

Reforming America's Healthcare System Through Choice and Competition



**U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
U.S. DEPARTMENT OF THE TREASURY
U.S. DEPARTMENT OF LABOR**

The President
The White House
Washington, DC 20500

Dear Mr. President:

On October 12, 2017, through Executive Order 13813, you directed the Administration, to the extent consistent with the law, to facilitate the development and operation of a health care system that provides high-quality care at affordable prices for the American people by promoting choice and competition. We are pleased to provide you with this report, prepared by the Department of Health and Human Services (HHS) in collaboration with the Departments of the Treasury and Labor, the Federal Trade Commission, and several offices within the White House. This report describes the influence of state and federal laws, regulations, guidance, and policies on choice and competition in health care markets and identifies actions that states or the Federal Government could take to develop a better functioning health care market.

As health care spending continues to rise, Americans are not receiving the commensurate benefit of living longer, healthier lives. Health care bills are too complex, choices are too restrained, and insurance premiums and out-of-pocket costs are climbing faster than wages and tax revenue. Health care markets could work more efficiently and Americans could receive more effective, high-value care if we remove and revise certain federal and state regulations and policies that inhibit choice and competition.

The Administration has already taken significant steps to improve health care markets by addressing government rules and programs that limit choice and competition and produce higher prices for the American people. Among the most significant actions:

- In October 2018, the Departments of HHS, the Treasury, and Labor proposed a rule that would provide employers with significant new flexibility in how they fund health coverage through Health Reimbursement Arrangements (HRAs). If finalized, this flexibility would empower individuals to take greater control over what health insurance benefits they receive. The Treasury estimates that more than 10 million employees would benefit from this change within the next decade.

- In August 2018, the Departments of HHS, the Treasury, and Labor finalized a rule to expand Americans' ability to purchase short-term, limited-duration insurance—coverage for which premiums are generally much more affordable than Affordable Care Act (ACA) plans. Millions of Americans, including middle-class families who cannot afford ACA plans, will benefit from the additional choice and competition resulting from this reform.
- In June 2018, the Labor Department finalized a rule to expand the ability of employers, including sole proprietors without common law employees, to join together and offer health coverage through Association Health Plans. For many employers, employees, and their families, these employee benefit plans will offer greater flexibility and more affordable benefits.
- In May 2018, HHS released “American Patients First,” a historic blueprint for actions to bring down the high price of drugs and reduce out-of-pocket costs. HHS has taken a number of actions that were laid out in the blueprint to empower consumers and promote competition, building on accomplishments such as the Food and Drug Administration's record pace of generic drug approvals.
- In December 2017, you signed the Tax Cuts and Jobs Act, which eliminated the onerous and regressive individual mandate tax penalty. This freed Americans to finance their health care needs in the way that works best for them.
- The Administration has enacted reforms to deliver better value through choice and competition in the Medicare program, including payment changes that establish site-neutral payment policies for a number of Medicare services, a simplification of how physicians are paid for evaluation and management visits, new consumer-transparency measures, and flexibility for insurers to offer more options and benefits in Medicare Advantage.
- HHS and the Treasury have issued revised guidance under section 1332 of the ACA that significantly expands the ability of states to reform their individual insurance markets while ensuring that people with pre-existing conditions are protected.

While the Administration has made much progress in reforming the American health care system significant obstacles remain. This report identifies four areas where federal and state rules inhibit adequate choice and competition and offers recommendations for improving public policy in each of these four areas.

Health Care Workforce and Labor Markets: Reduced competition among clinicians leads to higher prices for health care services, reduces choice, and negatively impacts overall health care quality and the efficient allocation of resources. Government policies have suppressed competition by reducing the available supply of providers and restricting the range of services that they can offer. This report recommends policies that will broaden providers' scope of practice while improving workforce mobility, including telehealth, to encourage innovation and to allow providers more easily to meet patients' needs. The report also recommends that the Federal Government streamline funding for graduate medical education to allocate taxpayer dollars efficiently and to address physician supply shortages.

Health Care Provider Markets: State policies that restrict entry into provider markets can stifle innovative and more cost-effective ways to provide care while limiting choice and competition. These policies have resulted in higher health care prices and fewer incentives for providers to improve quality. This report makes several recommendations to promote choice and competition in provider markets, including state action to repeal or scale back Certificate of Need laws and encourage the development of value-based payment models that offer flexibility and risk-based incentives for providers, especially without unduly burdening small or rural practices.

Health Care Insurance Markets: Government mandates often reduce choice and competition in insurance markets and increase overall premiums. In the individual and small group markets, many consumers face limited coverage options that cover services they do not want or need and that drive up premiums, while others have been completely priced out of the market. Regulations that limit coverage choices should be changed so that states have more flexibility to develop policies that account for diverse consumer preferences. This report recommends scaling back government mandates, eliminating barriers to competition, and allowing consumers maximum opportunity to purchase health insurance that meets their needs.

Consumer-Driven Health Care: Our health care system's excessive reliance on third-party payment insulates consumers from the true price of health care and offers them little incentive to search for low-cost, high-quality care. When federal and state health policies give consumers more control over their health care dollars, they can use that power to demand greater value. For example, promoting and expanding Health Saving Accounts (HSAs) and HRAs would expand personal control and introduce more consumer power into the health care market. The report recommends expanding access to HSAs, implementing reference pricing where appropriate, and developing price and quality transparency initiatives to ensure that newly empowered health care consumers can make well-informed decisions about their care.

Reforming America's Healthcare System Through Choice and Competition

We know the United States health care system too often fails to deliver the value it should. This report identifies barriers on the federal and state levels to market competition that stifle innovation, lead to higher prices, and do not incentivize improvements in quality. It recommends policies that will foster a health care system that delivers high-quality care at affordable prices through greater choice, competition, and consumer-directed health care spending. While American consumers and many providers would significantly benefit from the reforms laid out in this report, there are entrenched and powerful special interest groups that reap large profits from the status quo. It will take bold leadership to confront these incumbents and implement reforms, but under your direction, we are convinced we can significantly improve the American health care system.

We look forward to working with you as we create a more effective and efficient health care market that provides information for consumers as they make health care decisions for their families, rewards quality, encourages innovation, and delivers care at prices the American people can afford.

Sincerely,

/Alex M. Azar II/

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U.S. Department of Health
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/Steven T. Mnuchin/

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Background

Executive Order 13813, “Promoting Healthcare Choice and Competition Across the United States,” directs the administration, to the extent consistent with law, to facilitate “the development and operation of a healthcare system that provides high-quality care at affordable prices for the American people” by increasing consumer choice and promoting competition in healthcare markets and by removing and revising government regulation. Section 6 of the executive order requires the Secretary of Health and Human Services (HHS), in consultation with the secretaries of the Treasury and Labor and the Federal Trade Commission, to provide a report to the President. The purpose of the report is to review existing state and federal laws, regulations, guidance, requirements and policies that limit competition and choice and to identify actions that states or the federal government could take to further these goals. It also includes input contained in 262 comments received in response to a request for information (RFI) publicly released on December 26, 2017.¹

This report was the result of a working group created to research key issues related to healthcare choice and competition and draft the report. The working group consisted of staff within the departments of Health and Human Services, Treasury and Labor, as well as staff with the Federal Trade Commission, the Office of Management and Budget, the Council of Economic Advisers, the National Economic Council, the Domestic Policy Council, the White House Counsel's Office, and the Office of Information and Regulatory Affairs. The drafting was generally divided so that the department or component with lead jurisdiction and most expertise was the primary section author.

¹ Request for information—promoting healthcare choice and competition across the United States. December 26, 2017. <https://aspe.hhs.gov/pdf-report/competition-rfi>. Accessed April 11, 2018.

Introduction

The United States healthcare system increasingly imposes a bewildering array of complexity and inefficiency on consumers, employers, workers and taxpayers while powerful institutions that benefit from the status quo resist efforts at reform. Moreover, our nation's healthcare system is encumbered with mandates and regulations that raise costs, decrease competition, and sometimes do little on net to improve the nation's health. These inefficiencies, mandates and regulations contribute to higher costs and higher health insurance premiums. Health insurance premiums, particularly for individual coverage (the markets most affected by the Affordable Care Act, or ACA) have soared—more than doubling in the individual market between 2013 and 2017²—while out-of-pocket spending has also skyrocketed.³ Even though the ACA was supposed to hold down healthcare costs, premiums in the individual market rose after 2013 when the ACA's insurance rules took effect. The average monthly premiums for all plans rose: For the benchmark plan—the second-lowest cost silver plan—premiums increased by 88 percent between 2014 and 2018 in states with the federally run healthcare exchange (Healthcare.gov).⁴ Spending by employers for employer-sponsored health benefits is also rising. The average premium for family coverage has increased 20 percent since 2013 and 55 percent since 2008.⁵ While private spending is increasing, so, too, is government spending. Spending on government health programs now accounts for nearly half of all U.S. healthcare expenditures, increasing the burden on taxpayers.⁶ Part of this increase in government spending is driven by an aging population, as the baby boomer generation shifts from private coverage to Medicare. Given the magnitude of this spending, it should not be surprising that there are growing concerns about whether the spending is producing benefits that justify the cost.

In addition to increased spending, the federal regulation of healthcare has risen sharply. Unfortunately, government bureaucracies are often slow to change and adapt to health-care innovations and new payment models. Given government's large role in the healthcare sector, this likely contributes to lower productivity in the sector. For example, the Office of the Actuary at the Centers for Medicare and Medicaid Services (CMS) found that

² Assistant Secretary for Planning and Evaluation. Individual market premium changes: 2013-2017. May 23, 2017. <https://aspe.hhs.gov/system/files/pdf/256751/IndividualMarketPremiumChanges.pdf>. Accessed August 21, 2018.

³ Sawyer B, Cox C, Claxton G. An analysis of who is most at risk for high out-of-pocket health spending. Kaiser Family Foundation. Washington DC. October 4, 2017. <https://www.healthsystemtracker.org/brief/who-is-most-at-risk-for-high-out-of-pocket-health-spending/>. Accessed September 27, 2018

⁴ Table 3. ASPE Research Brief. Health plan choice and premiums in the 2018 Federal Health Insurance Exchange. October 30, 2017. https://aspe.hhs.gov/system/files/pdf/258456/Landscape_Master2018_1.pdf. Accessed September 20, 2018.

⁵ Kaiser Family Foundation. 2018 Employer Health Benefits Survey, Summary of Findings. <https://www.kff.org/report-section/2018-employer-health-benefits-survey-summary-of-findings/>

⁶ Centers for Medicare & Medicaid Services. National Health Expenditure Data-2016. . <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/highlights.pdf>. Accessed August 21, 2018.

multifactor productivity—the output from joined units of capital and labor—in hospitals had a 0.1 to 0.6 percent 10-year moving average productivity growth rate from 1990 to 2013, compared to 1 percent in private nonfarm businesses.⁷ Slower-than-average productivity growth suggests that there is a misallocation of resources and widespread inefficiency in the healthcare system, particularly in public programs.⁸ Since the government share of healthcare spending is so large, government rules impose inefficiencies on private firms dependent on public funding, even if they also serve privately funded patients. Simply put, government has played a large role in limiting the value Americans obtain for their healthcare spending. The United States is spending a large and increasing share of its national income on healthcare, and much of this spending does not lead to citizens living longer, healthier lives.

One of the most important mechanisms available to enhance the value Americans receive for their healthcare spending is increased competition. Market competition should encourage healthcare providers to charge lower prices and provide higher-quality services. Although the traditional view among economists is that government should step in to correct so-called market failures, this report finds many cases where government regulation and rules prevent healthcare markets from working efficiently. This report examines many sectors of the U.S. healthcare market to assess the degree to which competition for healthcare services exists and the role government regulation plays in affecting competition for healthcare services. In doing so, the report identifies numerous government policies that inhibit choice and competition in healthcare markets, dampen productivity gains among providers, lead to increased consolidation and market concentration, and prevent the introduction of more efficient or innovative ways of delivering and paying for care.

A highly-effective and well-functioning healthcare market is important for two reasons. First, the state of health and well-being Americans enjoy contributes in economic and non-economic ways to the quality of American life. Second, the significant resources Americans spend on healthcare crowd out resources that would otherwise be available for other individual and national priorities. The United States spends nearly one-fifth of its national income on healthcare,⁹ and much of this spending provides little, if any, positive value. For example, the 2018 Economic Report to the President, prepared by the Council of Economic Advisers, reviewed several studies that showed a poor relationship between government coverage expansions and health improvements.

⁷ Centers for Medicare & Medicaid Services. <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/Downloads/ProductivityMemo2016.pdf>. Accessed August 21, 2018.

⁸ *Best Care at Lower Cost: The Path to Continuously Learning Health Care in America*. Institute of Medicine. September 6, 2012. <http://www.nationalacademies.org/hmd/Reports/2012/Best-Care-at-Lower-Cost-The-Path-to-Continuously-Learning-Health-Care-in-America.aspx>. Accessed August 21, 2018.

⁹ Haislmaier E, Senger A. The 2017 health insurance exchanges: major decrease in competition and choice. The Heritage Foundation. January 30, 2017. <https://www.heritage.org/health-care-reform/report/the-2017-health-insurance-exchanges-major-decrease-competition-and-choice>. Accessed April 11, 2018.

When it comes to healthcare, Americans should expect more value for the dollars they spend. This report details many opportunities to increase the value provided throughout our healthcare system through the actions that create greater choice and competition.

Section 1:

The Importance of Choice and Competition in Healthcare Markets

Economists generally accept that free-market competition produces the most efficient production and distribution of goods and services. When consumers have choices, the incentives and information needed to optimize value, firms have the incentive to improve quality and lower costs through innovation. Competitive market forces and the incentive to innovate typically raise quality and drive down prices, including quality-adjusted prices, for goods and services over time (features observed in many well-functioning sectors of the economy but which are generally absent in the highly regulated healthcare market).¹⁰ However, when government policies and regulations suppress competition, producers may use their market power to raise prices, produce lower-quality goods and services, or become complacent in innovating. In other words, without competitive pressure, the incentive to lower prices, improve quality, and innovate diminishes. As the government share of healthcare spending has increased over time, the healthcare market has become increasingly vulnerable to rules and regulations that impede market forces.

The importance of market competition is apparent in the relevant data. Hospitals without local competitors typically charge higher prices, which could add thousands of dollars to a hospital bill.¹¹ Since healthcare expenses largely drive insurance premiums, these costs are mostly passed on to consumers or taxpayers. The lack of insurer competition also leads to higher prices: Researchers have estimated that adding a single insurer offering to health exchange plans in 2014 reduced premiums by 4.5 percent on average.¹² A recent paper in *Health Affairs* estimated that exchange plan premiums were 50 percent higher, on average, in rating areas with only one insurer compared to those with more than two insurers.¹³ The lack of competition produces similar affects within the employer market for health insurance. A paper in the *American Economic Review* estimated that premiums in average markets were approximately 7 percentage points higher by 2007 due to increases in local

¹⁰ Perry MJ. Chart of the day (century?): price changes 1997 to 2017. American Enterprise Institute. February 2, 2018. <http://www.aei.org/publication/chart-of-the-day-century-price-changes-1997-to-2017/>. Accessed August 21, 2018.

¹¹ Cooper Z, Craig S, Gaynor M, Van Reenen J. The price ain't right? Hospital prices and health spending on the privately insured. National Bureau of Economic Research 21815. May 2018. This study estimates that the average prices at hospitals without local competitors are 12.5 percent higher than prices at hospitals with four or more competitors. For example, a 12.5 percent cost increase on an average admission would amount to almost \$1,800.

¹² Dafny L, Gruber J, Ody C. More insurers lower premiums: evidence from initial pricing in the health insurance marketplaces. *Am J Health Econ*. 2015; 1(1):53-81.

