Addressing Cost Drivers in U.S. Healthcare Through Transparency, Competition, and Value



March 2021

by John O'Shea, MD



March 2021

by John O'Shea Texas Public Policy Foundation



U.S. Healthcare Costs: What Is the Problem? 3 Excessive Regulation Stifles Competition6 Pharmaceuticals.....7 Utilization, Lack of Competition, and Insufficient

Table of Contents

Addressing Cost Drivers in U.S. Healthcare Through Transparency, Competition, and Value

by John O'Shea, MD

U.S. Healthcare Costs: What Is the Problem?

The United States spends substantially more on healthcare than other nations, and this spending is expected to grow at a rate that is cause for serious concern (OECD, 2019). In 2019, National Health Expenditure (NHE) in the U. S. grew 4.6% to about \$3.8 trillion or about \$11,582 per person (Centers for Medicare & Medicaid Services [CMS], 2020a). Over the next decade, NHE is expected to grow at an average annual rate of 5.4%, 1.1 percentage points faster than the gross domestic product (GDP) per year on average, to reach \$6.2 trillion and 19.7% of GDP by 2028. (See Figure 1 for a breakdown of where the nation's healthcare dollars came from in 2019 and Figure 2 for a breakdown of where the nation's healthcare dollars went in 2019.)

In addition, survey data show that roughly 3 in 10 Americans have delayed or forgone seeking medical treatment due to costs (Saad, 2018). These trends are unsustainable and do not include the impact of the COVID-19 pandemic, which, although not yet fully known, is likely to drive up the cost of healthcare even further (Cox et al., 2020).

A number of factors drive healthcare cost growth in the United States. Some of the more important drivers include prices of labor and goods; pharmaceuticals; administrative costs; market consolidation; the burden of chronic disease; waste; excessive regulation; and new technology (<u>Papanicolas et al., 2018</u>). However, underlying these factors is the common theme of a dysfunctional market where healthcare consumers lack the information they need to make decisions based on value and a financing system that insulates most patients from the true cost of goods and services, making prices largely irrelevant. This systemic lack of price transparency is exacerbated by arcane and opaque business practices, along with market consolidation and other anti-competitive behavior, compounded by excessive regulation that, however well-intentioned, fails to correct perceived "market failures" and often exacerbates the problem it was meant to address.

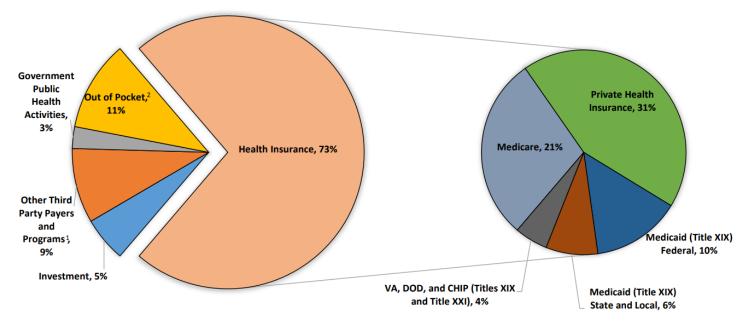
A comprehensive discussion of healthcare cost drivers is beyond the scope of this endeavor. However, this paper will provide a brief overview of three key areas that drive healthcare spending—hospital prices, health insurance, and pharmaceutical drug costs—and discuss some examples of how a dysfunctional market and excessive government intervention contribute to rising healthcare costs. Policy efforts to increase transparency and foster competition and consumer choice in these areas will also be discussed as a way to promote value and slow the growth of healthcare costs in the United States while avoiding unnecessary government intervention.

Key Points

- Rising healthcare costs are a concern for patients, policymakers, and taxpayers. Roughly 3 in 10 Americans have delayed or forgone seeking medical treatment due to costs.
- Hospitals, health insurance, and pharmaceuticals represent three areas with opportunities to address some of the main drivers of healthcare costs in the U.S.
- Underlying the various drivers of healthcare costs is the common theme of a dysfunctional marketplace hampered by anticompetitive behavior and excessive regulation.

Figure 1

Source of Healthcare Dollars 2019



¹ Includes worksite health care, other private revenues, Indian Health Service, workers' compensation, general assistance, maternal and child health, vocational rehabilitation, Substance Abuse and Mental Health Services Administration, school health, and other federal and state local programs.

² Includes co-payments, deductibles, and any amounts not covered by health insurance. Note: Sum of pieces may not equal 100% due to rounding.

SOURCE: Centers for Medicare & Medicaid Services, Office of the Actuary, National Health Statistics Group.

Note. Figure taken from *The Nation's Health Dollar: Where It Came From, Where It Went*, Centers for Medicare and Medicaid Services, 2020d, p. 1 (<u>https://www.cms.gov/files/document/nations-health-dollar-where-it-came-where-it-went.pdf</u>).

Hospitals

Hospital Prices

Although it is clear that overall growth in providers' prices drives growth in healthcare spending on the privately insured, it is important to differentiate the growth rates of hospital prices and physician prices. In 2018, hospital care represented 32.7% of personal healthcare spending while physician services accounted for 15.5% (Rama, 2020). In 2019, hospital spending grew 6.2% to \$1,192.0 billion, considerably faster than the 4.2% growth in 2018 (CMS, 2020a).

According to an analysis published in *Health Affairs* in 2019, between 2007 and 2014, hospital prices grew substantially faster than physician prices. Prices for inpatient hospital care grew 42%, while physician prices grew 18%. Similarly, prices for hospital-based outpatient care grew 25%, while physician prices grew 6%. The authors of the study suggested that, although the overall growth in provider prices is concerning, efforts to reduce healthcare spending should focus primarily on addressing growth in hospital prices rather than physician prices (Cooper et al., 2019a).

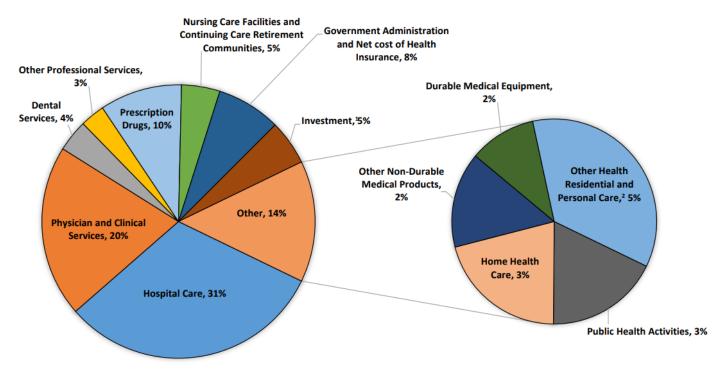
Transparency and Hospital Prices

Price transparency is an essential element in any wellfunctioning, competitive market, including healthcare. However, because of widespread opacity regarding hospital prices, most patients have no idea of the cost of an episode of care until they receive the bill. Complex terminology and arcane hospital accounting and billing practices contribute to the lack of hospital price transparency that drives up costs (Arora et al., 2015; Gottlieb et al., 2018). In fact, hospital pricing is so opaque that not only are patients confounded, but studies have observed that, when asked to give a complete price estimate for a common elective procedure (total hip arthroplasty), even a majority of hospitals were unable to do so (Mahomed et al., 2018).

