FAMILIESUSA
THE VOICE FOR HEALTH CARE CONSUMERS

June 5, 2024

The Honorable Xavier Becerra
Secretary
U.S. Department of Health and Human Services
200 Independence Ave, SW
Washington, DC 20201

The Honorable Lina M. Khan
Chair
Federal Trade Commission
600 Pennsylvania Ave, NW
Washington, DC 20580

The Honorable Jonathan Kanter
Assistant Attorney General
Antitrust Division
U.S. Department of Justice
950 Pennsylvania Avenue, NW
Washington, DC 20530

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

Dear Secretary Becerra, Chair Khan, and Assistant Attorney General Kanter:

As a leading national, non-partisan voice for health care consumers, Families USA appreciates the opportunity to respond to the *Request for Information (RFI) on Consolidation in Health Care Markets.* Central to Families USA's mission is a commitment to guaranteeing that families and individuals across the nation have access to high-quality, affordable, and equitable health care. We share the administration's deep concerns with the rise of unchecked health care industry consolidation and anti-competitive behavior that is driving unaffordable health care across the nation, and strongly support exploring additional ways to rein in the ability of large health care corporations to price gouge the American people. It is essential that federal policies promote healthy competition to achieve more affordable and high-quality care for our nation's families.

The United States is in the midst of a health care affordability and quality crisis. High and rising health care prices, particularly for hospital stays and prescription drugs, are a direct threat to the health and financial security of America's families. More than 100 million Americans face medical debt; a quarter of all Americans forgo needed medical care due to the cost; and a third of Americans indicate that the cost of medical services interferes with their ability to secure basic needs like buying groceries and paying rent.[1]

America's health care affordability crisis is driven by a fundamental misalignment between the business interests of the health care sector and the health and financial security of our nation's families – a business model that allows industry to set irrational health care prices that have little to do with the quality of the care they provide. High and rising prices are largely due to trends in health care industry consolidation and other anti-competitive practices that have eliminated competition and allowed monopolistic pricing to push our nation's families to the brink of financial ruin.[2]

The administration's Request for Information (RFI) poses a number of important questions that are critical both to understand and rein in health care industry consolidation and anti-competitive behaviors in the U.S. health care system, and ultimately to promote healthy competition to achieve affordable, high-quality health care. The following questions will be the focus of our comments:

- **Question 1: Effects of Consolidation** (i.e., what impact do certain health care transactions between various health care entities, such as hospitals and drug companies, have on health care consumers, workers, and other stakeholders that rely on health care markets);
- **Question 2: Claimed Business Objectives for Transactions** (i.e., to what extent the claimed business objectives associated with certain health care transactions are realized in practice and importantly align with the lived experience of consumers);
- **Question 4: Need for Government Action** (i.e., what are the ways in which the government and administration can identify and address health care transactions that may have particularly negative impacts on consumers, workers, and others.)

Question 1: Effects of Consolidation & Question 2: Claimed Business Objectives for Transactions

Background

High and rising health care costs not only threaten the health and financial security of American individuals and families but are also a critical problem for the federal government, state governments, and taxpayers. Ultimately, high health care costs affect the economic vitality of middle-class and working families whether or not they are directly accessing care by crippling the ability of working people to earn a living wage. Today's real wages – wages after accounting for inflation – are roughly the same as four decades ago, yet employer health insurance premiums have risen dramatically.[3] While there are several factors contributing to stagnating wages, evidence suggests that rising costs of health care have put significant downward pressure on workers' wages over the last 40 years.[4] At the same time, nearly 90% of large employers say that rising health care costs will threaten their ability to provide health care benefits to employees over the next five to 10 years if costs are not lowered.[5]

Importantly, America's health care affordability crisis stems from high, rising, and variable prices across a wide range of health care goods and services, particularly for hospital care and prescription drugs. For example, the price of Humira — a drug used to treat arthritis — is more than four times as expensive in our country as in the United Kingdom and almost twice as expensive as in Germany.[6] Further, the average price of a hospital-based MRI in the United States is $1,475,[7] while that same scan costs $503 in Switzerland and $215 in Australia.[8] These higher prices for an identical service are a primary driver of the dramatic increase in per capita health care spending in our country, where health care accounted for nearly 20% of the nation's GDP in 2022, far exceeding health care spending by our peer countries.[9]

