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Re: Request for Information on Consolidation in Health Care Markets (Docket No. ATR 102)

Dear Assistant Attorney General Kanter, Secretary Becerra, and Chair Kahn,

The Pharmaceutical Research and Manufacturers of America (PhRMA) appreciates the opportunity to comment in response to your joint request for information on consolidation in the health care market. PhRMA represents the country's leading innovative biopharmaceutical research companies, which are devoted to discovering and developing medicines that enable patients to live longer, healthier, and more productive lives. The biopharmaceutical sector is one of the most research-intensive industries in the United States: over the last decade, PhRMA member companies have more than doubled their annual investment in the search for new treatments and cures, including nearly $101 billion in 2022 alone.[1]

The U.S. competitive market is the engine that drives the innovative biopharmaceutical research and development ecosystem. Since 2000, biopharmaceutical companies have launched more than 750 new medicines in the U.S., resulting in significant progress against some of the most costly and challenging diseases.[2,3,4,5] Yet, as a result of robust negotiation and competition in the market, retail and physician-administered medicines continue to represent just 14 percent of overall health care spending, a substantially smaller share than the more than half of health care spending going towards hospitals and physicians' offices.[6,7] More than half of spending on medicines goes to entities other than the brand biopharmaceutical companies that researched and developed them, including pharmacy benefit managers (PBMs), health plans, the government, hospitals, pharmacies, and others, and the share of spending flowing to these entities has increased by 17 percentage points since 2013.[8,9] Many of the private entities retaining a share of medicine spending are part of vertically integrated organizations, allowing them to profit at multiple points along the supply and reimbursement chain.

For decades, competitive market dynamics have worked successfully to balance innovation, patient access to medicines, and cost containment. But that balance is increasingly threatened by misaligned financial incentives and conflicts of interest for PBMs, insurers, and hospitals. Years of horizontal consolidation in those industries, and vertical integration throughout the health care sector have resulted in a market dominated by just a handful of large corporations, whose business models often work to the detriment of patients and competition. We discuss the ramifications of increased market consolidation and vertical integration for patients, providers, other stakeholders, and the health care system as a whole, in detail below.

EXECUTIVE SUMMARY

After years of aggressive consolidation and integration in the health care system, a small number of corporate giants now wield overwhelming influence and control over health care decisions that impact patients and the broader system. This extensive consolidation has substantial implications for patients' access, choice and affordability; costs to the broader health care system; and stability of the competitive market.

Three pharmacy benefit managers (PBMs), CVS Caremark, Express Scripts and OptumRx, now control 80 percent of prescriptions dispensed in the United States. These same companies are vertically integrated with the three largest health insurance companies, Aetna, Cigna, and UnitedHealthcare. They each also own a specialty and mail order pharmacy, and some have and are acquiring provider groups at a rapid pace.

As a result, three large health care conglomerates exert unprecedented control over what medicines patients have access to, what they pay out of pocket, what pharmacies they visit, and the utilization management barriers they face. Patients are often steered towards medicines and pharmacies that make these corporate giants more money, regardless of what's best for patients and the health care system as a whole. Vertically integrated PBMs often exclude generics, biosimilars, and lower list priced versions of products from their formularies. In fact, between 2014 and 2020, there was a 676 percent increase in the number of medicines excluded from at least one of the three largest PBMs.

At the same time, physician practice and hospital consolidation within and across markets has skyrocketed, with help from private equity firms' investment, greatly impacting quality of care and creating perverse incentives. Continuous market consolidation has also consolidated risk, resulting in potential 'single points of failure,' as was seen in the recent cybersecurity breach of Change Healthcare–part of the health care giant UnitedHealth Group.

The extensive consolidation and vertical integration throughout the health care delivery system has dramatic consequences for patients, competition in the market, and costs across the system. Regulatory, legal, and legislative actions are needed to pursue market-based solutions that address misaligned incentives in the system and ensure patients can access the medicines they need.

PhRMA supports the efforts of the Department of Justice (DOJ), Federal Trade Commission (FTC), and Department of Health and Human Services (HHS) to better understand the effects of health care consolidation and encourages the FTC to complete the Section 6(b) study on the PBM industry launched in May 2022. We also support efforts by the agencies to provide greater oversight to 340B business relationships and scrutiny to hospital mergers and physician practice acquisitions. Additionally, Congress should act on a number of key reforms that would realign incentives, strengthen market competition, and improve patients' access to care.

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A Small Number of Large Vertically Integrated Corporations Wield Substantial Influence Over Health Care Decisions

The PBM industry is dominated by three large companies with opaque business practices

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

After nearly two decades of horizontal consolidation, the PBM industry is now dominated by three large companies: CVS Caremark, Express Scripts, and OptumRx.[10] The combined share of these three largest PBMs has grown significantly, from 48 percent of covered lives in 2010 to 80 percent in 2023.[11,12] Today, just six companies control access to 94 percent of patients with insurance[13] and patients residing in more than three quarters of states are subject to highly concentrated "PBM markets" per Department of Justice (DOJ) and Federal Trade Commission (FTC) Horizontal Merger Guidelines.[14] In many instances, smaller PBMs contract or partner with larger PBMs to leverage their infrastructure, with the larger entities acting as rebate aggregators in the commercial market for the smaller entities.[15,16] Such arrangements further contribute to the overall concentration of negotiating power.[17]

In recent years, the three largest PBMs have vertically integrated with health insurers, specialty and mail order pharmacies, and provider groups to form large health care conglomerates. These vertically integrated organizations have enormous influence over which medicines patients have access to, the circumstances under which those medicines are covered, and when and where they can be dispensed or administered to patients. The three largest PBMs have become key drivers of revenues and profits for their respective vertically integrated organizations.[18] Express Scripts generated more than 70 percent of its parent company's total revenues, and OptumRx and CVS Caremark were responsible for approximately one third of their affiliated insurance companies' total revenue in 2023.[19]

Despite their already considerable negotiating power, each of the three largest PBMs have also created a separate "rebate contracting entity" – referred to, misleadingly, by the PBMs themselves as a group purchasing organization,[20,21] or PBM GPO – that is responsible for negotiating, collecting, and disbursing manufacturer rebates for their commercial book of business. The three rebate contracting entities and their associated PBMs and health insurers are Ascent Health Services (Express Scripts and Cigna, launched in 2019), Zinc (CVS Health and Aetna, launched in 2020), and Emisar Pharma Services (OptumRx and UnitedHealthcare, launched in 2021). PBM rebate contracting entities introduce an additional non-transparent middleman to an already complex vertically integrated system. These "PBM GPOs" can contract not only for their own affiliates, but also on behalf of other large players in the health care system. These contracted client arrangements further increase industry consolidation. Experts have also raised concerns that "PBM GPOs" likely increase costs without providing any direct benefits for patients or additional savings for employers and plan sponsors.[22,23]

Health insurers have increasingly engaged in horizontal consolidation and vertical integration with PBMs

Today, 73 percent and 71 percent of metropolitan service area (MSA) commercial insurance and Medicare Advantage (MA) markets, respectively, meet the definition of "highly consolidated," based on DOJ and FTC Horizontal Merger Guidelines.[24]

According to an analysis by the American Medical Association, 90 percent of MSAs have at least one insurer with a commercial share of 30 percent or more, and nearly half (48 percent) of MSAs have a single insurer that controls 50 percent or more of the commercial market.[25] Consolidation has increased over time,[26] with insurers affiliated with a PBM taking an outsized role. Health insurers that are vertically integrated with a PBM cover 69 percent of all individuals with commercial drug insurance.[27] In Part D, three quarters of Medicare Advantage prescription drug plan (MA-PD) and stand-alone prescription drug plan (PDP) beneficiaries are concentrated among just five vertically integrated insurers.[28] Among newly enrolled MA beneficiaries, 86 percent were enrolled in plans managed by just three companies in 2023, two of which are affiliated with a PBM.[29]

PBMs and insurers have vertically integrated with health care providers, including pharmacies and physicians

Vertically integrated pharmacies represent a significant and growing source of PBM revenue and now account for more than half of PBM profits.[30] All three of the largest PBMs own a mail order and specialty pharmacy business, and one of the three, CVS Health, also owns a large retail pharmacy chain. The mail order and specialty pharmacies owned by the three largest PBMs account for nearly two-thirds of prescription revenues for specialty pharmaceuticals.[31] According to investment analysts at Nephron Research, PBM profits derived from specialty pharmacy operations more than doubled between 2012 and 2023 and now represent the fastest growing source of PBM profits.[32]

Unbeknownst to most patients and employers, for-profit insurers and vertically integrated PBMs have acquired thousands of formerly independent health care providers, introducing inherent conflicts of interest. For example, last year CVS Health acquired Oak Street Health, a chain of primary care providers across 21 states.[33] In addition to primary care providers, health care conglomerates are also acquiring physicians through purchases of home-health businesses,[34] dialysis clinics,[35] outpatient surgery centers,[36] and independent multi-specialty physicians' practices.[37,38] UnitedHealth Group has been particularly active in this space, acquiring or hiring a total of 90,000 physicians, including 20,000 in the last year alone.[39] UnitedHealth Group is now the single largest employer of physicians in the U.S., representing 10 percent of U.S. physicians.[40] Behind the scenes, payers that own provider practices may influence prescribing and other care decisions, exerting control over providers' financial outcomes. Speaking about a recent purchase of a large provider practice by a vertically integrated PBM and insurer, one drug pricing analyst observed, "The only thing that was missing was control over the pad in the prescriber's hand, which this acquisition helps facilitate."[41]

Continuously changing billing practices, insurance administrative burdens, shrinking margins, and complex federal requirements have made acquisitions by health care conglomerates or hospital/health systems particularly appealing to struggling physician practices. Physician consolidation increased in almost every metropolitan area from 2016 to 2018, with small-to-midsize markets experiencing the highest level of growth.[42] Today, nearly 4 in 5 individual physicians are employed by a hospital or corporate entity, and nearly 60 percent of physician practices are owned by a hospital or corporate entity.[43]

Hospital consolidation within and across markets has skyrocketed

In an effort to keep pace with the growing market power of insurers,[44] hospitals are increasingly consolidating into large health systems comprised of dozens of facilities. Nearly 90 percent of U.S. metropolitan areas have "highly concentrated" hospital markets as defined by the DOJ and FTC

Horizontal Merger Guidelines, [45] with two thirds of community hospitals now part of large health systems.[46] Hospitals that purchased other hospitals between 2016 and 2022 were, in comparison to the hospitals they purchased, more likely to be large (500+ beds), not-for-profit, and 340B-covered entities.[47]

Along with consolidation within single geographic areas, health systems are increasingly expanding their reach to cover multiple geographic areas and expanding to multiple states, further increasing their negotiating power.[48] Between 2010 and 2019, 55 percent of the 1,500 hospitals targeted for a merger or acquisition were located in a separate geographic market than the acquirer.[49] This trend extends to rural community hospitals as well. Between 2010 and 2018, 13 percent of rural hospitals were acquired by an out-of-market system.[50] Cross-market hospital mergers have been found to increase prices[51] and can also lead to reduced access to care, including obstetrics care and imaging at acquired rural hospitals.[52]

In 2020, 75 percent of local areas had over half of their hospital bed capacity controlled by the area's two largest hospital systems, nearly double the rate in 2000.[53] And the proportion of areas without a single independent hospital increased from 7 percent to 25 percent over this same period.[54] In 16 states and Washington DC, a single hospital system accounts for at least one-quarter of all Medicare inpatient hospital spending.[55] Today, the top 10 health systems manage a sixth of all hospitals (1,200) and generate a combined $225 billion in net patient revenues.[56]

Private equity firms are increasingly financing health care consolidation

In recent years, private equity and related asset management firms have taken a greater interest in the health care market, increasingly investing in and acquiring physician practices and hospitals. Between 2012 and 2021, the number of physician practices acquired by private equity firms increased from 816 practices located in 119 different MSAs to 5,779 practices located in 307 MSAs.[57] Private equity firms have contributed significantly to local provider consolidation by investing in multiple practices within the same area. In approximately one-third of the MSAs where private equity firms invested, a single firm owned 30 percent or more of the practices. And in one-sixth of MSAs, a single firm accounted for more than 50 percent of the market.[58]

340B covered entities and others acting on their behalf—including contract pharmacies, pharmacy outsourcing companies, third party administrators, and contract pharmacy administrators—have also seen an increase in private equity-related investment. This is particularly alarming given that 340B is a federal drug discount program that requires manufacturers to offer steep discounts on outpatient drugs to certain safety net providers that should benefit low-income and uninsured patients. As of 2023, there have been over 65 transactions totaling more than $5 billion involving an entity with ties to the 340B program and a combination of venture capital, private equity, and/or corporate investors.[59] Many of these investments were concentrated among companies that allow covered entities to outsource some of their 340B operations and compliance.[60]

This trend of purchasing provider practices appears to be the first step in a multi-step process that private equity firms use to generate profit from the health care system. According to health economists, "private equity has taken the lead in consolidating small providers, loading them with debt, and rolling them up into large powerhouses with substantial market power before exiting with handsome returns."[61] Through this process, private equity firms are fueling consolidation across the country, driving up costs without improving patient care.[62] One in five health care companies owned by private equity companies filed for bankruptcy in 2023, a result of what experts describe as "excessive use of

debt and aggressive financial strategies," which they say, "put healthcare companies at risk, and in turn threaten the stability of critical healthcare resources across the country."[63]

Impact of Health Care Consolidation and Vertical Integration

Extensive consolidation and vertical integration throughout the health care delivery system, including PBMs, insurers, hospitals, providers, and their affiliates, can have wide reaching effects on (1) patients' out-of-pocket costs, (2) patients' access, choice, and quality of care, (3) broader health system costs, and (4) market dynamics. These implications are discussed in detail in the following sections.

