. February 8, 2019.
[48] Testimony of Steve Miller, Executive Vice President and Chief Clinical Officer, Cigna. "Drug Pricing in America: A Prescription for Change, Part III. United States Senate Committee on Finance. April 9, 2019. https://www.finance.senate.gov/imo/media/doc/Cigna%20ExpressScripts%20Testimony%20of%20Steven%20Miller%20MD.pdf
[49] PCMA. "Comments on Department of Health and Human Services Office of Inspector General, Fraud and Abuse; Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees. Proposed Rule." April 8, 2019. https://www.pcmanet.org/wp-content/uploads/2019/04/PCMA-Comments-on-Safe-Harbor-Proposed-Regulations.pdf
[50] Gal A, Wilkes L, Chen A, et al. "Biopharma and managed care: UNH reaches out to pharma to manage rebate change, but change is hard and pain will spread." Bernstein Research. February 8, 2019.
[51] *Ibid*.

[52] Health and Human Services Office of Inspector General. "Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees." 84 Fed. Reg. 2340 (November 20, 2020). https://www.federalregister.gov/documents/2020/11/30/2020-25841/fraud-and-abuse-removal-of-safe-harbor-protection-for-rebates-involving-prescription-pharmaceuticals

[xxv] Senate Finance Committee. "Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug," 2021. https://www.finance.senate.gov/imo/media/doc/Grassley-Wyden%20Insulin%20Report%20(FINAL%201).pdf

[54] Fein AJ. "Express Scripts Launches a New Formulary for a World Without Rebates. Will Plan Sponsors and Drug Makers Play Along?" Drug Channels. November 14, 2018. https://www.drugchannels.net/2018/11/express-scripts-launches-new-formulary.html

[55] Vela L. "Reducing Wasteful Spending in Employers' Pharmacy Benefit Plans." The Commonwealth Fund. August 2019. https://www.commonwealthfund.org/sites/default/files/2019-08/Vela_wasteful_spending_employer_rx_plans_ib.pdf

[56] Fein AJ. "Express Scripts Launches a New Formulary for a World Without Rebates. Will Plan Sponsors and Drug Makers Play Along?" Drug Channels. November 14, 2018. https://www.drugchannels.net/2018/11/express-scripts-launches-new-formulary.html

[57] Senate Finance Committee. "Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug," 2021. https://www.finance.senate.gov/imo/media/doc/Grassley-Wyden%20Insulin%20Report%20(FINAL%201).pdf

[58] PBM Accountability Project. "Understanding the Evolving Business Models and Revenues of Pharmacy Benefit Managers," December 2021. https://www.pbmaccountability.org/_files/ugd/b11210_264612f6b98e47b3a8502054f66bb2a1.pdf?index=true

[59] *Ibid*.

[60] "2022 Prescription Drug List." UnitedHealthcare & Affiliated Companies. https://www.uhcprovider.com/content/dam/provider/docs/public/resources/pharmacy/pdl-commercial-effective-jan-2022.pdf

[61] "2022 National Preferred Formulary Exclusions." Express Scripts. March 22, 2022. https://www.express-scripts.com/art/pdf/NPF_Preferred_Formulary_Exclusions2022.pdf

[62] Medicare Payment Advisory Committee (MedPAC). Report to the Congress: Medicare Payment Policy. March 2022. https://www.medpac.gov/wp-content/uploads/2022/03/Mar22_MedPAC_ReportToCongress_SEC.pdf

[63] Xcenda. "Skyrocketing Growth in PBM Formulary Exclusions Raises Concerns About Patient Access," September 2020. https://www.xcenda.com/insights/skyrocketing-growth-in-pbm-formulary-exclusions-raises-concerns-about-patient-access

[64] Fein AJ. "Why PBMs and Payers Are Embracing Insulin Biosimilars with Higher Prices—And What That Means for Humira." Drug Channels. November 9, 2021. https://www.drugchannels.net/2021/11/why-pbms-and-payers-are-embracing.html

[65] Kansteiner F. "Viatris launched 2 version of its interchangeable insulin biosimilar. Why?" *Fierce Pharma*. November 16, 2021. https://www.fiercepharma.com/pharma/viatris-launches-two-versions-its-interchangeable-biosimilar-semglee-bid-to-tackle-pricing

[66] Avalere Health. "Utilization Management Trends in the Commercial Market, 2014-2020." November 24, 2021. https://avalere.com/insights/utilization-management-trends-in-the-commercial-market-2014-2020