These irrational prices are largely due to trends in health care industry consolidation that have eliminated healthy competition and allowed monopolistic pricing to flourish.[10] This consolidation has taken place without meaningful regulatory oversight or intervention, and is becoming more acute.[11] As a result, there are few truly competitive health care markets left, with 95% of metropolitan statistical areas (MSAs) having highly concentrated hospital markets, nearly 80% of MSAs having highly

concentrated specialist physician markets, and 58% of MSAs having highly concentrated insurer markets.[12] Consolidation has been particularly pronounced among hospitals, drug companies, and pharmacy benefit managers and is made worse by the increasingly harmful role of private equity firms in the U.S health care system:

- *Hospitals*, health systems and other providers have rapidly consolidated, via horizontal and vertical integration, into large health care corporations, amassing outsized market power in order to increase prices for hospital care year after year. In fact, over 1,500 hospital mergers have occurred between 1998 and 2017, with an estimated 40% of those mergers taking place from 2010 to 2015;[13] Moreover, between 2013 and 2021, the percentage of physician practices that were hospital-owned rose from 15% to 53%, and the percentage of physicians employed by a hospital rose from 27% to 52%.[14]
- *Private equity firms*, once largely uninvolved in the U.S. health care system, are increasingly purchasing and reselling a variety of health care provider organizations in order to make short term profit, largely to the detriment of the financial well-being of those providers and ultimately to health care access and affordability in a community.[15]
- *Drug manufacturers* have increasingly engaged in anti-competitive behavior and transactions to similarly amass significant market power, regularly buying up or paying off their competition in order to game the U.S. patent system and price gouge our nation's families for prescription medications. The vast majority (70%) of drug industry profits now go to only a handful (25) of the top prescription drug companies in the country.[16]
- *Pharmacy benefit managers,* as third-party administrators designed to serve as middlemen between health insurers and drug makers, have increasingly merged with insurers and pharmacies to increase their own market power to negotiate pricing structures that serve their financial interests, often, to the detriment of securing more affordable prescription medicines for consumers. This has led to the top three PBMs controlling 80% of the PBM market.[17]

Furthermore, there is growing consolidation among *health insurers*. Between 2006 and 2014, the four-firm concentration ratio — the extent of market control held by the four largest firms, Aetna, Anthem Blue Cross Blue Shield, UnitedHealthcare and Cigna — for the sale of private insurance increased from 74% to 83%.[18] This high concentration ratio means the health insurance market is heavily consolidated and lacking meaningful competition, which results in monopolistic health care prices that lead to unaffordable health care and poorer quality.[19] There is also growing vertical integration between insurers and health care providers; UnitedHealthcare for instance now employs almost 50,000 physicians as of 2021, and their reported share of medical expenses that flow to employed providers or other related businesses increased nearly 250% between 2016 and 2019.[20]

This widespread and largely unchecked consolidation has led to the deterioration of healthy competition across and within U.S. health care markets and has had a significantly negative impact on the affordability and quality of American health care.[21] Importantly, most health care consolidation has not resulted in reduced costs through economies of scale, improved care coordination or quality oversight as industry proponents have argued.[22] In fact, the evidence overwhelming confirms that consolidation has produced exploitative markets that drive high prices and costs, without improving the quality of care.[23] In many cases, consolidation is actually associated with *reductions* in health care quality.[24] For instance, one study found that mortality risk among heart attack patients is significantly higher in more

concentrated hospital markets.[25] On top of that, consolidation often leads to reduced geographic access to needed providers, which can contribute to longer travel times and serious health consequences, particularly for rural communities.[26] For example, rural hospitals that merge with larger hospital systems are more likely to eliminate key service lines in primary care, maternal and neonatal health, surgery, mental health, and substance use disorder services post-merger, significantly reducing access to critical health care services and threatening the health and well-being of rural communities.[27]

It is no wonder then, that despite spending two to three times more on health care than other peer countries, the United States has some of the worst health outcomes, including some of the lowest life expectancy and highest infant mortality rates.[28] These health outcomes are even worse for people of color who experience higher rates of illness and death across a range of health conditions compared with their white counterparts.[29]

These abysmal health outcomes and extraordinarily high prices are the product of broken financial incentives within the U.S. health care system. Our current system rewards building local monopolies and price gouging instead of rewarding success in promoting the health, well-being and financial security of the community.[30] As such, there are several health care related transactions and entities that represent important drivers of unaffordable and low-quality care in the U.S health care system that should be prioritized for oversight by officials across the U.S. Department of Justice (DOJ), Federal Trade Commission (FTC), and the U.S. Department of Health and Human Services (HHS). For the purpose of this comment, Families USA will focus on the following transactions and related health care entities' impact on consumers in answering *Question 1: Effects of Consolidation and Question 2: Claimed Business Objectives for Transactions:*

- The hospital market: horizontal consolidation and vertical integration;
- Private equity ownership of health care entities; and
- The prescription drug market: pharmacy benefit managers, plans, and pharmacies; prescription drug companies.