Impact of Consolidation and Vertical Integration in the Health Care Delivery System on Patient Costs

Experts note PBMs may have incentives to prefer medicines with higher list prices and large rebates, but rebate savings are rarely used to lower patient out-of-pocket costs [64]

The sheer volume of prescription claims managed by the three large PBMs provides them with significant leverage in negotiations with drug manufacturers, which they use to obtain sizable rebates on medicines. A large share of compensation received by vertically integrated PBMs is tied to the wholesale acquisition cost (i.e., list price) of medicines.[65] In the commercial market, PBMs historically contracted with employer plans and insurers to retain a portion of these rebates, which are calculated as a percentage of a medicine's list price, as payment for the services PBMs rendered to the plans.[66,67] The PBM business model has largely shifted away from retaining commercial rebates – perhaps in response to increased public and employer scrutiny – in favor of fees charged to manufacturers, payers, and pharmacies, and revenues generated by vertically integrated specialty and mail order pharmacies.[68,69] Fees and specialty pharmacy revenues are now the fastest growing components of PBM profits. The share of PBM profits from fees charged to manufacturers, pharmacies, health insurers, and employers increased by more than 300 percent over the last decade. The fees PBMs obtain from manufacturers – which the PBMs predominately tie to the list price of medicines – have more than doubled in the commercial market over the past five years, reaching $7.6 billion in 2022.[70]

Government agencies, economists, and other experts have noted that PBMs' fee models based on list prices can incentivize PBMs to favor medicines with higher list prices to maximize their revenues.[71,72] According to a Senate Finance Committee report, "PBMs have an incentive for manufacturers to keep list prices high, since the rebates, discounts, and fees PBMs negotiate are based on a percentage of a drug's list price—and PBMs may retain at least a portion of what they negotiate."[73] Industry analysts have noted that these market dynamics have prompted some manufacturers to introduce two identical versions of a product – one with a higher list price and large rebates and a version with a lower list price, giving payers the option of which to cover.[74] The three large PBMs appear to favor the versions with large rebates and have in some cases blocked access to the lower list priced options by excluding them from their formularies.[75,76] The Health and Human Services (HHS) Office of Inspector General (OIG) has 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.[77] In a recent survey, more than two thirds of biopharmaceutical company respondents indicated that they perceived list-price based fees charged by PBMs as a barrier to lowering list prices.[78]

Covering higher list price products with large rebates may financially benefit the PBM and health plan but can leave patients paying significantly more out of pocket due to benefit designs and pharmacy

network arrangements established by PBMs and their vertically integrated affiliates. PBMs and health plans typically require patients with deductibles and coinsurance – who pay a percentage of the cost of their medicine rather than a fixed copayment – to pay based on the undiscounted list price. Benefit designs that incorporate high deductibles and coinsurance expose patients to high out-of-pocket costs, even though PBMs and health plans are often receiving a significant discount. This can result in patients paying more for their medicines than their health plan. For example, among drugs with high rebates, Part D beneficiary cost sharing can exceed plans' net costs.[79] The Government Accountability Office (GAO) found that for 79 of the top 100 highly rebated medicines in Medicare Part D, the total costs to beneficiaries exceeded the total net costs to plan sponsors by nearly 400 percent ($21 billion vs. $5.3 billion).[80]

In addition, slow uptake of lower cost alternatives is directly related to the ability of PBMs and their affiliated specialty pharmacies to prefer medicines with higher list prices, which can increase costs for patients.[81] For example, newly available biosimilars for a leading biologic to treat autoimmune disorders initially struggled to gain market share due to significant access restrictions imposed by the big three PBMs. Despite estimates that substituting the biosimilar would lower employer costs by 58 percent and patient costs by 68 percent, early uptake was largely concentrated among patients covered by smaller PBMs and health plans.[82] According to a recent report from IQVIA, PBMs and PBM-owned specialty pharmacies have strong financial incentives to encourage uptake of the versions that are most profitable for them. IQVIA estimates that compared to utilization of the brand name biologic, a full transition to biosimilars for this autoimmune product would reduce PBM and affiliated specialty pharmacy profits by 84 percent and 78 percent, respectively.[83]

Likely in an effort to mitigate this potential loss of profit, two of the three largest PBMs, CVS Health and Express Scripts, have launched versions of this autoimmune biosimilar.[84, 85] CVS Health is marketing a biosimilar through their wholly owned Ireland-based company, Cordavis,[86] and Express Scripts' biosimilar will be marketed by Cigna's wholly owned private-label distributor, Quallent Pharmaceuticals, based in the Cayman Islands.[87,88] The PBMs appear to simply provide a captive referral stream.

These arrangements will allow CVS and Express Scripts to profit multiple times as the medicine makes its way through the supply chain. For example, once when the biosimilar is commercialized by their affiliate, again when the product is placed on formulary, and another time when the prescription is filled at a pharmacy they own. This profit potential creates a clear incentive for these PBMs to favor coverage of the biosimilar they have a financial stake in and to pad their own bottom lines by steering patients to fill those prescriptions at PBM-owned pharmacies. The extent to which these arrangements might enrich PBMs at the expense of patients is unclear, leading policymakers to ask why the company would not allow "for coverage of all of the lowest-cost biosimilar products on the market, incentivizing low costs and patient choice," rather than preferring a biosimilar co-branded by the PBM itself.[89]

Having access to lower list-priced medicines could reduce out-of-pocket costs for some patients by hundreds or thousands of dollars per prescription,[90] yet vertically integrated PBMs often exclude generics, biosimilars, and lower list priced versions of products from their formularies.[91] One study found the availability of lower list price versions of medicines to treat high cholesterol and hepatitis C was associated with a 14 percent to 60 percent reduction in out-of-pocket costs for commercially insured patients, with the largest savings observed for patients with coinsurance.[92] PBM decisions to deny or restrict coverage for generic drugs can also undermine market forces meant to drive investment in generic manufacturing, which can create or exacerbate generic drug shortages.[93,94]

Payers typically do not use the savings they negotiate with manufacturers to directly lower costs for patients at the pharmacy counter. This differs from all other types of health care where health plans typically base patient out-of-pocket spending for care received from doctors and hospitals within the plan's provider network on the discounted rates negotiated by the plan on patients' behalf. According to one actuarial firm, this results in a system of "reverse insurance," whereby payers require patients with high prescription medicine costs to pay more out of pocket, while rebate savings are spread out among all health plan enrollees in the form of lower premiums.[95] 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.

Payers use vertical integration to undermine patient assistance programs

To help address affordability challenges imposed by insurers and PBMs, manufacturers created patient assistance programs, which help patients access the medicines they need. In 2021, one in ten commercially insured patients taking brand medicines used manufacturer cost-sharing assistance to access their brand medicines.[96] Manufacturer cost-sharing assistance allows patients to fill prescriptions they otherwise may not be able to afford. In 2019, the use of manufacturer cost-sharing assistance programs reduced patients' likelihood of abandoning their brand medicines at the pharmacy by an estimated 82 percent.[97]

While these programs have helped millions of patients access their medicines, PBMs and their affiliates have developed methods to undermine patient assistance programs in an effort to extract more profit from the system. 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.[98] Copay maximizers adjust individual patient cost sharing upwards to match and exhaust the full value of the manufacturer-provided assistance. AAPs and copay maximizers are increasingly used by PBMs and payers. In 2023, researchers estimate that 49 percent of commercially insured beneficiaries were enrolled in plans with accumulator adjustment programs and 49 percent were enrolled in plans with maximizers, up from 28 percent and 6 percent, respectively, in 2018.[99] According to one industry expert, in 2023, nearly 45 percent of manufacturer cost-sharing assistance funds were absorbed by PBMs, plans, or third-party vendors, rather than benefiting patients.[100] The use of AAPs and copay maximizer programs also slows patients' progress through the health insurance benefit and can increase their out-of-pocket costs for other health care products and services.

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" are more than 13 times as likely to discontinue therapy as patients who experience consistent copays.[101] The Centers for Medicare & Medicaid services (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."[102]

The 2020 Notice of Benefit and Payment Parameters (NBPP) final rule required health plans to count manufacturer cost-sharing assistance toward the maximum annual limitation on cost sharing throughout commercial markets, except when a medically appropriate generic equivalent is available, effectively banning AAPs in most cases.[103] CMS subsequently reversed that policy in the 2021 NBPP.[104]

The HIV + Hepatitis Policy Institute and the Diabetes Leadership Council sued the federal government, and a 2023 federal court decision vacated the subsequent regulations and remanded them to HHS.[105] An additional opinion from the court in December 2023 clarified that the 2020 NBPP rules were explicitly reinstated.[106] The government dropped its appeal of the ruling, but federal officials have expressed no intention of enforcing the 2020 NBPP requirements. While state regulators share enforcement authority on AAPs with the federal government, the lack of clear federal guidance may result in inconsistent outcomes for patients. HHS should immediately enforce the 2020 NBPP to comply with the court's ruling and to bring much needed relief to patients.

Copay maximizer 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, such as 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.[107,108] When these pharmacies are not easily accessible, patients can face obstacles or delays in filling their prescriptions. This can be particularly burdensome for communities of color, who are 27 percent more likely to be exposed to copay maximizers than white patients.[109]

As discussed, health plans and PBMs currently divert necessary cost-sharing assistance from patients through the use of AAPs and copay maximizer programs. In addition, some health plans and employers use third-party vendors to manage so-called alternative funding programs (AFPs) to siphon manufacturer or independent charitable resources intended for the uninsured or underinsured.[110] AFPs employ deceptive benefit designs, discriminate based on economic status, health status, or disability, and circumvent the Affordable Care Act's (ACA) maximum annual limit on cost sharing. AFPs frequently target specialty drugs, disproportionately impacting individuals living with disabling chronic and rare conditions, who must undergo additional processes after their claim is denied. AFP exclusions and denials lack any discernable clinical justification and appear to be only due to the plan or PBM's decision to exploit patient assistance programs intended to aid patients in need. This process can delay therapy, interfere with the clinical decision making of their provider,[111] and potentially put patients at risk of negative health outcomes.

In April 2024, CMS released the final NBPP for 2025.[112] The final rule mandates all prescription medicines covered by a plan or issuer in the individual and small group commercial market in addition to a state's essential health benefits (EHB)-benchmark plans to be considered an EHB, and subject to ACA protections. An FAQ accompanying the final rule, issued by the Tri-agencies (HHS, the Department of Labor, and the Department of the Treasury),[113] announced the government's intention to promulgate regulations to "align the standards applicable to large group market health plans and self-insured group health plans with those applicable to individual and small group market plans" by requiring all group health plans to treat all covered prescription drugs as EHB.[114] This would significantly limit the impact of maximizer programs and provide patients with more transparency regarding their drug coverage and costs. The Tri-agencies must take this opportunity to prohibit copay maximizers throughout the commercial market, and to shut down alternative funding programs, which exploit manufacturer patient assistance funds and other charitable funds.

Impact of Consolidation and Vertical Integration in the Health Care Delivery System on Patient Access, Choice, and Quality of Care

Vertically integrated payers increasingly use utilization management and formulary exclusions to influence patients' access to medicines

The formularies that PBMs establish for their clients govern which medicines are covered, how much patients pay for those medicines, and any utilization management or other restrictions patients may face when trying to fill a prescription. PBMs use these tools to obtain deep discounts on medicines. In particular, formulary exclusions can significantly increase PBMs' negotiating leverage with manufacturers.[115] According to one industry expert, if placed on one of the three largest PBMs' formulary exclusions lists, a manufacturer may lose access to a significant portion of patients.[116] Similarly, the Senate Finance Committee notes that, "[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."[117] In the commercial market, PBMs may seek to leverage these tools in an effort to extract higher fees from manufacturers, which would be retained by the PBM and not benefit patients or the health care system more broadly.

The number of medicines excluded from at least one of the three largest PBMs' commercial standard formularies increased by 676 percent between 2014 and 2020, and each of the three largest PBMs excludes well over 500 medicines from their 2024 standard formularies.[118,119] Patients who require treatment with a medicine excluded from a PBM's formulary may be forced to pay the full price out of pocket or undertake a burdensome appeals process, which may delay onset of treatment. 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.[120] Evidence suggests a disproportionate impact on communities of color, with prescriptions filled by Black and Hispanic patients less likely to overcome the initial rejection and receive payer approval for a new antidiabetic medicine compared to prescriptions filled by white patients.[121]

The number of medicines subject to utilization management tools like step therapy and prior authorization has also grown over time. PBMs use step therapy to require patients to fail on one or more alternative drugs before the PBM will cover the medicine originally prescribed by the provider. Prior authorization requires providers to obtain approval from the PBM in order for a medicine to be covered. In the commercial market, Avalere Health found that prior authorization and step therapy for single-source brand medicines increased for all therapeutic areas studied, including conditions such as cancer, depression, rheumatoid arthritis (RA), and diabetes, between 2014 and 2020.[122] 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.[123]

Vertically integrated payers increasingly influence where patients can access care and which medicines they are prescribed

Vertically integrated organizations may require patients to use a PBM-owned retail, mail order, or specialty pharmacy or may disincentivize the use of non-affiliated pharmacies by requiring patients to pay higher cost sharing. For example, CVS Health leverages its joint ownership of a PBM, a chain of retail

pharmacies, and a mail order pharmacy to limit access by requiring some patients to use CVS mail order or retail pharmacies if they wish to fill prescriptions for a 90-day supply of a medicine.[124] By steering patients towards their affiliated specialty and mail order pharmacies, PBMs capture greater margins on each transaction.[125,126] In a recent presentation to investors, CVS Health executives highlighted this benefit, stating they are able to capture 3-4 times greater consumer lifetime value by keeping patients within their brand of pharmacies, insurance plans, and providers.[127] Steering, however, can happen without a patient's knowledge and can deny patients the benefits of visiting their local pharmacist. It can also result in unnecessary treatment delays, with patients potentially experiencing worse outcomes from not being able to fill prescriptions in a timely manner.[128]

Large PBMs – who create pharmacy networks for their clients – can disadvantage independent pharmacies, creating an unsustainable market for these businesses and compelling them to accept unfavorable and unsustainable contracts in order to remain in-network. These large companies deploy multiple practices, such as unfavorable reimbursement terms where pharmacies are reimbursed below their acquisition cost[129] and high fees, to capture more market share from independent pharmacies. Pharmacies that reject low reimbursement rates or other PBM contract terms face exclusion from networks that cover a large share of patients. Currently, 94 percent of stand-alone Medicare Part D plans, 51 percent of Medicare Advantage (MA) PDPs, and 61 percent of large commercial plans have a preferred pharmacy network.[130] As a result, independent pharmacies are increasingly closing, particularly in rural and low-income areas,[131] leaving patients in those communities with fewer options to access their medicines.[132] Pharmacy closures are associated with an immediate and sustained reduction in medication adherence, leading to poorer health outcomes for patients in impacted communities.[133]

Similarly, a vertically integrated entity like UnitedHealth Group's Optum Health – the largest employer of physicians in the U.S.[134] – can require the providers it employs to direct patients to pharmacies or other provider groups affiliated with the organization and may reward physicians for prescribing medicines that provide the largest financial benefits for the PBM. Such arrangements would be more difficult for PBMs to enforce if the provider and pharmacy were part of different organizations.[135]

PBMs may also generate new sources of revenue by enabling their vertically integrated pharmacies to dispense and manage specialty medicines historically administered by providers in outpatient health care settings. PBMs increasingly require provider-administered medicines to be filled at their affiliated specialty pharmacies and shipped directly to a provider's office for storage until the patient comes in for treatment (known as white bagging) or shipped to the patient to bring with them to their appointment (known as brown bagging). White and brown bagging practices may limit patients' treatment options by allowing PBMs to apply utilization management tools like prior authorization and step therapy to medicines that typically had not been subject to such restrictions when covered under the medical benefit.[136] Research also shows that brown and white bagging are associated with lower costs for PBMs and insurers but higher out-of-pocket costs for patients.[137] These practices also place added financial pressure on providers who could otherwise earn revenues from buying and then billing patients directly for physician-administered medicines, and can thereby contribute to health care consolidation trends discussed above.