¹³ Van Parys J. ACA marketplace premiums grew more rapidly in areas with monopoly insurers than in areas with more competition. *Health Aff*. 2018 Aug; 37(8):1243-1251. <https://www.healthaffairs.org/doi/abs/10.1377/hlthaff.2018.0054>. Accessed September 20, 2018.

concentration of health insurers from 1998 through 2006.¹⁴ One example is that, according to one study, the merger between Aetna and Prudential in 1999 led to a 7 percent increase in premiums for large employers.¹⁵ Similarly, according to another study, the merger of Sierra and United Health in 2008 led to an almost 14 percent increase in small group premiums.¹⁶

Perhaps more importantly, there is evidence that the lack of competition in provider markets leads to reduced quality of care.¹⁷ For example, a 2000 study of more than 500,000 Medicare beneficiaries found that those who experienced a heart attack had a statistically significant (1.5 percentage point) higher chance of dying within one year of treatment if they received care in a hospital with fewer potential competitors.¹⁸ To drive that point home, Americans have 790,000 heart attacks each year.¹⁹ Assuming that half the country lives in relatively noncompetitive hospital markets, we would expect from these findings that 5,925 premature deaths to be associated with a lack of competition. Of course, this calculation is just for heart attacks, just one of numerous diseases or conditions that kill Americans prematurely each year.

Other findings demonstrate the relationship between competitive healthcare markets and improved outcomes, increased quality, and lower prices. For example, the inflation-adjusted price of LASIK eye surgery declined by 25 percent between 1999 and 2011, even as quality markedly improved.²⁰ Notably, third-party payers (including the government) generally do not cover the procedure and so ophthalmologists have had to compete directly for consumer dollars.²¹ Similarly, though the price of healthcare grew at double the rate of inflation between 1992 and 2012, the price of cosmetic surgery—for which consumers pay

¹⁴ Dafny L, Duggan M, Ramanarayanan S. Paying a premium on your premium? Consolidation in the US health insurance industry. *Am Econ Rev*. 2012;102(2):1161-1185.

¹⁵ *Id.*

¹⁶ Guardado JR, Emmons DW, Kane CK. The price effects of a large merger of health insurers: a case study of UnitedHealth-Sierra. *Health Management, Policy and Innovation*. 2013;1(3):16-35.

¹⁷ For surveys of the research literature linking market-based competition among healthcare providers to positive results for consumers, such as reduced prices and improved quality of care, see, e.g., Gaynor M, Town R. The impact of hospital consolidation—update. Robert Wood Johnson Foundation. The Synthesis Project. Policy Brief. No. 9. June 2012. http://www.rwjf.org/content/dam/farm/reports/issue_briefs/2012/rwjf73261. Accessed August 21, 2018; Gaynor M, Ho K, Town R. The industrial organization of health-care markets. 53 *J Econ Lit*. 2015;53(2):235. https://www.researchgate.net/publication/278676719_The_Industrial_Organization_of_Health-Care_Markets. Accessed August 21, 2018.

¹⁸ Kessler DP, McClellan MB. Is hospital competition socially wasteful? *Q J Econ*. 2000;115(2): 577-615.

¹⁹ Benjamin EJ, Blaha MJ, Chiuve SE, et al.; on behalf of the American Heart Association Statistics Committee and Stroke Statistics Subcommittee. Heart disease and stroke statistics—2017 update: a report from the American Heart Association [published online ahead of print January 25, 2017]. doi: 10.1161/CIR.0000000000000485. https://healthmetrics.heart.org/wp-content/uploads/2017/06/Heart-Disease-and-Stroke-Statistics-2017-ucm_491265.pdf. Accessed August 21, 2018.

²⁰ Herrick DM. The Market for Medical Care Should Work Like Cosmetic Surgery. National Center for Policy Analysis Policy report No. 349. Dallas, TX. May 2013. <https://www.healthworkcollective.com/wp-content/uploads/2013/06/st349.pdf>. Accessed September 28, 2018

²¹ *Id.*

almost exclusively out of pocket—grew at less than half the rate of inflation.²² These examples also highlight that when consumers are spending their own dollars and shopping accordingly, providers have greater incentives to improve quality and cut costs.

Unfortunately, a lack of consumer choice permeates most health insurance markets as well. Most Americans receive insurance selected by their employer or receive coverage through government programs, characterized by exceptionally heavy regulation and bureaucratic controls. Because of the ACA, insurance companies were not allowed to offer certain low-cost plans and withdrew from some markets. Although some people who were previously uninsured are covered, many with subsidies, Americans without employer or publicly-supported coverage often face limited choices in the individual market.²³ Starting in 2014, new individual market plans had to satisfy ACA requirements. In 2017, people in one-third of U.S. counties could purchase health insurance only through the ACA exchanges from a single insurer.²⁴ As additional insurers have withdrawn from government-designed and regulated markets, people in more than half of U. S. counties (representing 29 percent of exchange enrollees) have options from only a single insurer in 2018.²⁵

Governments and Market Failure in Healthcare

It is a common refrain that healthcare is “unique,” and in some ways, it is. But “unique” is frequently used to imply that free-market principles that govern other major sectors of the economy cannot be applied to healthcare. The reasons given for the uniqueness of healthcare vary, but some of the most common are: the difficulties involved in shopping for services, the expertise gap between patients and healthcare professionals (asymmetric information), economies of scale intrinsic to the sector, and the predominant reliance on third-party payers. The merit of these commonly cited reasons for why healthcare is unique is considered below.

Notably, government policies promote some of these features, particularly third-party payment. While some of these features do limit the application of free-market principles, the common claim that the healthcare sector as a whole cannot function under free-market

²² Benjamin EJ, Blaha MJ, Chiuve SE, et al., on behalf of the American Heart Association Statistics Committee and Stroke Statistics Subcommittee. Heart disease and stroke statistics—2017 update: a report from the American Heart Association [published online ahead of print January 25, 2017]. doi: 10.1161/CIR.0000000000000485. P. 5. https://healthmetrics.heart.org/wp-content/uploads/2017/06/Heart-Disease-and-Stroke-Statistics-2017-ucm_491265.pdf. Accessed August 21, 2018.

²³ Haislmaier E. The 2017 health Insurance exchanges: major decrease in competition and choice. The Heritage Foundation. <https://www.heritage.org/health-care-reform/report/the-2017-health-insurance-exchanges-major-decrease-competition-and-choice>. Accessed April 11, 2018.

²⁴ Mendelson D. Experts predict sharp decline in competition across the ACA exchanges. Avalere. August 19, 2016. <http://avalere.com/expertise/life-sciences/insights/experts-predict-sharp-decline-in-competition-across-the-aca-exchanges>. Accessed August 21, 2018.

²⁵ County by county analysis of plan year 2018 insurer participation in health insurance exchanges. <https://www.cms.gov/CCIIO/Programs-and-Initiatives/Health-Insurance-Marketplaces/Downloads/2017-10-20-Issuer-County-Map.pdf>. Accessed August 21, 2018.

principles is not true. Notably, government policies promote many factors that prevent the free-market from operating. Specifically, government has encouraged excessive third-party payment, created counterproductive barriers to entry, incentivized opaque pricing practices, skewed innovation activity, and placed restrictions on the reimbursement policies of government programs. Overall, these practices have resulted in less choice, less competition, and sub-optimally functioning markets that deliver higher prices and lower quality.

Healthcare Emergencies

Some healthcare expenditures are for emergency services that are not conducive to consumer shopping. That said, the common claim that the healthcare sector as a whole cannot function under free-market principles is untrue. The vast majority of healthcare services are routine or elective services that can be organized by markets to enhance patient welfare. One study found that emergency department spending is roughly six percent of total United States health spending.²⁶ Another study classified 43 percent of healthcare spending as “shoppable,” with another 11 percent of spending on prescription drugs, an item that is generally shoppable.²⁷ Distinguishing between shoppable and non-shoppable healthcare services is important, and encouraging normal market economic forces to govern the shoppable transactions constituting the majority of the sector is prudent. As this report explains, government policy and regulation often does precisely the opposite, actively discouraging the application of normal market forces to the shoppable category of healthcare services, and, in effect, treating the whole sector as if it were similar to emergency services.

Asymmetric Information

Another common argument contends that the gap in expertise between the sellers of healthcare services (i.e., healthcare providers) and buyers (i.e., patients) makes the idea of informed consumer choices implausible. While true to some extent, the same could be said about other markets that operate successfully under free-market principles, as anyone who has taken a car to an auto-mechanic or employed a financial adviser can attest. Indeed, the implication that healthcare providers will take advantage of patients by selling them services they do not understand or need suspects the worst of professions (such as medicine and nursing) that adopt strict ethical standards. Even if there were agreement that this risk is justified, there are other ways to solve this problem without abandoning free-market principles. For instance, in many markets where there is a gap in expertise between buyers and sellers, the less knowledgeable party will employ an unbiased consultant to help them

²⁶ Lee MH, Schuur JD, Zink BK. Owning the cost of emergency medicine: beyond 2%. *Ann Emerg Med*. 2013;62(5):498-505.

²⁷ Spending on shoppable services in healthcare. Healthcare Cost Institute. Issue Brief No. 11. March 2016. https://www.healthcostinstitute.org/images/easyblog_articles/110/Shoppable-Services-IB-3.2.16_0.pdf. Accessed August 21, 2018.

make good decisions. In addition, third-party entities, like consumer watchdog groups, can produce reviews of actors within the healthcare system. The lack of transparent, reliable price and quality information currently inhibits such reviews.

Economies of Scale

Another reason given by some against market-based healthcare is that there are inherent economies of scale within healthcare that lead to natural monopolies and limit the extent to which markets can properly function. For example, there might be high fixed costs in building and equipping a healthcare facility. Once the facility is built, the marginal cost of extra services declines. This is why, the argument goes, it may make economic sense to have only a single hospital or nursing home in lightly-populated rural areas, and why certain healthcare mergers can increase economic efficiency by lowering production costs.²⁸ These natural economies of scale contribute to the creation of entities with significant pricing power. One can make a similar argument with regard to disease burdens, wherein smaller communities are only likely to have a need for so many specialists of a certain type given a population size and disease incidence rate. This leads to an economic incentive for specialists to form a practice together and take advantage of their pricing power. Furthermore, it is possible that a relatively small market cannot support the entrance of a competitor that would drive down prices since demand for the relevant type of specialist is roughly fixed among the population, meaning that the addition of another provider would merely drive prices to a point where neither entity were profitable and one ultimately would exit.

While these claims have some merit, most people live in areas with markets large enough to sustain multiple hospitals, nursing homes, or other providers. More importantly, economies of scale are inherent in many markets, yet the markets function well for consumers. Overall, there is little reason to think that these issues are so intrinsic to healthcare markets that they undermine a market-based approach. Indeed, with vigorous law enforcement to prevent unlawful consolidation and anti-competitive behavior, there is good reason to think that healthcare markets will function like most other competitive markets.

As this report will discuss, the government has actually adopted many policies that promote consolidation in the healthcare sector, favoring established incumbents at the expense of smaller providers and start-ups. Additionally, the ability to create regional monopolies in healthcare markets is largely dependent on geographic factors, which recent innovations such as telehealth could substantially disrupt. Rather than adopt policies that allow disruptive technology like telehealth to compete, the government has often intervened to

²⁸ While a theoretical possibility, the empirical evidence for such economies of scale is weak. A recent health economics paper looking at the impact of hospital mergers on costs summarized the extant literature, stating, "On balance, the evidence thus far fails to support strong claims of systematic cost savings from mergers; while these articles typically find cost savings for at least some subset of studied mergers, overall the evidence is mixed." Schmitt M. Do hospital mergers reduce costs? *J Health Econ.* 2017;52:75.

create an uneven playing field that limits choice and competition to the benefit of established incumbents and at the expense of consumers. While there are economies of scale in healthcare markets, they are hardly unique and do not prevent the market as a whole from functioning well. What is unique is the extent to which the government has adopted policies that exacerbate these issues.

Third-Party Payment

Why do healthcare markets not function like other economic markets with price transparency, clear quality metrics, shopping, and declining real, quality-adjusted prices through time? The answer is primarily because government policies have combined to produce an excessive reliance on third-party payment mechanisms and numerous barriers to entry.

Third-party payment mechanisms insulate the ultimate consumer from the direct payment for healthcare goods and services. Instead of paying for healthcare services directly, consumers rely on an intermediary to do so on their behalf. Some degree of third-party payment in healthcare is understandable and necessary since there are low-probability, hard-to-predict, and costly health events that would otherwise subject an individual or family to a large financial loss. While insurance, along with saving and financing, is an efficient mechanism to reduce the impact of unlikely and high-cost events, insurance that covers routine, predictable, or shoppable services has significant drawbacks. First, an insurance system is often administratively complex to implement and accordingly can have high administrative costs. Second, consumers are incented to extract as much value out of an insurance policy as possible (since the premium is in effect a fixed fee), which in turn creates a coverage-induced demand for low-value products and services, and generates greater administrative costs as insurers validate claims. For these reasons, firms offer, and insurance consumers in most other markets select, policies that provide protection against improbable but high-cost events. Because routine, predictable, or shoppable services are not covered by a third party in other insurance markets, consumers have significant incentive to maximize the value they receive from these uncovered, routine services.

Auto insurance is a good example. Auto insurance typically covers a car crash and related healthcare expenses, but it does not cover gasoline or routine maintenance. Imagine if auto insurance did provide coverage for gasoline and routine maintenance. First, consumers would shop for their gas less carefully (since the insurance pool would bear the marginal cost of premium gasoline versus standard gasoline), and they would consume more maintenance. Second, in response to rising utilization and corresponding premium increases, auto insurance companies might establish preferred networks of gasoline and maintenance providers to better incentivize consumer behavior and control cost. In the long term, complex bureaucratic management schemes might emerge to tackle resource allocation with large national networks coming to dominate the market. While one could keep going with this thought experiment, the example highlights that as insurance covers

more of an individual's routine expenses, consumers experience diminished incentives to obtain value.

Federal policy has a long history of subsidizing highly-comprehensive health insurance.²⁹ In the 1940s and 1950s, the exclusion of employer-provided health insurance premiums from income and payroll taxes created incentives for employers to offer comprehensive insurance coverage to compete for workers. Notably, this incentivized employers to compensate employees with health insurance rather than wage increases or other benefits that lacked a comparably generous tax exemption. The creation of Medicare and Medicaid in 1965 led to additional government subsidization of comprehensive coverage. Most recently, the ACA mandated that individuals have comprehensive coverage or pay a tax penalty. (This penalty has been reduced to \$0 as of 2019 because of the Tax Cuts and Jobs Act of 2017.) Similarly, employers with 50 or more full-time workers who do not offer comprehensive coverage pay a tax penalty if at least one of their employees receives a premium tax credit for an exchange plan. The ACA also created additional federal subsidies for comprehensive coverage through Medicaid expansion and premium tax credits and cost-sharing reduction payments for exchange plans.

Because of open-ended tax subsidies for employer-provided health insurance, health insurance in the United States generally covers routine, predictable and shoppable services in addition to low-probability events. Federal laws, including the ACA, and state laws governing health insurance policies also require coverage for specific health benefits, often with low or no copayments. The Medicaid program, with nominal or zero copays and deductibles, exemplifies this problem. As a result, consumers typically do not have an incentive to shop for value, eliminating one mechanism that could help constrain provider prices. This set of policy choices has created a market for healthcare goods and services that is inherently inflationary.

As healthcare costs increase, insurers should feel market pressure to aggressively manage these costs on behalf of their customers. In competitive insurance markets, insurers feel the pressure of market forces to lower healthcare costs and premiums. However, some have claimed that insurers benefit from rising provider costs.³⁰ One recent article discussed that insurers may lack adequate incentives to bring down provider charges, partly because higher provider prices translate into higher insurer profits.³¹ This may be particularly problematic in markets without vigorous competition among payers. Regardless of the motivation, one might ascribe to insurer actions, healthcare costs have consistently increased faster than wages and the overall economy.