[67] Wells A, et al. "The Big Pinch: Findings on Changing Insurance Coverage of Prescription Drugs," GoodRx, October 2021. https://assets.ctfassets.net/4f3rgqwzdznj/1RQzvjzRErFvrH1qqcQGMH/24cf74b6df58125caebc668a77add74b/the_big_pinch_october_2021.pdf

[68] Avalere Health. "Utilization Management Trends in the Commercial Market, 2014-2020." November 24, 2021. https://avalere.com/insights/utilization-management-trends-in-the-commercial-market-2014-2020

[69] Lenahan KL, Nichols DE, Gertler R, et al. Variation in Use and Content of Prescription Drug Step Therapy Protocols, Within and Across Health Plans. *Health Affairs*. 2021;40(11): 1749-1757. https://doi.org/10.1377/hlthaff.2021.00822

[70] Fein AJ. "The 2022 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers." Drug Channels Institute. March 2022.

[71] Senate Finance Committee. "Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug," 2021. https://www.finance.senate.gov/imo/media/doc/Grassley-Wyden%20Insulin%20Report%20(FINAL%201).pdf

[72] Xcenda. "Skyrocketing Growth in PBM Formulary Exclusions Raises Concerns About Patient Access," September 2020. https://www.xcenda.com/insights/skyrocketing-growth-in-pbm-formulary-exclusions-raises-concerns-about-patient-access

[73] *Ibid*.

[74] *Ibid*.

[75] *Ibid*.

[76] *Ibid*.

[77] Rayburg R. "Three Proactive Strategies for Reducing Waste in Your Plan's Formulary. Pharmaceutical Strategies Group." August 14, 2019. https://www.psgconsults.com/blog/three-proactive-strategies-for-reducing-waste-in-your-plans-formulary