The Hospital Market: Horizontal Consolidation and Vertical Integration

The hospital sector represents the largest source of domestic health care spending in the country. Hospitals provide essential lifesaving care for acute and complex conditions when patients are at their most vulnerable (e.g., during periods of acute illness, childbirth).[31] They also provide critical training for doctors, nurses and other health care providers, and are an important source of jobs for our nation's workforce. But the role of hospitals in our economy has shifted over the last 60 years.[32] What were once local charitable institutions built to serve the community have now become large corporate entities focused on maximizing revenue rather than improving health.[33]

Nowhere is the negative impact of consolidation more evident than the rising cost of hospital stays and services, which have increased dramatically in the last decade and make up a large portion of increasing health care costs overall.[34] These cost increases have occurred despite lower hospital utilization and are largely due to escalating prices, which are the result of hospitals buying other hospitals and community doctors to eliminate competition and form big health care corporations and medical monopolies.[35]

Fundamentally, the business interests of the hospital sector are not aligned with the interests of the patients they serve. These misaligned incentives are a fundamental driver of our nation's health care cost and quality crisis. The core business model of health care corporations is to generate high volumes of tests and procedures through fee-for-service payment, and to generate the highest possible fees (prices) for each service.[36] Hospitals have increasingly engaged in both horizontal consolidation (i.e., mergers between hospitals) and vertical integration (e.g., mergers between hospitals and other health care providers such as independent doctors' offices) in order to increase their market power and leverage in price negotiations with insurers.[37]

As noted above, between 1998 and 2017, over 1500 mergers between hospitals have occurred, [38] with an estimated 40% taking place from 2010 to 2015.[39] As a result, 90% of hospitals markets are considered "highly concentrated" which has allowed hospitals — and large hospital systems in particular — to amass significant market power to negotiate irrational prices with insurers in order to maximize their patient volumes and ultimately revenues and profits.[40] For instance, the FTC has found that price increases among competing hospitals range 20-50% following a merger.[41] Other research has confirmed that hospital prices in more concentrated markets are significantly higher than those in competitive markets (with four or more rivals) without any demonstrated improvement in the quality or access to care.[42]

Hospitals have also increasingly bought up independent physician practices and other provider groups in recent years. The number of hospital-acquired physician practices grew from 35,700 in 2012 to more than 80,000 in 2018.[43] Over this same time period, the percentage of physicians employed by a hospital or health system nearly doubled, from 25% to 44%.[44] Recent research found that over 55% of physicians are now employed in hospital-owned practices.[45] This trend was accelerated by the COVID-19 pandemic, which exacerbated the financial vulnerabilities of independent and smaller physician practices and threatened the near collapse of entire sectors of the health care system — particularly primary care.[46] Nearly 23,000 physicians left independent practice to work for a hospital or other corporate entity after the onset of the COVID-19 pandemic, while hospitals and other corporate entities acquired nearly 21,000 additional physician practices from 2019 to 2020, representing a 25% increase in corporate-owned practices.[47]

One of the most significant drivers of this form of vertical consolidation are site-of-service payment differentials under current Medicare reimbursement structures. Currently, Medicare reimburses hospitals at a higher rate for outpatient services than it does for the exact same services provided in independent physician's offices. These payment differentials across sites of service drive care delivery from physician's offices to higher-cost hospital outpatient departments[48] and create a significant financial incentivize for hospitals to purchase independent physician's practices and rebrand them as outpatient departments in order to generate a higher reimbursement.[49] This broken financial incentive in the Medicare payment system not only leads to higher prices and higher costs of care, but also significantly exacerbates consolidation.[50] Some studies suggest that the price of physician services increases 14 percent after a hospital purchases a physician's practice. Importantly, these price increases occur with *no* meaningful improvements to health care quality or patient outcomes or experience.[51]

The Hospital Market: Impacts on Health Care Affordability, Quality, and Access

Widespread and unchecked horizontal consolidation and vertical integration among hospitals and physicians' practices negatively impacts consumers, workers, and employers in a number of important and substantive ways.