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. Research shows that formulary exclusions and utilization management by PBMs in highly consolidated markets appear to have spillover effects on patients not covered by the market-leading PBM. An analysis of

prescribing patterns for commercially insured patients determined that in areas where a single PBM controls an outsized share of the industry, the leading PBM's preferred product achieves a disproportionately large market share among patients covered by non-market leading PBMs. [138] This dynamic likely occurs when physicians repeatedly face obstacles when prescribing certain products not preferred by the leading PBM. Researchers believe these results "demonstrate how the erosion of competition in PBM markets may be affecting the prescribing autonomy of health care professionals and limiting patient access to certain medicines."[139]

Impact of Consolidation and Vertical Integration in the Health Care Delivery System on Broader Health Care Costs

Vertically integrated PBMs and pharmacies can profit by marking up the price of medicines, exposing some patients to higher out-of-pocket costs

PBMs often bill their health plan clients more than what they pay to the pharmacy for medicines and keep the difference, a practice known as spread pricing. An investigation by the *Wall Street Journal* (WSJ) revealed another way that vertically integrated PBMs profit from spread pricing: by marking up the cost of low-cost generic drugs and reimbursing their vertically integrated pharmacies significantly more than their pharmacies' acquisition cost.

The WSJ investigation revealed that generic drugs dispensed by PBM-affiliated pharmacies can cost thousands of dollars more than the very same generic drugs dispensed at independent pharmacies because of this practice. Across a selection of generic drugs analyzed by the WSJ, the prices that CVS Health and Cigna/ Express Scripts charged to plan sponsors were 24 and 27 times higher, respectively, than the prices charged by the generic manufacturers themselves. For one generic cancer drug, CVS Health and Cigna/ Express Scripts reimbursed their own specialty pharmacies between $6,600 and $7,000 per prescription, while the same generic drug cost just $54 at a non-affiliated pharmacy.[140] The potential to earn high profits on otherwise low-cost generic drugs further incentivizes vertically integrated PBMs to steer patients to their own specialty and mail order pharmacies. These substantial markups also call into question how vertical integration may be used to undermine insurers' medical loss ratio (MLR) requirements, discussed in more detail below.

Generic drugs are a central part of the cost-containment mechanism built into the prescription medicine lifecycle. Once a brand medicine's patent protection ends and generics launch, it is not unusual for the cost of treatment to decline by upwards of 90 percent.[141] Marking up the prices of generic drugs eliminates this important source of cost savings in the health care system. It can also result in significantly higher out-of-pocket costs for patients, particularly those with coinsurance or deductibles. In the case of the aforementioned generic cancer drug, a CVS Health patient with 25 percent coinsurance would be responsible for paying $1,750 out of pocket if they filled their prescription at CVS Health's vertically integrated specialty pharmacy vs. $13.50 at an independent pharmacy. According to one health policy expert, "Someone in the middle of that transaction is making a lot of money, and they're doing it at the detriment of the consumers."[142]

Researchers estimate that misaligned PBM incentives result in U.S. consumers overpaying for generic drugs by as much as 20 percent.[143] Consequently, in 2021, 70 percent of Medicare Part D spending on 45 high-utilization generic drugs went to intermediaries' gross profit, rather than to the generic manufacturers who produced the drug.[144] These dynamics, whereby intermediaries leverage their

vertically integrated relationships to absorb would-be generic manufacturer margins, have contributed to the instability in the generics market leading to drug shortages.[145, 146]

Consolidation and vertical integration among PBMs, insurers, and providers increase prices without improving patient outcomes

Insurers and health care providers often argue that consolidation and vertical integration will produce savings by allowing them to leverage economies of scale and reduce administrative costs. However, a large body of evidence clearly shows that prices go up, not down, following provider consolidation.[147, 148] If consolidated health care providers and insurers are in fact lowering costs, those savings are not being reflected in lower prices or better outcomes for patients. Without competitors to keep prices in check, there is less incentive for insurers or providers to pass along any potentially generated savings. Although consolidation of commercial insurers has been associated with lower prices paid for health care services, research suggests that these lower prices are not passed on to consumers, who ultimately face higher premiums following consolidation.[149] In Medicare Part D, highly consolidated PDP markets, where beneficiaries have fewer plan options to choose from, were associated with higher patient out-of-pocket costs and lower rates of PDP enrollment among older patients.[150]

Among independent hospitals acquired by a health system, researchers observed a six percent decrease in operating margins. However, these savings were not reflected in the hospitals' prices, which increased by five percent over market average for commercially insured patients.[151] Providers in highly concentrated areas have significant negotiating power, and consumers, whether insurers or patients, have fewer choices. This gives consolidated entities the ability to demand high prices, and leaves consumers with few options other than to accept the offered price.[152] In areas with only one hospital, prices were 12 percent higher, on average, than prices among hospitals in markets with four or more competitors.[153] Research shows that vertical integration among providers is also associated with a pricing premium:

- A large study determined that the prices paid for care provided by physicians and hospitals associated with health systems are up to 26 percent and 31 percent higher, respectively, than non-health system physician and hospital prices.[154]
- Between 2013 and 2017, vertical integration and joint contracting between physicians and hospitals resulted in a 2 to 12 percent increase in prices for primary care physicians and up to a 6 percent increase in prices for specialists across all payers in Massachusetts. The largest increase in prices for physicians' services were observed among those affiliated with the largest health systems.[155]
- Nationally, hospital-physician integration is associated with a three to five percent increase in hospital prices following acquisition.[156]
- In general, a 10-percentage-point increase in physician-hospital vertical integration is associated with a 1 percent price increase for primary care, a 0.6 percent increase for orthopedics, and a 0.5 percent increase for cardiology.[157]
- Hospital acquisition of small and mid-size hospitals resulted in a 20-percentage point increase of within-system referral rates, as well as a 6 to 20 percent increase in hospital prices.[158]

Provider consolidation often translates into lower wages and less generous benefits for workers. One study estimates that hospital mergers alone resulted in a $521 increase in hospital prices, a $579 increase in hospital spending among privately insured patients, and a $638 reduction in wages, on average.[159] Health care workers are not immune from this impact. Following hospital mergers, wage growth for nurses and pharmacy workers falls to about a third lower than the national average.[160]

Research does not consistently demonstrate better patient outcomes or quality of care following provider consolidation or vertical integration. For example, for patients whose primary care physician became vertically integrated with a health system, there were significant decreases in medication adherence for patients who were Black, Asian, Hispanic, or Native American, or above 80 years old.[161]

Receiving care at higher priced hospitals increases spending but has little to no effect on reducing patient mortality, particularly in highly concentrated hospital markets.[162] Meanwhile, hospital consolidation has been associated with a decline in patient experience and no improvements in readmission or other key indicators of patient outcomes.[163] One study found that readmission rates among cardiac care patients increased by 10 to 12 percent at independent hospitals following acquisition by a health system.[164]

Private equity firms are increasingly driving provider consolidation and contributing to higher prices.[165] Their pattern of purchasing multiple providers, rolling them into a single entity, and commanding higher prices has resulted in higher system-wide costs without clear benefits for patients.[166,167] Research shows that private equity acquisitions of hospitals result in an 11 percent increase in health care spending, driven by higher prices at the private equity-owned hospitals as well as price spillovers to local rivals.[168]

While a large body of evidence has concluded that private equity ownership of health care providers is associated with increases in costs to patients or payers,[169] those higher costs do not appear to translate into superior patient care. In fact, hospitals acquired by private equity firms saw a 25 percent increase in adverse health events compared to non-acquired peer hospitals. For example, even though private-equity owned hospital staff placed 16 percent fewer central lines, which are used administer medicines and other fluids to a patient, the rate of central-line associated bloodstream infections increased by 38 percent.[170]

Provider consolidation incentivizes shifting patient care to higher cost settings

Vertical integration among health care providers incentivizes organizations to steer patients towards affiliated providers, even if those sites of service result in higher costs for patients, employers, and the government. This trend has been observed among PBMs and insurers integrated with pharmacies and physicians and for hospitals and health systems that own other hospitals and physician practices.

The margins providers are able to collect from dispensing and administering medicines have driven consolidation in the market by incentivizing hospitals to acquire physicians' practices and convert them into hospital outpatient departments (HOPDs). This practice has accelerated the shift of care to more expensive hospital sites, particularly among 340B eligible providers, and drives up costs for patients and the health care system as a whole. From 2014 through 2018, hospital and health system ownership of physician practices increased by 89 percent.[171] Hospital and corporate ownership of physician practices increased by another 25 percent between 2019 and 2020.[172]

When HOPDs submit claims for provider-administered medicines, they are typically reimbursed separately for both the acquisition of the medicine and the administration of the medicine. By marking up the cost of drugs, HOPDs can collect revenue on both the act of administering the treatment and the

margin between what they paid to acquire the medicine and what they charge the commercial insurer. These markups significantly contribute to the cost of care without offering commensurate benefits for patients. For instance, a study in the *Journal of the American Medical Association* found that for 25 commonly used oncology medicines, the median mark-up cancer centers charged to commercial insurers ranged from 118 percent to 634 percent of the acquisition cost.[173]

On average, HOPDs mark up physician-administrated drugs for commercially insured patients three times the amount received by physician offices.[174] One study estimates that if price differentials between HOPDs and physician offices were eliminated for physician-administered medicines, employers and workers would collectively save $14.1 billion annually.[175]

Site of service shifts are particularly stark for physician-administered medicines. Since 2008, billing for physician-administered medicines under Medicare has shifted from physician offices to HOPDs, with a 10-percentage point decrease in billing for physicians and an 18-percentage point increase for HOPDs.[176] Similarly, physician offices saw a 16 percent decline in the volume of chemotherapy administration services provided to Medicare patients, while HOPDs saw a 52 percent increase from 2012 to 2018.[177] While care has 'shifted' from independent physicians' offices to HOPDs, hospital acquisition of physicians' offices often means that patients are still seeing the same doctor, at the same location, for the same medicine. Despite patient care remaining effectively the same, hospitals are able to charge insurers higher prices than physicians' offices, ultimately increasing health care spending without improving quality of care or outcomes.

Vertical integration among providers also leads to increased utilization of higher-intensity care and diagnostics, without any clear evidence of better patient outcomes. For example, patients seen by hospital-integrated cardiologists were more likely to receive high-intensity, hospital-based interventions than independent cardiologists.[178] Provider consolidation may also encourage low-value care, particularly for diagnostics. One study found patients were 20 percent more likely to receive an inappropriate MRI referral after a physician transitioned from independent practice to hospital employment.[179] Between 2013 and 2016, physician consolidation with hospitals and health systems was linked to a 2.6 percent and 4.5 percent increase in hospital-based laboratory tests and diagnostic imaging for Medicare beneficiaries, respectively, resulting in an additional $73.1 million in Medicare spending.[180]

The 340B program further intensifies misaligned incentives in the system

The increasing shift of patient care to higher cost settings has been intensified by the 340B program, a program that requires manufacturers to provide discounted medication to certain entities, but does not require that these savings be passed on to patients. This has further incentivized hospital acquisition of physicians' practices to expand the profitability of hospitals' involvement in the 340B program through the establishment of "child sites." While not expressly contemplated in the 340B statute, the Health Resources and Services Administration (HRSA), which oversees the 340B program, has allowed child sites to participate in the program without addressing abuses. In particular, HRSA has not implemented specific requirements for child sites to advance the purpose of the program, such as by treating a minimum threshold of low-income or uninsured patients. This lax agency oversight has undermined the program's integrity. It has enabled 340B hospitals to use child sites as a way to chase 340B profits, contributing to significant program growth, instead of improving access to care for patients.[181] [182] As detailed in a September 2022 article in the *New York Times*, child sites create incentives for hospitals to shift care to more expensive settings and more affluent areas (as 340B hospitals buy up smaller care

sites in wealthy areas to generate more 340B profits), increase costs, and drive consolidation that can negatively impact patient access to care.[183] Government reports and congressional testimony reinforce this concern, indicating that hospitals frequently exploit HRSA's lax child site guidance.[184,185,186]

Hospitals eligible for the 340B program can collect large margins because they are able to acquire medicines at a significant discount, on average 57 percent less than the list price (and by as much as 99% less than list[187]), and they are not required to share these discounts with patients or payers.[188] Nor are they required to dispense discounted drugs only to poor or underserved patients: there are no income or health insurance restrictions on the patients eligible for 340B-discounted drugs. Accounting for 340B discounts, recent research shows that the median markup applied to cancer medicines by 340B hospitals is 3.8 times what they paid to acquire the medicines, ranging from a low of 2.4 to a high of 11 times the medicine's acquisition cost.[189] And commercial insurers reimburse 340B hospitals 6.6 times, on average, the amount they reimburse independent physicians' offices for provider-administered medicines.[190] The same study found that that hospitals eligible for 340B discounts retained an average of 64 percent of total insurer spending on these medicines, which is more than the drug manufacturer that researched and developed the therapy.[191] These perverse incentives have caused large numbers of independent physician practices, such as community oncology clinics, to close or be acquired by large hospital systems over the last 10 years, which raises costs for patients and payors.[192]

Researchers have observed a tendency for 340B hospitals to prescribe more medicines and prefer higher cost medicines than comparable non-340B hospitals, both of which increase profit margins. 340B hospitals administer about 10 percent more prescriptions per patient receiving medicines and the average cost per prescription is more than 150 percent greater than the cost per prescription at non-340B hospitals.[193] As a result, average spending per commercially insured patient taking outpatient medicines was more than two and a half times higher at 340B DSH hospitals than non-340B DSH hospitals.[194] Multiple studies have also found 340B hospitals are less likely to use lower list priced biosimilars than non-340B hospitals.[195] For example, 340B program eligibility was associated with a 23 percentage-point reduction in biosimilar adoption.[196] Prescribing incentives at 340B hospitals not only drive up system-wide costs but may also have a direct impact on patient out-of-pocket spending. Among commercially insured patients with cost sharing receiving medicine at a 340B HOPD, those who received a brand-name biologic paid 16.1 percent more out of pocket compared to patients who received a biosimilar.[197]

Increased costs have not translated into better patient care. For example, 340B hospital eligibility and participation is not associated with improved all-cause in-hospital mortality, 30-day readmissions, or other condition-specific quality measures among Medicaid or uninsured patients.[198] Additionally, research has not shown a difference between 340B and non-340B hospitals in the prevalence of disparities for drug treatments or adverse outcomes among beneficiaries with moderate to severe asthma.[199] This finding calls into question whether 340B hospitals are effectively using discounts to focus on improved access and outcomes for vulnerable beneficiaries.

Impact of Consolidation and Vertical Integration in the Health Care Delivery System on Market Dynamics

Highly consolidated health care delivery and reimbursement sectors can lead to increased vulnerability in the market

Increasingly consolidated health care delivery and reimbursement sectors can create system-wide vulnerabilities that are particularly concerning. Two recent occurrences illustrate the unintended vulnerabilities introduced by consolidation: cybersecurity attacks and generic drug shortages.