[78] Fein AJ. "The 2022 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers." Drug Channels Institute. March 2022.
[79] The Doctor-Patient Rights Project. "The De-List: How Formulary Exclusions Deny Patients Access to Essential Care." December 2017.
[80] Wong M. "Non-Medication Switching is a Patient Safety Issue." Physician-Patient Alliance for Health & Safety. March 22, 2022. https://ppahs.org/2022/03/non-medication-switching/#more-39332
[81] Letter from Ryan Gough, Executive Director, Partnership to Advance Cardiovascular Health, to Troyen Brennan MD, Chief Medical Office, CVS Health. December 2, 2021. https://static1.squarespace.com/static/56e6efdb5559866c54beb696/t/61b3b6a6916aab0fc1bee793/1639167659313/CVS+Switch+Letter+Final.pdf
[82] Park Y, Raza S, George A, Agrawal R, Ko J. The effect of formulary restrictions on patient and payer outcomes: a systematic literature review. Journal of Managed Care & Specialty Pharmacy. 2017;23(8), 893-901. https://doi.org/10.18553/jmcp.2017.23.8.893
[83] Nguyen W, Weeda ER, Sobieraj DM, et al. Impact of non-medical switching on clinical and economic outcomes, resource utilization and medication-taking behavior: a systematic literature review. *Current Medical Research and Opinion*. 2016;32(7):1281-1290. https://doi.org/10.1185/03007995.2016.1170673
[84] PhRMA. "Patient Experience Survey: Barriers to Health Care Access in the Patient Experience." October 2021. https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/P-R/PES-Report_100621_Final.pdf
[85] Lenahan KL, Nichols DE, Gertler R, et al. Variation in Use and Content of Prescription Drug Step Therapy Protocols, Within and Across Health Plans. *Health Affairs*. 2021;40(11): 1749-1757. https://doi.org/10.1377/hlthaff.2021.00822
[86] *Ibid*.
[87] *Ibid*.
[88] Cancer Support Community. "Access to Care in Cancer 2016: Barriers and Challenges." 2016. https://www.cancersupportcommunity.org/sites/default/files/migrated/pdf/csc-access-to-care-barriers-challenges.pdf
[89] Dawn Holcombe. "New Policies Regarding Intravenous Iron Replacement Are Creating Conundrum for Providers and Payers," Oncology Practice Management. February 2022. https://oncpracticemanagement.com/issues/2022/february-2022-vol-12-no-2/2775-new-policies-regarding-intravenous-iron-replacement-are-creating-conundrum-for-providers-and-payers
[90] OptumRx. "Step therapy — Premium," Accessed April 13, 2022. https://professionals.optumrx.com/content/dam/optum3/professional-optumrx/resources/pdfs/UM_Premium_ST_Drug_List.pdf
[91] Nayak RK, Pearson SD. The Ethics of 'Fail First': Guidelines and Practical Scenarios for Step Therapy Coverage Policies. 2014;33(10):1779-1785. https://doi.org/10.1377/hlthaff.2014.0516
[92] O'Reilly KB. "Time to scrutinize PBMs' outsized role in Rx decision-making." American Medical Association. June 10, 2019. https://www.ama-assn.org/delivering-care/public-health/time-scrutinize-pbms-outsized-role-rx-decision-making
[93] National Pharmaceutical Council. "Toward Better Value: Employer Perspectives on What's Wrong with the Management of Prescription Drug Benefits and How to Fix It." October 25, 2017. https://www.npcnow.org/sites/default/files/media/npc-employer-pbm-survey-final.pdf
[94] Express Scripts. "White Paper: Formulary Development at Express Scripts". December 2020. https://www.express-scripts.com/aboutus/formularyinformation/development/formularyDevelopment.pdf
[95] CVS Caremark. "Formulary Development and Management at CVS Caremark." 2021. https://www.caremark.com/portal/asset/FormDevMgmt.pdf
[96] Testimony of John M. Price, CEO, OptumRx. "Drug Pricing in America: A Prescription for Change, Part III." United States Senate Committee on Finance. April 9, 2019. https://www.finance.senate.gov/imo/media/doc/John%20Prince%20OptumRx%20Testimony%20Senate%20Finance%20Committee_04.09.19.pdf
[97] Express Scripts. "White Paper: Formulary Development at Express Scripts." December 2020. https://www.express-scripts.com/aboutus/formularyinformation/development/formularyDevelopment.pdf
[98] CVS Caremark. "Formulary Development and Management at CVS Caremark." 2021. https://www.caremark.com/portal/asset/FormDevMgmt.pdf
[99] Senate Finance Committee. "Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug," 2021. https://www.finance.senate.gov/imo/media/doc/Grassley-Wyden%20Insulin%20Report%20(FINAL%201).pdf
[100] National Pharmaceutical Council. "NPC Comments on URAC PBM Revisions." August 12, 2020. https://www.npcnow.org/resources/npc-comments-urac-pbm-revisions
[101] Institute for Clinical and Economic Review (ICER). "Assessment of Barriers to Fair Access. Final Report." December 1, 2021. https://icer.org/wp-content/uploads/2021/05/Barriers-to-Fair-Access-Assessment-Final-Report-120121.pdf
[102] *Ibid*.