1. Health Care Affordability

Hospital consolidation is a major driver of high and rising hospital prices, and relatedly high and rising health insurance premiums which put downward pressure on incomes and wages. Between 1990 and 2023, hospital prices have increased a staggering 600%, now accounting for nearly one-third of U.S. health care spending and growing more than four times faster than workers' paychecks.[52] What's more, consumers and employers, who are the ultimate purchasers of health care, have limited insight into what the prices of health care services are, until *after* they've received a bill. For the majority of Americans (66%) who receive health care through private insurance, health care prices are established in closed-door negotiations between large hospital corporations and health plans based on who has more market power.[53] These health care prices, often referred to as the negotiated rate, are buried in proprietary contracts without insight into or oversight over the price of health care services by the public and policymakers.[54]

Not only do consumers and patients experience these high prices at the point of care in the form of expensive medical bills, but these rising hospital prices are a major contributor to skyrocketing health insurance costs, which come directly out of workers' paychecks as annual increases in premiums and cost sharing.[55] This results in stagnating wages, rising income inequality, and ultimately leaves workers with less in take home pay over time, making it more difficult for them to afford housing, pay their regular expenses, send their children to school, and retire.[56]

This is particularly notable when looking at health insurance premium increases. The total cost of a family employer-sponsored insurance (ESI) plan increased an astounding 272% in the past two decades, rising from $6,438 annually in 2000 to $23,968 in 2023.[57] As a result, the median U.S. family of four is estimated to have lost more than $125,000 in wages over roughly the same time period.[58] These rising health insurance premiums and the resulting wage stagnation particularly harms low- and middle-income workers, a group that disproportionately includes people of color. As a result, rising hospital prices and health premiums are an important driver of income inequality.[59] To make matters worse, workers are increasingly subjected to health insurance plans with larger cost-sharing requirements, including higher-deductible health plans, in an effort to contain rising health care spending and costs. Deductible-related costs for workers have also grown significantly, with the average annual deductible for an individual employee's coverage nearly doubling in just a decade, from $1,025 in 2010 to $2,004 in 2021.[60] Importantly, the 153 million Americans who rely on ESI for health insurance cannot always access the care they need, with more than a quarter putting off or postponing needed medical care due to the high cost.[61]

2. Health Care Access

Hospital consolidation often leads to reduced access to health care services, including access to needed health care providers in key geographic areas.[62] Hospital consolidation, particularly horizontal consolidation, often leads to the reduction or complete elimination of essential health care services for

the communities that rely on them. For example, rural hospitals that merge with larger hospital systems are more likely to eliminate key service lines in primary care, maternal and neonatal health, surgery, mental health, and substance use disorder services post-merger.[63] Moreover, increasing the distance to the nearest site of health care can result in people not getting the care they need due to a lack of transport or the time needed to get there, which disproportionally affects the elderly, racially and ethnically marginalized groups, those with low incomes, and people with disabilities.[64]As a result, consolidation resulting in the elimination of health care service lines also contributes to serious health consequences, particularly for rural communities which already face persistent provider shortages.[65] For example, more than 32 million reproductive age women are already vulnerable to worse health outcomes due to losing access to maternal or reproductive health care services.[66]

Hospitals and providers with significant market power also utilize tactics like anticompetitive provisions in their contracts with insurers which can also harm access to high-value health care.[67] In highly consolidated markets, large providers have the upper hand in contract negotiations to build networks and set prices. As a result, many of these contracts include terms that limit patient access to alternative sources of higher-quality, lower-cost care such as "anti-tiering" and "anti-steering" clauses that restrict the plan from directing or incentivizing patients to use other providers and facilities with higher quality and lower prices.[68] Other anticompetitive contracting provisions such as "all-or-nothing" clauses require health insurance plans to contract with all providers in a particular system or none of them.

3. Health Care Quality

The evidence is clear that hospital consolidation does not lead to higher quality or more efficient cost-effective care, despite arguments from the hospital industry.[69] In fact, research suggests that most hospital mergers either *decrease* health care quality and patient outcomes or have no effect at all, with one study finding that risk-adjusted one-year mortality for heart attack patients significantly increased in more concentrated hospital markets.[70]

Private Equity Ownership and its Impact on Health Care Affordability, Quality, and Access

Private equity (PE) firms use capital from institutional investors to invest in private companies that have potential to return a profit over a relatively short time horizon. Over the past decade, these firms have become increasingly involved in the U.S. health care system. In 2020, health care became the second largest sector for private equity investment, accounting for 18 percent of all reported deals, up from 12 percent in 2010.[71] Moreover, private equity investors spent more than $750 billion on health care acquisitions in just 10 years (between 2010 and 2019).[72] In the case of hospitals and hospital systems, private equity firms now own at least 386 hospitals, making up 30% of all for-profit hospitals in the U.S., while at least 130 of which are located in rural areas.[73]

Importantly, private equity firms often apply a very short-term, profit-driven business model to their investment strategy.[74] The business model is characterized by buying an entity that could be struggling financially or that could offer short-term growth potential, investing in it, loading it up with debt, and then extracting value by selling their stake, all in a 3-to-7-year period.[75] This business model is in direct conflict with ensuring that American families have access to high-quality, affordable health care and the health the deserve. [76] PE firms often deploy a number of harmful business practices including:

- Taking out a loan(s) to purchase a health care facility and using the facility as collateral by having the health care organization carry the debt (i.e., leveraged buyouts)[77];
- Purchasing and selling the land a facility is on for a quick profit, forcing the underlying health care provider or organization to rent their space back from new owners (i.e., sale-leaseback transaction)[78]; and
- Inflating the margins of the underlying health care organization through staff layoffs,[79] the cutting of critical but less profitable services,[80] raising prices,[81] and exploiting government funding programs,[82] all before selling the facility at a profit for the PE firm.[83]

Private equity firms may also contribute to health care consolidation as another way to maximize profits associated with their investment by employing "roll ups" where they purchase a single health care provider and then buy up multiple additional providers to merge with the original provider - all in order to consolidate providers in a given market, achieve economies of scale and increase market power.[84] Importantly, many of these roll ups are designed to circumvent anti-trust oversight or enforcement by keeping these mergers relatively smaller in size[85]

As a result of these practices, PE firms' acquisitions of health care providers often contribute to higher health care prices, lower quality care, poor health outcomes for patients, and financial instability for facilities in a variety of health settings, including but not limited to hospitals and nursing homes. Recent studies show that PE ownership was associated with a number of harmful health care related impacts, including but not limited to:

- *Decreases in health care quality and patient safety:* PE-owned hospitals experience a 25% increase in hospital-acquired conditions, including a 27% increase in patient falls and an almost 38% increase in infections.[86] Importantly, these outcomes may be partially due to reductions in staffing, among other potential causes.[87] PE-owned nursing homes experienced a 10% increase in excess mortality, 50% increase in prescribing of antipsychotic drugs, and a 30% and 40% higher COVID-19 infection and death rates (respectively) than statewide averages.[88] Residents who live in PE-owned nursing homes are 11.1% more likely to have a preventable emergency department visit and 8.7% more likely to have a preventable hospitalization.[89] Furthermore, private equity backed nursing homes showed an 11% increase in taxpayer spending per resident;
- *Increases in health care prices and charge-to-cost ratios:* PE-owned hospitals have been found to charge $400 higher per inpatient stay on average compared to non-PE owned hospitals;[90] and
- *Increased out of network costs* due to PE firms buying up specialty physician staffing firms.[91]

One specific example of the proliferation of bad behavior driven by private equity investment in health care is the role of private equity in balance billing. Hospitals have started to outsource many of their emergency departments (EDs) to physician staffing agencies, many of which are owned by private equity firms, because it is cheaper than staffing the ED themselves.[92] These firms cut corners in a variety of ways including by reducing the number of staff or relying heavily on clinicians like nurse practitioners who on average command lower salaries than doctors and therefore result in a higher margin for the facility and its ownership.[93] Prior to the enactment of the *No Surprises Act,* private equity firms were readily abusing existing laws to engineer higher prices and threatening to go out-of-network in order to force private insurers to raise reimbursement rates. In some cases, PE-backed providers would actually go out-of-network for a few months and then re-negotiate their contracts with private payers at higher

payment rates before agreeing to come back in-network.[94] This practice undermined families' health insurance coverage, threatened access to preferred providers, and led to higher health care costs for individuals and to the health care system overall.[95]

Since the Independent Dispute Resolution (IDR) process opened - a function of the *No Surprises Act* to help determine out-of-network reimbursement rates - providers have submitted 13 times as many cases as CMS had originally predicted.[96] The outcomes have disproportionately favored providers and have exceeded the Congressional Budget Office's (CBO's) cost projections, ultimately putting consumers at risk for higher costs in the form of increased premiums.[97] Many of the top ten initiating parties in the IDR process are private equity backed or owned.[98]

The Prescription Drug Market: Consolidation, Anti-Competitive Behaviors, and the Impact on Health Care Affordability, Quality, and Access

The high and rising cost of prescription drugs in the U.S. is both a profound health problem and significant economic burden on our nation's families. Nearly 20 million Americans cannot afford their prescription medications because of the unchecked power of big drug companies and their ability to price gouge our nation's families.[99] Almost 30% of adults did not take their medications as prescribed in the past year — rationing their medications, skipping doses, or not filling their prescriptions at all, leading to an estimated 125,000 deaths a year.[100]