On November 27, 2019, following an executive order (Exec. Order No. 13,877, 2019), CMS finalized its price transparency requirements for hospitals to make their standard charges public, including payer-specific negotiated charges, the amount the hospital is willing to accept in cash from a patient for an item or service, and the minimum and maximum negotiated charges for 300 common services

Figure 2

Healthcare Spending 2019



¹ Includes Noncommercial Research and Structures and Equipment.

² Includes expenditures for residential care facilities, ambulance providers, medical care delivered in non-traditional settings (such as community centers, senior citizens centers, schools, and military field stations), and expenditures for Home and Community Waiver programs under Medicaid. Note: Sum of pieces may not equal 100% due to rounding.

SOURCE: Centers for Medicare & Medicaid Services, Office of the Actuary, National Health Statistics Group.

Note. Figure taken from *The Nation's Health Dollar: Where It Came From, Where It Went*, Centers for Medicare and Medicaid Services, 2020d, p. 2 (<u>https://www.cms.gov/files/document/nations-health-dollar-where-it-came-where-it-went.pdf</u>)

(Medicare and Medicaid Programs, 2019). Although the United States District Court for the District of Columbia dismissed a lawsuit challenging the authority of the Department of Health and Human Services to enforce the rule in June 2020 (*American Hospital Association v. Alex M. Azar, II*, 2020), the American Hospital Association is appealing the decision. The rule went into effect on January 1, 2021.

The Role of Consolidation

Another critical factor propelling the increase in hospital prices is the decades-long trend of hospital consolidation, as well as hospital acquisition of physician practices. A central argument in favor of consolidation is that economies of scale can reduce excess capacity, lower overhead, improve standardization, and reduce costs (Noether et al., 2019). However, according to a recent Medicare Payment Advisory Commission (MedPAC, 2020) report to Congress on provider consolidation, market power has a statistically significant association with higher costs per hospital discharge for non-Medicare patients; "commercially insured patients appear to pay higher prices for care and higher prices for insurance in consolidated markets"; and increasing commercial prices could "create pressure to increase Medicare prices as well" (<u>p. 459</u>).

A number of studies of hospital markets have found that concentrated markets lacking competition are associated with higher hospital prices, and when mergers occur in these concentrated markets, the resulting price increases can exceed 20%. A further concern is the finding that the price increases do not appear to be associated with an improvement in the quality of care, and, in fact, greater hospital concentration is actually associated with higher mortality rates in some cases (<u>Gaynor & Town, 2012</u>).

A 2018 analysis of insurance claims data from three of the five largest private insurers covering 28% of individuals in the United States with employer-sponsored health insurance showed that competition in hospital market structure is strongly associated with price levels, with prices at monopolistic hospitals 12% higher on average than those in markets with four or more rivals (Cooper et al., 2019b). The analysis also examined 366 mergers and acquisitions

that occurred between 2007 and 2011 and found that prices increased more than 6% when the merging hospitals were geographically close (e.g., 5 miles or less apart), but that similar increases were not seen when the hospitals were over 25 miles apart, supporting the claim that higher prices resulted in areas where the level of competition was reduced by the merger.

Excessive Regulation Stifles Competition

Although legislative and regulatory efforts are generally meant to address legitimate concerns or perceived healthcare market failures, excessive regulation too often stifles competition and can exacerbate the problem it was attempting to correct. Two examples of this are certificate of need regulations and restrictions on physician-owned hospitals.

Certificate of Need Regulations

Certificate of need (CON) regulations vary by state but in general require providers who wish to expand certain services, open or expand a facility, or even purchase new equipment, such as CT or MRI scanners, to first prove to a state regulator that their community "needs" the particular service. The approval process, intended to reduce excessive healthcare spending, is, however, often long and expensive. CON regulations were first introduced in New York state in 1964. Within a decade, the federal government added a strong incentive for states to adopt CON laws by withholding federal funding from states that failed to do so (National Health Planning and Resources Development Act, 1975, p. 2,246). However, research over the next decade (Salkever & Bice, 1976; Sloan & Steinwald, 1980) generally showed no evidence that the regulations were achieving the goals of an adequate and equitable supply of healthcare services, higher-quality care, more charity care for indigent and underserved communities, or lower costs, and the federal mandate was lifted. More recent research comparing states with and without CON laws supports earlier findings that the laws restrict access to facilities and services, do not expand indigent care, are not associated with higher quality care, and do not lower costs (Mitchell et al., 2020). It is clear that, by creating regulatory barriers rather than incentivizing competition, CON laws have failed to address and may even have exacerbated the problems they were meant to solve. Currently, 36 states and the District of Columbia maintain CON laws.

Limits on Physician-Owned Hospitals

In response to concerns that providers at physician-owned hospitals (POHs) may have adverse financial incentives and cherry-pick healthier and better-insured patients, Section 6001 of the Patient Protection and Affordable Care Act (ACA) effectively banned new POHs and prohibited existing POHs from expanding, unless the hospital satisfies the requirements of either the whole hospital exception or the rural provider exception to the physician self-referral law (ACA, 2010). However, research shows that the concerns that prompted the ban are likely to be overstated. For example, a comprehensive analysis of POHs in the U.S. from Harvard University and the University of California, San Francisco, compared 219 POHs with 1,967 non-POHs and found no evidence that POHs systematically avoid poorer patients or those from ethnic and racial minority groups. Furthermore, the POHs in the study performed as well as, or better than, non-POHs on a variety of quality and cost of care measures. Based on these findings, the authors of the study suggested that blunt public policies that penalize all hospitals with physician ownership need to be re-evaluated (Blumenthal et al., 2015).

Insurance

The increasing cost of health insurance is a central concern for healthcare consumers, employers, and policymakers. The cost of health insurance premiums, as well as the amount individuals pay out of pocket for healthcare through deductibles and co-pays, have been steadily rising, amounting to nearly 12% of median income for individuals with employer-based insurance in 2017 (<u>Collins & Radley</u>, <u>2018</u>). According to the Kaiser Family Foundation, in 2019, 49.6% of the population had employer-based health insurance coverage,¹ 5.9% had non-group coverage,² 35.4% were covered in a public program,³ and 9.2% were uninsured⁴ (<u>Kaiser Family Foundation, 2019</u>).

Consolidation

In parallel with hospitals, health insurance markets have become increasingly concentrated. According to the most recent update to the American Medical Association (AMA, 2020) study of competition in the health insurance market, in 2019, 74% of metropolitan statistical areas (MSAs) had markets that were highly concentrated; in 92% of MSA-level markets, at least one insurer had more than 30% market share; and in 48% of MSA-level markets, one insurer had at least a 50% share of the market (p. 2). High levels of market concentration can be the result of consolidation, in the form of mergers and acquisitions, as well as barriers to entry into health insurance markets (Robinson, 2004).

A key consideration is whether this trend in insurance market consolidation allows for adequate competition or whether insurers have inappropriate market power that can

¹ Includes individuals and dependents covered by a current or former employer or union.