[103] Xcenda. "Skyrocketing Growth in PBM Formulary Exclusions Raises Concerns About Patient Access," September 2020. https://www.xcenda.com/insights/skyrocketing-growth-in-pbm-formulary-exclusions-raises-concerns-about-patient-access
[104] Fein AJ. "Five Takeaways from the Big Three PBMs' 2022 Formulary Exclusions." Drug Channels. January 19, 2022. https://www.drugchannels.net/2022/01/five-takeaways-from-big-three-pbms-2022.html
[105] *Ibid*.
[106] Cohen J et al, "Rising Drug Costs Drives the Growth of Pharmacy Benefit Managers Exclusion Lists: Are Exclusion Decisions Value-Based?." *Health Services Research*. 2018(53:Suppl 1):2758-2769. https://doi.org/10.1111/1475-6773.12781
[107] *Ibid*.
[108] Frois C, Howe A, Jarvis J, et al. "Drug Treatment Value in a Changing Oncology Landscape: A Literature and Provider Perspective." *Journal of Managed Care Specialty Pharm*. 2019 Feb;25(2):246-259. https://doi.org/10.18553/jmcp.2019.25.2.246
[109] Caro JJ, Brazier JE, Karnon J, et al. "Determining Value in Health Technology Assessment: Stay the Course or Tack Away?" *Pharmacoeconomics*. 2019 Mar;37(3):293-299. https://doi.org/10.1007/s40273-018-0742-2
[110] Perfetto EM. "ISPOR's Initiative on US Value Assessment Frameworks: A Missed Opportunity for ISPOR and Patients." *Value in Health*. 2018 Feb;21(2):169-170. https://doi.org/10.1016/j.jval.2017.12.002
[111] Express Scripts. "White Paper: Formulary Development at Express Scripts." December 2020. https://www.express-scripts.com/aboutus/formularyinformation/development/formularyDevelopment.pdf
[112] CVS Caremark. "Formulary Development and Management at CVS Caremark." 2021. https://www.caremark.com/portal/asset/FormDevMgmt.pdf
[113] Nguyen E, et al. "Impact of Non-Medical Switching on Clinical and Economic Outcomes, Resource Utilization and Medication-Taking Behavior: A Systematic Literature Review." *Current Medical Research and Opinions.* 2016; 32. https://www.ncbi.nlm.nih.gov/pubmed/27033747.
[114] Gill LL. "When Your Insurer Drops Your Prescription Drug." *Consumer Reports*. July 2,2020. https://www.consumerreports.org/prescription-drugs/when-your-insurer-drops-your-prescription-drug/
[115] Centers for Medicare & Medicaid Services. "Medicare Prescription Drug Benefit Manual: Chapter 6 – Part D Drugs and Formulary Requirements." https://www.cms.gov/medicare/prescription-drug-coverage/prescriptiondrugcovcontra/downloads/part-d-benefits-manual-chapter-6.pdf
[116] Silverman E. "Advocacy groups outraged after a PBM offers a $500 gift care to persuade patients to switch drugs." *STAT+*. https://www.statnews.com/pharmalot/2021/04/19/pbm-cosentyx-gift-card/
[117] *Ibid*.
[118] 42 CFR 423.120(b)(1)(ii)
[119] Health and Human Services Office of Inspector General. "Gaps in Oversight of Conflicts of Interest in Medicare Prescription Drug Decisions." March 2013. https://oig.hhs.gov/oei/reports/oei-05-10-00450.pdf
[120] Fein AJ. "The 2022 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers." Drug Channels Institute. March 2022.
[121] *Ibid*.
[122] Mulcahy AW, Kareddy K. "Prescription Drug Supply Chains: An Overview of Stakeholders and Relationships." ASPE, October 2021. https://aspe.hhs.gov/sites/default/files/documents/0a464f25f0f2e987170f0a1d7ec21448/RRA328-1-Rxsupplychain.pdf
[123] Centers for Medicare & Medicaid Services. "Medicare Program: Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs; Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency; Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency." Final Rule. May 9, 2022. https://www.govinfo.gov/content/pkg/FR-2022-05-09/pdf/2022-09375.pdf
[124] *Ibid*.
[125] Frier Levitt, LLC and Community Oncology Alliance. "Pharmacy Benefit Manager Exposé: How PBMs Adversely Impact Cancer Care While Profiting at the Expense of Patients, Providers, Employers, and Taxpayers." February 2022. https://communityoncology.org/wp-content/uploads/2022/02/COA_FL_PBM_Expose_2-2022.pdf
[126] Centers for Medicare & Medicaid Services. "Medicare Program: Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs; Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency; Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency." Final Rule. May 9, 2022. https://www.govinfo.gov/content/pkg/FR-2022-05-09/pdf/2022-09375.pdf
[127] *Ibid*.
[128] Frier Levitt, LLC and Community Oncology Alliance. "Pharmacy Benefit Manager Exposé: How PBMs Adversely Impact Cancer Care While Profiting at the Expense of Patients, Providers, Employers, and Taxpayers." February 2022. https://communityoncology.org/wp-content/uploads/2022/02/COA_FL_PBM_Expose_2-2022.pdf
[129] PBM Accountability Project. "Understanding the Evolving Business Models and Revenues of Pharmacy Benefit Managers," December 2021. https://www.pbmaccountability.org/_files/ugd/b11210_264612f6b98e47b3a8502054f66bb2a1.pdf?index=true