Consolidation and vertical integration among entities responsible for health care delivery and reimbursement inherently consolidate risk, resulting in potential 'single points of failure.' Without market incentives to develop backups that can step in if and when a single point fails, there is no safety net to prevent consequences from spreading across the system. The recent cybersecurity breach of Change Healthcare, a subsidiary of UnitedHealth Group that processes one third of the countries' insurance claims and provider reimbursements and handles other administrative services,[200] exemplifies how an attack on one system can have compounding effects across the entire U.S. health care market. As House Energy & Commerce Chair Cathy McMorris Rodgers (R-WA) observed during a recent hearing, "As our healthcare system becomes more consolidated, the impacts of cyberattacks – if successful – may be more widespread."[201]

Change Healthcare was acquired in 2022 by Optum, a UnitedHealth Group subsidiary, and currently processes 15 billion health care transactions each year for 900,000 physicians, 33,000 pharmacies, and 5,500 hospitals.[202] The health care system's reliance on this one company was made abundantly clear when a cyberattack forced the system offline in February. As a result, hospitals, physicians' offices, and pharmacies across the country were left without the system they rely on to get paid for their services.

The Change Healthcare attack has demonstrated the vulnerability of the U.S. health care system for patients, who faced challenges filling prescriptions and using manufacturer cost-sharing assistance,[203] and providers, who were unable to receive payments from insurers. According to a survey by the American Hospital Association, the Change Healthcare cyberattack impacted 82 percent of hospitals' cash flow. Among these hospitals, more than a third reported that more than half of their revenue was impacted. Additionally, two in five hospitals reported the cyberattack directly impacted the care provided to patients.[204]

The Change Healthcare attack is just the most recent of a growing number of cyberattacks on the health care sector.[205] A recent survey found that two-thirds of health care organizations reported a ransomware attack in the past year, up seven percentage points from the previous year.[206] As systems become highly integrated and reliant on one another, the risk of one attack having a ripple effect across the entire health care system grows. As a former leader in the Federal Bureau of Investigation's Cyber Division, John Riggi, observed, "Where you have this concentration of mission-critical services, that also results in the concentration of risk if those services become unavailable for any reason."[207]

Highly consolidated systems tamp down on incentives for competing companies to create duplicative or redundant systems. As a result, competitors have little to no incentive to enter the market and offer alternatives, which could have been leveraged immediately following the attack. By disincentivizing market entry, consolidation has also contributed to recent shortages of generic medicines. The misaligned incentives of PBMs and their affiliates, as well as provider GPOs that act as bulk purchasers for hospitals and physicians,[208] may undermine competitive pressures that should encourage investment in generic manufacturing, leading to or exacerbating drug shortages.[209] For example, three provider

GPOs control roughly 90 percent of all generic non-retail medicine purchasing. This concentration in the market has resulted in downward pricing pressure on manufacturers, impacting manufacturers' revenue and profitability. As the trade association representing generic and biosimilar manufacturers has described, "fewer buyers means fewer markets".[210] The practical result of this is, when generic drug manufacturers fail to win GPO contracts, manufacturers may either exit or decide not to enter the market for those drugs, eliminating critical suppliers in the system and contributing to diminished manufacturing capacity, which ultimately raises the risk of drug shortages.

Vertical integration may allow insurers to undermine Medical Loss Ratio requirements

Medical loss ratio (MLR) refers to the percentage of premium (including certain other revenue) spent on incurred claims or activities that improve health care quality. Medicare Advantage (MA), Part D, Medicaid managed care plans (MCOs), and certain commercial health insurance plans are subject to MLR standards.[211] Under the Affordable Care Act, health insurance issuers are subject to an 80 or 85 percent minimum MLR, depending on the market in which the issuer offers coverage. This means at least 80 or 85 percent of the revenue that issuers receive from premiums (and certain other revenue) must be used for patient care, rather than administrative costs or profit.

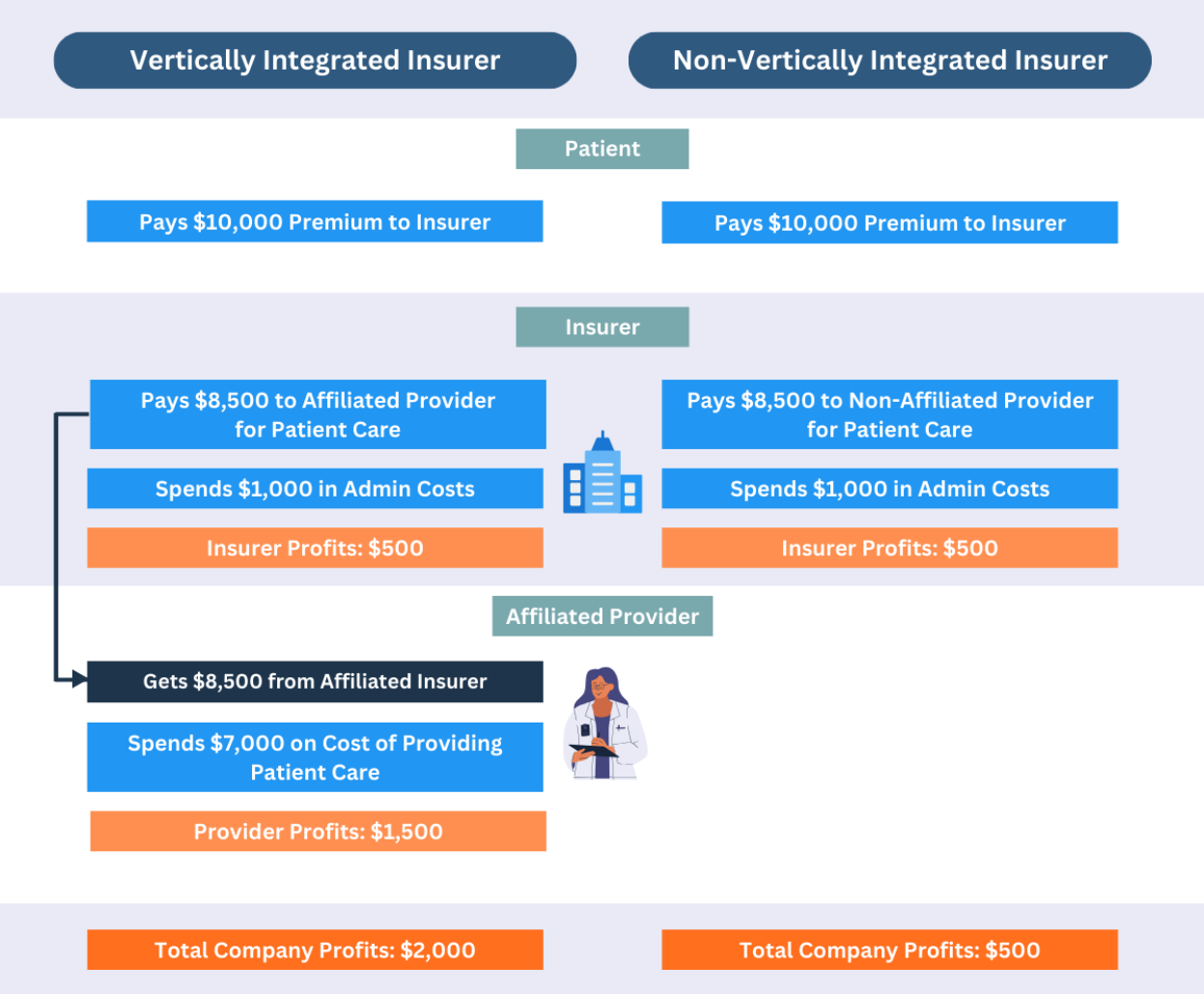
Because federal regulations require issuers to deduct manufacturer rebates and other price concessions received by the issuer from incurred pharmacy claims, MLR is calculated based on issuers' *net* pharmacy costs.[212,213] Issuers of individual or group health insurance coverage that do not achieve a minimum MLR are required to rebate the difference to policyholders. MA organizations and Part D prescription drug plan sponsors that do not achieve a minimum MLR must remit the difference to CMS and face additional penalties if they continue to fail to achieve a minimum MLR in subsequent years.[214]

The growing vertical integration between health insurers and PBMs raises questions about how business arrangements between affiliated entities in these large, vertically integrated organizations are treated when determining whether issuers have met MLR standards. In a vertically integrated organization, the licensed health insurance issuer entity may pay affiliated entities (e.g., PBMs, pharmacies, providers) for incurred claims for prescription drug costs or other patient care. Practically speaking, this means that vertically integrated health insurers may achieve MLR requirements through expenditures that include profits that accrue to affiliated companies in the same vertically integrated organization. Said another way, vertically integrated insurers may hold onto more revenue by using "intercompany eliminations," an accounting term under which the parent organization in a vertically integrated organization (e.g., health insurer) pays for direct patient and other care by transferring revenue to an affiliated entity (e.g., PBM, pharmacy, or provider), the profits from which accrue to the entire organization.[215]

According to reporting from the news outlet Axios, "[i]nsurers keep more of the premiums they collect when they also own the medical providers that are paid those premium dollars…there are no limits to how much profit a provider can keep. So if an insurer can steer its members toward its own providers, the company is able to keep a lot more of those premium dollars."[216] Similarly, the Brookings Institute has observed that vertical integration "permits MA plans to circumvent regulations aimed at constraining the profits that can be earned from the MA program." Specifically, "a vertically integrated MA plan can move profits from the MA plan to the related business. This increases the MA plan's MLR without reducing the parent company's profits, weakening the MLR constraint."[217]

Figure 1 illustrates the MLR calculation for a vertically integrated health insurer with an affiliated entity that directly provides medical and pharmacy care to its members (such as through a PBM-owned pharmacy) and uses intercompany eliminations and a non-vertically integrated health insurer without an

affiliated entity that provides medical and pharmacy care to its members. Both examples account for profits in technical compliance with an 85 percent MLR.[218] These examples demonstrate vertically integrated insurers' ability to earn organizational profits can undermine MLR requirements through intercompany eliminations with their affiliated PBMs, pharmacies, and providers.



Intercompany eliminations have skyrocketed in recent years, and now account for a significant share of vertically integrated organizations' total revenue. For example, 62 percent of OptumRx revenue comes from UnitedHealth Group affiliated businesses[219] and more than $49 billion of the combined $273 billion in CVS Pharmacy and CVS Healthcare services' revenues resulted from transactions between these two segments.[220]

PBMs maintain their profitability by keeping customers, patients, and manufacturers in the dark about how their business works

PBMs' vertical integration with insurers, pharmacies, and providers is riddled with conflicts of interest, which often go unchecked due to the lack of transparency in the system. 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'."[221] For example, industry analysts have noted that PBM contracts with employers often include clauses that prohibit the employer from conducting an independent audit.[222] This information asymmetry constrains the ability for employers to understand how conflicts of interest may influence the decisions their PBMs makes, 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 largest margins when filled through the PBM's affiliated mail order pharmacy.[223]

Another conflict of interest stems from the financial relationships between vertically integrated PBMs and the insurance consultants and brokers who help employers evaluate pharmacy benefit options. These relationships represent another downstream entity that is financially affiliated with, and influenced by, large vertically integrated PBMs.[224] A recent investigation revealed that "a largely hidden flow of money" between benefits consultants and PBMs can undermine consultants' ability to provide impartial advice, prompting consultants to recommend contract terms that favor PBMs at the expense of employers and enrollees.[225, 226]

Transparency to plan sponsors in the commercial market is further obfuscated by the creation of so-called "PBM GPOs," which have introduced an additional, non-transparent layer into the reimbursement system and, according to experts, may be an attempt by PBMs to sidestep ongoing legislative and regulatory reform initiatives, including efforts to increase PBM transparency.[227] PBMs may also use "PBM GPOs" to create new revenue streams via additional fees charged to manufacturers that are less transparent to employers and plan sponsors and create additional challenges for PBM clients attempting to conduct audits.[228] These "PBM GPOs" have been addressed in recent suits brought by state Attorneys General in Ohio and Hawaii.[229, 230] The Ohio complaint alleges Ascent serves as a vehicle for Express Scripts to conspire with other PBMs and health insurers to share pricing information and fix prices, to the detriment of others in the market.[231]

Market incentives encourage for-profit companies and wealthy hospital chains to siphon money intended for the safety net

As previously discussed, 340B hospitals are not required to share manufacturer-provided discounts with low-income patients, frequently mark up the cost of medicines, incentivize the use of higher cost medicines, and purchase independent physicians' offices to expand their reach. The proliferation of contract pharmacies has allowed additional entities, including PBMs, pharmacies and other for-profit companies, to divert funds intended for the safety net. In 2018, 340B covered entities and their contract pharmacies generated an estimated $13 billion in gross profits on 340B purchased medicines.[232] Congress did not create 340B to help 13 of the top 30 Fortune 500 companies generate additional profit.[233]

Contract pharmacy arrangements have given PBMs, PBM-owned retail and specialty pharmacies, and other large for-profit businesses a substantial, and growing, role in the 340B program. Half of U.S. pharmacies currently act as contract pharmacies for hospitals or health care providers in the 340B

program, with more than 2,000 locations added in just the past 12 months.[234] These contract pharmacies are disproportionately affiliated with large, vertically integrated companies. Nearly three quarters (71 percent) of pharmacies in the four largest chains and 41 percent of institutional pharmacies participated in the 340B program as a contract pharmacy in 2022 compared with just 22 percent of independent pharmacies.[235]

Overall, 44 percent of all contract pharmacy relationships are between a 340B covered entity and a pharmacy associated with one of the three largest PBMs.[236] And over half of total 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).[237] These profits are largely driven by prescriptions filled through PBMs' mail order pharmacies, which 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.[238]

Contractual terms established by PBMs often dictate the terms of contract pharmacy partnerships with covered entities, including when establishing provider networks,[239] and health plans and PBMs engage in steering patients to contract pharmacies that are more financially beneficial for plans or PBMs. Health plans and PBMs accomplish this by offering lower cost sharing at contract pharmacies, thereby encouraging patients to fill prescriptions at these locations.[240] Additionally, certain pharmacy chains require covered entities to engage with their other related 340B profit generating businesses as a prerequisite to contracting.[241]

The significantly higher margins on 340B medicines have incentivized greater consolidation and rapid expansion of contract pharmacy relationships. The average profit margin obtained 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.[242] Because profits per 340B prescription are much higher than the average profit for prescriptions filled on behalf of a third-party payer, vertically integrated conglomerates are able to use profits generated by the 340B program to subsidize other parts of their business, allowing PBMs and their pharmacies to accept lower reimbursement rates from plans in exchange for becoming a preferred pharmacy or part of an exclusive network. In other words, pharmacies are likely using 340B profits to subsidize network rates, allowing them to provide more competitive rates and capture market share, pushing out independent and community pharmacies.[243] Taken together, these dynamics further contribute to destabilizing the independent pharmacy market.