²⁹ In World War II, employers offered health insurance as a way to get around wage controls. The IRS then decided that those health insurance benefits would not be taxed as income, and Congress codified the practice in 1954.

³⁰ Goldhill D. *Catastrophic Care: Why Everything We Think We Know about Health Care is Wrong*. New York: Vintage Books; 2013

³¹ Allen M. Why your health insurer doesn't care about your big bills. NPR. May 25, 2018. <https://www.npr.org/sections/health-shots/2018/05/25/613685732/why-your-health-insurer-doesnt-care-about-your-big-bills>. Accessed September 20, 2018.

Third-party payment also creates notable separation between producers and consumers, and leaves bureaucracies with the role of allocating resources. Bureaucracies are extremely susceptible to pressure from special interest groups, which lobby lawmakers to require coverage for the products they produce or services they provide. While a boon to special interests, mandated benefits cause a greater amount of healthcare services to be financed through third-party arrangements, raising premiums and taxes. The increased premiums, in turn, may incentivize some people to obtain more treatment and services so as to maximize the value received for the premium paid. This behavior drives up utilization and increases low-value spending. Moreover, excessive third-party payment results in providers serving the interest of payers—government bureaucracies and insurance companies—rather than consumers.

In conclusion, in most other markets, consumers pay the full price of what they purchase and are therefore likely to carefully consider the value of products relative to alternatives. Active shopping by consumers motivates competition on price and quality among producers. Third-party payment for routine, predictable and shoppable expenses reduces consumers' incentives to obtain maximum value and has contributed to opaque and byzantine prices and bureaucratic complexities. As a result, consumers have less ability and less incentive to carefully shop for healthcare, compare prices and quality, and select the most efficient providers. This, in turn, means that providers have a diminished incentive to innovate and increase their efficiency.

Barriers to Entry

Under normal market conditions, high prices and/or high profit margins attract new producers and sellers. This increased supply leads to lower prices and higher quality over time. Without the possibility of new entrants and real competition, however, existing producers can use market power to keep prices high and quality low.

While barriers to entry can be the result of normal market forces, such as economies of scale, they may also be the result of government restrictions. Government-erected barriers to entry can lead to a highly-concentrated and inefficient market. Moreover, firms protected from competitive forces can be expected to devote resources to maintaining these rents (e.g., by erecting or maintaining entry barriers) rather than to improving efficiency and innovating.³² Some government-erected barriers, such as patents, are enacted to support a careful balance that promotes innovation and consumer options. However, many government-erected barriers harm consumers by blocking or restricting market entry.³³

³² Tullock G. The welfare costs of tariffs, monopolies, and theft. *West Econ J.* 1967;5(3):224–232; Murphy KM, Shleifer A, Vishny RW. Why is rent-seeking so costly to growth? *Am Econ Rev.* 1993;83(2):409–414.

³³ See, for instance, the *Statement of the Federal Trade Commission in the Matter of Phoebe Putney Health Services, Inc., et al.*, Dkt. No. 9348 (Sept. 4, 2014), discussing entry restrictions imposed by Georgia's Certificate of Need

These harmful barriers, such as state laws requiring potential new entrants to gain governmental permission (and, occasionally, permission from established incumbents) to enter markets, or preventing healthcare professionals from practicing to their full ability, are of primary interest in this report.

Over the past few decades, there has been a substantial increase in mergers and acquisitions throughout the healthcare sector, particularly among healthcare providers. More recently, industry consolidation (fewer and larger firms in the market) and industry concentration (the extent to which a small number of firms control most of the transactions) has occurred, in part, due to the increased complexity and administrative burden resulting from the ACA³⁴ and other government requirements. As will be discussed in Section 2 of this report, significant evidence shows that reduced competition in healthcare markets contributes to higher prices and reduced quality.

Need for Better Health Policies

Perhaps the best evidence for why the healthcare system needs reform and that the ACA moved the system in the wrong direction was outlined in the President's 2018 Economic Report.³⁵ This report (at pages 283-285) details the literature showing that our previous focus on expanding health insurance coverage has had mixed and surprisingly small effects on health outcomes. Probably the best investigation—the oft-cited Oregon Medicaid study—found that low-income, uninsured individuals randomly selected to enroll in Medicaid did not experience statistically significant improvement in any of the physical measures of health observed—cholesterol, blood pressure, and blood sugar—although there were some benefits for mental health.³⁶

A subsequent Oregon Medicaid expansion study estimated that Medicaid enrollees only valued each dollar of program spending at between 20 to 40 cents, and that 60 percent of expansion costs were transfers to providers who would have otherwise provided

(CON) law: “Moreover, this case also illustrates how state CON laws, despite their original and laudable goal of reducing healthcare facility costs, often act as a barrier to entry to the detriment of competition and healthcare consumers.” Available online at

https://www.ftc.gov/system/files/documents/public_statements/634181/150331phoebeputneycommstmt.pdf. Accessed August 21, 2018.

³⁴ Pope C. How the ACA fuels healthcare market consolidation. The Heritage Foundation. August 1, 2014. <https://www.heritage.org/health-care-reform/report/how-the-affordable-care-act-fuels-health-care-market-consolidation>. Accessed August 21, 2018.

³⁵ Council of Economic Advisers. 2018 Economic Report of the President. Washington DC. February 2018. https://www.whitehouse.gov/wp-content/uploads/2018/02/ERP_2018_Final-FINAL.pdf. Accessed September 28, 2018.

³⁶ Baiker K, Taubman SL, Allen HL, Bernstein M, Gruber JH, Newhouse JP, et al. The Oregon experiment —effects of Medicaid on clinical outcomes. *N Engl J Med*. 2013 May 2; 368:1713-1722. <https://www.nejm.org/doi/full/10.1056/NEJMsa1212321>. Accessed September 20, 2018.

uncompensated care to these patients.³⁷ A separate study of how many enrollees dropped out when charged higher premiums for Medicaid-like coverage in Massachusetts found that most enrollees valued coverage at less than half the cost. The availability of uncompensated care was the central reason that enrollees place low value on the coverage – substantially less than the cost of providing that coverage.³⁸

Notably, despite the ACA expanding coverage options to the uninsured, largely through Medicaid, American life expectancy dropped three-tenths of a year from 2014 to 2017—in part due to rising opioid abuse—something that has not happened since the 1960s.³⁹ The Economic Report of the President outlined several explanations for why insurance, particularly expansions of public programs like the ACA's Medicaid expansion, have limited health benefits and in many locations contribute to access problems. Some Medicaid recipients have difficulty finding providers to provide care.⁴⁰ Moreover, as Atul Gawande, former adviser to President Bill Clinton, has discussed, some medical care can actually decrease health because there are separate health risks associated with the receipt of medical care, including over-testing and resulting issues like stress, radiation exposure and over-treatment (e.g. medically unnecessary surgeries), that need to be counted.⁴¹

This report discusses government-induced barriers to competition and choice and makes recommendations that would reduce or eliminate these barriers. These reforms are critical to unleashing competitive forces to improve consumer choices and spur provider and payer innovation to deliver high-value products and services to consumers. Without enacting a bold set of reforms that increase choice and competition in healthcare, government-created inefficiencies will continue to dominate the U.S. healthcare system, particularly publicly-financed care, frustrating Americans as the rising cost of healthcare squeezes family and government budgets. Reform will involve taking on entrenched special interests that maintain their advantage over consumers by lobbying government to restrain competitive forces.

In particular, this report aims to address these issues as crystalized in the following problem statement: Many government laws, regulations, guidance, requirements and policies, at both the federal and state level, have reduced incentives for price- and non-price competition, increased barriers to entry, promoted and allowed excessive consolidation,

³⁷ Finkelstein A, Hendren N, Luttmer EFP. The value of Medicaid: Interpreting results from the Oregon health insurance experiment. NBER Working Paper No. 21308. Cambridge, MA. June 2015. <http://www.nber.org/papers/w21308>. Accessed September 27, 2018.

³⁸ Finkelstein A, Mahoney N, Notowidigdo MJ. What does (formal) health insurance do, and for whom? *Annu Rev Econom.* 2018;10:261-286

³⁹ Murphy S, Xu J, Kochanek K, Arias E. Mortality in the United States, 2017. National Center for Health Statistics. November, 2018. <https://www.cdc.gov/nchs/products/databriefs/db328.htm>. Accessed November 30, 2018.

⁴⁰ Dayaratna K. Studies Show: Medicaid Patients Have Worse Access and Outcomes than the Privately Insured. The Heritage Foundation. November 7, 2012. <https://www.heritage.org/health-care-reform/report/studies-show-medicaid-patients-have-worse-access-and-outcomes-the>. Accessed September 20, 2018.

⁴¹ Gawande A. Overkill. *The New Yorker*. May 11, 2015. <https://www.newyorker.com/magazine/2015/05/11/overkill-atul-gawande>. Accessed September 20, 2018.

and resulted in healthcare markets that lack the benefits of vigorous competition. Increasing competition and innovation in the healthcare sector will reduce costs and increase quality of care—improving the lives of Americans.

The remaining three sections of this report are devoted to analyzing these important issues with a focus on changing government regulations to improve health-market outcomes through enhancing choice and competition. Section 2 provides detailed analysis of trends in consolidation and concentration in certain healthcare markets. Section 3 provides analysis of several specific areas of federal and state policies associated with increased consolidation or reduced competition. Section 4 presents recent and emerging policy alternatives that can address these issues by facilitating more efficient allocation of healthcare dollars. The final section offers specific policy recommendations based on these analyses.

Section 2:

Trends in Healthcare Market Consolidation

Assessing the Competitiveness of Healthcare Markets

Healthcare markets, like all other markets, benefit from vigorous competition. Recent trends, however, point to a level of consolidation that is changing the competitive landscape for the worse. Although the relationship between market concentration and competitive conditions is not always clear (particularly when markets are not, or cannot be, defined carefully), rising levels of concentration may provide a basis for concern that some markets are becoming less competitive. This section reviews recent evidence about hospital and physician consolidation, the impact of such consolidation on the competitiveness of local markets, and the degree to which government regulations have contributed to consolidation.

While it may be appealing to analyze trends in common measures of market concentration to investigate how the competitiveness of markets has changed over time, economists and antitrust experts recognize that such analysis can be misleading.⁴² For one thing, trends in concentration can be caused by underlying market forces that may or may not be related to the competitiveness of markets.⁴³ In addition, computing these trends in overly broad areas that include providers that do not compete for the same patients can skew results.⁴⁴ This is why national trends in concentration for services that are usually procured on a local level (such as healthcare) may not be particularly meaningful. Only determining the set of competing suppliers in a particular local area enables calculation of concentration measures that reflect plausible levels of competition in economically relevant markets.

Of course, consolidation leading to concentration beyond a certain point harms consumers by reducing competition. That is why U.S. antitrust agencies have continued to pursue an active healthcare merger enforcement agenda. However, if a major hospital provides a

⁴² See Salinger M. The concentration-margins relationship reconsidered. Brookings Papers on Economic Activity. Microeconomics 1990; Ohlhausen MK. Does the United States economy lack competition? *Criterion J Innov.* 2016 Aug 20;1:47-63.

⁴³ For instance, suppose the population in a well-defined hospital market that had been served by two similarly sized independent hospitals was growing, and one of the hospitals expanded to better serve the area. This market would become more concentrated because the expanded hospital would have more than half the market, but this increased concentration would not necessarily represent lost competition. An insurer interested in adding a hospital to its network could still benefit from the competition between these two hospitals. The expansion of the hospital generally would not constitute an antitrust problem. Alternatively, suppose the population in this market was shrinking, causing one of the two hospitals to close. This would produce a more concentrated and less competitive market, but the closing of an under-utilized hospital would not necessarily raise antitrust concerns.

⁴⁴ For a fuller discussion, see Gaynor M, Vogt W, Antitrust and competition in healthcare markets. In Culyer A, Newhouse J, eds. *Handbook of Health Economics*. Amsterdam: Elsevier; 2000.

superior level of service and takes over less-skilled providers, the quality of care delivered to patients could rise. As discussed below, some specific instances of recent consolidation have produced less competitive markets.

Trends in Merger Activity

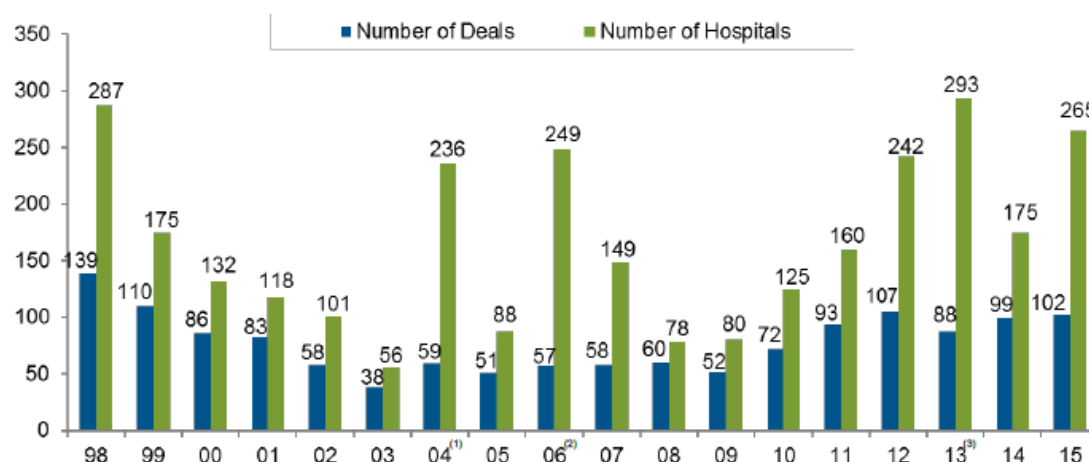
According to a recent analysis of metropolitan areas that are considered single markets, roughly 77 percent of Americans in these urban markets live in highly concentrated hospital markets.⁴⁵ Over the past several decades, many hospitals have consolidated into multi-hospital systems.⁴⁶ According to data compiled by Irving Levin Associates, depicted by the American Hospital Association in Figure 1, the number of announced hospital transactions (including mergers and acquisitions) per year fell from 139 in 1998 to 38 in 2003, before starting to increase in 2010 and reaching 102 in 2015.⁴⁷ In 2010 alone, the number of mergers jumped 40 percent to 59, with more than 60 deals in each subsequent year. The number of hospitals involved in those deals has shown more variation from year to year, although data from recent years show a rise in mergers and acquisition.

⁴⁵ Mathews AW. Behind your rising health-care bills: secret hospital deals that squelch competition. *Wall Street Journal*. September 18, 2018. <https://www.wsj.com/articles/behind-your-rising-health-care-bills-secret-hospital-deals-that-squelch-competition-1537281963>. Accessed September 20, 2018.

⁴⁶ Haas-Wilson D. *Managed Care and Monopoly Power: The Antitrust Challenge*. Cambridge: Harvard University Press; 2003; Dranove D, Lindrooth R. Hospital consolidation and costs: another look at the evidence. *J Health Econ*. 2003 Nov;22(6):983-997; Cuellar AW, Gertler PJ. Trends in hospital consolidation: the formation of local systems, *Health Aff*. 2003 Nov/Dec;22(6):77-87; Vogt WB, Town R. How has hospital consolidation affected the price and quality of hospital care? *Synth Proj Res Synth Rep*. 2006 Feb;(9):pii. <https://www.ncbi.nlm.nih.gov/pubmed/22051574>. Accessed August 21, 2018.

⁴⁷ Chart 2.9: announced hospital mergers and acquisitions, 1998-2015. American Hospital Association. Trendwatch Chartbook 2016 Organizational Trends. 2016. <https://www.aha.org/system/files/research/reports/tw/chartbook/2016/chart2-9.pdf>. Accessed August 21, 2018.