[130] Herman B. "The biggest PBMs are handling more and more of the country's drug price negotiations. *STAT+.* March 22, 2021. https://www.statnews.com/2022/03/22/pharmacy-benefit-managers-revenue-contracts/
[131] PBM Accountability Project. "Understanding the Evolving Business Models and Revenues of Pharmacy Benefit Managers," December 2021. https://www.pbmaccountability.org/_files/ugd/b11210_264612f6b98e47b3a8502054f66bb2a1.pdf?index=true
[132] Frier Levitt, LLC and Community Oncology Alliance. "Pharmacy Benefit Manager Exposé: How PBMs Adversely Impact Cancer Care While Profiting at the Expense of Patients, Providers, Employers, and Taxpayers." February 2022. https://communityoncology.org/wp-content/uploads/2022/02/COA_FL_PBM_Expose_2-2022.pdf
[133] PBM Accountability Project. "Understanding the Evolving Business Models and Revenues of Pharmacy Benefit Managers," December 2021. https://www.pbmaccountability.org/_files/ugd/b11210_264612f6b98e47b3a8502054f66bb2a1.pdf?index=true
[134] *Ibid*.
[135] *Ibid*.
[136] Motheral BR, Fairman KA. Changes in PBM Business Practices in 2019: True Innovation or More of the Same? *Journal of Managed Care & Specialty Pharmacy*. 2016;26(10):1325-1333. https://doi.org/10.18553/jmcp.2020.20213
[137] "2017 Trends in Drug Benefit Design." Pharmacy Benefit Management Institute. 2018.
[138] Levitt JE, Lee DY. "Cautionary tale: Plan sponsors losing manufacturer rebate dollars to PBMs through rebate aggregators." BenefitsPRO. April 15, 2021. https://www.benefitspro.com/2021/04/15/cautionary-tale-plan-sponsors-losing-manufacturer-rebate-dollars-to-pbms-through-rebate-aggregators/
[139] Congressional Budget Office. "Cost Estimate: S.1895, Lower Health Care Costs Act." July 16, 2019. https://www.cbo.gov/system/files/2019-07/s1895_0.pdf
[140] Qato DM et al. Association Between Pharmacy Closures and Adherence to Cardiovascular Medications Among Older US Adults. *JAMA Network Open*. 2019;2(4):e192606. https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2730785;
[141] Pednekar P, et al. Comparing Medication Adherence Rates Between Pharmacy Desert And Non-Desert Areas Among Elderly In Pennsylvania. *Value in Health*, 19(3):2016. https://www.valueinhealthjournal.com/article/S1098-3015(16)01321-8/fulltext
[142] Qato DM et al. Association Between Pharmacy Closures and Adherence to Cardiovascular Medications Among Older US Adults. *JAMA Network Open*. 2019;2(4):e192606. https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2730785;
[143] Guadamuz JS, Alexander GC, Zenk SN, et al. Assessment of Pharmacy Closures in the United States From 2009 Through 2015. *JAMA Internal Medicine.* 2019;180(1): 157-160. https://doi.org/10.1001/jamainternmed.2019.4588
[144] *Ibid*.
[145] *Ibid*.
[146] Mulcahy AW, Kareddy K. "Prescription Drug Supply Chains: An Overview of Stakeholders and Relationships." ASPE, October 2021. https://aspe.hhs.gov/reports/prescription-drug-supply-chains
[147] *Ibid*.
[148] Only 5 percent of patients abandoned newly prescribed brand medicines when using cost-sharing assistance. Analysis suggests that abandonment would have been 28 percent if not for this cost-sharing assistance. IQVIA analysis of LAAD dataset for PhRMA. February 2021.
[149] Fein AJ. "The 2022 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers." Drug Channels Institute. March 2022.
[150] For more detail, see PhRMA's comment letter on the 2023 NBPP: https://www.phrma.org/policy-issues/Access/Insurance-Coverage/PhRMA-Comments-on-the-2023-Notice-of-Benefit-and-Payment-Parameters-Proposed-Rule
[151] Fein AJ. "Hidden policies: the search for copay accumulator policies in Florida qualified health plans." Drug Channels. June 2018. https://www.drugchannels.net/2018/06/hidden-policies-search-for-copay.html.
[152] The AIDS Institute. "Discriminatory Copay Policies Undermine Coverage for People with Chronic Illness: Copay Accumulator Adjustment Policies In 2022." January 2022. https://aidsinstitute.net/documents/final_TAI_2022-Report-Update_020122.pdf
[153] Greenwalt L. "Trends to Watch through 2023: Copay Accumulator Adjuster Programs." IQVIA Blog. March 21, 2022. https://www.iqvia.com/locations/united-states/blogs/2022/03/trends-copay-accumulator-adjuster-programs
[154] Centers for Medicare & Medicaid Services. "Medicaid Program: Establishing Minimum Standards in Medicaid State Drug Utilization Review (DUR) and Supporting Value-Based Purchasing (VBP) for Drugs Covered in Medicaid, Revising Medicaid Drug Rebate and Third Party Liability (TPL) Requirements." 85 Fed. Reg. 87000. December 31, 2020. https://www.federalregister.gov/documents/2020/12/31/2020-28567/medicaid-program-establishing-minimum-standards-in-medicaid-state-drug-utilization-review-dur-and
[155] PhRMA v. Becerra. No. 1:21-cv-1395 -CJN. (D.D.C. May 17, 2022). https://ecf.dcd.uscourts.gov/cgi-bin/show_public_doc?2021cv1395-37