² Includes individuals and dependents covered by a policy directly purchased from an insurance company in the individual market.

³ Includes Medicare, Medicaid, the military and Veterans Administration.

⁴ Includes individuals without health insurance and those covered under the Indian Health Service.

expenses (Transparency in Coverage, 2020). The rule, which

disclose the cost-sharing information along with in-network

provider negotiated rates, historical out-of-network allowed amounts, and drug pricing information. Unless held up by

legal or congressional challenges, the requirements will be

phased in over 3 years, beginning January 1, 2022.

Medical Loss Ratio: Unintended Consequences

With the goals of providing "greater transparency and

accountability around the expenditures made by health

insurers," set standards intended to "help ensure policy-

holders receive value for their premium dollars" and to

"brin[g] down the cost of health care coverage" (Health

"that cover individuals and small businesses to spend at

administration, marketing, and profit" (Kaiser Family

least 80% of their premium income on health care claims and quality improvement, leaving the remaining 20% for

Insurance Issuers Implementing, 2010, p. 74,865), the ACA's

medical loss ratio (MLR) provision requires health insurers

was finalized on October 29, 2020, will require issuers to

disadvantage healthcare consumers. Theoretically, consolidation should allow insurers to negotiate lower prices from providers, as well as create economies of scale that lower costs, and there is some evidence that this occurs. However, given the substantial rise in premiums in recent years, there is little evidence that any of the savings are being passed on to healthcare consumers (Scheffler & Arnold, 2017). In fact, evidence from case studies suggests that increased market concentration due to mergers and acquisitions result in a significant increase in health insurance premiums (Guardado et al., 2013). There is also evidence that the ACA has contributed to insurance market consolidation in the program's insurance exchanges (Haislmaier & Senger, 2017), and in 2018, Jessica Van Parys found that in ACA marketplaces with only one local payer, premiums were 50% higher than in areas where consumers had a choice of two or more insurers (Van Parys, 2018).

Transparency

While concentration in the health insurance market limits

choice for healthcare consumers, a lack of trans-

There is little evidence that any of the savings by insurers are being passed on to healthcare consumers.

insurers in the large group market, the MLR threshold is 85%. Insurers who fail to meet the specified percentages must pay rebates to their customers. However, since the amount the insurers get to keep is based on

Foundation, 2012). For

a fixed percentage, there is no incentive for them to curb premium growth.

Pharmaceuticals

U.S. Spending on Pharmaceuticals

Although the U.S. represents roughly 4.5% of the world's population, it accounts for a disproportionate (more than 40%) of spending on pharmaceuticals globally (Emanuel et al., 2020). Drug spending in the U.S. has increased by 330% over the past 20 years, far outpacing the growth in overall healthcare spending (208%; Kirzinger et al., 2019).

In 2019, prescription drug spending in the U.S. grew 5.7% to \$369.7 billion, faster than the 3.8% growth in 2018 (CMS, 2020a). Over the years 2021-23, the annual growth in prescription drug spending is projected to average 5.4% and will increase to 5.9% over the years 2024-28 (CMS, 2020b). Adding to these concerns is evidence that as patients experience greater cost exposure, the rate of prescription abandonment increases, resulting in non-adherence to treatment regimens, which can undermine treatment goals, negatively impact health outcomes, and further add to the escalating cost of healthcare (QuintilesIMS, 2017).

parency also means that consumers do not have sufficient knowledge about the value of the health insurance products that they choose, often leaving them underinsured or causing them to pay for coverage that they do not need. According

to a national consumer survey conducted in 2019, 27.2% of respondents said that they avoided medical treatment because of uncertainty about what services their health plan covered, and a significant number did not understand basic insurance terms such as "co-pay," "deductible," and "premium" (Ma, 2019). In a 2014 Kaiser Family Foundation survey, a majority of U.S. adult survey respondents were unable to calculate their out-of-pocket expense in various health insurance payment scenarios (Norton et al., 2014). Such health illiteracy is an important cause of inefficiency in the U.S. healthcare system that can result in poor health outcomes (Fabbri et al., 2020) as well as needless costs (Vernon et al., 2007).

On November 27, 2019, the same day that the hospital price transparency rule was finalized and prompted by the same executive order that led to the hospital rule, CMS released a proposed rule that set forth recommended requirements for health insurance issuers in the individual and group markets to disclose cost-sharing information to enrollees, including an estimate of cost-sharing liability, in order to give patients a better understanding of their out-of-pocket

Utilization, Lack of Competition, and Insufficient Transparency

Drug utilization is a key factor that contributes to the growth in spending on prescription drugs. Drug utilization can reflect demographic changes in the population, changes in disease burden, or changes in treatment. For example, the aging of the population, the increased prevalence of chronic diseases, and the introduction of an effective but costly drug to treat a condition can all have a significant impact on drug spending. The mix of drugs that are utilized, especially brand versus generic, can also drive costs. In 2018, 9 out of 10 filled prescriptions were for generic drugs, but generics accounted for only about 22% of prescription drug spending (Tichy et al., 2020). The Government Accountability Office (GAO, 2016) found that, although prices for generic drugs are generally lower than brand name equivalents, as many as 20% of established generics had large (more than 100%) price increases in the years 2010 to 2015, offsetting a general decline in generic drug prices. More recent work supports this trend (Tessema et al., 2020).

Furthermore, there is clear evidence that generic drug prices reflect the level of competition in the generic market. According to the U.S. Food and Drug Administration (FDA), when a drug has a single generic producer, the average manufacturer price (AMP) is 39% lower than the brand name AMP. The price reduction increases to 79% with four competitors and to 95% with six or more competitors (FDA, 2019). In the past several years, the FDA has made a concerted effort to promote competition by reducing the barrier to entry into the generic market for smaller companies, streamlining the generic drug approval process, addressing the issue of multiple review cycles, and opposing efforts by brand-name manufacturers to impede generic drug competition (Gottlieb, 2018).

Pharmacy Benefit Managers

The role of pharmacy benefit managers (PBMs) has come under scrutiny in recent years. PBMs are companies that manage prescription drug benefits on behalf of health insurers, set terms for how much pharmacies are paid, and can influence which drug products are used most frequently. Their revenue comes from a combination of sources: fees from payers, a portion of the savings from rebates negotiated from drug companies, and fees from the maintenance of pharmacy networks (<u>Werble, 2017</u>). PBM practices are largely opaque, raising questions about whether PBMs contribute to rising drug prices. The process of negotiating rebates is a key tool that PBMs use to try to address high drug prices. However, there is concern that rebates based on a percentage of the drug's list price may create an incentive for PBMs to prioritize high-priced drugs, and the higher costs may be passed on to patients whose cost-sharing is also based on a percentage of the list price. Rebates have grown substantially in recent years (<u>Pew Charitable Trusts, 2019</u>), and manufacturers have argued that this has forced them to raise list prices to offset those rebates (<u>Walker, 2016</u>).