Figure 1: Announced Hospital Mergers and Acquisitions, 1998-2015



Source: Irving Levin Associates, Inc. (2016). *The Health Care Services Acquisition Report*, Twenty-Second Edition.

⁽¹⁾ In 2004, the privatization of Select Medical Corp., an operator of long-term and acute-care hospitals, and divestiture of hospitals by Tenet Healthcare Corporation helped to increase the number of hospitals affected.

⁽²⁾ In 2006, the privatization of Hospital Corporation of America, Inc. affected 176 acute-care hospitals. The acquisition was the largest health care transaction ever announced.

⁽³⁾ In 2013, consolidation of several investor-owned systems resulted in a large number of hospitals involved in acquisition activity. Chart 2.10 in 2009 and earlier years' *Chartbooks*.

An acquisition that combines healthcare providers that were competing in some aspect of their business may substantially lessen competition and thereby violate Section 7 of the Clayton Act.⁴⁸ Because preservation of healthcare competition is vital to preserving consumer choice, price containment, and quality, federal antitrust authorities, specifically the Federal Trade Commission (FTC) and the Department of Justice, have for many years maintained vigorous enforcement programs to scrutinize healthcare mergers for their potential effects on competition. Antitrust enforcers seek to identify and challenge mergers likely to have anti-competitive effects.

Empirical evidence on the impact of mergers on competition in healthcare markets—based on studies by FTC staff and independent scholars—shows that healthcare consumers benefit from competitive markets and the associated lower prices and higher quality services.⁴⁹ Economic studies also consistently demonstrate that reducing hospital

⁴⁸ 15 U.S.C. § 18. Section 7 of the Clayton Act prohibits mergers if “in any line of commerce or in any activity affecting commerce in any section of the country, the effect of such acquisition may be substantially to lessen competition, or to tend to create a monopoly.”

⁴⁹ See, e.g., Gaynor M, Town R. The impact of hospital consolidation—update. Robert Wood Johnson Foundation, The Synthesis Project. Policy Brief No. 9. June 2012.

http://www.rwjf.org/content/dam/farm/reports/issue_briefs/2012/rwjf73261. Accessed August 21, 2018 (synthesizing research on the impact of hospital mergers on prices, cost, and quality and finding that hospital consolidation generally results in higher prices, hospital competition improves quality of care, and physician-hospital consolidation has not led to either improved quality or reduced costs); Gaynor M, Town RJ. Competition in healthcare markets. In *Handbook of Health Economics*. Vol 2, 1st ed. Waltham, MA: North Holland; 2012:499, 637 (2012). Gaynor M, Ho K, Town R. The industrial organization of health-care markets. 53 *J Econ Lit*. 2015;53(2):235, 294, (2015).

https://www.researchgate.net/publication/278676719_The_Industrial_Organization_of_Health-Care_Markets.

competition leads to higher prices for hospital care.⁵⁰ These effects are not limited to for-profit hospitals: mergers between not-for-profit hospitals can also result in substantial anti-competitive price increases.⁵¹ Economic evidence also shows that hospital competition tends to be highly localized.⁵²

The Impact of Lost Competition

FTC merger retrospective studies, supplemented by a large and growing body of literature, strongly suggest that healthcare providers with significant market power can (and often do) negotiate higher-than-competitive payment rates.⁵³ The price differences ultimately paid by consumers in concentrated markets can be significant.⁵⁴ For example, price increases as high as 40 percent have resulted when competition was lost after one hospital system acquired a competing hospital.⁵⁵

Federal antitrust agencies prevailed in some early challenges to anti-competitive hospital mergers⁵⁶ and obtained a number of consent decrees that allowed problematic hospital

Accessed August 21, 2018 (critical review of empirical and theoretical literature regarding markets in healthcare services and insurance).

⁵⁰ Gaynor M, Town R. The impact of hospital consolidation—update. Robert Wood Johnson Foundation, The Synthesis Project. Policy Brief No. 9. June 2012, at 1.

http://www.rwjf.org/content/dam/farm/reports/issue_briefs/2012/rwjf73261. Accessed August 21, 2018, Studies cited include Haas-Wilson D, Garmon C. *Hospital mergers and competitive effects: two retrospective analyses*. *Int J Econ Bus*. 2011;17, 30 (post-merger review of Agency methods applied to two hospital mergers; data “strongly suggests” that large price increases in challenged merger be attributed to increased market power and bargaining leverage); Dafny L. Estimation and identification of merger effects: an application to hospital mergers. *J Law Econ*. 2009;52(3):523, 544 (“[H]ospitals increase price by roughly 40 percent following the merger of nearby rivals”); Capps C, Dranove D. Hospital consolidation and negotiated PPO Prices. *Health Aff*. 2004 Mar-Apr;23:175, 179 (“Overall, our results do not support the argument that efficiencies from consolidations among competing hospitals lead to lower prices. Instead, they are broadly consistent with the opposing view that consolidations among competing hospitals lead to higher prices.”); see also, e.g., Farrell J, Pautler P, Vita M. Economics at the FTC: retrospective merger analysis with a focus on hospitals. *Ref Indus Org* 2009;35(4):369 (Mergers between not-for-profit hospitals can result in substantial anti-competitive price increases).

⁵¹ Farrell J, Pautler P, Vita M. Economics at the FTC: retrospective merger analysis with a focus on hospitals. *Ref Indus Org* 2009;35(4):382 (corroborating Michael G. Vita MG, Sacher S. The competitive effects of not-for-profit hospital mergers: a case study. *J Indus Econ*. 2001;49:63).

⁵² *Id.*

⁵³ See, e.g., Ginsburg PB. Wide variation in hospital and physician payment rates evidence of provider market Power. Center for Studying Health System Change, Research Brief No. 16. November 2010. <http://www.hschange.org/CONTENT/1162/>. Accessed August 21, 2018.

⁵⁴ Gaynor M. Competition policy in healthcare markets: navigating the enforcement and policy maze. *Health Aff*. 2014 Jun;33:1088.

⁵⁵ Tenn S. The price effects of hospital mergers: a case study of the Sutter-Summit Transaction. *Int J Econ Bus*. 2011;18:65-82.

⁵⁶ See, e.g., *In the Matter of Hospital Corp. of Am.*, 106 FTC 361 (1985), *aff'd*, 807 F.2d 1381 (7th Cir. 1986); *American Med. Int'l, Inc.*, 104 FTC 1 (1984), as modified by 104 FTC 617 (1984) and 107 FTC 310 (1986).

mergers to proceed only if certain hospitals were divested.⁵⁷ However, in the 1990s, several courts rejected the agencies' attempts to block hospital mergers (on the grounds that the government had not established geographic or products markets) that they claimed would harm competition.⁵⁸ This string of losses led the FTC to launch a Hospital Merger Retrospective Project to determine whether consummated hospital mergers led to higher prices. The FTC selected four consummated hospital mergers for intensive study and published retrospective studies in early 2011.⁵⁹ The study of one consummated merger in particular—the Evanston/Highland Park (Illinois) merger—led to an FTC administrative challenge determining that the acquisition had violated the antitrust laws.⁶⁰

The Hospital Merger Retrospective Project led to important insights about the nature of hospital competition and the competitive effects of hospital mergers that have continued to guide FTC case selection and enforcement decisions today.⁶¹ For instance, in 2011, the FTC challenged ProMedica Health System's acquisition of its rival, St. Luke's Hospital.⁶² The proposed merger would have given ProMedica, already the largest hospital system in the Toledo, Ohio, area, over half the market for general acute care hospital services and over 80 percent of the market for inpatient obstetrics services. Hospital documents indicated that St. Luke's management saw the acquisition leading to higher prices by increasing its "negotiating clout" over insurers. The FTC's order required ProMedica to

⁵⁷ *Columbia/HCA Health Care Corp./Healthtrust, Inc.—The Hosp. Co.*, 120 FTC 743 (1995) (consent order); *Healthtrust, Inc.—The Hosp. Co./Holy Cross Health Servs. of Utah*, 118 FTC. 959 (1994) (consent order); *Columbia Health Corp./HCA-Hosp. Corp. of Am.*, 118 FTC 8 (1994) (consent order).

⁵⁸ *FTC v. Tenet Health Care Corp.*, 186 F.3d 1045 (8th Cir. 1999); *FTC v. Freeman Hosp.*, 911 F. Supp. 1213 (W.D. Mo. June 9, 1995), *aff'd*, 69 F.3d 260 (8th Cir. 1995); *California v. Sutter Health Sys.*, 84 F. Supp.2d 1057 (N.D. Cal. 2000), *aff'd*, 217 F.3d 846 (9th Cir. 2000), amended by 130 F. Supp. 2d 1109 (N.D. Cal. 2001); *United States v. Long Island Jewish Med. Ctr.*, 983 F. Supp. 121, (E.D.N.Y. 1997); *FTC v. Butterworth Health Corp.*, 946 F. Supp. 1285 (W.D. Mich. 2006), *aff'd per curiam*, 121 F.3d 708 (6th Cir. 1997); *United States v. Mercy Health Servs. & Finley Tri-States Health Group, Inc.*, 902 F. Supp. 968 (N.D. Iowa 1995), vacated as moot, 107 F.3d 632 (8th Cir. 1997).

⁵⁹ See Romano PS, Balan DJ. A retrospective analysis of the clinical quality effects of the acquisition of Highland Park Hospital by Evanston Northwestern Health. *Int J Econ Bus.* 2011;18:45; Haas-Wilson D, Garmon C. Two hospital mergers on Chicago's North Shore: a retrospective study. *Int J Econ Bus.* 2011;18:17; Thompson A. Effect of hospital mergers on inpatient prices: a case study of the New Hanover-Cape Fear transaction. *Int J Econ Bus.* 2011;18:91; Tenn S. The price effects of hospital mergers: a case study of the Sutter-Summit transaction. *Int J Econ Bus.* 2011;18 :65. For an overview, see Ashenfelter O, Hosken D, Vita M, Weinberg M. Retrospective analysis of hospital mergers. *Int J Econ Bus.* 2011;18:5-16; Farrell J, Pautler PA, Vita MG. Economics at the FTC: retrospective merger analysis with a focus on hospitals. *Rev Indus Org.* 2009;35:375-383.

⁶⁰ *In the Matter of Evanston Northwestern Health Corp.*, FTC Dkt. No. 9315 (Opinion of the Commission, Aug. 6, 2007).

⁶¹ The agencies analyze hospital mergers using the same analytical framework they use for other mergers, following the 2010 Horizontal Merger Guidelines, which specify that "mergers should not be permitted to create, enhance, or entrench market power or to facilitate its exercise." U.S. Department of Justice and Federal Trade Commission. Horizontal Merger Guidelines. § 1. August 19, 2010. <http://www.ftc.gov/os/2010/08/100819hmg.pdf>. Accessed August 21, 2018.

⁶² *ProMedica Health System, Inc. v. FTC*, No. 12-3583 (6th Cir. Apr. 22, 2014).

undo its merger and re-establish St. Luke's as an independent competitor. The FTC has since successfully challenged other hospital mergers as well.⁶³

The FTC has also challenged mergers between competing physician practices. For example, the FTC and the State of Idaho successfully challenged the acquisition by St. Luke's Health System of Saltzer Medical Group in Nampa, Idaho.⁶⁴ St. Luke's, the state's dominant health system, had numerous employed primary care physicians from prior acquisitions, including eight primary care physicians in Nampa, before acquiring from Saltzer 16 additional primary care physicians also practicing in Nampa. Although their prior acquisitions gave St. Luke's greater bargaining power, payers had been able to resist at least some of St. Luke's demands because of the presence of an alternative provider, Saltzer. The FTC alleged, and the court agreed, that the St. Luke's acquisition of Saltzer eliminated that remaining competitive option and would have led to higher prices for physician services.⁶⁵

In sum, consolidation in well-defined antitrust markets can harm competition and consumers. Retrospective studies of healthcare mergers provide credible examples of harmful consolidation. These studies lend support for vigorous antitrust enforcement to prevent the accumulation of market power in healthcare markets. They can also help to guide case selection by the antitrust agencies and illustrate the mechanism by which excessive consolidation can stifle competition and harm healthcare consumers. However, as will be discussed in Section 3, certain state policies, such as certificate-of-need laws and certificates of public advantage, may suppress entry or prevent antitrust scrutiny of mergers that lead to increased concentration in local healthcare markets.⁶⁶

Consolidation in Specific Healthcare Markets

While the evidence above demonstrates that some specific transactions have had anti-competitive consequences, it does not speak to general trends in the ownership structure of healthcare service providers. This section discusses research tracking various measures of concentration that differ from those used in antitrust analysis, generally calculating concentration in geographic areas that are broader than geographic markets consistent with antitrust standards, as well as explaining possible limitations with measures.⁶⁷

⁶³ *FTC v. Advocate Health Care Network*, 841 F.3d 460 (7th Cir. 2016); *FTC v. Penn State Hershey Med. Center*, 838 F.3d 327 (3rd Cir. 2016).

⁶⁴ *FTC and State of Ohio v. St. Luke's Health Sys., Ltd.*, Case No. 1:13-CV-00116-BLW (D. Idaho Jan. 24, 2014).

⁶⁵ *St. Alphonsus Med. Center-Nampa Inc. v. St. Luke's Health Sys., Ltd.*, 778 F.3d 775 (9th Cir. 2015). See also *FTC et al. v. Sanford Health*, No. 1-17-cv-133 (memorandum decision Dec. 15, 2017).

⁶⁶ *Statement of the Commission, Phoebe Putney Health System, Inc.*, Dkt. No. 9348 (Mar. 31, 2015), https://www.ftc.gov/system/files/documents/public_statements/634181/150331phoebeputneycommstmt.pdf. Accessed August 22, 2018.

⁶⁷ As noted earlier, commonly used measures of concentration in the literature may be misleading and not as meaningful regarding the level of competition, compared to measures that take into account specific market attributes such as the set of competing suppliers in a particular local area or underlying market forces that may or may not be related to the competitiveness of a market.

Consequently, while these studies provide information about trends in changes of ownership of various types of healthcare providers, they do not reliably distinguish between concentration that may lessen competition and concentration that may be competitively benign.

Measures of Concentration

Industrial organization economists and antitrust practitioners have developed several market concentration indices. Two of the more common are the “four firm concentration ratio” (CR₄) and the Herfindahl-Hirschman Index (HHI). The CR₄ is the sum of the market shares of the four largest firms (as measured by market share), and the HHI is the sum of the squared share of each firm in the market, multiplied by 10,000. For example, a market with five firms each having a share of 20 percent would have a CR₄ of 80 percent and an HHI of 2,000. A merger between any two of those five firms will yield a CR₄ of 100 percent and an HHI of 2,800. The 2010 Department of Justice-Federal Trade Commission Horizontal Merger Guidelines⁶⁸ explain the HHI as a measure of market concentration for use in merger analysis. These guidelines generally classify markets with an HHI below 1,500 as unconcentrated and markets with an HHI exceeding 2,500 as highly concentrated. However, these thresholds apply only to well-defined antitrust markets, i.e., markets carefully defined to reflect the scope of both geographic and product/service competition that is relevant in antitrust analysis. HHIs calculated for broader geographic units, such as counties or metropolitan statistical areas (MSAs), may sometimes be informative, but considerable care is required in interpreting the results. HHIs calculated for larger geographic regions can both overstate and understate changes in the level of concentration in a relevant geographic market as it would be defined for purposes of antitrust analysis.⁶⁹

⁶⁸ U.S. Department of Justice and Federal Trade Commission. *Horizontal Merger Guidelines*. Section 1. August 19, 2010. <http://www.ftc.gov/os/2010/08/100819hmg.pdf>. Accessed August 21, 2018.