[156] OptumRx provides maximizers with its Variable Copay solution. The other large PBMs provide maximizers only via partnerships with secretive, independent private companies: SaveonSP (Express Scripts/Cigna) and PrudentRx (CVS Caremark/CVS Health).
[157] Frier Levitt, LLC and Community Oncology Alliance. "Pharmacy Benefit Manager Exposé: How PBMs Adversely Impact Cancer Care While Profiting at the Expense of Patients, Providers, Employers, and Taxpayers." February 2022. https://communityoncology.org/wp-content/uploads/2022/02/COA_FL_PBM_Expose_2-2022.pdf
[158]Fein AJ. "Why Do CVS And Express Scripts Rely on Secretive Private Companies to Run Their Copay Maximizer Programs?" Drug Channels. May 2020. https://www.drugchannels.net/2020/05/why-do-cvs-and-express-scripts-rely-on.html
[159] Fein AJ. "The 2022 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers." Drug Channels Institute. March 2022.
[160] *Ibid*.
[161] PBM Accountability Project. "Understanding the Evolving Business Models and Revenues of Pharmacy Benefit Managers," December 2021. https://www.pbmaccountability.org/_files/ugd/b11210_264612f6b98e47b3a8502054f66bb2a1.pdf?index=true
[162] *Ibid*.
[163] Mulcahy AW, Kareddy K. "Prescription Drug Supply Chains: An Overview of Stakeholders and Relationships." ASPE, October 2021. https://aspe.hhs.gov/reports/prescription-drug-supply-chains
[164] Duy D, Geldsetzer P. Trends in Mail-Order Prescription Use among U.S. Adults from 1996 to 2018: A Nationally Representative Repeated Cross-Sectional Study. American Journal of Preventive Med. 2021 May 3;S0749-3797(21)00182-3. https://doi.org/10.1016/j.amepre.2021.02.017
[165] Fein AJ. "The 2022 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers." Drug Channels Institute. March 2022.
[166] PBM Accountability Project. "Understanding the Evolving Business Models and Revenues of Pharmacy Benefit Managers," December 2021. https://www.pbmaccountability.org/_files/ugd/b11210_264612f6b98e47b3a8502054f66bb2a1.pdf?index=true
[167] American Hospital Association. Letter to the Centers for Medicare & Medicaid Services. February 4, 2021. https://www.aha.org/system/files/media/file/2021/02/aha-expresses-concerns-regarding-series-of-UnitedHealthcare-health-plan-coverage-policies-letter-2-4-21.pdf
[168] Fein AJ. "The 2022 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers." Drug Channels Institute. March 2022.
[169] Health Resources and Services Administration. "Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Contract Pharmacy Services." 61 FR 43549, August 23, 1996. https://www.govinfo.gov/content/pkg/FR-1996-08-23/pdf/96-21485.pdf
[170] Health Resources and Services Administration. "Notice Regarding 340B Drug Pricing Program-Contract Pharmacy Services." 75 FR 10272, March 5, 2010. https://www.federalregister.gov/documents/2010/03/05/2010-4755/notice-regarding-340b-drug-pricing-program-contract-pharmacy-services
[171] Vandervelde A, Erb K, Hurley L. "For-Profit Pharmacy Participation in the 340B Program." Berkeley Research Group, October 2020. https://media.thinkbrg.com/wp-content/uploads/2020/10/06150726/BRG-ForProfitPharmacyParticipation340B_2020.pdf
[172] Fein AJ. "Exclusive: 340B Continues Its Unbridled Takeover of Pharmacies and PBMs." Drug Channels. June 15, 2021. https://www.drugchannels.net/2021/06/exclusive-340b-continues-its-unbridled.html
[173] Vandervelde A, Erb K, Hurley L. "For-Profit Pharmacy Participation in the 340B Program." Berkeley Research Group, October 2020. https://media.thinkbrg.com/wp-content/uploads/2020/10/06150726/BRG-ForProfitPharmacyParticipation340B_2020.pdf
[174] *Ibid*.
[175] Drug Channels Institute analysis of OPA Daily Contract Pharmacy Database. April 2022.
[176] Vandervelde A, Erb K, Hurley L. "For-Profit Pharmacy Participation in the 340B Program." Berkeley Research Group, October 2020. https://media.thinkbrg.com/wp-content/uploads/2020/10/06150726/BRG-ForProfitPharmacyParticipation340B_2020.pdf
[177] Growth of the 340B Program Accelerates in 2020, Martin, IQVIA Blog, March 2021. https://www.iqvia.com/locations/united-states/blogs/2021/03/growth-of-the-340b-program-accelerates-in-2020
[178] Barron's: CVS Health Stock Gets Downgraded. This Analyst Sees Multiple Risks. March 29, 2022. https://www.barrons.com/amp/articles/cvs-health-stock-downgrade-51648567375
[179] 83 Fed. Reg. 2340. See regulatory impact analysis, Table 2.B.
[180] Klaisner J, Holcomb K, Filipek T. "Impact of Potential Changes to the Treatment of Manufacturer Rebates." Milliman, January 2019. https://aspe.hhs.gov/system/files/pdf/260591/MillimanReportImpactPartDRebateReform.pdf