Additional scrutiny involves the PBM practice known as "spread pricing," whereby PBMs are reimbursed by health plans and employers at a higher price than what the PBMs pay pharmacies for the drugs, with PBMs keeping the difference. Since the payment schedules that PBMs generate for pharmacies are confidential, this lack of transparency makes it difficult to assess the extent of spread pricing and the impact on patients through higher prices and out-of-pocket costs, although it is thought to be substantial (Langreth et al., 2018).

340B

Although initially well-intended, the 340B program does not align with the original intent behind it. The 340B program was created in 1992 when Congress enacted Section 340B of the Public Health Service Act, created under Section 602 of the Veterans Health Care Act of 1992. The law requires manufacturers to sell outpatient drugs to certain purchasers (safety-net providers and programs identified in statute⁵) at a discounted price. The original congressional intent was for the savings from 340B-purchased drugs to enable covered entities to stretch federal resources, allowing providers to offer needed services to the most vulnerable patients at safety-net organizations (<u>Veterans Health</u> <u>Care Act, 1992</u>).

As laudable as the original aim of the program is, subsequent policies have greatly expanded the program and as the program has grown, so have concerns about whether it has strayed beyond the original intent. In 1996, the Health Resources and Services Administration (HRSA), which administers the 340B program within the Department of Health & Human Services, issued guidance that "enabled any 340B covered entity that did not operate its own pharmacy to contract with a single third-party pharmacy to dispense 340B purchased medicines to eligible patients on its behalf" (Vandervelde et al., 2020, p. 4). In 2010, the ACA greatly expanded the program eligibility⁶ and by 2014 nearly

⁵ The statute lists 16 groups of eligible purchasers. As a group, they are referred to as "covered entities." They include federally qualified health centers, various diseasespecific programs (AIDS drug assistance programs, black-lung clinics, and hemophilia treatment centers), and publicly owned hospitals with a disproportionate-share hospital percentage of at least 11.75%.

⁶ The ACA expanded 340B eligibility to the following categories of hospitals: critical access hospitals, sole community hospitals, rural referral centers, free-standing children's hospitals, and free-standing cancer hospitals.

45% of all Medicare acute care hospitals were covered by the program (MedPAC, 2015, p. 11). In addition, HRSA issued guidance effective on April 5, 2010, allowing 340B-covered entities to use an unlimited number of contract pharmacies and eliminated the limitation that only 340B entities that lack an on-site pharmacy could utilize contract pharmacies (Notice Regarding 340B Drug Pricing Program, 2010). Consequently, as of 2017, there were more than 12,000 covered entities participating in the program, and the number of contract pharmacies grew from about 1,300 in 2010 to approximately 20,000 by 2017 (GAO, 2018, p. 1).

Although the details of 340B revenues are proprietary, discounts in the program are substantial. HRSA (2019) reported that total 340B sales in 2017 amounted to approximately \$19 billion, or about 4.3% of the U.S. drug market

healthcare are beyond the scope of this analysis. However, it is possible to offer broader policy recommendations to address healthcare costs by promoting transparency, increasing competition, and improving value in the three major segments of the U.S. healthcare system discussed above with the intention of encouraging further discussion and future research.

Hospitals

Policymakers need to address hospital spending through policies that remove barriers to market entry and address other forms of anti-competitive behavior. For one thing, further research is needed to evaluate the overall impact of hospital consolidation on healthcare consumers in order to inform policies that can take advantage of efficiencies that could lower costs while limiting anti-competitive behavior

and maximizing consumer welfare (<u>Fulton, 2017</u>).

Policymakers also need to

address the decades-long

opacity in hospital prices.

The Trump administra-

tion's price transparency

requirements (Medicare

and Medicaid Programs,

(p. 286). Conservative estimates of savings to covered entities range from 25 to 50%, and there are few requirements on how the revenue generated from these discounts is to be used (MedPAC, 2015, p. 8). Recent reports from Milliman (Bunger et al., 2019) and the Berkeley Research Group (Vandervelde et al., 2020) suggest that the savings and profit margins on 340B-purchased medicines

Policies that inhibit competition by restricting market entry or fostering anticompetitive practices, as well as excessive regulation, contribute to growth in healthcare spending and fail to enhance consumer welfare.

dispensed through contract pharmacies may be substantially higher. Furthermore, a 2018 GAO review found substantial weaknesses in HRSA's oversight of the 340B program that hinder the agency's ability to ensure that contract pharmacies are compliant with program requirements (GAO, 2018, p. 38).

Policy Recommendations

The U.S. healthcare system needs to foster competition in the provider, health insurance, and pharmaceutical markets to lower costs and improve quality of care. Policies that inhibit competition by restricting market entry or fostering anti-competitive practices, as well as excessive regulation meant to address a perceived market failure, contribute to the growth in healthcare spending and fail to enhance consumer welfare. Detailed and specific policy recommendations to address the entire range of cost drivers in U.S. Another way to address the issue of lack of competition is to consider repeal of CON laws in those states where the legislation remains. While the evidence strongly suggests that repeal of CON laws would remove barriers to entry and increase competition, Mitchell et al. (2020) have noted that full and immediate repeal is likely to be politically challenging and suggest a number of alternatives, including eliminating CON laws for certain services or technologies, such as those that restrict access to services for vulnerable populations;⁷ for procedures that are unlikely to be overused;⁸ for low-cost modes of care;⁹ and for small investments. Other options are a phasing-in of repeal, temporary

nd fail to enhance 2019) that were finalized on November 27, 2019, are an improvement over past efforts in that, for the first time, payer-specific negotiated charges—the amount the hospital is willing to accept in cash from a patient for an item or service—and minimum and maximum negotiated charges will be made available to the public.

⁷ CON laws for substance abuse treatment centers are found in 24 states, for psychiatric care facilities in 28 states, and for intermediate-care facilities for those with intellectual disabilities in 28 states.

⁸ CON laws for neonatal intensive care units are found in 22 states, for burn care units in 14 states, and hospice facilities in 18 states.

⁹ For example, ambulatory surgical centers (28 states) and home healthcare facilities (19 states).

repeal to test the impact, a gradual increase in the approval rate of applications, and other forms of administrative relief, such as reducing application fees.

Policymakers also need to re-examine the restrictions on physician-owned hospitals. The recently finalized 2021 Medicare Hospital Outpatient Prospective Payment System and Ambulatory Surgical Facility final rule (CMS, 2020c), released on December 2, 2020, eases some of the restrictions on expansion for hospitals that qualify for an exception as "high Medicaid" facilities.¹⁰ Although this rule gives existing POHs a modicum of flexibility, it does not go far enough. POHs have been shown to provide high-quality, efficient care, and they have the potential to foster competition and value. A blanket moratorium on these facilities is not appropriate. A more focused approach to the issue of POHs is needed that will promote equity in access to care without stifling competition through excessive regulation (Wilensky & Miller, 2020).