⁶⁹ For example, consider 10 properly defined identical geographic markets, each served by a distinct monopolist hospital. Within the actual geographic markets, the HHIs would be 10,000. If all 10 of those hospitals were to merge into a hospital system, the post-merger HHI in each properly defined market would still be 10,000, so there would be no change. However, if the market was defined too broadly to include all of these true geographic markets, the pre-merger HHI would reflect 10 hospitals each having a 10 percent market share, or $10 \times 10^2 = 1,000$, and the post-merger HHI would be 10,000. Defining the market too broadly suggests that this merger increased concentration significantly even though it did not change the competitive landscape in any properly defined geographic market. Alternatively, suppose each of these identical geographic markets was served by two identical hospitals each, all of which are initially independent. The HHI in each geographic market would be $50^2 + 50^2 = 5,000$. Suppose a hospital system forms by combining the two hospitals in one of these geographic markets. The HHI in that geographic market would now be 10,000. Now, suppose that the market was again defined overly broadly to include all 20 hospitals in 10 geographic markets. The pre-merger HHI would reflect 20 hospitals, each with a 5 percent share, or $20 \times 5^2 = 500$, and the post-merger HHI would be $18 \times 5^2 + 10^2 = 550$. The very significant increase in concentration in the one geographic market impacted by the merger is muted by absence of change in the nine other geographic markets.

Inpatient Hospital Industry

Much of the research into concentration in the healthcare sector has been focused on hospitals, largely due to data availability and the outsized role of hospitals in the healthcare system. Recent analysis suggests a noticeable shift during 2010-2016 in site of practice for primary care physicians into hospital systems, as well an increase in the number of hospital consolidations since 2009.⁷⁰ One recent study by Gaynor et al.⁷¹ measured concentration in the hospital industry by calculating the HHI for each MSA in the United States. The study calculated concentration measures at the MSA level using each hospital system's share of admissions.⁷² It found that the mean HHI across MSAs in the inpatient hospital industry increased from 2,370 in 1987 to 3,261 in 2006—an increase of more than 900 points.⁷³ It also found that most of this increase had occurred by the year 2000. The report found that the mean hospital HHI increased by an average of about 100 points per year over the period 1990-2000 but was largely flat over the period 2000-2006. It also found that the percentage of MSAs with an HHI that exceeded 2,500 increased from 65 percent in 1990 to 77 percent in 2006.

⁷⁰ Mathews, Anna Wilde. Behind Your Rising Health-Care Bills: Secret Hospital Deals That Squelch Competition. September 18, 2018. <https://www.wsj.com/articles/behind-your-rising-health-care-bills-secret-hospital-deals-that-squelch-competition-1537281963>

⁷¹ See Gaynor M, Ho K, Town RJ. The industrial organization of healthcare markets. *J Econ Lit* 2015;53(2):235-284.

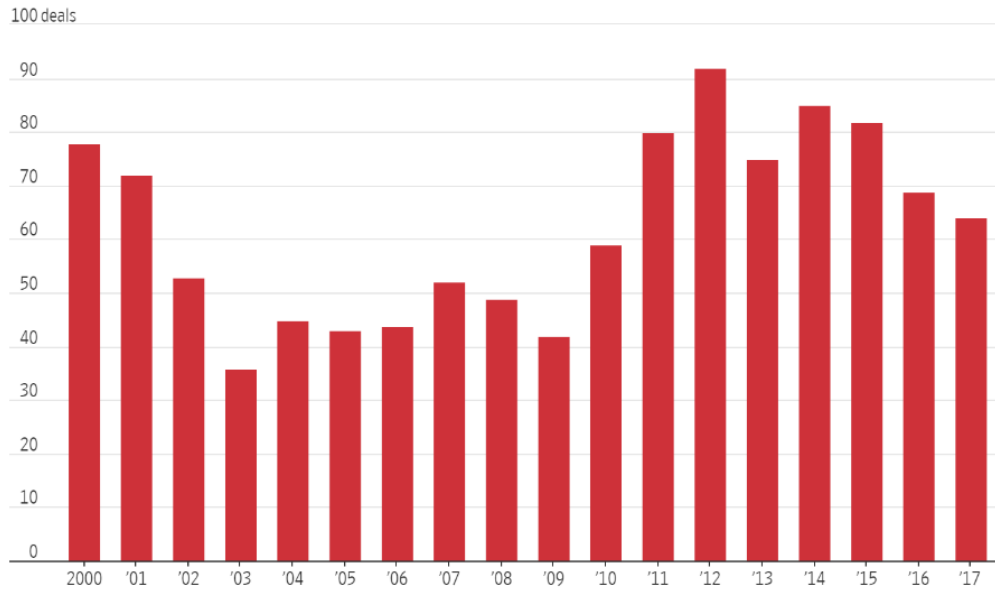
⁷² In this and similar analyses, all hospitals in the same system are treated as part of the same “firm” for purposes of evaluating market concentration indices.

⁷³ Gaynor, et al. used a population weighted average mean in computing their mean HHI. They also dropped any MSA for which the population exceeded 3 million. They did so because in it is likely that there were multiple relevant hospital markets in these MSAs. Hence, the MSA-level HHI is more likely to be uninformative in these MSAs. See Gaynor M, Ho K, Town RJ. The industrial organization of health-care markets. *J Econ Lit* 2015;53(2):235-284.

Figure 2: The Pace of Hospital Mergers Has Ticked Up Since 2010⁷⁴

Bigger Players

The pace of hospital mergers has ticked up since 2010.



Source: Irving Levin Associates

More recent work by Fulton measured hospital concentration over the period 2010-2016.⁷⁵ Like Gaynor et al., Fulton calculated the HHI for inpatient hospitals within each MSA in the United States. He found that the mean HHI across MSAs increased from about 5,500 to about 5,786, an increase of 5.2 percent. This finding implies an average increase in the mean HHI of about 48 points per year. Fulton also reported that the percentage of MSAs with an HHI that exceeded 2,500 increased from about 87 percent in 2010 to 90 percent in 2016. The mean HHI of 5,500 in 2010 found by Fulton is substantially higher than the mean HHI of 3,261 in 2006 found earlier by Gaynor.⁷⁶

⁷⁴ Mathews, Anna Wilde. Behind Your Rising Health-Care Bills: Secret Hospital Deals That Squelch Competition. September 18, 2018. <https://www.wsj.com/articles/behind-your-rising-health-care-bills-secret-hospital-deals-that-squelch-competition-1537281963>

⁷⁵ See Fulton, BD. Health care market concentration trends in the United States: evidence and policy responses. *Health Aff.* 2017;36(9):1530-1538.

⁷⁶ Methodological differences between the two studies largely explain this difference in the mean HHI. Specifically, Fulton applied an unweighted mean HHI across MSAs, whereas, as noted above, Gaynor, et al. applied a population-weighted mean. Since lower-population MSAs are generally more concentrated than higher-population MSAs, weighting the mean HHI by MSA population will likely result in a significantly lower mean HHI. This methodological difference likely explains most the jump in the mean HHI in 2006 found by Gaynor, et al. and the mean HHI in 2010 found by Fulton. Gaynor M, Ho K, Town RJ. The industrial organization of health-care markets. *J Econ Lit* 2015;53(2):235-284 and Fulton, BD. Health care market concentration trends in the United States: evidence and policy responses. *Health Aff.* 2017;36(9):1530-1538.

Physician Services

More recently, researchers have been able to obtain data to study consolidation involving physician practices. Fulton calculated HHIs at the MSA level for primary care physicians and specialist physicians.⁷⁷ He found a high degree of concentration at the MSA level for specialist physician services, but the increase over the period 2010-2016 was modest. The mean HHI across MSAs ranged from about 3,000 to about 3,400 over the period. The mean HHI increased by about 5 percent over the period 2010-2016. This implies an average increase in the mean HHI of about 26 points per year. The percentage of MSAs with an HHI that exceeded 2,500 for specialist physicians increased from about 60 percent in 2010 to about 62 percent in 2016. Fulton also found that the levels of concentration for primary care physician services were much lower, but the increase over the period 2010-2016 was more substantial. The mean HHI for primary care services across MSAs ranged from about 1,700 to about 2,300 over the period 2010-2016, but increased by about 29 percent over this period. This implies an average increase in the mean HHI of about 87 points per year. The percentage of MSAs with an HHI greater than 2,500 for primary care physicians increased from about 21 percent in 2010 to about 35 percent in 2016.

Other research, while not examining trends in physician consolidation, also found higher concentration levels for specialist physicians than for primary care physicians. Kleiner examined shares by physician practice within specialty-specific geographic areas using

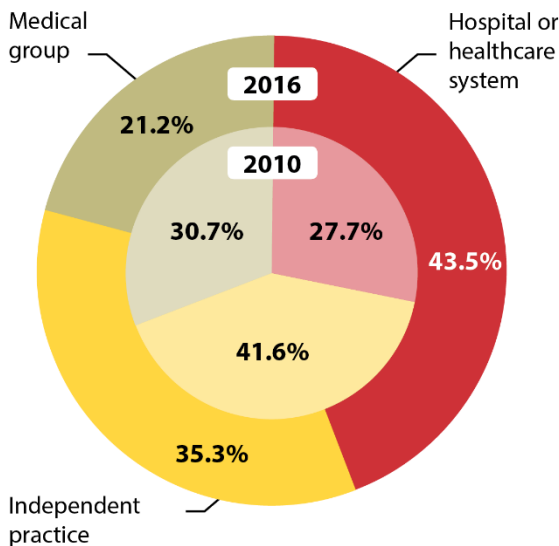
⁷⁷ Among specialist physicians, Fulton included cardiologists, hematologists/oncologists, radiologists, and orthopedists. To calculate the specialist-physician HHI at the MSA level, he calculated the HHI for each of the aforementioned specialties, and then calculated a weighted average of the HHI across specialties at the MSA level. Fulton, BD. Health care market concentration trends in the United States: evidence and policy responses. *Health Aff.* 2017;36(9):1530-1538.

Figure 3: Hospital Systems are Increasingly Acquiring Primary Care Practices⁷⁸

Power Shift

Hospital systems have been acquiring primary-care practices. Often, prices go up after doctors join hospital systems.

Where primary-care doctors work



Source: Brent Fulton, University of California, Berkeley

2009 patient-level Medicare data.⁷⁹ The study found median two firm concentration ratios (CR₂) across all areas of 33 percent for primary care services, but 58 percent for cardiology, 72 percent for oncology, 49 percent for orthopedics, and 57 percent for radiology. Similarly, it found a median HHI of 761 for primary care services, but 2,370 for cardiology, 3,606 for oncology, 1,751 for orthopedics, and 2,190 for radiology. These differences in concentration metrics between specialist physicians and primary care physicians may be due to higher barriers to entry faced by specialists.

Some of the consolidation in physician services might be due to the acquisition of physician practices by local hospitals, as opposed to mergers between physician practices. For example, in a market consisting of two hospitals and

ten physician practices, an acquisition of the ten practices by the two local hospitals would yield a significant increase in concentration in the market for physician services. Hospitals have increasingly been acquiring physician practices. One study reported that the share of physician practices in the United States owned by hospitals doubled over the period 2002-2008.⁸⁰ Another study examined the effect of the acquisition of physician practices by hospitals on prices and expenditures over the period 2007-2013.⁸¹ It reported that hospitals

⁷⁸ Mathews, Anna Wilde. Behind Your Rising Health-Care Bills: Secret Hospital Deals That Squelch Competition. September 18, 2018. <https://www.wsj.com/articles/behind-your-rising-health-care-bills-secret-hospital-deals-that-squelch-competition-1537281963>

⁷⁹ See Kleiner S, Lyons S, White WD. Provider concentration in markets for physician services for patients with traditional Medicare. *Health Management, Policy and Innovation* 2012;1(1):3-18.

⁸⁰ See Baker L, Bundorf MK, Kessler DP. Vertical integration: hospital ownership of physician practices is associated with higher prices and spending. *Health Aff.* 2014;33(5):756-763.

⁸¹ See Capps C, Dranove D, Ody C. The effect of hospital acquisitions of physician practices on prices and spending. Working Paper. 2017. Available at <http://www.ipr.northwestern.edu/publications/papers/2015/ipr-wp-15-02.html>. Accessed August 22, 2018.

acquired 10 percent of the physician practices in their sample during their sample period. In its 2013 Report to the Congress, the Medicare Payment Advisory Commission (MedPAC), an independent, non-partisan, Congressional support agency, similarly reported that while the number of physicians and dentists employed by hospitals was relatively constant from 1998 to 2003, it increased by 55 percent from 2003 to 2011.⁸² Another survey by the Medical Group Management Association found a 75 percent increase in the employment of doctors by hospitals between 2000 and 2012.⁸³ The overall effects of a hospital becoming the owner of a physician practice raise significant anti-competitive concerns, although in some cases they can produce pro-competitive effects.⁸⁴

Need for Continued Vigilance

While the studies cited above do not definitively confirm that increased concentration has led to increased market power or increased payments, they do demonstrate a steady stream of transactions affecting the ownership of hospitals and physician services. Given the strong evidence of consumer harm from some transactions that have been shown to diminish competition, these concentration trends highlight the need for continued vigilance by the antitrust authorities to identify and prevent anti-competitive activity. Furthermore, in instances where markets have become concentrated due to a lawful accumulation of market power, elimination of regulatory barriers to entry can help to keep that in check, as will be discussed in the next section.

Recommendations: Address Potential Antitrust and Provider Consolidation

- The administration should continue monitoring market competition, especially in areas that may be less competitive and thus more likely to be affected by alternative payment models.
- The administration should ascertain the impact of horizontal and vertical integration among provider practices on competition and prices.

⁸² MedPAC. Report to Congress: Medicare and the health care delivery system. Policy Brief. June 2013.

<http://www.ipr.northwestern.edu/publications/papers/2015/ipr-wp-15-02.html>. Accessed August 22, 2018.

⁸³ Kocher R, Sahni NR. Hospitals' race to employ physicians—the logic behind a money-losing proposition. *N Engl J Med*. 2011;364(19):1790-1793.

⁸⁴ See, for example, the FTC's 2013 enforcement action challenging the acquisition of Saltzer Medical Group by St. Luke's Health System. While some people characterized the transaction as a vertical one, the FTC alleged, and the court found, that the combination of the hospital's employed physicians and Saltzer's 16 primary care physicians would lead to higher reimbursement rates for adult primary care services in Nampa, Idaho. *St. Alphonsus Med. Center-Nampa Inc. v. St. Luke's Health Sys., Ltd.*, 778 F.3d 775 (9th Cir. 2015).

Section 3:

Government Healthcare Policies and Their Effect on Competition

Healthcare Workforce and Labor Markets

In competitive markets, suppliers of goods or services respond to market signals that suggest growing demand for the goods or services by increasing prices, which provides incentives to increase the supply of goods and services. Government policies that reduce the available supply of qualified healthcare service providers or the range of services they may safely offer can increase the prices paid for healthcare services, reduce access to care, and suppress the benefits of competition and innovation in healthcare delivery. Such regulations can also unnecessarily limit the types or locations of providers authorized to practice or the range of services they can provide.

Government rules restrict competition if they keep healthcare providers from practicing to the “top of their license”— i.e., to the full extent of their abilities, given their education, training, skills, and experience, consistent with the relevant standards of care. Such rules, including restrictions on the appropriate use of telehealth technologies, unnecessarily limit the types or locations of providers authorized to practice, or the range of services they can provide, in contrast to regulations tailored to address specific and non-speculative health and safety concerns.

With respect to physicians in particular, certain policies relating to graduate medical education (GME), as well as significant restrictions on the ability of foreign-trained doctors to practice in the United States may also unnecessarily limit the supply of physicians available to provide care to Americans. Reduced competition among qualified physicians inevitably leads to higher prices for physician services and generally reduces the quality of care. Consistent with overarching patient health and safety concerns, the discussion below examines potential benefits of more flexible approaches to GME and the treatment of foreign-trained doctors that could increase physician supply and promote additional competition and consumer choice.