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 the 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.[244] Two of the largest pharmacy chains have both reported they rely heavily on the 340B program for their profits, and any negative change in their relationship with the 340B program could materially impact their financial performance and their ability to exceed earnings projections.[245] The generation of 340B profits from these companies and their financial relationships with various third-party administrators (TPAs), discussed below, are now the subject of an ongoing 340B investigation by Senator Cassidy.[246]

Increased use of contract pharmacies – fueled in part by policies that are not contemplated by the governing statute – has not increased access to affordable medicines for patients living in low-income communities. From 2011 to 2019, the share of contract pharmacies in the highest income neighborhoods increased by 5.0 percent, while the share in the lowest income neighborhoods decreased by 5.6 percent, adding to the growing body of evidence questioning the degree to which 340B program growth serves vulnerable communities.[247] PBM-affiliated contract pharmacies are exploiting the 340B program to obtain outsized profits without any clear benefit to patients, despite the program's original focus to serve safety-net entities.

Building on the success of their initial involvement in the 340B program, large vertically integrated corporations are exploring other opportunities to profit off of this safety net program. TPAs' service offerings have emerged to mine pharmacy claims and covered entities' medical encounter data and 'tag' prescriptions they believe likely qualify for 340B (at varying degrees of certainty based on the covered entity's interpretation of the definition of a 'patient').[248] In this way, for-profit companies are able to abuse the system to passively generate income from these patients' prescriptions without maintaining responsibility of care or sharing any of the discounts with low-income or uninsured patients.

TPAs represent an opaque area of the program with little publicly available data on ownership or affiliations. TPAs often profit based off of each 340B script they identify,[249] moving money intended for the safety net into for-profit companies' pockets. PBMs have capitalized on this new revenue source and acquired their own TPAs. By leveraging their negotiating power, they are able to compel covered entities to contract with their affiliated vertically integrated TPAs, rather than one of the independent options. Based on reviews of available information, researchers estimate that 14 percent of software-based TPAs are owned by a vertically integrated pharmacy chain. [250] Some program participants wield their significant market control to require use of the chain pharmacy's TPA software for contract pharmacy-related transactions.[251]

Policy Reforms Should Seek to Address Market Distortions, Restore Competition, and Protect Patients

PhRMA supports the efforts of the DOJ, FTC, and HHS to better understand the effects of health care consolidation. 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 that they are not sidelined by PBMs, consolidated 340B covered entities, and vertically integrated affiliates seeking to maximize their bottom lines.

PBM reforms have received broad, bipartisan support at the state and federal level,[252] and we encourage policymakers to capitalize on this support

In our response to FTC's May 2022 request for information on the impact of PBMs' business practices on independent pharmacies and consumers, we supported the agency's initiation of a broad Section 6(b) study on the PBM industry, which we encourage the agency to complete in a timely manner. Since that time, bicameral and bipartisan support has emerged in Congress for reforms addressing problematic PBM practices as well as abuses in the 340B program. Below, we describe a number of key opportunities for policymakers to realign incentives, strengthen market competition, and improve patients' access to care:

Break the link between PBM compensation and the price of medicines: To the extent that PBMs provide services to stakeholders in the pharmaceutical supply chain, they should be entitled to

compensation based on the value of those services. PBM compensation should not be tied to the price of a medicine. PhRMA supports efforts in the both the House and the Senate to "delink" PBM compensation from the price of a medicine in both the commercial and Part D markets and instead limit PBM compensation to bona fide service fees based on the fair market value of services appropriately rendered for a manufacturer.[253] Multiple bills that would accomplish this goal are currently under consideration by Congress, including the Modernizing and Ensuring PBM Accountability Act (S.2973) and the Delinking Revenue from Unfair Gouging Act (DRUG) Act (H.R. 6283).[254,255,256,257] The Congressional Budget Office (CBO) has projected that delinking in both the Part D and commercial market would reduce federal spending.[258,259]

Rebate pass through at the point-of-sale: Requiring PBMs and health plans to share the savings they receive on medicines directly with patients at the pharmacy counter in the commercial market and Medicare Part D would lower patient out-of-pocket costs and help realign payer incentives. Patients who take brand medicines with large rebates could see sizable reductions in out-of-pocket costs if the rebates were passed on to them at the pharmacy counter.[260] Actuaries estimate that sharing negotiated rebates directly with patients at the point-of-sale would have a negligible impact on premiums.[261] The substantial savings for patients at the pharmacy counter would outweigh those premium increases and provide patients with increased access and affordability for often lifesaving medicines.

PBM transparency: Lack of transparency and the complexity of PBM arrangements can make it difficult for plan sponsors to assess PBM performance on their behalf. Requiring PBMs (and their affiliates) to report aggregate information on prescription drug utilization, costs, rebates, and fees, as well as conflicts of interest would provide information necessary for employers and plan sponsors to properly evaluate whether PBMs are effectively managing the pharmaceutical benefit and would help ensure accountability to PBM customers.[262] According to CBO, proposed federal legislation that would require PBMs to disclose detailed aggregate information on prescription medicine spending and utilization to plan sponsors could enable employers and plan sponsors to better evaluate PBM contract provisions and obtain more favorable contracting terms, as well as increase competition among PBMs.[263,264,265] Improved transparency into PBMs' business model, including existing conflicts of interest, would provide valuable information to federal and state policymakers, employers, and patients.

Protect patient assistance: Policymakers should ensure that patient assistance actually benefits patients by closing policy loopholes that allow PBMs, their affiliates, and other vendors to utilize accumulator adjustment programs (AAPs), copay maximizers, and alternative funding programs to capture money intended for patients. The bipartisan Help Ensure Lower Patient (HELP) Copays Act would require commercial health plans to count patient assistance towards deductibles, coinsurance, copayments and out-of-pocket limits. This patient-centered reform would protect patients' choices about how they pay their cost-sharing obligations, effectively prohibiting the use of AAPs in all non-grandfathered commercial health plans and mitigating copay maximizers. The bill builds on action taken by 19 states, DC, and Puerto Rico that have already passed AAP bans in their state-regulated markets.[266]

The 340B program requires comprehensive legislative reforms

PhRMA also supports efforts by the agencies to provide greater oversight to 340B business relationships and scrutiny to hospital mergers and physician practice acquisitions. While the FTC is able to review mergers involving nonprofit hospitals, the agency is currently limited in its enforcement ability.[267,268] With the majority of hospitals in the United States operating as nonprofit entities, we believe the FTC and DOJ should not be restricted in their ability to address anti-competitive practices in this industry. Additionally, the FTC should closely monitor the behavior of for-profit vertically integrated entities involved in the 340B program to ensure they are not engaging in anti-competitive arrangements. The 340B program requires comprehensive legislative reforms, including the below policies that would specifically address some of the misaligned incentives driving provider consolidation.

***Limit PBM and other for-profit companies' involvement in 340B*:** In the context of broader reforms, Congress should enact policies to curb the abuses of vertically integrated payers, PBMs, and pharmacies, including by establishing limits on 340B program-related fees. As a condition of working with 340B covered entities, authorized pharmacies should not be able to charge fees that are tied to the list price of a medicine or that exceed a certain threshold (e.g., 125% of the average per-prescription dispense fee paid to pharmacies by all third-party payers). Greater restrictions on these for-profit 340B supply chain middlemen are needed to mitigate the misaligned incentives in the market that are driving consolidation throughout the health care system.

Reform covered entity eligibility criteria: The ability for hospitals to merge and to acquire physicians' offices to expand their ability to profit from the 340B program has directly fueled consolidation across the health care system. Congress should update covered entity eligibility criteria to require, among other changes, a minimum charity care threshold that helps ensure only providers that serve a disproportionate share of low income and vulnerable patients are eligible to participate in the program. Similar eligibility reforms should be extended to hospitals' child sites, which could help to reduce incentives for hospitals to acquire community physicians' offices. Tailoring the program to true safety net providers would lessen the incentives that 340B creates for more vertical and horizontal consolidation.

***Require sliding fee scale for 340B medicines*:** Covered entities should be required to ensure qualifying low income and uninsured patients benefit directly from 340B through reduced out-of-pocket costs for their 340B medicines. This can be accomplished by requiring 340B hospitals to establish a sliding fee scale that sets cost sharing for 340B medicines at $0 for uninsured or privately insured patients with incomes below 100% of poverty and limits cost sharing for these patients with incomes at or above 100% but below 200% of poverty to the lesser of 20% of their applicable cost sharing or $35. For medicines filled at a pharmacy, the sliding fee scale reductions in cost sharing should be reflected at the point of sale. In addition to these specifications, 340B hospitals and their entity-owned and contract pharmacies should have their sliding-fee-scale policies prominently posted and included in any billing-related correspondence to a patient who received a 340B drug.

***Improve 340B program integrity*:** A lack of definitional clarity in the current 340B statute has prompted covered entities to try to push the bounds of the program to include more purported "patients," which

has contributed to the program's continued growth. Among other changes, Congress should establish a clear and reasonable "patient" definition that applies uniformly to all covered entities and ensure uninsured and low-income privately insured patients directly benefit from lower cost medicines. To ensure cost-sharing assistance can be provided at the point of medicine dispense, a determination of whether an individual is a covered entity's patient should occur at the time a medicine is prescribed to the individual, not days, weeks or months later. These changes, among others, would decrease the ability of hospitals and their profit-driven business partners to abuse the 340B program.

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PhRMA appreciates the opportunity to provide feedback on this request for information. We look forward to opportunities for continued collaboration on these important issues. We are happy to discuss these comments and provide any further details or supplemental materials that you may request. Please reach out to Rachel Weissman (rweissman@phrma.org) with any follow up questions or requests.

Sincerely,

/s/
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[1] PhRMA. 2023 PhRMA Annual Membership Survey, July 2023. https://phrma.org/resource-center/Topics/Research-and-Development/2023-PhRMA-Annual-Membership-Survey

[2] US Food and Drug Administration. Summary of NDA Approvals & Receipts, 1938 to the Present. http://www.fda.gov/aboutfda/whatwedo/history/productregulation/summaryofndaapprovalsreceipts1938tothepresent/default.htm

[3] US Food and Drug Administration. New Drugs at FDA: CDER's New Molecular Entities and New Therapeutic Biological Products 2012 – 2014. http://wayback.archive-it.org/7993/20161022052126/http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DrugInnovation/default.htm

[4] US Food and Drug Administration: Novel Drug Approvals for 2022. https://www.fda.gov/drugs/new-drugs-fda-cders-new-molecular-entities-and-new-therapeutic-biological-products/novel-drug-approvals-2022

[5] US Food and Drug Administration. New Drugs at FDA: CDER's New Molecular Entities and New Therapeutic Biological Products 2015 – 2021. https://www.fda.gov/drugs/development-approval-process-drugs/new-drugs-fda-cders-new-molecular-entities-and-new-therapeutic-biological-products;

[6] Altarum Institute. Projections of the Non-Retail Prescription Drug Share of National Health Expenditures. July 2022. https://drugchannelsinstitute.com/files/Projections-of-Non-Retail-Drug-Share-of-NHE-2022.pdf

[7] Fein A. The 2024 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers. *Drug Channels Institute,* March 2024.

[8] Brownlee A. The Pharmaceutical Supply Chain, 2013-2020. Berkeley Research Group, January 2022. https://www.thinkbrg.com/insights/publications/pharmaceutical-supply-chain-2013-2020/

[9] Altarum Institute. Projections of the Non-Retail Prescription Drug Share of National Health Expenditures. July 2022. https://drugchannelsinstitute.com/files/Projections-of-Non-Retail-Drug-Share-of-NHE-2022.pdf
[10] Herman B. FTC may probe pharmacy benefit managers. Axios, February 2022. https://www.axios.com/ftc-study-pharmacy-benefit-managers-drug-prices-3078116f-382a-4b05-ac62-da5bc1d1b892.html
[11] Top 50 PBM Companies and Market Share by Annual Prescription Volume (Second Quarter 2010). *Drug Benefit News*, April 2010.
[12] Fein A. The 2024 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers. *Drug Channels Institute,* March 2024.
[13] *Ibid.*
[14] Guardado J. Competition in Commercial PBM Markets and Vertical Integration of Health Insurers with PBMs: 2023 Update. American Medical Association, 2023. https://www.ama-assn.org/system/files/prp-pbm-shares-hhi.pdf
[15] Fein A. The 2024 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers. *Drug Channels Institute,* March 2024.
[16] Levitt JE, Lee DY. Cautionary tale: Plan sponsors losing manufacturer rebate dollars to PBMs through rebate aggregators. BenefitsPRO. April 2021. https://www.benefitspro.com/2021/04/15/cautionary-tale-plan-sponsors-losing-manufacturer-rebate-dollars-to-pbms-through-rebate-aggregators/
[17] 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
[18] Potter W. Big Insurance Earnings Report Analysis 2023, April 2024. https://wendellpotter.substack.com/p/big-insurance-2023-revenues-reached
[19] *Ibid*.
[20] Express Scripts. Group Purchasing Organizations and Ascent. https://express-scriptsfacts.com/key-topics/group-purchasing-organizations-ascent/
[21] Nephron Research. Optum Launches 'Emisar' Contracting Entity; Navitus Aligns with Ascent via Prime. July 2021.
[22] Livingston S. Powerful drug-industry middlemen have quietly launched businesses to get better deals from drugmakers. It could drive up costs for patients. Business Insider. November 22, 2021. https://www.businessinsider.com/inside-pharmacy-benefit-managers-new-drug-negotiating-businesses-2021-11
[23] Drug Channels. Five (or Maybe Six?) Reasons that the Largest PBMs Operate Group Purchasing Organizations. May 24, 2023. https://www.drugchannels.net/2023/05/five-or-maybe-six-reasons-that-largest.html
[24] American Medical Association. Competition in health insurance: A comprehensive study of U.S. markets, 2023. https://www.ama-assn.org/system/files/competition-health-insurance-us-markets.pdf
[25] *Ibid*.
[26] *Ibid*.
[27] Guardado JR. Competition in Commercial PBM Markets and Vertical Integration of Health Insurers with PBMs: 2023 Update. American Medical Association, 2023. https://www.ama-assn.org/system/files/prp-pbm-shares-hhi.pdf
[28] HHS OIG. Effects of Vertical Integration on Medicare Part D. https://oig.hhs.gov/reports-and-publications/workplan/summary/wp-summary-0000843.asp
[29] Potter W. Big Insurance Earnings Report Analysis 2023, April 2024. https://wendellpotter.substack.com/p/big-insurance-2023-revenues-reached
[30] Percher E. Trends in Profitability and Compensation of PBMs and PBM Contracting Entities. Nephron Research. September 2023. https://nephronresearch.com/trends-in-profitability-and-compensation-of-pbms-and-pbm-contracting-entities/
[31] Fein A. The 2024 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers. *Drug Channels Institute,* March 2024.
[32] Percher E. Trends in Profitability and Compensation of PBMs and PBM Contracting Entities. Nephron Research. September 2023. https://nephronresearch.com/trends-in-profitability-and-compensation-of-pbms-and-pbm-contracting-entities/
[33] CVS Health. CVS Health reports first quarter results, completes acquisitions of Signify Health and Oak Street Health, May 2023. https://www.cvshealth.com/news/company-news/cvs-health-reports-first-quarter-2023-results.html
[34] Schladen M. With new acquisition, CVS to get bigger and broader, raising concerns. *Ohio Capital Journal,* September 2022. https://ohiocapitaljournal.com/2022/09/14/with-new-acquisition-cvs-to-get-bigger-and-broader-raising-concerns/
[35] UnitedHealth Group. Optum completes acquisition of DaVita Medical Group from DaVita, June 2019. https://www.unitedhealthgroup.com/newsroom/2019/2019-06-19-optum-davita-medical-acquisition.html
[36] Herman B. UnitedHealth is on a buying spree of outpatient surgery centers. STAT, March 2024. https://www.statnews.com/2024/03/11/unitedhealth-outpatient-surgery-centers-medicare-advantage-ncp-fresenius/