People in America pay much more for drugs than those in peer countries. A recent RAND report found that drug prices in the U.S. are more than 250% higher than prices in 32 of the most economically comparable countries.[101] In July 2022, the U.S. Department of Health and Human Services reported that over the previous year, drug makers raised prices on more than 1,200 drugs beyond the rate of inflation (8.5 percent for that period), resulting in price increases averaging more than 30%, with some prices increasing by $20,000 or 500%.[102] There is no economic rationale for price increases that are higher than inflation long after a drug has been introduced and priced, particularly when there are no changes in clinical value or innovation. Yet, this trend is not new - from 2008 to 2021 prescription drug launch prices increased 20% *per year*, far exceeding increases in inflation and forcing millions of Americans to choose between their life-saving or sustaining drugs and putting food on the table to feed their families.[103]

High and irrational prescription drug prices reflect a prescription drug market that is not functioning properly nor holding the drug supply chain accountable – including prescription drug companies, pharmacy benefit managers, and others – to delivering the affordable and innovative medications that our nation's families need and deserve. *Drug manufacturers* have increasingly engaged in anticompetitive behavior and transactions to amass significant market and monopoly power, regularly buying up or paying off their competition in order to game the U.S. patent system and price gouge our nation's families for prescription medications.

While drug manufacturers bear the lion share of responsibility for our nation's high drug costs, pharmacy benefit managers (PBMs) also have played an increasingly important role in driving unaffordable drug prices, particularly as they have increasingly merged with insurers and pharmacies to increase their own market power to negotiate pricing structures that serve their financial interests. While PBMs have been effective in lowering the cost of prescription drugs for consumers compared to

the price of drugs without PBMs, the PBM pricing structure also creates a set of financial incentives that contribute to increasing drug costs for consumers.[104]

Pharmacy Benefit Managers, Plans, and Pharmacies

PBMs are third-party administrators organized to serve as intermediaries between health insurance providers and drug manufacturers. Their key function is to negotiate drug price concessions from pharmacies and drug manufacturers to secure lower prescription drug costs for health plans, employers, and ultimately consumers.[105] As such, they play a critical role in the prescription drug supply chain and need to be held accountable to helping secure affordable prices for prescription medications.

Yet, there is a lack of transparency into PBM business practices and pricing structures. For instance, there is too much opaqueness and limited ability to oversee the negotiated rates PBMs negotiate with drug manufacturers on behalf of plans. Not even the employers who may hire PBMs to manage their employee drug benefits know the actual drug prices PBMs negotiate, the price concessions and rebates PBMs receive, and importantly, whether those rebates are being appropriately passed down to the benefit of the employer and employees.[106]

PBMs receive rebates and discounts from drug companies in exchange for formulary placement, or a place on the list of drugs a PBM has agreed to cover.[107] Importantly, although PBMs negotiate rebates, their revenue is based on a percentage of the drug's list price.[108] The result is that PBMs have a strong financial incentive to prioritize higher-cost drugs. In many plan designs, PBMs actually pocket a percent of the rebate they get for consumers, making it advantageous for them to negotiate a higher rebate for a higher-priced drug than one with a lower overall list price.[109] Pharmaceutical companies, then, raise both the list price and the rebate year after year, making the overall cost of the drug higher.[110] A 2020 study showed that for every $1 increase in drug rebates there is a $1.17 correlating increase in the drug list price.[111] As result, PBMs can substantially increase their profits by negotiating rebates in this manner. These profits are well beyond what PBMs earn from administrative fees for their services, and in some cases PBMs are not actually lowering the costs of drugs for consumers.[112]

The lack of PBM transparency is exacerbated by an increasingly concentrated prescription drug market fueled by mergers between PBMs (i.e., horizontal consolidation) and between PBMs, insurers, and pharmacies (i.e., vertical integration). As a result, the top three PBMs now control 80% of the PBM market.[113] Just as consolidation causes price increases among hospitals and large hospital systems, this trend can lead to increased costs for patients who are trying to access and afford their medications.[114] As PBMs buy up more and more of the market, they have increased negotiating power with drug manufacturers, which results in pricing structures that too often can serve PBM financial interests at the expense of the financial security of individuals and families. For example, a Delaware state auditor report found the PBM Express Scripts overcharged the state employee prescription drug plan by $24.5 million.[115] Or, consider the Ohio Department of Health which found that CVS Caremark and Optum Rx pocketed the nearly 9% difference between what they billed managed care plans and what they paid pharmacies.[116]

Consolidation in the PBM market also allows PBMs to prioritize the pharmacies they own, which reduces patient choice and access to some drugs by "steering" patients to specific pharmacies.[117] As of 2017, PBM-owned pharmacies represented 46% of the industry's revenue growth.[118] This is a major threat to

the ability of independent pharmacies to operate and threatens access to pharmaceutical medications for millions of families living in rural and underserved communities.