Scope of Practice

State licensing and scope-of-practice (SOP) restrictions are common components of state licensure statutes and regulatory codes for healthcare professions.⁸⁵ Licensure regulates entry into an occupation since a worker must obtain the permission of a government agency or government-authorized regulatory board before providing certain services.⁸⁶ For numerous healthcare occupations, a state licensing authority stipulates minimum education, training requirements, and certification, among other criteria, for those who seek to acquire or maintain a license to practice a given profession or provide certain services.⁸⁷ SOP regulations “describe the metes-and-bounds of licensure—what a given professional license permits a person to do and, often, prohibits others from doing.”⁸⁸

SOP laws and regulations, like other health and safety regulations, may be justified when there are substantial risks of consumer harm.⁸⁹ These regulations may be especially important with respect to certain healthcare professions, where consumers might be at risk of serious harm if they were treated by unqualified individuals, and where patients might find it difficult (if not impossible) to assess quality of care at the time of delivery.⁹⁰ Still, even well-intentioned regulations may impose unnecessary restrictions on provider supply and, therefore, competition. Oftentimes, too, SOP restrictions limit provider entry and ability to practice in ways that do not address demonstrable or substantial risks to consumer

⁸⁵ Occupational licensing: a framework for policy makers. U.S. Department of the Treasury, Council of Economic Advisors, and the Department of Labor. July 2015, at 31-32.
https://obamawhitehouse.archives.gov/sites/default/files/docs/licensing_report_final_nonembargo.pdf. Accessed August 25, 2018.

⁸⁶ Stigler GJ. The theory of economic regulation. *Bell J Econ Man Sci.* 1971 Spring;2(1):18-20; Kleiner MM. Occupational licensing. *J Econ. Persp* 2000;14:189,191.

⁸⁷ See *Joint Hearing on Health Care and Competition Law and Policy Before the FTC and Department of Justice*, 33-34 (Jun. 10, 2003), (statement of Dr. Morris Kleiner).
http://www.ftc.gov/sites/default/files/documents/public_events/health-care-competition-law-policy-hearings/030610ftctrans.pdf. Accessed August 22, 2018.

⁸⁸ Gilman DJ, Fairman J. Antitrust and the future of nursing: federal competition policy and the scope of practice. *Health Matrix.* 2014;24:143,163; Occupational licensing: a framework for policy makers. U.S. Department of the Treasury, Council of Economic Advisors, and the Department of Labor. July 2015, at 7 n.6, 31-34.
https://obamawhitehouse.archives.gov/sites/default/files/docs/licensing_report_final_nonembargo.pdf. Accessed August 25, 2018.

⁸⁹ Occupational licensing: a framework for policy makers. U.S. Department of the Treasury, Council of Economic Advisors, and the Department of Labor. July 2015.
https://obamawhitehouse.archives.gov/sites/default/files/docs/licensing_report_final_nonembargo.pdf. Accessed August 25, 2018; Cox C, Foster S. Bureau of Economics, Federal Trade Commission. The Costs and Benefits of Occupational Regulation 4-16. 1990. http://www.ramblemuse.com/articles/cox_foster.pdf. Accessed August 22, 2018.

⁹⁰ See, e.g., *Prepared Statement of the Federal Trade Commission on Competition and Occupational Licensure, Before the H. Comm. on the Judiciary, Subcomm. on Regulatory Reform, Commercial, and Antitrust Law*, 115th Cong., 7-8 (Sept. 12, 2017).
https://www.ftc.gov/system/files/documents/public_statements/1253073/house_testimony_licensing_and_rbi_act_sept_2017_vote.pdf. Accessed August 22, 2018; FTC Staff. Policy perspectives: competition and the regulation of advanced practice nurses. Federal Trade Commission. March 7, 2014. <https://www.ftc.gov/reports/policy-perspectives-competition-regulation-advanced-practice-nurses>. Accessed August 22, 2018.

health and safety.⁹¹ When this happens, these undue restrictions are likely to reduce healthcare competition and harm consumers—including patients, and taxpayers more generally.⁹²

When state regulators impose excessive entry barriers and undue restrictions on SOP for particular types of providers, they often are not responding to legitimate consumer protection concerns. There is a risk that healthcare professionals with overlapping skill sets will seek these restrictions; they view SOP restrictions as an easy, state-sanctioned opportunity to insulate themselves from competition.⁹³ The risk of anti-competitive harm may be even greater when the regulatory board that imposes SOP restrictions on one occupation is controlled by members of another, overlapping occupation that provides complementary or substitute services,⁹⁴ and the board members are themselves active market participants with a financial stake in the outcome.⁹⁵

⁹¹ Occupational licensing: a framework for policy makers. U.S. Department of the Treasury, Council of Economic Advisors, and the Department of Labor. July 2015, at 12-13; Cox C, Foster S. Bureau of Economics, Federal Trade Commission. The Costs and Benefits of Occupational Regulation, at 3. 1990. http://www.ramblemuse.com/articles/cox_foster.pdf. Accessed August 22, 2018. Policy perspectives: competition and the regulation of advanced practice nurses. Federal Trade Commission. March 7, 2014, at 14-15. <https://www.ftc.gov/reports/policy-perspectives-competition-regulation-advanced-practice-nurses>. Accessed August 22, 2018.

⁹² *Id.* Policy Perspectives: Competition and the Regulation of Advanced Practice Nurses, *supra* note 86, at 14.; Prepared Statement of the Federal Trade Commission on Competition and the Potential Costs and Benefits of Professional Licensure, Before the H. Comm. on Small Business, 113th Cong. (July 16, 2014), https://www.ftc.gov/system/files/documents/public_statements/568171/140716professionallicensurehouse.pdf. Accessed August 22, 2018. Correspondingly, the adoption of regulations that recognize new provider categories can sometimes lower the average regulatory burden placed on certain healthcare services, to the extent that these newly licensed workers may compete with professionals in established licensure categories.

⁹³ Stigler GJ. The theory of economic regulation. *Bell J Econ Man Sci.* 1971 Spring;2(1):18-20; Kleiner MM. Occupational licensing. *J Econ. Persp.* 2000;14:13-14. By restricting the entry of competitors, licensure can restrict supply, which can increase the income of incumbents (at consumer expense) or decrease the pressure on incumbents to improve non-price aspects of their services, such as quality or convenience. See also Kleiner MM, Krueger AB. Analyzing the extent and influence of occupational licensing on the labor market. 31 *J Lab Econ.* 2013 Apr;31 S1, Part 2:73,75.

⁹⁴ Occupational licensing: a framework for policy makers. U.S. Department of the Treasury, Council of Economic Advisors, and the Department of Labor. July 2015, at 30. https://obamawhitehouse.archives.gov/sites/default/files/docs/licensing_report_final_nonembargo.pdf. Accessed August 25, 2018; Gilman DJ, Fairman J. Antitrust and the future of nursing: federal competition policy and the scope of practice. *Health Matrix.* 2014;24:157.

⁹⁵ *License to Compete: Occupational Licensing and the State Action Doctrine, Hearing Before the S. Comm. on the Judiciary, Subcomm. on Antitrust, Competition Pol'y and Consumer Rights*, 114th Cong., 1 (Feb. 2, 2016); cf. *N.C. State Bd. of Dental Exam'rs v. FTC*, 135 S. Ct. 1101, 1114 (2015).

For example, advanced practice registered nurses (APRNs),⁹⁶ physician assistants (PAs),⁹⁷ pharmacists,⁹⁸ optometrists,⁹⁹ and other highly trained professionals can safely and effectively provide some of the same healthcare services as physicians, in addition to providing complementary services. Similarly, dental therapists and dental hygienists can safely and effectively provide some services offered by dentists, as well as complementary services.¹⁰⁰

SOP statutes and rules often unnecessarily limit the services these “allied health professionals”¹⁰¹ can offer. A 2011 Institute of Medicine (IOM) report surveyed “[e]vidence suggest[ing] that access to quality care can be greatly expanded by increasing

⁹⁶ See, e.g., Institute of Medicine, National Academy of Sciences. *The Future of Nursing: Leading Change, Advancing Health*. Washington DC: National Academies Press; 2011:98-103,157- 161, annex 3-1; Eibner CE, Hussey PS, Ridgely MS, McGlynn EA. Controlling healthcare spending in Massachusetts: an analysis of options. RAND Health Report Submitted to the Commonwealth of Massachusetts. August 2009.

http://www.rand.org/content/dam/rand/pubs/technical_reports/2009/RAND_TR733.pdf. Accessed August 22, 2018; National Governors Association (NGA). The role of nurse practitioners in meeting increasing demand for primary care. 2012:7-8 (study funded by U.S. Department of Health and Human Services, reviewing literature pertinent to nurse-practitioner (NP) safety and concluding: “None of the studies in the NGA’s literature review raise concerns about the quality of care offered by NPs. Most studies showed that NP-provided care is comparable to physician-provided care on several process and outcome measures.”)

⁹⁷ U.S. Congress, Office of Technology Assessment. *Nurse Practitioners, Physician Assistants, and Certified Nurse-Midwives: A Policy Analysis*. Health Technology Case Study 37. OTA-HCS-37. Washington, DC: U.S. Government Printing Office; December 1982:39. <https://www.princeton.edu/~ota/disk2/1986/8615/8615.PDF>. Accessed August 22, 2018. (“Most observers conclude that most primary care traditionally provided by physicians can be delivered by [nurse practitioners and physician assistants].”)

⁹⁸ Jorgenson D, Dalton D, Farrell B, Tsuyuki RT, Dolovich L. Guidelines for pharmacists integrating into primary care teams. *Can Pharm. J.* 2013 Nov;146(6):342-352; Durham MJ, Goad JA, Neinstein LS, Lou M. A comparison of pharmacist travel-health specialists' versus primary care providers' recommendations for travel-related medications, vaccinations, and patient compliance in a college health setting. *J Travel Med.* 2011 Jan-Feb;18(1):20-25; Hecox N. Tuberculin skin testing by pharmacists in a grocery store setting. *J Am Pharm Assoc.* 2008 Jan-Feb;48(1):86-91.

⁹⁹ FTC, Bureau of Consumer Protection. *Staff Report on Advertising of Ophthalmic Goods and Servs and Proposed Trade Reg. Rule*, 16 CFR Part 456, 17-19 (1977).

For example, dental hygienists can provide preventive dental care, while dental therapists can provide limited restorative services as well as preventive services. Dentists can provide these services as well as the full range of more complex dental services. See, e.g., *FTC Staff Comment to the Ohio State Senate Regarding the Competitive Effects of SB 330 in Increasing Access to Quality Dental Care* (2017),

https://www.ftc.gov/system/files/documents/advocacy_documents/ftc-staff-comment-ohio-state-senate-regarding-competitive-effects-sb-330-increasing-access-quality/v170003_ftc_staff_comment_to_ohio_state_senate_re_ohio_sb_330_re_dental_therapists_and_hygienists.pdf (accessed September 26, 2018); *FTC Staff Comment Before the Commission on Dental Accreditation Concerning Proposed Accreditation Standards for Dental Therapy Education Programs* (2013). https://www.ftc.gov/sites/default/files/documents/advocacy_documents/ftc-staff-comment-commission-dental-accreditation-concerning-proposed-accreditation-standards-dental/131204codacomment.pdf. Accessed September 20, 2018.

¹⁰¹ We use the term broadly, acknowledging that “[t]he allied health workforce includes hundreds of professionals employed in different professions with different job duties and different levels of preparation, but there is no single definition of “allied health” or list of allied health occupations. All formulations exclude physicians and dentists, and most exclude nurses. Others exclude pharmacists, physician assistants, and more.” IOM (Institute of Medicine). *Allied Health Workforce and Services: Workshop Summary*. Washington, D.C.: The National Academies of Sciences Engineering Medicine; 2011.

the use of . . . APRNs in primary, chronic, and transitional care,”¹⁰² and expressed concern that SOP restrictions “have undermined the nursing profession’s ability to provide and improve both general and advanced care.”¹⁰³ In fact, research suggests that allowing allied health professionals to practice to the full extent of their abilities is not a zero sum game for other medical professionals, and may actually improve overall health system capacity.¹⁰⁴ The previously mentioned IOM report found that APRNs’ scope of practice varies widely “for reasons that are related not to their ability, education or training, or safety concerns, but to **the political decisions of the state** in which they work.”¹⁰⁵

State decisions about scope of practice and reimbursement can also affect the development and utilization of allied health professionals, particularly in public programs. Private insurance has the flexibility to incentivize patients to find lower-cost, higher-quality provider alternatives when feasible. Public programs, more restricted by state regulations, can be less responsive to such changes in the healthcare workforce, even after scope of practice regulations accommodate them. Currently, for example, states vary widely in the degree to which they permit their Medicaid programs to reimburse allied health professionals directly for services. Services provided under the direct supervision of a physician are reimbursed as if the physician provided those services. State Medicaid programs can also pay for PA, nurse practitioner, and certified nurse midwife (CNM) services provided outside of a physician’s office, but only if state scope-of-practice laws do not require onsite supervision by physicians. Some states allow allied health professionals to bill Medicaid directly, while other states require them to bill under the physician’s number. For patients to realize the benefits of changes to state SOP restrictions, state Medicaid programs would need to reimburse allied health professionals independently for their services.

As noted by FTC staff, “when APRN access to the primary care market is restricted, healthcare consumers—patients and other payers—are denied some of the competitive

¹⁰² Institute of Medicine, National Acad. of Sciences. *The Future of Nursing: Leading Change, Advancing Health*. Washington DC: National Academies Press; 2011:27; see also IOM (Institute of Medicine). *Allied Health Workforce and Services: Workshop Summary*. Washington, D.C.: The National Academies of Sciences Engineering Medicine; 2011:88 (“Given current concerns about a shortage of primary care health professionals, the committee paid particular attention to the role of nurses, especially APRNs, in this area.”). The extent to which APRNs and other professionals might augment the primary care workforce has been of policy interest for some time. See, e.g., U.S. Congress, Office of Technology Assessment. *Nurse Practitioners, Physician Assistants, and Certified Nurse-Midwives: A Policy Analysis*. Health Technology Case Study 37. OTA-HCS-37. Washington, D.C.: U.S. Government Printing Office; December 1986. (“Most observers conclude that most primary care traditionally provided by physicians can be delivered by [nurse practitioners and physician assistants].”)

¹⁰³ Institute of Medicine, National Academy of Sciences. *The Future of Nursing: Leading Change, Advancing Health*. Washington D.C.: National Academies Press; 2011:4.

¹⁰⁴ Improving efficiency in the healthcare system: removing anti-competitive barriers for advanced practice registered nurses and physician assistants. The Hamilton Project. Policy brief 2018-08. June 2018. http://www.hamiltonproject.org/assets/files/AM_PB_0608.pdf. Accessed August 22, 2018.