Insurance

The effect of consolidation in the private insurer market is

a complex issue, and the question of who benefits or loses depends on the details of the marketplace structure. Greater concentration in the insurer marketplace should put downward pressure on provider prices, although

Policymakers need to ensure that healthcare consumers and not just payers and providers benefit from their policies.

the evidence suggests that any savings are not necessarily passed on to the consumer through lower premiums (<u>Ho &</u> <u>Lee, 2016</u>). As noted above, consolidation limits choice, and often healthcare consumers find themselves with coverage that is not appropriate for their needs or leaves them financially exposed. Policymakers need to consider options that increase competition in the health insurance marketplace and ensure that healthcare consumers and not just payers and providers benefit.

Healthcare consumers lack the basic understanding of health insurance needed to make informed decisions. The recently finalized "Transparency in Coverage" (2020) rule is an effort to make patients better informed by requiring issuers to disclose cost-sharing information, in-network provider negotiated rates, historical out-of-network allowed amounts, drug pricing information, and estimated out-ofpocket expenses. However, in addition to greater health insurance transparency, consumers need incentives to use the information to make better choices that can lead to more value for the patient and lower healthcare spending. Traditional insurance models that insulate patients from the true cost of care do not provide those incentives.

Currently, there is an increasing number of value-based insurance design (VBID) models that give consumers "skin in the game" and attempt to influence consumer choice without exposing them to excessive or unexpected financial risk. These models include high-deductible health plans, limited provider networks, reference-based pricing (RBP), and direct rewards programs. Of these, RBP, where an insurer agrees to reimburse a service based on an established price (the reference price), and the patient is responsible for any costs above the reference price, seems to have the greatest potential to reduce spending by incentivizing consumers to shop and obliging providers to lower prices to remain competitive. RBP may be implemented through contracting with providers, which removes any concern for balance billing to the patient. Without contracting, implementation of RBP requires considerable communication and even decision support on the part of the plan to avoid exposing patients to unexpected out-of-pocket costs (Mehrotra et al., 2018). VBID models should be further

refined as a way to increase choice and add value to the current health insurance market.

Pharmaceuticals

Although many nations use direct regulation of pharmaceutical prices to

limit spending on drugs, implementing similar drug price control in the United States would likely incur unwanted consequences, and any policy that includes a substantial reduction in prices would need to weigh the considerable inhibitory effect this would have on innovation (Lieberman et al., 2020).

Policy options to address the growth in prescription drug spending should include removing government interventions that distort the market, as well as removing barriers to entry into the market for generic and biosimilar manufacturers, lowering research and development (R&D) costs without compromising safety and clinical effectiveness, and increasing transparency concerning the pharmaceutical supply chain.

A number of measures have been introduced at the state level to control drug prices, including greater drug price transparency, requiring drug manufacturers to give advance notice and justification for price increases that exceed a certain limit, and prohibitions on pharmacy "gag clauses"

¹⁰ High Medicaid facilities are those that serve more Medicaid inpatients than other hospitals in the same county.

that constrain pharmacists from informing patients if a drug is cheaper if not paid for through insurance (Gupta et al., 2019). The recently finalized Transparency in Coverage (2020) rule addresses the opacity in drug pricing by requiring health insurance companies to make known the estimated out-of-pocket costs for prescription drugs and disclose to the public the negotiated prices they pay for drugs. Physicians and their patients need this information in order to make appropriate treatment decisions at the point of care.

Greater transparency is also needed concerning the operations of pharmacy benefit managers, including financial incentives that influence coverage decisions, to ensure that patients and not just PBMs and payers benefit from negotiated discounts and that PBM practices are not contributing to the growth in pharmaceutical prices. A recently finalized rule from the HHS attempts to address this issue by modifying a regulatory provision that had previously protected certain pharmaceutical manufacturer rebates from sanctions under the federal Anti-Kickback Statute (42 U.S.C. § 1320a-7b(b)) and by creating new protections for price reductions for rebates that are passed on to the patient at the point of sale and for PBM service fees that are not linked to the list price of drugs (Fraud and abuse, 2019). The rule is likely to face significant political and procedural challenges that may delay implementation (Sachs, 2020; Fraud and Abuse, 2021). A separate rule (Most Favored Nation, 2020) to address drug prices in Medicare Part B may face similar challenges.

On December 10, 2020, the U.S. Supreme Court upheld the authority of an Arkansas law to impose certain regulations on PBMs and that federal law, specifically the Employment Retirement Income Security Act (ERISA), does not bar states from regulating PBMs (*Rutledge, Attorney General of Arkansas v. Pharmaceutical Care Management Association*, 2020). Although the Arkansas law deals specifically with drug pricing, the 8-0 ruling could have a bearing on future state oversight of PBMs (Fuse Brown & McCuskey, 2020). As of December 3, 2020, 46 states have passed laws aimed at reducing drug costs through increased PBM oversight (National Academy for State Health Policy, 2020).

Reform of the 340B program is essential in order to reduce unnecessary spending on pharmaceuticals and ensure that the program functions as originally intended. For one thing, the program needs to become truly patient-centered. A key feature of the current program is that it makes safety-net providers eligible for the program rather than a particular patient category. An individual becomes a "qualified patient" if the covered entity has an established relationship with the individual, the individual receives healthcare services from a healthcare professional who is either employed by or has a contractual or other arrangement with the covered entity, or the individual receives healthcare services for which certain grant funding has been provided (Notice Regarding Section 602, 1996). Importantly, the patient's income is not a determining factor. Drugs purchased at 340B prices can be dispensed to insured patients, and entities that purchase the drugs profit by billing payers, including Medicare, at the higher rates. Transparency and clear guidance are needed regarding the definition of an "eligible patient," as well as how savings from 340B discounts are used to ensure that the benefits are passed through to low income and uninsured patients.

In addition to providing accurate information about which entities are eligible to receive discounted prices, the program needs to confirm that manufacturers are charging the correct prices. In particular, clear criteria are needed to address the varied and complex contract pharmacy arrangements, as well as the practice of hospitals acquiring independent physician practices, enabling the practices to access the hospitals' 340B discounts, which can drive up costs for patients and payers.

Conclusion

Although the United States spends considerably more on healthcare than other wealthy nations, some have argued that the high level of spending may be worth the cost. However, escalating healthcare costs place a burden on many families, forcing some to forgo medical care because of the cost, and there is evidence that a significant portion of spending does not result in improved health outcomes (<u>Cutler, 2018</u>).

The drivers of healthcare spending are numerous, and a detailed examination of each is beyond the scope of this analysis. However, some of the principal drivers of healthcare costs in three main segments of the U.S. healthcare system (hospitals, health insurance, and pharmaceuticals) have been discussed. A key finding of this analysis is that a common theme of a dysfunctional market underlies many of the drivers of escalating healthcare costs in the U.S. Because effective competition is lacking, healthcare consumers do not have the information and incentives they need to make better value choices. In addition, government efforts to address perceived market failures often compound the problem. Excessive healthcare spending is best addressed through policies that promote competition, greater transparency, and more choice through elimination of anti-competitive practices, as well as the avoidance of excessive regulation.