Market concentration among PBMs allows consumers to be steered to preferred pharmacies to the detriment of patient access, the proliferation of drugs with higher list prices, complex and opaque formulary and rebate systems, spread pricing, and overcharging to state employee plans. All of these harmful business practices worsen health care affordability and accessibility to the life saving and sustaining medication that consumers and their families need and deserve.

Prescription Drug Companies

Drug manufacturers (i.e., drug companies) have increasingly engaged in anticompetitive behavior and transactions that fundamentally undermine the prescription drug supply chain and the extent to which the prescription drug market and competitive forces can hold them accountable to delivering affordable and innovative medications.

Drug companies have amassed significant market and monopoly power, regularly buying up or paying off their competition in order to game the U.S. patent system and price gouge our nation's families for prescription medications. When drug companies file patents to bring a new drug to market, they can receive "exclusivity" on those drugs during which time no other company can market a competing drug.[119] Exclusivity is meant to be a critical mechanism to incentivize the development of innovative new drug treatments, allowing drug makers to recoup any costs associated with developing a new drug, while at the same time putting in place a specific time frame for when generic competition may be introduced in order to achieve lower drug prices. Yet, drug companies have employed a number of harmful and anticompetitive practices that undermine this arrangement, with an eye towards extending drug exclusivities as long as possible in order to maximize their monopoly power and therefore profits, threatening access to affordable prescription drugs for our nation's families and individuals. Common examples of tactics employed by drug companies include:

- Pay for delay schemes, where drug companies pay off competition to keep a generic off the market, as well as purchasing the rights of new drugs in development from competitor drug companies in order to stifle the development of future generic competition;
- Patent thickets, where companies blanket a given drug with multiple and overlapping patents to help block future generic competition well past the period of exclusivity envisioned under federal law; and
- Product hopping, or shifting demand from a brand-name drug about to face competition to a similar, newer product with market exclusivity.[120]

These harmful practices allow drug companies to increase their market power by maintaining market exclusivity for their drugs far beyond the initial exclusivity period granted under FDA and U.S. Patent law. This problematic behavior allows drug makers to charge high and rising drug prices (often for drugs with no meaningful changes in clinical effectiveness), but also *disincentivizes* the development of new life-saving medications.[121] Instead of investing in research in the next life-saving cure, drug makers can readily focus on hiring lawyers to extend patents to make additional revenue off existing drugs.[122] In fact, the 10 top-selling drugs on the market today have been granted an average of 74 patents per drug, with an average of 140 patents filed for each of them.[123] And three-quarters of new patents are for

existing drugs. From 2005 until 2015, 5,369 patents were granted to manufacturers for drugs that already had patents, representing 74% of new drug patents.[124]

Once drug companies have established market dominance, they raise prices year after year on the medications that they have long-since released, often with no new therapeutic value to patients; One study of high-spend drugs showed that seven of the ten drugs reviewed provided no additional clinical benefit relative to the other available drugs that could justify their high list price or price hikes.[125] Additionally, some examples of price gouging are particularly predatory: Even though the FDA first approved the use of naloxone to treat opioid overdose in 1971, the company manufacturing the drug raised the price from $1 to $150 for a two-pack of nasal spray in the mid-2010's and charged $4,500 for an auto-injected version of the drug — putting it out of reach for people who needed it right as demand for tools to manage a national opioid epidemic were skyrocketing.[126] Since then, opioid overdose deaths in the U.S. continued to rise each year, reaching 80,411 deaths in 2021.[127]

The impact of these high prices does not end at the pharmacy counter or with people who take medications. High and rising drug prices are also paid by insurance carriers which in turn pass those costs along to families and employers in the form of higher insurance premiums. In fact, around 20% of health insurance premiums are driven by the rising cost of prescription drugs.[128] These premium increases result in a cascade of negative impacts on health care affordability for employers and employees alike. In the past decade, health insurance premiums for those with private insurance rose faster than the rate of inflation and workers' wages.[129] This problem is especially concerning for individuals who are already paid low wages and are then forced to contribute a disproportionately high percentage of their wages toward health insurance premiums.[130] A 2019 Consumer Reports survey revealed that 30% of adults who take a prescription drug regularly experienced out-of-pocket cost increases from one year to the next, and 12% said those costs went up by $100 or more.[131]

Fortunately, Congress and the administration recently took important action to systematically bring down drug prices and rein in the rate of skyrocketing price increases – and finally address abusive price gouging by prescription drug companies. The Inflation Reduction Act (IRA) of 2022 is landmark legislation that includes several key provisions to address the underlying prices of certain medications and control the rate of price increases for drugs in Medicare; most notably, by allowing the federal government to negotiate prices with prescription drug companies for a select subset of high-cost drugs.[132]

Question 4: Need for Government Action

Health care entities across the health care system — including hospitals, PE firms, drug companies, and pharmacy benefit managers — have engaged in widespread consolidation and employed harmful business practices that are directly and indirectly harming health care consumers, workers, and employers.