¹⁰⁵ Institute of Medicine, National Academy of Sciences. *The Future of Nursing: Leading Change, Advancing Health*. Washington D.C.: National Academies Press; 2011:5.

benefits that APRNs, as additional primary care service providers, can offer.”¹⁰⁶ Slightly more than half the states require supervision and “collaborative practice” requirements, which can operate as de facto supervision requirements. These are a particular source of concern to the extent that they raise the cost of APRN-provided services.¹⁰⁷ In addition, rigid “collaborative practice agreement” requirements can impede collaborative care rather than foster it because they limit the ability of healthcare professionals to adapt to varied healthcare demands, thereby constraining provider innovation in team-based care.¹⁰⁸ Economic analysis indicates that expanding APRN SOP, consistent with APRN education, training, and experience, would have clear consumer benefits, particularly in rural and poorer areas:

In underserved areas and for underserved populations, the benefits of expanding supply are clear: Consumers will have access to services that were otherwise unavailable. Even in well-served areas, the supply expansion will tend to lower prices for any given level of demand, thus lowering healthcare costs.¹⁰⁹

Similar concerns about the competitive impact of supervision and “collaborative practice” requirements can apply to other healthcare occupations. Even when some form of collaboration or supervision might be desirable, particular requirements might be unnecessary, over-rigid, and costly barriers to the efficient delivery of healthcare services.¹¹⁰

Extremely rigid collaborative practice agreements and other burdensome forms of physician and dentist supervision are generally not justified by legitimate health and safety concerns. Thus, many states have granted full practice authority to APRNs, but there is significant room for improvement in other states and for other professions.¹¹¹ Emerging

¹⁰⁶ FTC Staff. Policy perspectives: competition and the regulation of advanced practice nurses. Federal Trade Commission. March 7, 2014. <https://www.ftc.gov/reports/policy-perspectives-competition-regulation-advanced-practice-nurses>. Accessed August 22, 2018.

¹⁰⁷ Dep’t Veterans Affairs, Economic Impact Analysis for RIN 2900-AP44, Advanced Practice Registered Nurses, attachment 1, 5-7 (Nov. 9, 2016), [https://www.va.gov/ORPM/docs/RegMgmt_ImpactAnalysis_AP44\(F\)_AdvancedPracticeRegisteredNurses.docx](https://www.va.gov/ORPM/docs/RegMgmt_ImpactAnalysis_AP44(F)_AdvancedPracticeRegisteredNurses.docx).

¹⁰⁸ *Id.* at 20.

¹⁰⁹ *Id.* at 27.

¹¹⁰ See generally, e.g., FTC Staff. Policy perspectives: competition and the regulation of advanced practice nurses. Federal Trade Commission. March 7, 2014. <https://www.ftc.gov/reports/policy-perspectives-competition-regulation-advanced-practice-nurses>. Accessed August 22, 2018, (regarding APRNs); *FTC Staff Comment to the Ohio State Senate Regarding the Competitive Effects of SB 330 in Increasing Access to Quality Dental Care* (2017). <https://www.ftc.gov/policy/advocacy/advocacy-filings/2017/03/ftc-staff-comment-ohio-state-senate-regarding-competitive>. Accessed August 22, 2018 (regarding dental therapy); *FTC Staff Comments to the Iowa Board of Physician Assistants on Proposed New Rules: 645—327.8: Definition of Physician Supervision of a Physician Assistant* (2016). https://www.ftc.gov/system/files/documents/advocacy_documents/ftc-staff-comment-professional-licensure-division-iowa-department-public-health-regarding-proposed/v170002_ftc_staff_comment_to_iowa_dept_of_public_health_12-21-16.pdf. Accessed August 22, 2018 (regarding physician assistants).

¹¹¹ According to the American Academy of Nurse Practitioners, 22 states plus the District of Columbia now grant full practice authority to APRNs. <https://www.aanp.org/legislation-regulation/state-legislation/state-practice-environment>.

healthcare occupations, such as dental therapy, can increase access and drive down costs for consumers, while still ensuring safe care. States should be particularly wary of undue statutory and regulatory impediments to the development of such new occupations.

Recommendations: Broaden Scope of Practice

- States should consider changes to their scope-of-practice statutes to allow all healthcare providers to practice to the top of their license, utilizing their full skill set.
- The federal government and states should consider accompanying legislative and administrative proposals to allow non-physician and non-dentist providers to be paid directly for their services where evidence supports that the provider can safely and effectively provide that care.
- States should consider eliminating requirements for rigid collaborative practice and supervision agreements between physicians and dentists and their care extenders (e.g., physician assistants, hygienists) that are not justified by legitimate health and safety concerns.
- States should evaluate emerging healthcare occupations, such as dental therapy, and consider ways in which their licensure and scope of practice can increase access and drive down consumer costs while still ensuring safe, effective care.

Workforce Mobility

State-based licensing requirements, by their nature, inhibit provider mobility.¹¹² These requirements add time and expense when healthcare providers seek to move or work across state lines. Markets cannot be as responsive to economic change when workers cannot easily move to meet the demand for their services.¹¹³

Accessed August 22, 2018. For examples of state restrictions on SOP besides supervision requirement see, e.g., Institute of Medicine, National Academy of Sciences. *The Future of Nursing: Leading Change, Advancing Health*. Washington, D.C.: National Academies Press; 2011:100-102, Box 3-1 Variation in State Licensure Requirements; FTC Staff. Policy perspectives: competition and the regulation of advanced practice nurses. Federal Trade Commission. March 7, 2014. <https://www.ftc.gov/reports/policy-perspectives-competition-regulation-advanced-practice-nurses>. Accessed August 22, 2018, at notes 35-37 and accompanying text.

¹¹² Licensing rules are almost always state-based. See, e.g., *Dent v. West Virginia*, 129 U.S. 114 (1889) (upholding the authority of the State of West Virginia to license physicians); Health Resources and Services Administration, U.S. Department of Health and Human Services. Telehealth licensure report. Report 111-66. Special Report to the Senate Appropriations Committee (Requested by Senate). 2010. ("For over 100 years, health care in the United States has primarily been regulated by the states. Such regulation includes the establishment of licensure requirements and enforcement standards of practice for health providers, including physicians, nurses, pharmacists, mental health practitioners, etc.")

¹¹³ See, e.g., *Occupational Licensing: Regulation and Competition: Hearing Before the Subcomm. on Regulatory Reform, Commercial and Antitrust Law of the House Comm. on the Judiciary*, 115th Cong. 1, 8-9 (2017) (statement of Maureen K. Ohlhausen, Acting Chairman, Federal Trade Commission). https://www.ftc.gov/system/files/documents/public_statements/1253073/house_testimony_licensing_and_rbi_act_sept

State-based licensing also often inhibits delivery of healthcare services across state lines by making it more difficult for qualified healthcare professionals licensed in one state to work in another state, even though most healthcare providers complete nationally certified education and training programs and sit for national qualifying exams.¹¹⁴ Appropriate standards of care do not differ from state to state. Yet, even when a profession's underlying standards are national in scope, and when state licensing requirements are similar throughout the United States, the process of obtaining a license in another state is often slow, burdensome, and costly.¹¹⁵ There is little economic justification for the redundant licensing processes that many states impose on licensed, out-of-state applicants. Even when there may be plausible consumer-protection concerns, the harm to consumers likely outweighs any benefits.¹¹⁶

The effects of state-based licensing are especially apparent in fields where providers routinely communicate electronically and provide services in multiple states. For this reason, state-based licensing requirements can inhibit the efficient development and use of telehealth (discussed below), as well as in-person services.¹¹⁷

Interstate compacts and model laws can mitigate the effects of state-based licensing requirements by enhancing license portability. Professional associations and associations

[2017_vote.pdf](#). Accessed August 22, 2018; Occupational licensing: a framework for policy makers. U.S. Department of the Treasury, Council of Economic Advisors, and the Department of Labor. July 2015, at 12-16.

https://obamawhitehouse.archives.gov/sites/default/files/docs/licensing_report_final_nonembargo.pdf. Accessed August 25, 2018.

¹¹⁴ See, e.g., Health Resources & Services Administration, U.S. Department of Health & Human Services. *Special Report to the Senate Appropriations Committee, Telehealth Licensure Report, Requested by Senate Rep't 111-66* (2010), at 9, ("The basic standards for medical and nursing licensure have become largely uniform in all states. Physicians and nurses must graduate from nationally approved educational programs and pass a national medical and nursing licensure examination.")

¹¹⁵ See, e.g., American Medical Association. Obtaining a medical license. <http://www.ama-assn.org/ama/pub/education-careers/becoming-physician/medical-licensure.page>. Accessed August 22, 2018. ("The process of obtaining a medical license can be challenging and time consuming.... Physicians seeking initial licensure or applying for a medical license in another state should anticipate delays due to the investigation of credentials and past practice as well as the need to comply with licensing standards."); U.S. Department of the Treasury and U.S. Department of Defense, Supporting our military families: best practices for streamlining occupational licensing across state lines. February 2012:12-13.

http://archive.defense.gov/home/pdf/Occupational_Licensing_and_Military_Spouses_Report_vFINAL.PDF. Accessed August 22, 2018. ("Nurses moving across state lines must apply for licensure by endorsement and pay any applicable fees.")

¹¹⁶ See, e.g., Nicholson S, Propper C. Medical workforce. In *Handbook of Health Economics*. Vol. 2. 1st ed. Waltham, MA: North Holland; 2012:885. (In medical labor markets, "[l]icensing is associated with restricted labor supply, an increased wage of the licensed occupation, rents, increased output prices, and no measurable effect on output quality.")

¹¹⁷ See, e.g., *Comment from FTC Staff to Department of Veterans Affairs*, 3 (Nov. 1, 2017), https://www.ftc.gov/system/files/documents/advocacy_documents/ftc-staff-comment-department-veterans-affairs-regarding-its-proposed-telehealth-rule/v180001vatelehealth.pdf. Accessed August 22, 2018. ("State laws and regulations that require licensure of telehealth providers licensed in another state inhibit VA employees from delivering telehealth services to beneficiaries in states in which they are not licensed.")

of licensing boards typically draft model laws, which may be passed with minor variations between jurisdictions. Almost all states and other United States jurisdictions have adopted model laws with license portability provisions in other professions such as accountancy and pharmacy.¹¹⁸ By contrast, interstate compacts, which are binding contracts between two or more states authorized by the United States Constitution, must be identical and have been used only recently to improve licensure portability.¹¹⁹ The first interstate licensure compact, on nurse licensure, was initially implemented in 1999 and has been adopted by 30 states.¹²⁰ Other licensure compacts in the health professions are in the early stages of implementation.¹²¹ Federal grants to state professional licensing boards have encouraged the development and implementation of various licensure compacts in several professions.¹²²

Model laws and interstate compacts typically use one of two approaches to enhance licensure portability. One is reciprocity as practitioners licensed by one state are able to practice in other states without obtaining another license. Second, some states require a license in each state of practice but expedite the process.¹²³ By making it easier to practice in multiple states, interstate compacts and model laws can enhance access to healthcare services and improve provider mobility.

¹¹⁸ See, e.g., American Institute of Certified Public Accountants and National Association of State Boards of Accountancy. *Uniform Accountancy Act: Standards for Regulation*. 8th ed. Nashville, TN: American Institute of Certified Public Accountants; 2018. <https://nasba.org/app/uploads/2018/02/Uniform-Accountancy-Act-%E2%80%93-Eighth-Edition-%E2%80%93-January-2018.pdf>. Accessed August 22, 2018; Streamlining licensing across state lines: initiatives to enhance occupational licensing portability. FTC Economic Liberty Taskforce. July 27, 2017, at 19. https://www.ftc.gov/system/files/documents/public_events/1224893/ftc_economic_liberty_roundtable_-_license_portability_transcript.pdf. Accessed August 22, 2018 (transcript of roundtable). (UAA mobility provisions adopted by 53 jurisdictions.) See also National Association of Boards of Pharmacy (“NABP”). *Comment to the FTC* (2017), at 1-2, https://www.ftc.gov/system/files/documents/public_comments/2017/07/00016-141084.pdf. Accessed August 22, 2018. (“As required by the *NABP Constitution and Bylaws*, all NABP members participate in e-LTP and the NABP Clearinghouse.”) The number of model laws with license portability provisions is unknown because they are not tracked by any organization.

¹¹⁹ U.S. Constitution Art. I, § 10, cl. 3.

¹²⁰ See FTC Staff. Policy perspectives: options to enhance occupational license portability. Federal Trade Commission. September 24, 2018, at 9-10. https://www.ftc.gov/system/files/documents/reports/options-enhance-occupational-license-portability/license_portability_policy_paper.pdf. Accessed September 26, 2018.

¹²¹ See, e.g., Interstate Medical Licensure Compact. <http://www.imlcc.org/>. Accessed August 22, 2018, (adopted by 22 states); Physical Therapy Licensure Compact. <http://www.fsbpt.org/FreeResources/PhysicalTherapyLicensurecompact.aspx>. Accessed August 22, 2018, (adopted by 16 states).

¹²² See 42 U.S.C. §254c-18; Office for the Advancement of Telehealth, U.S. Department of Health and Human Services. Funding Opportunity Announcement HRSA-16-014. 2016. https://grants.hrsa.gov/2010/Web2External/Interface/Common/EHBDisplayAttachment.aspx?dm_rtc=16&dm_attid=2f098e80-40a0-43ec-b4e7-2002033a031a. Accessed August 22, 2018.

¹²³ See, e.g., Streamlining licensing across state lines: initiatives to enhance occupational licensing portability. FTC Economic Liberty Taskforce. July 27, 2017, at 11-12, 16, 18-19. https://www.ftc.gov/system/files/documents/public_events/1224893/ftc_economic_liberty_roundtable_-_license_portability_transcript.pdf. Accessed August 22, 2018.

Recommendations: Improve Workforce Mobility

- States should consider adopting interstate compacts and model laws that improve license portability, either by granting practitioners licensed in one state a privilege to practice elsewhere, or by expediting the process for obtaining licensure in multiple states.
- The federal government should consider legislative and administrative proposals to encourage the formation of interstate compacts or model laws that would allow practitioners to more easily move across state lines, thereby encouraging greater mobility of healthcare service providers.

Telehealth

Telehealth, the use of telecommunications to provide healthcare services, has been hailed as a significant innovation in healthcare delivery.¹²⁴ It encompasses a broad variety of services and technologies, and is particularly effective when it replicates in-person care, speeds input from knowledgeable practitioners, provides information more frequently than would be possible with in-person visits, or involves conditions that can be evaluated from digital images. Examples of healthcare services that may be provided by telehealth include mental health services,¹²⁵ dermatology,¹²⁶ ophthalmology,¹²⁷ specialist-to-provider

¹²⁴ See, e.g., Rheuban KS. Welcome from IOM Planning Committee. *The Role of Telehealth in an Evolving Health Care Environment: Workshop Summary*. Washington, D.C.: The National Academies Press; 2012. <http://www.nap.edu/catalog/13466/the-role-of-telehealth-in-an-evolving-health-care-environment>. Accessed August 22, 2018. (“[T]elehealth programs have served as innovative tools for delivery of care, linking patients and providers separated by geographic and socioeconomic barriers, all the while mitigating specialty workforce shortages”); Committee on Geographic Adjustment Factors in Medicare Payment, Institute of Medicine. *Geographic Adjustment in Medicare Payment—Phase II, Implications for Access, Quality, and Efficiency*. Washington, D.C.: The National Academies Press; 2012:8. <http://iom.nationalacademies.org/Reports/2012/Geographic-Adjustment-in-Medicare-Payment-Phase-II.aspx>. Accessed August 22, 2018. (Telehealth is a “very promising and rapidly developing strategy to improve access and efficiency of care” and is being used by 50 medical subspecialties.)

¹²⁵ See, e.g., Hilty DM, Ferrer DC, Parish MB, Johnson B, Callahan EJ, Yellowlees PM. The effectiveness of telemental health: a 2013 review. *Telemed J E Health*. 2013 Jun;19(6):444, 449 (citing randomized controlled clinical trial of the use of telehealth services to treat depression and other mental conditions in adults). See also Gilman M, Stensland J. Telehealth and Medicare: payment policy, current use, and prospects for growth. *Medicare Medicaid Res Rev*. 2013;3(4):E1, E8. (“[O]f the 38,000 telehealth visits that Medicare beneficiaries had in 2009, most visits [62 percent] were for mental health services.”)