Reference List

- *American Hospital Association v. Alex M. Azar, II*, Civil Action No. 1:19-cv-03619 (D.D.C. 2020). <u>https://ecf.dcd.uscourts.gov/cgi-bin/show_public_doc?2019cv3619-35</u>
- American Medical Association. (2020). *Competition in health insurance. A comprehensive study of U.S. markets.* <u>https://www.ama-assn.org/system/files/2020-10/competition-health-insurance-us-markets.pdf</u>
- Arora, V., Moriates, C., & Shah, N. (2015). The challenge of understanding health care costs and charges. *American Medical Association Journal of Ethics*, 17(11), 1046–52. <u>https://journalofethics.ama-assn.org/article/challenge-understanding-health-care-costs-and-charges/2015-11</u>
- Blumenthal D., Orav E., Jena B., Dudzinski D., Le, S., & Jha, A. (2015). Access, quality, and costs of care at physician owned hospitals in the United States: observational study. *British Medical Journal*, *351*:h4466. <u>https://www.bmj.com/content/351/bmj.h4466</u>
- Bunger, A., Hunter, M., & Kim, C. (2019). Analysis of 340B hospitals' outpatient department acquisition cost and commercial reimbursement for physician-administered brand medicines. Milliman. <u>https://www.milliman.com/en/insight/</u> analysis-of-340b-hospitals-outpatient-department
- Centers for Medicare and Medicaid Services. (2020a). *NHE Fact Sheet*. <u>https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NHE-Fact-Sheet</u>
- Centers for Medicare and Medicaid Services. (2020b). *National Health Expenditure Projections 2019-2028. Forecast Summary*. <u>https://www.cms.gov/files/document/nhe-projections-2019-2028-forecast-summary.pdf</u>
- Centers for Medicare and Medicaid Services. (2020c). *CY 2021 Medicare hospital outpatient prospective payment system and ambulatory surgical center payment system final rule (CMS-1736-FC)* [Fact sheet]. <u>https://www.cms.gov/newsroom/fact-sheets/cy-2021-medicare-hospital-outpatient-prospective-payment-system-and-ambulatory-surgical-center-0</u>
- Centers for Medicare and Medicaid Services. (2020d). *The nation's health dollar: Where it came from, where it went*. <u>https://www.cms.gov/files/document/nations-health-dollar-where-it-came-where-it-went.pdf</u>
- Collins, S. R., & Radley, D. C. (2018). *The cost of employer insurance is a growing burden for middle-income families*. Commonwealth Fund. <u>https://www.commonwealthfund.org/publications/issue-briefs/2018/dec/</u> <u>cost-employer-insurance-growing-burden-middle-income-families</u>
- Cooper, Z., Craig, S., Gaynor, M., Harish, N., Krumholz, H., & Van Reenen, J. (2019a). Hospital prices grew substantially faster than physician prices for hospital-based care in 2007–14. *Health Affairs*, *38*(2). https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2018.05424
- Cooper, Z., Craig, S., Gaynor, M., & Van Reenen, J. (2019b). The price ain't right? Hospital prices and health spending on the privately insured. *Quarterly Journal of Economics*, 134(1), 51–107. https://academic.oup.com/gje/article/134/1/51/5090426
- Cox, C., Rudowitz, R., Neuwan, T., Cubanski, J., & Rae, M. (2020). *How health costs might change with COVID-19*. Peterson-Kaiser Family Foundation. <u>https://www.healthsystemtracker.org/brief/how-health-costs-might-change-with-covid-19/</u>
- Cutler, D. (2018). What is the US health spending problem? *Health Affairs*, *37*(3), 493–497. <u>https://scholar.harvard.edu/</u><u>files/cutler/files/hlthaff.2017.1626.pdf</u>
- Emanuel, Z., Zang, C., Glickman, A., Gudbranson, E., DiMagno, S., & Urwin, J. (2020). Drug reimbursement regulation in 6 peer countries. *JAMA Internal Medicine*, *180*(11), 1510–1517. <u>https://jamanetwork.com/journals/jamainternalmedicine/article-abstract/2771097</u>
- Exec. Order No. 13,877, 84 Fed. Reg. 30,849 (June 27, 2019). <u>https://www.federalregister.gov/documents/2019/06/27/2019-13945/improving-price-and-quality-transparency-in-american-healthcare-to-put-patients-first</u>

- Fabbri, M., Murad, M., Wennberg, A., Turcano, P., Erwin, P., Alahdab, F., Berti, A., Manemann, S., Yost, K., Finney-Rutten L., & Roger, V. (2020). Health literacy and outcomes among patients with heart failure: A systematic review and meta-analysis. *JACC Heart Failure*, 8(6), 451–460. <u>https://pubmed.ncbi.nlm.nih.gov/32466837/</u>
- 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, 84 Fed. Reg. 2,340. (February 6, 2019). <u>https://www.federalregister.gov/documents/2019/02/06/2019-01026/fraud-and-abuse-removal-of-safe-harbor-protection-for-rebates-involving-prescription-pharmaceuticals</u>
- 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, 86 Fed. Reg. 7,815. (February 2, 2021). <u>https://www.federalregister.gov/documents/2021/02/02/2021-02132/fraud-and-abuse-removal-of-safe-harbor-protection-for-rebates-involving-prescription-pharmaceuticals</u>
- Fulton, B. (2017). Health care market concentration trends in the United States: Evidence and policy responses. *Health Affairs*, *36*(9), 1530–1538. <u>https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2017.0556</u>
- Fuse Brown, E., & McCuskey, E. (2020, December 17). The implications of *Rutledge v. PCMA* for state health care cost regulation. *Health Affairs Blog*. <u>https://www.healthaffairs.org/do/10.1377/hblog20201216.909942/full/</u>
- Gaynor, M., & Town, R. (2012). *The impact of hospital consolidation—Update* [Policy brief]. Robert Wood Johnson Foundation. <u>http://www.rwjf.org/content/dam/farm/reports/issue_briefs/2012/rwjf73261</u>
- Gottlieb, J., Shapiro, A., Dunn, A. (2018). The complexity of billing and paying for physician care. *Health Affairs*, *37*(4), 619-626. <u>https://www.healthaffairs.org/doi/10.1377/hlthaff.2017.1325</u>
- Gottlieb, S. (2018, July 18). Opening remarks for Part 15 public meeting on generic drug competition [Speech]. *United* States Food and Drug Administration. <u>https://www.fda.gov/news-events/speeches-fda-officials/opening-remarks-part-15-public-meeting-generic-drug-competition-07182018</u>
- Government Accountability Office. (2016). *Generic drugs under Medicare. Part D generic drug prices declined overall, but some had extraordinary price increases.* [GAO 16-706]. <u>https://www.gao.gov/assets/680/679022.pdf</u>
- Government Accountability Office. (2018). *Federal oversight of compliance at 340B contract pharmacies needs improvement.* [GAO-18-480]. <u>https://www.gao.gov/assets/700/692697.pdf</u>
- Guardado, J., Emmons, D., & Kane, C. (2013). The price effects of a large merger of health insurers: A case study of UnitedHealth-Sierra. *Health Management, Policy and Innovation, 1*(3), 16–35. <u>https://www.ama-assn.org/sites/ama-assn.org/files/corp/media-browser/public/government/advocacy/united-sierra-merger-premiums-hmpi_0.pdf</u>
- Gupta, R., Shah, N. D., & Ross, J. S. (2019). Generic drugs in the United States: Policies to address pricing and competition. *Clinical pharmacology and therapeutics*, 105(2), 329–337. <u>https://www.ncbi.nlm.nih.gov/pmc/articles/</u> <u>PMC6355356/pdf/nihms-998327.pdf</u>
- Haislmaier, E., & Senger, A. (2017). *The 2017 health insurance exchanges: Major decrease in competition and choice*. Heritage Foundation. <u>https://www.heritage.org/health-care-reform/report/the-2017-health-insurance-exchanges-major-decrease-competition-and-choice</u>
- Health Insurance Issuers Implementing Medical Loss Ratio (MLR) Requirements Under the Patient Protection and Affordable Care Act, 75 Fed. Reg. 74,864 (December 1, 2010). <u>https://www.govinfo.gov/content/pkg/FR-2010-12-01/pdf/2010-29596.pdf</u>
- Health Resources and Services Administration. (2019). *Justification of estimates for appropriations committees*. Department of Health and Human Services. <u>https://www.hrsa.gov/sites/default/files/hrsa/about/budget/budget-justification-fy2020.pdf</u>