[181] Department of Health and Human Services Office of Inspector General. "Fraud and Abuse; Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees." Final Rule. November 30, 2020. https://www.federalregister.gov/documents/2020/11/30/2020-25841/fraud-and-abuse-removal-of-safe-harbor-protection-for-rebates-involving-prescription-pharmaceuticals

[182] PhRMA. "The Patient Experience: Out-of-Pocket Costs Are Driving Patients' Affordability and Access Challenges." October 19, 2021. https://catalyst.phrma.org/the-patient-experience-out-of-pocket-costs-are-driving-patients-affordability-and-access-challenges.

[183] Milliman. "Measuring the Impact of Point of Sale Rebates on the Commercial Health Insurance Market," July 2021. https://www.milliman.com/en/insight/measuring-the-impact-of-point-of-sale-rebates-on-the-commercial-health-insurance-market,

[184] UnitedHealth Group. "Successful Prescription Drug Discount Program Expands to Benefit More Consumers at Point-of-Sale." March 12, 2019. https://www.unitedhealthgroup.com/newsroom/2019/2019-03-12-prescription-drug-program-expands-to-benefit-consumers-point-of-sale.html

[185] "Prescription Coverage: CVS/Caremark." Indiana State Personnel Department. Accessed March 12, 2022. https://www.in.gov/spd/benefits/prescription-coverage/

[186] Kelly C. "Rebate Reform: West Virginia Law Requires PBMs to Share the Savings." *Pink Sheet*. April 29, 2021. https://pink.pharmaintelligence.informa.com/PS144231/Rebate-Reform-West-Virginia-Law-Requires-PBMs-To-Share-The-Savings

[187] Advisory Council on Employee Welfare and Pension Plan Benefits. "Report to the Honorable Thomas E. Perez, United States Secretary of Labor: PBM Compensation And Fee Disclosure." 2014. https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/about-us/erisa-advisory-council/2014-pbm-compensation-and-fee-disclosure.pdf

[188] Mercer. "Will point-of-sale rebates disrupt the PBM business?" July 2017. https://www.mercer.us/our-thinking/healthcare/willpoint-of-sale-rebates-disrupt-the-pbm-business.html

[189] Herman B. "The biggest PBMs are handling more and more of the country's drug price negotiations." *STAT+*. March 22, 2022. https://www.statnews.com/2022/03/22/pharmacy-benefit-managers-revenue-contracts/

[190] Midwestern Business Group on Health. "Drawing a line in the sand: employers must rethink pharmacy benefit strategies." September 2017. https://higherlogicdownload.s3.amazonaws.com/MBGH/4f7f512a-e946-4060-9575-b27c65545cb8/UploadedImages/Specialty%20Pharmacy/DMJ_MBGH_Line_in_the_Sand_RV12_9617.pdf

[191] National Pharmaceutical Council. "Toward Better Value: Employer Perspectives on What's Wrong with the Management of Prescription Drug Benefits and How to Fix It." October 25, 2017. https://www.npcnow.org/sites/default/files/media/npc-employer-pbm-survey-final.pdf

[192] *Ibid*.