[37] Bartlett J. In acquisition, Atrius rejected the biggest names in Massachusetts health care. Here's what it all means. *Boston Globe,* July 2022. https://www.bostonglobe.com/2022/07/14/metro/acquisition-atrius-rejected-biggest-names-massachusetts-health-care-heres-what-it-all-means/
[38] NCPA. PBM Mergers – Acquisitions – Contracts Timeline, 2023. https://ncpa.org/sites/default/files/2023-02/PBM percent20MergerTimeline_2023.pdf
[39] Herman B. UnitedHealth Group now employs or is affiliated with 10% of all physicians in the U.S. *STAT,* November 2023. https://www.statnews.com/2023/11/29/unitedhealth-doctors-workforce/
[40] Condon A. Optum spending spree continues, adding to 70K+ physicians. *Becker's Healthcare*, April 2023. https://www.beckershospitalreview.com/finance/optum-spending-spree-continues-adding-to-70k-physicians.html
[41] Schladen M. With new acquisition, CVS to get bigger and broader, raising concerns. *Ohio Capital Journal,* September 2022. https://ohiocapitaljournal.com/2022/09/14/with-new-acquisition-cvs-to-get-bigger-and-broader-raising-concerns/
[42] Kimmey L, Furukawa MF, Jones DJ, Machta RM, Guo J, Rich EC. Geographic Variation In The Consolidation Of Physicians Into Health Systems, 2016-18. Health Aff (Millwood). 2021 Jan;40(1):165-169. doi: 10.1377/hlthaff.2020.00812.
[43] Avalere. Updated Report: Hospital and Corporate Acquisition of Physician Practices and Physician Employment 2019-2023. Physicians Advocacy Institute, April 2024. https://www.physiciansadvocacyinstitute.org/PAI-Research/PAI-Avalere-Study-on-Physician-Employment-Practice-Ownership-Trends-2019-2023
[44] Trish EE, Herring BJ. How do health insurer market concentration and bargaining power with hospitals affect health insurance premiums? J Health Econ. 2015 Jul;42:104-14. doi: 10.1016/j.jhealeco.2015.03.009. Epub 2015 Apr 8.
[45] Cooper Z. Consolidation and Corporate Ownership in Health Care. Senate Finance Committee Written Testimony, June 2023. https://www.finance.senate.gov/imo/media/doc/20230605_sfc_testimony.pdf
[46] Fulton BD, Arnold DR, King JS, Montague AD, Greaney TL, Scheffler RM. The Rise Of Cross-Market Hospital Systems And Their Market Power In The US. Health Aff (Millwood). 2022 Nov;41(11):1652-1660. doi: 10.1377/hlthaff.2022.00337.
[47] Morley M, Isaiah E, Diskey R. Characteristics of Hospitals Undergoing Mergers and Acquisitions. Avalere, February 2023. https://avalere.com/insights/characteristics-of-hospitals-undergoing-mergers-and-acquisitions
[48] Fulton BD, Arnold DR, King JS, Montague AD, Greaney TL, Scheffler RM. The Rise Of Cross-Market Hospital Systems And Their Market Power In The US. Health Aff (Millwood). 2022 Nov;41(11):1652-1660. doi: 10.1377/hlthaff.2022.00337.
[49] *Ibid.*
[50] Carroll C. Effect of Cross-Market Mergers on Hospital Choice: Evidence from Rural Markets. ASHEcon Poster, June 2023. https://ashecon.confex.com/ashecon/2023/meetingapp.cgi/Paper/14088
[51] Navathe AS, Connolly JE. Hospital Consolidation: The Rise of Geographically Distant Mergers. JAMA. 2023;329(18):1547–1548. doi:10.1001/jama.2023.5391
[52] O'Hanlon CE, Kranz AM, DeYoreo M, Mahmud A, Damberg CL, Timbie J. Access, Quality, And Financial Performance Of Rural Hospitals Following Health System Affiliation. *Health Aff* (Millwood). 2019 Dec;38(12):2095-2104. doi: 10.1377/hlthaff.2019.00918.
[53] Elevance Health Public Policy Institute. Costs & Quality After Independent Hospitals Are Acquired by Health Systems, August 2023. https://www.elevancehealth.com/public-policy-institute/costs-and-quality-after-independent-hospitals-are-acquired-by-health-systems
[54] *Ibid*.
[55] Shah A, Jacobson G, Ji W, Grace S. Which Parts of the United States Have the Most Consolidated Medicare Hospital Spending? *Commonwealth Fund,* January 2023. https://www.commonwealthfund.org/blog/2023/which-parts-united-states-have-most-consolidated-medicare-hospital-spending.
[56] Definitive Healthcare. Top 10 largest health systems in the U.S. January 2024. https://www.definitivehc.com/blog/top-10-largest-health-systems
[57] Abdelhadi O, Fulton BD, Alexander L, Scheffler RM. Private Equity-Acquired Physician Practices And Market Penetration Increased Substantially, 2012-21. Health Aff (Millwood). 2024 Mar;43(3):354-362. doi: 10.1377/hlthaff.2023.00152.
[58] *Ibid*.
[59] Berkeley Research Group Analysis of Public Datasets and Company Disclosures, 2023.
[60] *Ibid*.
[61] Appelbaum E, Batt R. Private Equity Buyouts in Healthcare: Who Wins, Who Loses? Institute for New Economic Thinking Working Paper Series No. 118, March 2020. https://doi.org/10.36687/inetwp118
[62] Blumberg L, Watts K. Evidence On Private Equity Suggests That Containing Costs And Improving Outcomes May Go Hand-In-Hand. *Health Affairs Forefront,* April 2024. Evidence On Private Equity Suggests That Containing Costs And Improving Outcomes May Go Hand-In-Hand

[63] Private Equity Stakeholder Project. Private Equity Healthcare Bankruptcies are on the Rise, 2024. https://pestakeholder.org/private-equity-healthcare-bankruptcies-are-on-the-rise/
[64] 84 Fed. Reg. at 2341.; 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/
[65] Percher E. Trends in Profitability and Compensation of PBMs and PBM Contracting Entities. Nephron Research, September 2023. https://nephronresearch.com/trends-in-profitability-and-compensation-of-pbms-and-pbm-contracting-entities/
[66] 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.
[67] 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
[68] *Ibid*.
[69] Percher E. Trends in Profitability and Compensation of PBMs and PBM Contracting Entities. Nephron Research. September 2023. https://nephronresearch.com/trends-in-profitability-and-compensation-of-pbms-and-pbm-contracting-entities/
[70] *Ibid*.
[71] 84 Fed. Reg. at 2341.; 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/
[72] Sood N, Ribero R, Van Nuys K. The Association Between Drug Rebates and List Prices. USC Schaeffer White Paper, February 2020. https://healthpolicy.usc.edu/research/the-association-between-drug-rebates-and-list-prices/
[73] 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 percent20Insulin percent20Report percent20(FINAL percent201).pdf
[74] Kansteiner F. Viatris launched 2 version of its interchangeable insulin biosimilar. Why? Fierce Pharma, November 2021. https://www.fiercepharma.com/pharma/viatris-launches-two-versions-its-interchangeable-biosimilar-semglee-bid-to-tackle-pricing
[75] Fein AJ. Four Crucial Questions About the Humira Biosimilar Price War. Drug Channels Institute, July 2023. https://www.drugchannels.net/2023/07/four-crucial-questions-about-humira.html
[76] Fein AJ. The Big Three PBMs' 2023 Formulary Exclusions: Observations on Insulin, Humira, and Biosimilars. Drug Channels Institute, January 2023. https://www.drugchannels.net/2023/01/the-big-three-pbms-2023-formulary.html
[77] 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
[78] Percher E. Trends in Profitability and Compensation of PBMs and PBM Contracting Entities. Nephron Research. September 2023. https://nephronresearch.com/trends-in-profitability-and-compensation-of-pbms-and-pbm-contracting-entities/
[79] Hayes T, Schmidt R, Suzuki S. Assessing Postsale Rebates for Prescription Drugs in Medicare Part D. MedPAC, 2023. https://www.medpac.gov/wp-content/uploads/2022/07/Tab-F-DIR-data-April-2023-SEC.pdf
[80] Government Accountability Office. Medicare Part D: CMS Should Monitor Effects of Rebates on Plan Formularies and Beneficiary Spending, September 2023. https://www.gao.gov/products/gao-23-105270
[81] IQVIA. Adalimumab Biosimilar Tracking. Biosimilar Council, April 2024. https://biosimilarscouncil.org/wp-content/uploads/2024/04/04022024_IQVIA-Humira-Tracking-Executive-Summary.pdf
[82] *Ibid*.
[83] *Ibid*.
[84] Wainer D. Coming to a CVS Near You: A Store Brand Monoclonal Antibody, *Wall Street Journal*. April 29, 2024. https://www.wsj.com/health/pharma/cvs-biosimilar-drugs-production-08227182.
[85] Fein AJ. What's Behind CVS Health's Novel Vertical Integration Strategy for Humira Biosimilars. Drug Channels. September 6, 2023. https://www.drugchannels.net/2023/09/whats-behind-cvs-healths-novel-vertical.html.

[86] Fein AJ. "What's Behind CVS Health's Novel Vertical Integration Strategy for Humira Biosimilars." Drug Channels. September 6, 2023. https://www.drugchannels.net/2023/09/whats-behind-cvs-healths-novel-vertical.html.
[87] David Wainer. "Coming to a CVS Near You: A Store Brand Monoclonal Antibody," *Wall Street Journal*. April 29, 2024. https://www.wsj.com/health/pharma/cvs-biosimilar-drugs-production-08227182.
[88] Fein AJ. "What's Behind CVS Health's Novel Vertical Integration Strategy for Humira Biosimilars." Drug Channels. September 6, 2023. https://www.drugchannels.net/2023/09/whats-behind-cvs-healths-novel-vertical.html.
[89] U.S. Senator James Lankford (R-OK). "Lankford Calls for Answers in CVS' Attempt to Block Access to Low-cost Prescriptions." February 1, 2024. https://www.lankford.senate.gov/news/press-releases/lankford-calls-for-answers-in-cvs-attempt-to-block-access-to-low-cost-prescriptions/.
[90] 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
[91] *Ibid*.
[92] Wong WB, Seetasith A, Hung A, Zullig LL. Impact of list price changes on out-of-pocket costs and adherence in four high-rebate specialty drugs. PLoS One. 2023 Jan 19;18(1):e0280570. doi: 10.1371/journal.pone.0280570.
[93] GAO. Drug Shortages: Public Health Threat Continues, Despite Efforts to Help Ensure Product Availability, February 2014. https://www.gao.gov/assets/d14194.pdf
[94] FDA. Drug Shortages: Root Causes and Potential Solutions, February 2020. https://www.fda.gov/media/131130/download
[95] 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.
[96] PhRMA. Deductibles and Coinsurance Drive High Out-Of-Pocket Costs For Commercially Insured Patients Taking Brand Medicines, November 2022. https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Refresh/Report-PDFs/G-I/IQVIA-Report-High-OOP-for-Brand-Medicines_November-2022_v2.pdf
[97] 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.
[98] 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
[99] Fein A. The 2024 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers. *Drug Channels Institute,* March 2024.
[100] *Ibid.*
[101] 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
[102] 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
[103] 84 Fed. Reg. 17454 (April 25, 2019) (codified at 45 C.F.R. § 156.130(h); version effective from June 24, 2019 to July 12, 2020).
[104] 85 Fed. Reg. 29164 (May 14, 2020).
[105] HIV & Hepatitis Policy Institute et al. v. U.S. Dep't of Health & Human Services et al., (D.D.C. Sept. 29, 2023), https://law.justia.com/cases/federal/district-courts/district-of-columbia/dcdce/1:2022cv02604/246787/42/.
[106] HIV & Hepatitis Policy Institute et al. v. U.S. Dep't of Health & Human Services et al., (D.D.C. December 22, 2023). https://hivhep.org/wp-content/uploads/2023/12/Clarification-decision.pdf
[107] 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
[108] Fein A. 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
[109] Ingham M, Sadik K, Zhao X, et al. Assessment of Racial and Ethnic Inequities in Copay Card Utilization and Enrollment in Copay Adjustment Programs. *Journal of Managed Care Pharmacy*. 2023; 29(9), 1084-1092.
[110] "Underinsured" refers to those individuals and families that have health coverage but are still exposed to high financial risk because they cannot afford their out-of-pocket costs. *See* Lavarreda, S. "Underinsurance in the United States: An Interaction of Costs to Consumers, Benefit Design, and Access to Care. Ann. Rev. Public Health. (Vol. 32, pg. 471-82). https://www.annualreviews.org/doi/pdf/10.1146/annurev.publhealth.012809.103655.