Consumers across the country are feeling this crisis firsthand and want the government to act. Large majorities of voters support a range of policies to address consolidation and lower prices. Voters from both sides of the aisle broadly support:[133]

- Requiring hospitals to provide real prices in advance, not estimates (93%)
- Limiting outpatient fees to the same price charged by doctors in the community (85%)

- Preventing hospitals from engaging in business tactics that reduce competition (75%)
- Limiting mergers and acquisitions (74%)

Building on the meaningful steps already taken by this administration, the FTC, DOJ, and HHS have the opportunity to take additional action to rein in these harmful practices, promote healthy competition, and help guarantee affordable and high-quality health care for families across the nation. In particular, we urge the administration to take the following actions:

- **Increase FTC oversight and strengthen regulatory authority to monitor and control future mergers and acquisitions:**
    - The administration should continue to ensure the FTC and the DOJ are fully applying federal anti-trust laws to horizontal integration within the health sector, including among hospitals, health systems, pharmacy benefit managers, and drug companies, as well as vertical integration between physician practices and hospitals, and health plans and pharmacy benefit managers. Special attention should also be given to private equity firms and their strategically smaller transactions that may traditionally fall below existing thresholds of review.

- **Promote meaningful transparency across the health care system:**
    - CMS should use its existing authority to continue to strengthen the federal hospital price transparency rule including by requiring negotiated rates be posted in dollars and cents with no exceptions and no estimates; requiring a standard code format with no facility specific codes; mandating a nationally uniform set of services to be reported instead of allowing hospitals to select 230 of the 300 shoppable services; removing the price estimator loophole, and prohibiting the posting of a price estimator tool alone to satisfy the 300 shoppable services requirement.
    - CMS should require that hospitals report (and submit to CMS) comprehensive ownership transparency information including their parent company name, address, and ownership structure (e.g., private equity, insurer, or hospital) as well as any recent mergers, acquisitions, or any other changes to ownership status on an ongoing basis.[134] This data should be made publicly available by CMS and easily linked to health care claims data, including health care utilization, cost and quality data. Strengthening ownership transparency allows researchers and policymakers to more easily track horizontal and vertical consolidation in hospital markets and assess their impact on health care costs and quality.[135]
    - CMS should – to the extent of its authority – require PBMs to report comprehensive and accurate data, including but not limited to revenue, price, and utilization data resulting from their negotiations with drug manufacturers and contracts with insurers. The administration needs to be able to fully understand the business practices and financial incentives that drive PBM behavior.

- **Enact comprehensive site neutral payments and advance billing transparency reforms:**
    - CMS should expand site neutral payments across both on- and off-campus hospital outpatient services. Specifically, CMS should apply site neutral payment policies as recommended by MedPAC for the 66 groups of medical services that can be safely delivered

in multiple settings to both on- and off-campus hospital outpatient departments,[136] building upon its 2019 Hospital Outpatient Prospective Payment System final rule which expanded site neutral reimbursement to office visits delivered by all off-campus hospital outpatient departments, including those "grandfathered" under the Bipartisan Budget Act of 2015.[137]
    - CMS should advance billing transparency reforms and specifically rein in dishonest billing practices where hospitals overcharge for the care they deliver in outpatient settings. These reforms should require off-campus hospital outpatient departments to separately bill Medicare and commercial insurers using a unique national provider identification (NPI) number in order to accurately report where care is being delivered.[138]

- **Ban anti-competitive practices:**
    - HHS, FTC, and DOJ, in collaboration with the U.S. Patent and Trademark Office (USPTO), should take steps to address anticompetitive practices and behaviors among prescription drug companies, including by reining in patent-related abuses such as patent thickets, product hopping, and pay-for-delay schemes that result in reduced competition and elongated patent and market exclusivity periods.

Families USA thanks the administration for the opportunity to discuss these critical issues stemming from consolidation in health care markets that affect families and individuals across the country, and looks forward to our continued collaboration on solutions. Families USA stands ready to work with you to ensure that everyone in our nation has access to the high-quality care and coverage options they deserve. For more information, please reach out to Jane Sheehan, Deputy Senior Director of Government Relations (JSheehan@familiesusa.org) at Families USA.

Sincerely,

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Families USA

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