- Ho, K., & Lee, R. (2016). *Insurer competition in health care markets* [Working paper 19401]. National Bureau of Economic Research. <u>https://www.nber.org/papers/w19401</u>
- Kaiser Family Foundation. (2012). *Explaining health care reform: Medical Loss Ratio (MLR)*. <u>https://www.kff.org/health-reform/fact-sheet/explaining-health-care-reform-medical-loss-ratio-mlr/</u>
- Kaiser Family Foundation. (2019). *Health insurance coverage of the total population*. <u>https://www.kff.org/other/state-indicator/total-population/</u>
- Kirzinger, A., Muñana, C., Fehr, R., & Rousseau D. (2019). US public's perspective on prescription drug costs. *JAMA*, 322(15), 1440. <u>https://jamanetwork.com/journals/jama/fullarticle/2752910</u>
- Langreth, R., Ingold, D., & Gu, J. (2018, September 11). *The secret drug pricing system middlemen use to rake in millions*. Bloomberg. <u>https://www.bloomberg.com/graphics/2018-drug-spread-pricing/</u>
- Lieberman, S., Ginsburg, P., & Patel, K. (2020, November 24). Balancing lower U.S. prescription drug prices and innovation Part 1. *Health Affairs Blog*. <u>https://www.healthaffairs.org/do/10.1377/hblog20201123.804451/full/</u>
- Ma, M. (2019, October 29). Health insurance literacy survey 2019: Americans are increasingly confused about health care. *Policygenius*. <u>https://www.policygenius.com/blog/health-insurance-literacy-survey-2019/</u>
- Mahomed S., Rosenthal J., Matelski J., & Cram, P. (2018). Changes in ability of hospitals to provide pricing for total hip arthroplasty from 2012 to 2016. *JAMA Internal Medicine*, *178*(8), 1132–1133. <u>https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2682615</u>
- Medicare and Medicaid Programs: CY 2020 Hospital Outpatient PPS Policy Changes and Payment Rates and Ambulatory Surgical Center Payment System Policy Changes and Payment Rates. Price Transparency Requirements for Hospitals To Make Standard Charges Public, 84 Fed. Reg. 65,524 (November 27, 2019). <u>https://www.federalregister.gov/documents/2019/11/27/2019-24931/medicare-and-medicaid-programs-cy-2020-hospital-outpatient-pps-policy-changes-and-payment-rates-and</u>
- Medicare Payment Advisor Commission. (2015). *Overview of the 340B drug pricing program*. <u>http://www.medpac.gov/</u> <u>docs/default-source/reports/may-2015-report-to-the-congress-overview-of-the-340b-drug-pricing-program</u>. <u>pdf?sfvrsn=0</u>
- Medicare Payment Advisor Commission. (2020). *Medicare Payment Policy* [Report to Congress]. <u>http://medpac.gov/docs/</u> <u>default-source/reports/mar20_entirereport_sec.pdf</u>
- Mehrotra, A., Chernew, M., & Sinaiko, A. (2018). Promise and reality of price transparency. *New England Journal of Medicine*, 379(14), 1351. <u>https://www.nejm.org/doi/full/10.1056/NEJMhpr1715229</u>
- Mitchell, M., Amez-Droz, E., & Parsons, A. (2020). *Phasing out Certificate-of-Need laws: a menu of options* [Policy brief]. Mercatus Center, George Mason University. <u>https://www.mercatus.org/system/files/mitchell_amez-droz_and_parsons_policy_brief_repealing_con_laws_a_menu_of_options_for_state_policymakers_v11.pdf</u>
- Most Favored Nation (MFN) Model, 42 CFR 513 (November 27, 2020). <u>https://www.federalregister.gov/</u> <u>documents/2020/11/27/2020-26037/most-favored-nation-mfn-model</u>
- National Academy for State Health Policy. (2020). State drug pricing laws. https://www.nashp.org/rx-laws/
- Noether, M., May, S., & Stearns, B. (2019). *Hospital merger benefits: views from hospital leaders and econometric analysis* - *An update*. American Hospital Association. <u>https://www.aha.org/system/files/media/file/2019/09/cra-report-merger-benefits-2019-f.pdf</u>
- Norton, M., Hamel, L., & Brodie, M. (2014). Assessing Americans' familiarity with health insurance terms and concepts. Kaiser Family Foundation. <u>https://www.kff.org/health-reform/poll-finding/assessing-americans-familiarity-with-health-insurance-terms-and-concepts/</u>

- Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Patient and Entity Eligibility, 61 Fed. Reg. 55,156 (October 24, 1996). <u>https://www.govinfo.gov/content/pkg/FR-1996-10-24/pdf/FR-1996-10-24.pdf</u>
- Notice Regarding 340B Drug Pricing Program—Contract Pharmacy Services, 75 Fed. Reg. 10,272 (March 5, 2010). https://www.govinfo.gov/content/pkg/FR-2010-03-05/pdf/2010-4755.pdf
- OECD. (2019). Health spending. https://data.oecd.org/healthres/health-spending.htm
- Papanicolas, I., Woskie, L. R., & Jha, A. (2018). Health care spending in the United States and other high-income countries. *JAMA*, *319*(10), 1024–1039. <u>https://jamanetwork.com/journals/jama/article-abstract/2674671</u>
- Patient Protection and Affordable Care Act, Pub. L. 111-148, § 6001 (2010). <u>https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Downloads/Section 6001 of the ACA.pdf</u>
- Pew Charitable Trusts. (2019). *The prescription drug landscape, explored. A look at retail pharmaceutical spending from 2012* to 2016. <u>https://www.pewtrusts.org/-/media/assets/2019/03/the_prescription_drug_landscape-explored.pdf</u>
- National Health Planning and Resources Development Act of 1974, Pub. L. No. 93-641 (1975). <u>https://uscode.house.gov/</u> <u>statutes/pl/93/641.pdf</u>
- QuintilesIMS Institute. (2017). Medicines use and spending in the U.S. A review of 2016 and outlook to 2021. <u>https://structurecms-staging-psyclone.netdna-ssl.com/client_assets/dwonk/media/attachments/590c/6aa0/6970/</u> <u>2d2d/4182/0000/590c6aa069702d2d41820000.pdf</u>
- Rama, A. (2020). National health expenditures, 2018: Spending growth remains steady even with increases in private health insurance and Medicare spending. American Medical Association. <u>https://www.ama-assn.org/system/files/2020-08/</u> prp-annual-spending-2018.pdf
- Robinson, J. (2004). Consolidation and the transformation of competition in health insurance. *Health Affairs*, 23(6), 11–24. https://www.healthaffairs.org/doi/pdf/10.1377/hlthaff.23.6.11
- Rutledge, Attorney General of Arkansas v. Pharmaceutical Care Management Association, 891 F. 3d 1109 (8th Cir. 2018), cert. granted, 140 S. Ct. 812 (2020), rev'd and remanded, No. 18-540, 2020 WL 7250098 (U.S. 10 Dec. 2020). https://www.supremecourt.gov/opinions/20pdf/18-540_m640.pdf
- Saad, L. (2018, December 17). *Delaying care a healthcare strategy for three in 10 Americans*. Gallup. <u>https://news.gallup.com/poll/245486/delaying-care-healthcare-strategy-three-americans.aspx</u>
- Sachs, R. (2020, November 23). Administration finalizes drug pricing rebate rule at the last minute. *Health Affairs Blog.* <u>https://www.healthaffairs.org/do/10.1377/hblog20201122.985836/full/</u>
- Salkever, D., & Bice, T. (1976). The impact of certificate-of need controls on hospital investment. *Milbank Memorial Fund Quarterly. Health and Society*, 54(2), 185-214. <u>https://www.jstor.org/stable/3349587?origin=pubexport&seq=1</u>
- Scheffler, R., & Arnold, D. (2017). Insurer market power lowers prices in numerous concentrated provider markets. *Health Affairs*, *36*(9), 1539–46. <u>https://www.healthaffairs.org/doi/pdf/10.1377/hlthaff.2017.0552</u>
- Sloan, F., & Steinwald, B. (1980). Effects of regulation on hospital costs and input use. *Journal of Law & Economics*, 23(1), 81-109. <u>https://www.jstor.org/stable/725286</u>
- Tichy, E., Schumock, G., Hoffman, J., Suda, K., Rim, M., Tadrous, M., Stubbings, J., Cuellar, S., Clark, J., Weist, M., Matusiak, L., Hunkler, R., & Vermeulsen, L. (2020). National trends in prescription drug expenditures and projections for 2020. American Journal of Health-System Pharmacy, 77(15), 1213–1230. <u>https://academic.oup.com/ ajhp/article/77/15/1213/5837520</u>
- Tessema, F., Kesselheim, A., & Sinha, M. (2020). Generic but expensive: Why prices can remain high for off-patent drugs. *Hastings Law Journal*, 71 (4), 1019–52. <u>https://repository.uchastings.edu/cgi/viewcontent.cgi?article=3898&context=hastings_law_journal</u>

- Transparency in Coverage, 85 Fed. Reg. 72,158 (November 12, 2020). <u>https://www.federalregister.gov/documents/2020/11/</u> 12/2020-24591/transparency-in-coverage
- U.S. Food and Drug Administration. (2019). *Generic competition and drug prices*. <u>https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/generic-competition-and-drug-prices</u>
- Vandervelde, A., Erb, K., & Hurley, L. (2020). *For-profit pharmacy participation in the 340B Program*. Berkeley Research Group. <u>https://media.thinkbrg.com/wp-content/uploads/2020/10/06150726/BRG-ForProfitPharmacyParticipation</u> <u>340B_2020.pdf</u>
- Van Parys, J. (2018). ACA marketplace premiums grew more rapidly in areas with monopoly insurers than in areas with more competition. *Health Affairs*, *37*(8), 1243–51. <u>https://www.healthaffairs.org/doi/abs/10.1377/hlthaff.2018.0054</u>
- Vernon, J., Trujillo, A., Rosenbaum, S., & DeBuono, B. (2007). *Low health literacy: Implications for national health policy*. George Washington University. <u>https://publichealth.gwu.edu/departments/healthpolicy/CHPR/downloads/</u> LowHealthLiteracyReport10_4_07.pdf
- Veterans Health Care Act of 1992, Pub. L.102-585, § 602 (1992). <u>https://www.hrsa.gov/opa/program-requirements/public-law-102-585.html#602</u>
- Walker, J. (2016, October 3). Drugmakers point finger at middlemen for rising drug prices. *Wall Street Journal*. https://www.wsj.com/articles/drugmakers-point-finger-at-middlemen-for-rising-drug-prices-1475443336
- Werble, C. (2017). *Pharmacy benefit managers* [Policy brief]. Health Affairs. <u>https://www.healthaffairs.org/do/10.1377/</u> hpb20171409.000178/full/
- Wilensky, G., & Miller, B. (2020). Time to consider a new look at physician-owned hospitals to increase competition in health care? *JAMA*, *323*(19), 1884–1885. <u>https://jamanetwork.com/journals/jama/fullarticle/2766149</u>

ABOUT THE AUTHOR



John O'Shea, MD, is senior fellow for Right on Healthcare at the Texas Public Policy Foundation. He is also a surgeon and independent researcher. From 2014-2019 O'Shea was a senior fellow in the Center for Health Policy Studies at the Heritage Foundation in Washington, D.C., where he worked on a number of health policy issues, including implementation of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), healthcare payment and delivery reform, Medicare Advantage, VA healthcare, emergency medical care, and graduate medical education.

From 2013-2015, O'Shea was a visiting scholar in the Engelberg Center for Health Care Reform at the Brookings Institution, where he was clinical lead on a project with MITRE and CMMI to develop alternative payment models for specialty care. From 2011 to 2013, he served as senior health policy advisor to the U.S. House Committee on Energy and Commerce, where he helped draft the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) that replaced the Sustainable Growth Rate formula for reimbursing physician services in the Medicare program.

Before moving to D.C. in 2011, O'Shea was an assistant professor of surgery at the Albert Einstein College of Medicine in Bronx, NY. He completed his surgical training at New York Medical College in New York City and holds a master of public administration from the Harvard Kennedy School and master's degrees in history and sociology of science from the University of Pennsylvania.

O'Shea has published widely on health policy, clinical surgery, the history of surgery, and the history of health policy.

About Texas Public Policy Foundation

The Texas Public Policy Foundation is a 501(c)3 non-profit, non-partisan research institute. The Foundation promotes and defends liberty, personal responsibility, and free enterprise in Texas and the nation by educating and affecting policymakers and the Texas public policy debate with academically sound research and outreach.

Funded by thousands of individuals, foundations, and corporations, the Foundation does not accept government funds or contributions to influence the outcomes of its research.

The public is demanding a different direction for their government, and the Texas Public Policy Foundation is providing the ideas that enable policymakers to chart that new course.