[111] Lana Pine, *David Charles, MD: Unintended Consequences of Alternative Funding Programs*, HCP Live (Nov. 6, 2023) ("[AFPs] may recommend different medications than those prescribed by clinicians, creating a disconnect between patients and their healthcare providers."), https://www.hcplive.com/view/david-charles-md-unintended-consequences-of-alternative-funding-programs.
[112] U.S. Department of Health and Human Services. Patient Protection and Affordable Care Act, HHS Notice of Benefit and Payment Parameters for 2025; Updating Section 1332 Waiver Public Notice Procedures; Medicaid; Consumer Operated and Oriented Plan (CO-OP) Program; and Basic Health Program, 89 Fed. Reg. 26218 (Apr. 15, 2024) (to be codified at 42 CFR 600, 45 CFR 153, 45 CFR 155, 45 CFR 156).
[113] U.S. Department of Labor, Employee Benefits Security Administration. FAQ about Affordable Care Act Implementation Part 66, April 2024. https://www.dol.gov/agencies/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-66
[114] *Ibid.*
[115] Fein A. The 2022 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers. Drug Channels Institute. March 2022.
[116] *Ibid.*
[117] 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 percent20Insulin percent20Report percent20(FINAL percent201).pdf
[118] *Ibid.*
[119] Xcenda. Skyrocketing growth in PBM formulary exclusions continues to raise concerns about patient access. May 2022. https://www.xcenda.com/-/media/assets/xcenda/english/content-assets/white-papers-issue-briefs-studies-pdf/xcenda_pbm_exclusion_may_2022.pdf
[120] 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.
[121] IQVIA. Disparities in Pharmaceutical Access: How Demographics Impact Patients' Abilities to Overcome Prescription Initiation Barriers, September 2022. https://www.iqvia.com/locations/united-states/library/white-papers/disparities-in-pharmaceutical-access-how-demographics-impact-patients
[122] 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
[123] 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
[124] Fein A. The 2022 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers. Drug Channels Institute. March 2022.
[125] 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
[126] 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. doi.org/10.1016/j.amepre.2021.02.017
[127] CVS Health. CVS Health Investor Day 2023 Presentation. https://s2.q4cdn.com/447711729/files/doc_downloads/2023/investor-day/05/CVS_Health_Investor_Day_2023_Presentation.pdf
[128] Community Oncology Alliance. COA Formal Comments to FTC on Harm of Pharmacy Benefit Manager Integration. May 25, 2022. https://communityoncology.org/research-publications/comment-letters/coa-formal-comments-to-ftc-on-harm-of-pharmacy-benefit-manager-integration/
[129] Khemlani A. Amid increased federal scrutiny, PBMs pivot strategy to further squeeze independent pharmacies. *YahooHealth,* March 2024. https://finance.yahoo.com/news/amid-increased-federal-scrutiny-pbms-pivot-strategy-to-further-squeeze-independent-pharmacies-150017649.html?guccounter=1
[130] Fein A. The 2022 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers. Drug Channels Institute. March 2022.
[131] Guadamuz JS, Alexander GC, Zenk SN, Qato DM, Wilder JR, Mouslim MC. Fewer Pharmacies in Black and Hispanic/Latino Neighborhoods Compared with White or Diverse Neighborhoods, 2007–15. *Health Affairs*, 802-11, 2021. doi/full/10.1377/hlthaff.2020.01699

[132] Hawryluk M. The last drugstore: Rural America is losing its pharmacies. *The Washington Post,* November 2021. https://www.washingtonpost.com/business/2021/11/10/drugstore-shortage-rural-america/
[133] Levin JS, Komanduri S, Whaley C. Association between hospital-physician vertical integration and medication adherence rates. Health Serv Res. 2023; 58(2): 356-364. doi:10.1111/1475-6773.14090
[134] Condon A. Optum spending spree continues, adding to 70K+ physicians. *Becker's Healthcare*, April 2023. https://www.beckershospitalreview.com/finance/optum-spending-spree-continues-adding-to-70k-physicians.html
[135] 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
[136] *Ibid*.
[137] Shih YT, Xu Y, Yao JC. Financial Outcomes of "Bagging" Oncology Drugs Among Privately Insured Patients With Cancer. JAMA Network Open. 2023;6(9):e2332643. doi:10.1001/jamanetworkopen.2023.32643
[138] Hayden Consulting. PBM Consolidation and its Impact on Geo Prescribing Patterns, November 2023. https://haydencg.com/pbm-consolidation-and-its-impact-on-geo-prescribing-patterns/
[139] *Ibid*.
[140] Walker J. Generic Drugs Should Be Cheap, but Insurers Are Charging Thousands of Dollars for Them. *Wall Street Journal*, September 2023. https://www.wsj.com/health/healthcare/generic-drugs-should-be-cheap-but-insurers-are-charging-thousands-of-dollars-for-them-ef13d055
[141] Conrad R, Lutter R. Generic Competition and Drug Prices: New Evidence Linking Greater Generic Competition and Lower Generic Drug Prices. US Food and Drug Administration, December 2019. https://www.fda.gov/media/133509/download
[142] Walker J. Generic Drugs Should Be Cheap, but Insurers Are Charging Thousands of Dollars for Them. Wall Street Journal, September 2023. https://www.wsj.com/health/healthcare/generic-drugs-should-be-cheap-but-insurers-are-charging-thousands-of-dollars-for-them-ef13d055
[143] Trish E, Van Nuys K, Popovian R. U.S. Consumers Overpay for Generic Drugs. *USC Schaeffer,* May 2022. https://healthpolicy.usc.edu/research/u-s-consumers-overpay-for-generic-drugs/
[144] Mattingly TJ 2nd, Ben-Umeh KC, Bai G, Anderson GF. Pharmacy Benefit Manager Pricing and Spread Pricing for High-Utilization Generic Drugs. *JAMA Health Forum*. 2023 Oct 6;4(10):e233660. doi: 10.1001/jamahealthforum.2023.3660.
[145] GAO. Drug Shortages: Public Health Threat Continues, Despite Efforts to Help Ensure Product Availability, February 2014. https://www.gao.gov/assets/d14194.pdf
[146] FDA. Drug Shortages: Root Causes and Potential Solutions, February 2020. https://www.fda.gov/media/131130/download
[147] Schwartz K, Lopez E, Rae M, Neuman T. What We Know About Provider Consolidation. *Kaiser Family Foundation,* September 2020. https://www.kff.org/health-costs/issue-brief/what-we-know-about-provider-consolidation/
[148] LoSasso AT, Toczydlowski K, Yang Y. Insurer Market Power and Hospital Prices in the US. *Health Affairs*. 2023; 42(5): 615-621. https://www.healthaffairs.org/doi/10.1377/hlthaff.2022.01184
[149] Liu JL, Levinson ZM, Zhou A, Zhao X, Nguyen P, Qureshi N. Environmental Scan on Consolidation Trends and Impacts in Health Care Markets. Rand Health Q. 2023 Jun 16;10(3):2.
[150] Chatterji P, Ho C, Jin T, Wang Y. Does Consolidation in Insurer Markets affect Insurance Enrollment and Drug Expenditures? Evidence from Medicare Part D. NBER Working Paper 32267. March 2024. https://www.nber.org/papers/w32267
[151] Elevance Health. Costs and Quality After Independent Hospitals Are Acquired by Health Systems, August 2023. https://www.elevancehealth.com/public-policy-institute/costs-and-quality-after-independent-hospitals-are-acquired-by-health-systems
[152] Baker LC, Bundorf MK, Kessler DP. Does Multispecialty Practice Enhance Physician Market Power? American Journal of Health Economics, 324-47, 2020. doi/pdf/10.1086/708942.
[153] Cooper Z, Craig SV, Gaynor M, Van Reenen J. The Price Ain't Right? Hospital Prices And Health Spending On The Privately Insured. Q J Econ. 2019 Feb;134(1):51-107. doi: 10.1093/qje/qjy020. Epub 2018 Sep 4.
[154] Beaulieu ND, Chernew ME, McWilliams JM, et al. Organization and Performance of US Health Systems. JAMA. 2023;329(4):325–335. doi:10.1001/jama.2022.24032
[155] Curto V, Sinaiko AD, Rosenthal MB. Price Effects Of Vertical Integration And Joint Contracting Between Physicians And Hospitals In Massachusetts. Health Aff (Millwood). 2022 May;41(5):741-750. doi: 10.1377/hlthaff.2021.00727.
[156] Lin H, McCarthy IM, Richards M. Hospital Pricing Following Integration with Physician Practices. J Health Econ. 2021 May;77:102444. doi: 10.1016/j.jhealeco.2021.102444.

[157] Godwin J, Arnold DR, Fulton BD, Scheffler RM. The Association between Hospital-Physician Vertical Integration and Outpatient Physician Prices Paid by Commercial Insurers: New Evidence. INQUIRY: The Journal of Health Care Organization, Provision, and Financing. 2021;58. doi:10.1177/0046958021991276
[158] Venkatesh S. The Effects of Physician Practice Acquisitions on Hospital Competition, November 2023. https://shruthi-venkatesh.github.io/files/JMP_ShruthiVenkatesh_Nov2023.pdf
[159] Arnold D, Whaley CM. Who Pays for Health Care Costs? The Effects of Health Care Prices on Wages. Santa Monica, CA: RAND Corporation, 2020. https://www.rand.org/pubs/working_papers/WRA621-2.html
[160] Wofford D. Hospital Consolidation Suppresses Workers' Wages. *Third Way,* September 2023. https://www.thirdway.org/memo/hospital-consolidation-suppresses-workers-wages
[161] Levin JS, Komanduri S, Whaley C. Association between hospital-physician vertical integration and medication adherence rates. Health Serv Res. 2023; 58(2): 356-364. doi:10.1111/1475-6773.14090
[162] Beaulieu ND, Dafny LS, Landon BE, Dalton JB, Kuye I, McWilliams JM. Changes in Quality of Care after Hospital Mergers and Acquisitions. *New England Journal of Medicine*, 51-59, 2020. doi/full/10.1056/NEJMsa1901383.
[163] Elevance Health. Costs and Quality After Independent Hospitals Are Acquired by Health Systems, August 2023. https://www.elevancehealth.com/public-policy-institute/costs-and-quality-after-independent-hospitals-are-acquired-by-health-systems
[164] *Ibid*.
[165] Borsa A, Bejarano G, Ellen M, Bruch J D. Evaluating trends in private equity ownership and impacts on health outcomes, costs, and quality: systematic review *BMJ* 2023; 382 :e075244 doi:10.1136/bmj-2023-075244
[166] Kannan S, Bruch JD, Song Z. Changes in Hospital Adverse Events and Patient Outcomes Associated With Private Equity Acquisition. JAMA. 2023;330(24):2365–2375. doi:10.1001/jama.2023.23147.
[167] Appelbaum, Eileen and Batt, Rosemary, Private Equity Buyouts in Healthcare: Who Wins, Who Loses? (March 15, 2020). Institute for New Economic Thinking Working Paper Series No. 118. doi.org/10.36687/inetwp118
[168] Liu, Tong, Bargaining with Private Equity: Implications for Hospital Prices and Patient Welfare (November 1, 2022). doi.org/10.2139/ssrn.3896410
[169] Borsa A, Bejarano G, Ellen M, Bruch J D. Evaluating trends in private equity ownership and impacts on health outcomes, costs, and quality: systematic review *BMJ* 2023; 382 :e075244 doi:10.1136/bmj-2023-075244
[170] Kannan S, Bruch JD, Song Z. Changes in Hospital Adverse Events and Patient Outcomes Associated With Private Equity Acquisition. JAMA. 2023;330(24):2365–2375. doi:10.1001/jama.2023.23147
[171] Whaley CM, Arnold DR, Gross N, Jena AB. Physician Compensation In Physician-Owned And Hospital-Owned Practices. Health Aff (Millwood). 2021 Dec;40(12):1865-1874. doi: 10.1377/hlthaff.2021.01007.
[172] Avalere. Covid-19's Impact on Acquisitions of Physician Practices and Physician Employment 2019-2020. Physicians Advocacy Institute, 2021. http://www.physiciansadvocacyinstitute.org/Portals/0/assets/docs/Revised-6-8-21_PAI-Physician-Employment-Study-2021-FINAL.pdf.
[173] Xiao R, Ross JS, Gross CP, Dusetzina SB, McWilliams JM, Sethi RKV, Rathi VK. Hospital-Administered Cancer Therapy Prices for Patients With Private Health Insurance. *JAMA Intern Med*. 2022 Jun 1;182(6):603-611. doi: 10.1001/jamainternmed.2022.1022.
[174] Employee Benefit Research Institute. Cost Differences for Physician-Administered Outpatient Drugs. 2021. Interactive Web Graphic. https://www.ebri.org/publications/research-publications/ebrinteractive/cost-differences-for-physician-administered-outpatient-drugs.
[175] Employee Benefit Research Institute. Shifting From Hospital Outpatient Departments to Physician Offices Equates to Significant Cost Reductions. 2021. https://www.ebri.org/docs/default-source/fast-facts-(public)/ff.405.locationx3.9sep21.pdf?sfvrsn=286a3b2f_4
[176] Nguyen, NX, Olsen, TA, Sheingold SH, De Lew N. Medicare Part B Drugs: Trends In Spending and Utilization, 2008-2021. *Assistant Secretary for Planning and Evaluation*. 2023. https://aspe.hhs.gov/sites/default/files/documents/fb7f647e32d57ce4672320b61a0a1443/aspe-medicare-part-b-drug-pricing.pdf
[177] Cameron S, Zabinski D, Stensland J. Congressional Request on Health Care Provider Consolidation. *MEDPac*. 2019. https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/default-document-library/consolidation-draft-3.pdf
[178] Post B, Alinezhad F, Mukherjee S, Young GJ. Hospital-Physician Integration is Associated with Greater Use of Cardiac Catheterization and Angioplasty. *Health Affairs*. 2023;42(5): 606-614. doi/10.1377/hlthaff.2022.01294
[179] Young GJ, Zepeda ED, Flaherty S, Thai N. Hospital Employment of Physicians in Massachusetts Is Associated with Inappropriate Diagnostic Imaging. *Health Affairs*. 2021;40(5): 710-718. doi/full/10.1377/hlthaff.2020.01183.