[193] American Benefits Council. Comments on Regulations Regarding Prescription Drug and Health Care Spending. January 2022. https://www.americanbenefitscouncil.org/pub/?id=89D24D82-1866-DAAC-99FB-99C3CB15C043

[194] American Medical Association. "2021 Prior Authorization State Law Chart." 2021. https://www.ama-assn.org/system/files/2021-04/pa-state-chart.pdf

[195] American Medical Association. "2021 AMA prior authorization (PA) physician survey." https://www.ama-assn.org/system/files/prior-authorization-survey.pdf

[196] The Promise of Shared Decision Making in Improving Value in the US Healthcare System. Avalere Health. December 2017. http://go.avalere.com/acton/attachment/12909/f-0506/1/-/-/-/-/Avalere%20Shared%20Decision%20Making%20Issue%20Brief.pdf

[197] NV SB 392 of 2021.

[198] Department of Health and Human Services Office of Inspector General. "Fraud and Abuse; Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees." Final Rule. November 30, 2020. https://www.federalregister.gov/documents/2020/11/30/2020-25841/fraud-and-abuse-removal-of-safe-harbor-protection-for-rebates-involving-prescription-pharmaceuticals

[199] Cubanski J, Neuman T, Freed M. "Explaining the Prescription Drug Provisions in the Build Back Better Act. Kaiser Family Foundation." November 23, 2021. https://www.kff.org/medicare/issue-brief/explaining-the-prescription-drug-provisions-in-the-build-back-better-act/#:~:text=Therefore%2C%20repealing%20the%20rebate%20rule,provision%20takes%20effect)%20and%202031.

[200] 29 CFR § 2510.3-21.

[201] 29 CFR 2509.75-8 - Questions and answers relating to fiduciary responsibility under the Employee Retirement Income Security Act of 1974.

[202] New York Ch 128 of the Laws of 2022.
[203] Ohio's Medicaid Managed Care Pharmacy Services, Auditor of State Report. August 2018. https://audits.ohioauditor.gov/Reports/AuditReports/2018/Medicaid_Pharmacy_Services_2018_Franklin.pdf
[204] CMS issues new guidance addressing spread pricing in Medicaid, ensures pharmacy benefit managers are not up-charging taxpayers. May 15, 2019. https://www.cms.gov/newsroom/press-releases/cms-issues-new-guidance-addressing-spread-pricing-medicaid-ensures-pharmacy-benefit-managers-are-not.
[205] Tepper, Nona. "PBM clawbacks sidestep state bans on spread pricing," Modern Healthcare, October 2021. https://www.modernhealthcare.com/payment/pbm-clawbacks-sidestep-state-bans-spread-pricing?adobe_mc=MCMID%3D84382931027412571591411966027321820076%7CMCORGID%3D138FFF2554E6E7220A4C98C6%2540AdobeOrg%7CTS%3D1635559965&CSAuthResp=1%3A%3A1042569%3A7461%3A24%3Asuccess%3A7B2869D9F448BE6E6633CBB3379746EA.
[206] Introduced legislation includes: Elijah E. Cummings Lower Drug Costs Now Act, H.R. 3, 117th Cong. (2021). https://www.congress.gov/bill/117th-congress/house-bill/3?q=%7B%22search%22%3A%5B%22hr3%22%2C%22hr3%22%5D%7D&s=2&r=1; Lower Costs, More Cures Act of 2021, H.R. 19, 117th Cong. (2021). https://www.congress.gov/bill/117th-congress/house-bill/19?q=%7B%22search%22%3A%5B%22hr19%22%2C%22hr19%22%5D%7D&s=3&r=1; Fair Care Act of 2020, H.R. 8527, 116th Cong. (2020). https://www.congress.gov/bill/116th-congress/house-bill/8527/text; Prescription Drug Pricing Reduction Act of 2019, S. 2543, 116th Cong. (2019); Lower Health Care Costs Act, S. 1895, 116th Cong. (2019). https://www.congress.gov/bill/116th-congress/senate-bill/1895; PBM Transparency in Prescription Drug Costs Act, H.R. 5304, 116th Cong. (2019). https://www.congress.gov/bill/116th-congress/house-bill/5304; and Drug Price Transparency in Medicaid Act of 2019, H.R. 5281, 116th Cong. (2019). https://www.congress.gov/bill/116th-congress/house-bill/5281.