[180] Whaley CM, Zhao X, Richards M, Damberg CL. Higher Medicare Spending On Imaging And Lab Services After Primary Care Physician Group Vertical Integration. *Health Affairs*. 2021;40(5):702-709. doi/10.1377/hlthaff.2020.01006
[181] In 1994, there were 34 child sites. Nearly three decades later, in 2023, this had increased to over 30,000, of which more than 75 percent are affiliated with a 340B DSH hospital. *See*: HRSA OPAIS Database, Jun. 2023.
[182] Conti R, Bach P. Cost Consequences of the 340B Drug Discount Program. *JAMA*, 2013;309(19):1995-1996. doi:10.1001/jama.2013.4156.
[183] Thomas K, Silver-Greenberg J. How a Hospital Chain Used a Poor Neighborhood to Turn Huge Profits. *The New York Times*, September 2022. https://www.nytimes.com/2022/09/24/health/bon-secours-mercy-health-profit-poor-neighborhood.html.
[184] GAO. Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals, June 2015. https://www.gao.gov/products/gao-15-442
[185] 59 Fed. Reg. 47884, 47885 (Sept. 19, 1994)
[186] Gaynor M. Diagnosing the Problem: Exploring the Effects of Consolidation and Anticompetitive Conduct in Health Care Markets, Statement before the Committee on the Judiciary Subcommittee on Antitrust, Commercial, and Administrative Law U.S. House of Representatives, March 7, 2019.
[187] HRSA, 340B Ceiling Price Final Rule, 82 Fed. Reg. 1210 (Jan. 5, 2017); HRSA, Delay of Effective Date of 340B Ceiling Price Final Rule, 83 Fed. Reg. 61563 (Nov. 30, 2018).
[188] 340B Industry Roundtable. 340B Program at a Glance. Berkeley Research Group (BRG), January 2024. https://media.thinkbrg.com/wp-content/uploads/2024/01/12123932/340B-Program-at-a-Glance_2024-FINAL-CLEAN.pdf.
[189] Community Oncology Alliance. Examining Hospital Price Transparency, Drug Profits, and the 340b Program, 2021. https://communityoncology.org/featured/hospital-340b-drug-profits-report/.
[190] Robinson, et al. Hospital Prices for Physician-Administered Drugs for Patients with Private Insurance. *New England Journal of Medicine* 390, no. 4 (2024): 338-45. doi.org/10.1056/NEJMsa2306609.
[191] *Ibid*.
[192] Community Oncology Alliance. COA Comments on Bipartisan Senate 340B RFI. April 1, 2024. mycoa.communityoncology.org/education-publications/comment-letters/coa-comments-on-bipartisan-senate-340b-rfi
[193] Hunter MT, Holcomb KM, Kim CJ. Analysis of 2020 Commercial Outpatient Drug Spend at 340B Participating Hospitals. *Milliman.* September 2022. https://www.milliman.com/en/insight/2020-outpatient-drug-spend-at-340b-hospitals
[194] *Ibid*.
[195] Chang J, Karaca-Mandic P, Go RS, Schondelmeyer S, Weisdorf D, Jeffery MM. Provider barriers in uptake of biosimilars: case study on filgrastim. Am J Manag Care. 2023 May 1;29(5):e155-e158. doi: 10.37765/ajmc.2023.89363.
[196] Bond AM, Dean EB, Desai SM. The Role Of Financial Incentives In Biosimilar Uptake In Medicare: Evidence From The 340B Program. Health Aff (Millwood). 2023 May;42(5):632-641. doi: 10.1377/hlthaff.2022.00812.
[197] Holcomb K, Change P. Biosimilar Utilization at 340B and Non-340B Outpatient Hospitals in the Commercial Market. *Milliman,* July 2022. https://www.milliman.com/-/media/milliman/pdfs/2022-articles/11-17-22-biosimilar-utilization-340b-non-340b-outpatient-hospitals.ashx
[198] Smith K, Padmanabhan P, Chen A, Glied S, Desai S. The impacts of the 340B Program on health care quality for low-income patients. Health Serv Res. 2023 Oct;58(5):1089-1097. doi: 10.1111/1475-6773.14204. Epub 2023 Jul 20.
[199] Tripp AS, Marrufo G, Kornfield T, Morley M, Nichols D, Yeh A. The 340B Program and Health Disparities Among Medicare Beneficiaries With Chronic Asthma. Health Serv Insights. 2023 Apr 27;16:11786329231169257. doi: 10.1177/11786329231169257.
[200] Cass A. Change Healthcare Attack Costing Hospitals $2B a Week: Report. *Becker's Hospital Review,* March 2024. https://www.beckershospitalreview.com/finance/change-healthcare-attack-costing-hospitals-2b-a-week-report
[201] Leyden J. Consolidation blamed for Change Healthcare ransomware attack, CSO. April 2024. https://www.csoonline.com/article/2093196/consolidation-blamed-for-change-healthcare-ransomware-attack.html
[202] Reed T. Cyberattack Affecting Prescriptions Reveals Weakness in Health Care System. *Axios.* February 27, 2024. https://www.axios.com/2024/02/27/cyberattack-prescriptions-health-care
[203] Optum. Change Healthcare Copay/Coupon Savings Program update: Affected copay/coupon programs. April 2024. Accessed April 30, 2024. https://www.optum.com/en/csp.html
[204] Muoio D. AHA: 94% of Hospitals Financially Impacted by Change Healthcare's Cyberattack. *Fierce Healthcare.* March 15, 2024. https://www.fiercehealthcare.com/providers/aha-94-hospitals-financially-impacted-change-healthcares-cyberattack
[205] Eaton-Robb P. A Cyberattack Has Disrupted Hospitals and Health Care in Several States. *AP News.* August 4, 2023. https://apnews.com/article/cyberattack-hospital-emergency-outage-4c808c1dad8686458ecbeababd08fecf

[206] Sophos. The State of Ransomware 2024. April 2024. https://www.sophos.com/en-us/press/press-releases/2024/04/ransomware-payments-increase-500-last-year-finds-sophos-state
[207] Trang B, Bannow T, Herman B. Experts Say Scale of Change Cyberattack Shows Risk of Centralized Claims Processing. *Stat.* February 27, 2024. https://www.statnews.com/2024/02/27/change-healthcare-cyber-attack-reveals-consolidation-risks/
[208] Provider and hospital GPOs are distinctly different businesses than so-called PBM GPO.
[209] GAO. Drug Shortages: Public Health Threat Continues, Despite Efforts to Help Ensure Product Availability, February 2014. https://www.gao.gov/assets/d14194.pdf
[210] AAM. Drug Shortages: Causes & Solutions. June 22, 2023. https://accessiblemeds.org/sites/default/files/2023-06/AAM_White_Paper_on_Drug_Shortages-06-22-2023.pdf
[211] 42 C.F.R. §§ 422.2420, 423.2420; 45 C.F.R. § 158.221. Note: self-funded plans are not subject to MLR requirements under the Affordable Care Act.
[212] 45 C.F.R. § 158.140(b)(1)(i); 42 CFR 438.8(e)(2)(ii)(B))
[213] 42 C.F.R. §§ 423.2410; 423.2420(b)(2)(i).
[214] 42 C.F.R. §§ 422.2410, 423.2410; 45 C.F.R. § 158.210.
[215] Why Health Care is Unaffordable: Anticompetitive and Consolidated Markets*: Hearing before the Subcommittee on Health, of the House Committee on Ways and Means*. Testimony of Cheryl L. Damberg. 118th Congress. May 17, 2023 at 7-8.
[216] Herman B. Profits swell when insurers are also your doctors. *Axios,* July 2021. https://www.axios.com/2021/07/16/unitedhealth-optum-providers-intercompany-eliminations
[217] Frank RG, Milhaupt C. Related businesses and preservation of Medicare's Medical Loss Ratio Rules. *Brookings*, June 2023. https://www.brookings.edu/articles/related-businesses-and-preservation-of-medicares-medical-loss-ratio-rules/
[218] Examples adapted from AHealthcareZ – Healthcare Finance Explained. https://www.youtube.com/watch?v=wu-RhIxCUkA
[219] Fein A. The 2024 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers. *Drug Channels Institute,* March 2024.
[220] *Ibid*.
[221] *Ibid.*
[222] 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
[223] 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. doi.org/10.18553/jmcp.2020.20213
[224] Herman B. 'It's beyond unethical': Opaque conflicts of interest permeate prescription drug benefits. *STAT+*, June 2023. https://www.statnews.com/2023/06/20/pbms-consulting-firms-investigation/
[225] *Ibid.*
[226] Hansard S. Frustrated Employers Outline Ways to Work With PBMs. *Bloomberg Law,* June 2023. https://news.bloomberglaw.com/employee-benefits/frustrated-employers-outline-playbook-for-working-with-pbms
[227] Kaplan DA. PBMs are Creating GPOs, and Stirring Debate as to Why. Managed Healthcare Executive. July 12, 2022. https://www.managedhealthcareexecutive.com/view/pbms-are-creating-gpos-and-stirring-debate-as-to-why
[228] Purchaser Business Group on Health. 6 Things Every Employer Should Know About Their Pharmacy Benefit Manager. May 11, 2022. https://www.pbgh.org/6-things-employers-should-know-about-pbms/
[229] State of Hawaii v Caremark PCS Health LLC, Express Scripts, Inc. and OptumRx, Inc. https://ag.hawaii.gov/wp-content/uploads/2023/10/SOH-v-CaremarkPCS-Health-et-al-COMPLAINT.pdf
[230] State of Ohio v. Ascent Health Services LLC, Express Scripts, Inc., Cigna Group, Evernorth Heatlh, Inc., Prime Therapeutics LLC, Humana Pharmacy Solutions, Inc., and Humana Inc. https://www.ohioattorneygeneral.gov/Files/Briefing-Room/News-Releases/Yost-v-Ascent.aspx
[231] *Ibid.*
[232] 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
[233] Fortune, 2023. https://fortune.com/ranking/fortune500/
[234] Fein A. Exclusive: 340b Continues Its Unbridled Takeover of Pharmacies and PBMs. In Drug Channels, 2021. https://www.drugchannels.net/2021/06/exclusive-340b-continues-its-unbridled.html.
[235] McGlave C, Bruno JP, Watts E, Nikpay S. 340B Contract pharmacy growth by pharmacy ownership: 2009–2022, *Health Affairs Scholar*, Volume 2, Issue 1, January 2024, qxad075, doi.org/10.1093/haschl/qxad075

[236] Drug Channels Institute analysis of OPA Daily Contract Pharmacy Database, April 2022.
[237] 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
[238] 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
[239] Fein A. Vertical Integration Lessons: The Economics and Strategies of Hospital-Owned Specialty Pharmacies. Drug Channels, November 2023. https://www.drugchannels.net/2023/11/vertical-integration-lessons-economics.html
[240] Berkeley Research Group. For-Profit Pharmacy Participation in the 340B Program, October 2020. https://www.thinkbrg.com/insights/publications/for-profit-pharmacy-participation-340b/.
[241] Complaint, Brandywine Hospital v. CVS Health Corp. et al., No. 2:23-cv-01458 (E.D. Pa. Apr. 17, 2023); Complaint, New York v. CVS Health Corp., No. 452197/2022 (N.Y. 2022).
[242] 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
[243] Fein A. The 2024 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers. *Drug Channels Institute,* March 2024.
[244] Barron's: CVS Health Stock Gets Downgraded. This Analyst Sees Multiple Risks. March 2022. https://www.barrons.com/amp/articles/cvs-health-stock-downgrade-51648567375
[245] *See* CVS Health Corporation, Annual Report (Form 10-K) at 22-23 (Feb. 9, 2022), https://bit.ly/3HVWvn5; Walgreens Boots Alliance, Inc., Annual Report (Form 10-K) at 23 (Oct. 15, 2020), https://bit.ly/3ISDfIA; Barron's on Deutsche Bank downgrading CVS: https://www.barrons.com/amp/articles/cvs-health-stock-downgrade-51648567375; CVS Earnings Call. May 3, 2023: https://s2.q4cdn.com/447711729/files/doc_financials/2023/q1/Q1-2023-Earnings-Presentation.pdf#page=14
[246] Press release. Ranking Member Cassidy Seeks Information from Major Contract Pharmacies as Part of Ongoing 340B Investigation. January 17, 2024. https://www.help.senate.gov/ranking/newsroom/press/ranking-member-cassidy-seeks-information-from-major-contract-pharmacies-as-part-of-ongoing-340b-investigation
[247] Lin JK, Li P, Doshi JA, Desai SM. Assessment of US Pharmacies Contracted With Health Care Institutions Under the 340B Drug Pricing Program by Neighborhood Socioeconomic Characteristics. *JAMA Health Forum*. 2022 Jun 17;3(6):e221435. Doi: 10.1001/jamahealthforum.2022.1435.
[248] *See* Turn Key Pharmacy Solutions. White Paper: 340B Eligible Patient Definition. https://www.spendmend.com/wp-content/uploads/2022/05/White-Paper-Patient-Definition-Final-Draft.pdf; Cook E. What Makes a Patient a "Patient"? Court Rejects Restrictive 340B Definition. JD Supra, November 2023. https://www.jdsupra.com/legalnews/what-makes-a-patient-a-patient-court-2243602/; ProxsysRx. Comprehensive Guide To The 340B Drug Pricing Program. https://www.proxsysrx.com/a-comprehensive-guide-to-the-340b-drug-pricing-program/#chapter4
[249] ProxsysRx. Which TPAs Are The Best At Optimizing 340B Savings And Revenue? December 2022. https://www.proxsysrx.com/2022/12/08/which-tpas-are-the-best-in-optimizing-340b-savings-and-revenue/
[250] Nikpay, Sayeh, and Lucas Halvorson. Growing administrative complexity in the 340B program and the rise of third-party administrators. *Health Affairs Scholar* 1.5 (2023): qxad052.
[251] *Ibid*.
[252] National Association of Attorney General. Letter to House and Senate Leadership on Support for Reforming Pharmacy Benefit Managers. February 20, 2024. https://www.naag.org/wp-content/uploads/2024/02/PBM-Letter-_NAAG-Letterhead-Final.pdf
[253] United States, Congress, Senate Finance. Business meeting to consider an original bill entitled, "Modernizing and Ensuring PBM Accountability (MEPA) Act". Congress.gov, https://www.congress.gov/event/118th-congress/senate-event/334680?s=1&r=29. 118th Congress, Senate Committee Meeting, 26 Jul. 2023.
[254] United States, Congress, House. Protecting Patients Against PBM Abuses Act. Congress.gov, https://www.congress.gov/bill/118th-congress/house-bill/2880. 118th Congress, House Resolution 2880, Introduced 26 April 2023.
[255] United States, Congress, Senate. Modernizing and Ensuring PBM Accountability Act. Congress.gov, https://www.congress.gov/bill/118th-congress/senate-bill/2973. 118th Congress, Senate Bill 2973, Introduced 28 Sep. 2023.
[256] United States, Congress, Senate. DRUG Act. Congress.gov, https://www.congress.gov/bill/118th-congress/senate-bill/1542. 118th Congress, Senate Bill 1542, Introduced 10 May 2023.

[257] United States, Congress, House. DRUG Act. Congress.gov, https://www.congress.gov/bill/118th-congress/house-bill/6283. 118th Congress, House Resolution 6283, Introduced 08 Nov. 2023.
[258] Congressional Budget Office. Health Care Legislation As ordered reported by the House Committee on Energy and Commerce on December 6, 2023. March 2024. https://www.cbo.gov/system/files/2024-03/hr4881.pdf
[259] Wanneh G. Senate Finance Passes Extra Policies To Build On MEPA PBM Bill. Inside Health Policy, November 2023. https://insidehealthpolicy.com/daily-news/senate-finance-passes-extra-policies-build-mepa-pbm-bill
[260] 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
[261] 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.
[262] 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
[263] Congressional Budget Office. Cost Estimate: Estimated Direct Spending and Revenue Effects of H.R. 5378, the Lower Costs, More Transparency Act. December 8, 2023. https://www.cbo.gov/system/files/2023-12/hr5378-DS-and-Revs_12-2023.pdf
[264] 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
[265] CBO has continued to recognize savings from PBM transparency proposals. For example, see: https://www.cbo.gov/system/files/2022-06/ hr7666.pdf
[266] Avalere. Cort Ruling Will Limit Accumulators. October 2023. https://avalere.com/insights/court-ruling-will-limit-accumulators
[267] Schwartz K, et al. What We Know About Provider Consolidation. *Kaiser Family Foundation,* September 2020. https://www.kff.org/health-costs/issue-brief/what-we-know-about-provider-consolidation/
[268] Slaughter R. Antitrust and Health Care Providers Policies to Promote Competition and Protect Patients. Center for American Progress. Washington, DC: Federal Trade Commission, May 14, 2019. https://www.americanprogress.org/events/antitrust-health-care-providers/