¹²⁶ See, e.g., Coates SJ, Kvedar J, Granstein RD. Teledermatology: from historical perspective to emerging techniques of the modern era. Part I: history, rationale, and current practice. *J Am Acad Derm*. 2015 Apr;72(4):563, 566-567; Coates SJ, Kvedar J, Granstein RD. From historical perspective to emerging techniques of the modern era. Part II: emerging technologies in teledermatology, limitations and future directions. *J Am Acad Derm*. 2015 Apr;72(4):577.

¹²⁷ See, e.g., Fierson WM, Capone A. The American Academy of Pediatrics Section on Ophthalmology, American Academy of Ophthalmology, and the American Association of Certified Orthoptists. Telemedicine for evaluation of retinopathy of prematurity. *Pediatrics*. 2015 Jan;135(1):e238 (report providing guidance on the use of telemedicine-based retinal imaging techniques that “have the potential to allow diagnosis and monitoring of [retinopathy of prematurity] to occur in lieu of the necessity for some repeated on-site examinations in” neonatal intensive care units); Silva PS, Aiello LP. Telemedicine and eye examinations for diabetic retinopathy: a time to maximize real-world outcomes. *JAMA Ophthalmol*. 2015 May;133(5):525 (“a telemedicine approach for diabetic retinopathy evaluation can

consultations in neurology and pathology,¹²⁸ and direct-to-consumer services for minor conditions.¹²⁹

Telehealth often increases the virtual supply of providers and extends their reach to new locations, promoting beneficial competition. By doing so, telehealth can enhance price and non-price competition, reduce transportation expenditures, and improve access to quality care.¹³⁰ Indeed, telehealth has great potential to improve access in underserved locations, reduce costs, and generate improved short- and long-term health outcomes.¹³¹

Nonetheless, a variety of regulatory barriers have kept telehealth from reaching its full potential to increase competition and access. State laws and regulations typically require that providers be licensed in the state where the patient is located, thus restricting the provision of telehealth services across state lines.¹³² State licensing requirements and

effectively increase the rates of eye examinations, thereby potentially reducing the rates of blindness and vision loss in the diabetic population”).

¹²⁸ See, e.g., Darkins A. U.S. Department of Veterans Affairs. In: Institute of Medicine of the National Academies. *The Role of Telehealth in an Evolving Health Care Environment: Workshop Summary*. Washington, DC: The National Academies Press; 2012: 99, 101. <http://www.nap.edu/catalog/13466/the-role-of-telehealth-in-an-evolving-health-care-environment>. Accessed August 22, 2018; Schwamm LH, Holloway RG, Amarenco P, Audebert HJ, Bakas T, Chumbler NR, et al. A review of the evidence for the use of telemedicine within stroke systems of care: a scientific statement from the American Heart Association/American Stroke Association. *Stroke*. 2009 Jul;40(7): 2630-2631 (recommending the use of telestroke, teleradiology, and other telehealth services for stroke care).

¹²⁹ See, e.g., Mehrotra A. The convenience revolution for treatment of low-acuity conditions. *JAMA*. 2013;310:35, 36; Mehrotra A, Paone S, Martich GD, Albert SM, Shevchik GJ. A comparison of care at e-visits and physician office visits for sinusitis and urinary tract infections. *JAMA Int. Med.* 2013 Jan 14;173(1):72, 73.

¹³⁰ See, e.g., *Comment from FTC Staff to Steve Thompson, Representative, Alaska State Legislature* (March 25, 2016). <https://www.ftc.gov/policy/policy-actions/advocacy-filings/2016/03/ftc-staff-comment-alaska-state-legislature-regarding>. Accessed August 23, 2018. (Regarding telehealth provisions in Senate Bill 74, which would allow licensed Alaska physicians located out-of-state to provide telehealth services.) See also Health care: telehealth and remote patient monitoring use in Medicare and selected federal programs. U.S. Government Accountability Office. GAO-17-365. 2017. Highlights, at 21 (“[P]rovider and regional medical specialty shortages can be addressed through telehealth.”) <https://www.gao.gov/products/GAO-17-365#summary>. Accessed August 23, 2018.

¹³¹ See generally Committee on Pediatric Workforce, Marcin JP, Rimsza ME, Moskowitz WB. The use of telemedicine to address access and physician workforce shortages. *Pediatrics*. 2015 Jul;136(1):202, 203 ([U]rban as well as rural children “face significant disparities in access and time-distance barriers, which could be partly alleviated by the use of telehealth”); Bashshur RL, Shannon GW, Smith BR, Alverson DC, Antoniotti N, Barsan WG, et al. The empirical foundations of telemedicine interventions for chronic disease management. *Telemed J E Health*. 2014 Sep;20(9):769, 770 (“Differences in access to care reflect economic, geographic, and functional as well as social, cultural, and psychological factors....[M]any residents of the inner city have limited access to medical resources for economic reasons.”); Daniel H, Sulmasy LS, Health and Public Policy Committee of the American College of Physicians. Policy recommendations to guide the use of telemedicine in primary care settings: an American College of Physicians position paper. *Ann Intern Med*. 2015 Nov 17;163(10):787 (“Limited access to care is not an issue specific to rural communities; underserved patients in urban areas have the same risks as rural patients if they lack primary or specialty care....”)

¹³² See, e.g., Fish EM, Hickman SA, Chaudhry HJ. *SciTech Lawyer*. 2014;10:n.p. https://www.americanbar.org/content/dam/aba/publications/scitech_lawyer/2014/spring/state_licensure_regulations_evolve_to_meet_demands_modern_medical_practice.authcheckdam.pdf. Accessed August 23, 2018. (“Fifty-seven state medical and osteopathic boards and the District of Columbia Board of Medicine now require physicians engaging in telemedicine to be licensed in the state in which the patient is located.”); Fleisher LD, Dechene JC. *Telemedicine and*

variations in scope of practice are barriers for even well-established and natural telehealth services, such as mental and behavioral healthcare.¹³³ Public and private reimbursement laws and policies are also frequently cited as major impediments to the development and use of telehealth services.¹³⁴ For example, Medicare fee-for-service pays for telehealth services only when patients are located at certain types of healthcare facilities (“originating sites”)¹³⁵ in rural areas with a shortage of health professionals.¹³⁶ Another barrier is that states may require practitioners to have first provided services in person before caring for a patient by telehealth.¹³⁷

E-Health Law. N.p: Law Journal Press; 2014, 1.02[2] (“A large number of states require out-of-state telemedicine physicians to obtain a full, unrestricted medical license in order to ‘see’ patients in the state via telemedicine.”)

¹³³ See, e.g., Thomas L, Capistrant, G. 50 state telemedicine gaps analysis: psychologist clinical practice standards & licensure. American Telemedicine Association. June 2016. https://higherlogicdownload.s3.amazonaws.com/AMERICANTELEMED/3c09839a-fffd-46f7-916c-692c11d78933/UploadedImages/Policy/State%20Policy%20Resource%20Center/Psychol%20-%2050-state-telehealth-gaps-analysis-pysch-pgl_final.pdf. Accessed August 23, 2018. (“Across the care spectrum, inadequate licensure portability and arbitrary scope of practice standards challenge telehealth adoption and utilization....Mental and behavioral health providers are not spared from this fragmented policy landscape.”)

¹³⁴ See, e.g., Daniel H, Sulmasy LS, Health and Public Policy Committee of the American College of Physicians. Policy recommendations to guide the use of telemedicine in primary care settings: an American College of Physicians position paper. *Ann Intern Med*. 2015 Nov 17;163(10):App. (“One of the most significant challenges to wide-spread telemedicine adoption is reimbursement.”); Burke BL, Hall WR, Section on Telehealth Care. Telemedicine: pediatric applications. *Pediatrics*. 2015 Jul;136(1):e294, e303 (“The most significant barriers are payment, licensing across state borders, and liability.”)

¹³⁵ See 42 U.S.C. § 1395m(m)(4)(C)(ii); 42 C.F.R. § 410.78(b)(3).

¹³⁶ See 42 U.S.C. § 1395m(m)(4)(C)(i); 42 C.F.R. § 410.78(b)(4). See also Health care: telehealth and remote patient monitoring use in Medicare and selected federal programs. U.S. Government Accountability Office. GAO-17-365. 2017. Highlights, at 8-9, 21-25. <https://www.gao.gov/products/GAO-17-365#summary>. Accessed August 23, 2018. (Medicare telehealth coverage restrictions that limit the geographic and practice settings in which beneficiaries may receive services are barriers to the use of telehealth). Legislators have been cautious about expanding coverage of telemedicine services in part because of concerns that its ease of use could lead to overutilization. In practice, however, Medicare telemedicine-related spending is very low. See *ibid.* at 14, 18 (in 2014, Medicare paid 175,000 telehealth claims for a total of about \$14 million, less than 0.01 percent of the approximately \$257 billion in total annual Medicare expenditures on Part B services); Neufeld JD, Doarn CR. Telemedicine spending by Medicare: a snapshot from 2012. *Telemed J E Health*. 2015 Aug;21(8):686-693. In addition, concerns about improper claims for reimbursement of telehealth services have been overblown. An Office of Inspector General (OIG) audit found that the Centers for Medicare and Medicaid Services (CMS) paid for some telehealth services that did not meet Medicare requirements, but most claims for telehealth services were appropriate. To reduce the number of unallowable claims, OIG recommended post-payment reviews to detect errors, and education and training of practitioners on Medicare telehealth requirements. See CMS paid practitioners for telehealth services that did not meet Medicare requirements. Department of Health and Human Services, Office of Inspector General. A-05-16-00058. April 2018. <https://oig.hhs.gov/oas/reports/region5/51600058.pdf>. Accessed August 23, 2018.

¹³⁷ See, e.g., *Comment from FTC Staff to the Delaware Bd. of Speech/Language Pathologists, Audiologists & Hearing Aid Dispensers* 6 & nn.57, 59 (Nov. 29, 2016). https://www.ftc.gov/system/files/documents/advocacy_documents/ftc-staff-comment-delaware-board-speech/language-pathologists-audiologists-hearing-aid-dispensers-regarding-its-proposed-revisions-its/161130_ftc_dealers_final_.pdf. Accessed August 23, 2018. (Discussing initial in-person evaluation requirements before speech/language/pathology or audiology services may be provided by telehealth in Kentucky and Texas.) It is difficult to draw a bright line between services for which health and safety considerations warrant a prior in-person examination and those that do not, in part because rapid changes in technology and healthcare priorities may lead to changing views of the need for an in-person visit. See, e.g., Letter from Jonathan Linkous, chief executive officer, American Telemedicine Association, to Imelda L. Paredes, executive assistant, Drug Enforcement

Recommendations: Facilitate Telehealth to Improve Patient Access

- States should consider adopting licensure compacts or model laws that improve license portability by allowing healthcare providers to more easily practice in multiple states, thereby creating additional opportunities for telehealth practice. Interstate licensure compacts and model laws should foster the harmonization of state licensure standards and approaches to telehealth.
- States and the federal government should explore legislative and administrative proposals modifying reimbursement policies that prohibit or impede alternatives to in-person services, including covering telehealth services when they are an appropriate form of care delivery. In particular, Congress should consider proposals modifying geographic location and originating site requirements in Medicare fee-for-service that restrict the availability of telehealth services to Medicare beneficiaries in their homes and in most geographic areas.
- States generally should consider allowing individual healthcare providers and payers to mutually determine whether and when it is safe and appropriate to provide telehealth services, including when there has not been a prior in-person visit.
- Congress and other policymakers should increase opportunities for license portability through policies that maintain accountability and disciplinary mechanisms, including permitting licensed professionals to provide telehealth service to out-of-state patients.

Foreign-Trained Doctors

The United States has the highest physician salaries in the world, with per-capita physician spending significantly higher than in other countries and making up about a fifth of overall healthcare spending.¹³⁸ Increasing the supply of goods or services in any market is generally the best approach to lowering prices, and physician services are no exception. Expanding domestic education and training opportunities—including the opening of new medical schools is a priority—efforts should be made to reduce the burdens on highly skilled, fully trained, foreign medical doctors looking to practice in the United States. Currently, any physician trained outside the United States or Canada must obtain an

Administration, Department of Justice 8-11 (October 6, 2015). (Discussing changing views on telemedicine prescribing of controlled substances without a prior in-person examination). See also *FTC Staff Comment to Washington State Rep. Paul Graves, regarding S.S.B. 5411/H.B. 1473*, 4-5 (Feb. 9, 2018), <https://www.ftc.gov/policy/advocacy/advocacy-filings/2018/02/ftc-staff-comment-washington-state-rep-paul-graves>. Accessed August 23, 2018. This letter explains why allowing a practitioner to determine whether the use of telehealth care is appropriate is better than a rigid in-person examination requirement.

¹³⁸ Centers for Medicare and Medicaid Services. National Health Expenditure Data. 2016. <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/downloads/highlights.pdf>. Accessed September 21, 2018.

Educational Commission for Foreign Medical Graduates (ECFMG) certification, complete a United States residency program, and apply for a state license.¹³⁹ This process is expensive (exams can cost up to \$15,000).¹⁴⁰

In the interim, easing the licensing pathway for highly qualified, foreign-trained doctors is one step that could be taken in the short-run to expand the supply of medical practitioners and thus constrain the price of physician services and lower overall healthcare costs for American consumers.

While increasing the supply of high-skilled, domestically trained United States medical professionals might help to constrain salaries for specialty physicians, facilitating the entry of additional foreign-trained doctors would be particularly helpful in alleviating the country's shortage of primary care physicians (PCPs). On average, PCPs earn 46 percent less than medical specialists. Because American medical school students graduate with an average of \$180,000 of debt, many of them pursue higher paid specialties rather than the much needed primary-care fields.¹⁴¹ While forecasts are often inaccurate, it is projected that by 2025, the United States will face a shortage of between 14,900 and 35,600 PCPs.¹⁴² Foreign-trained doctors have already helped meet this growing need—over 40 percent of current American PCPs were trained abroad; however, if it were easier for foreign-trained doctors to enter the United States marketplace, this percentage would likely rise.¹⁴³

Highly skilled, foreign-trained doctors could also be encouraged to practice in underserved regions of the country, where Americans often are unwilling to practice. For example, under the Conrad 30 Waiver Program, foreign-trained doctors can receive sponsorship to work in the United States if they commit to spend at least three years in an underserved region.¹⁴⁴ Over the past decade, this program has attracted more than 10,000 foreign-trained doctors to practice in areas faced with physician shortages.¹⁴⁵

¹³⁹ IMGs in the United States. Educational Commission for Foreign Medical Graduates.

<https://www.ecfm.org/certification/imgs-united-states.html>. Accessed September 21, 2018.

¹⁴⁰ Baier E. Foreign-trained doctors could soon have easier path in MN. *MPR News*. February 27, 2015.

<https://www.mprnews.org/story/2015/02/27/foreign-trained-doctors>. Accessed August 23, 2018.

¹⁴¹ Grisham S. Medscape physician compensation report 2017. Medscape. April 5, 2017.

<https://www.medscape.com/slideshow/compensation-2017-overview-6008547>. Accessed August 23, 2018.

¹⁴² The Complexities of Physician Supply and Demand: Projections from 2014 to 2025. Prepared for Association of American Medical Colleges. 2016 Apr 5: 5.

¹⁴³ Carroll AE. Why America needs foreign medical graduates. *New York Times*. October 6, 2017.

<https://www.nytimes.com/2017/10/06/upshot/america-is-surprisingly-reliant-on-foreign-medical-graduates.html>. Accessed August 23, 2018.

¹⁴⁴ Conrad 30 J1 visa waiver requirements by state. U.S. Immigration Website. <http://conrad30.com>. Accessed August 23, 2018.

¹⁴⁵ Patel D. Foreign doctors assist with Iowa's physician shortage. *Quad-City Times*. March 18, 2017.

https://globegazette.com/business/foreign-doctors-assist-with-iowa-s-physician-shortage/article_d1549069-4d05-5f25-ad52-d804e4b0bee4.html. Accessed September 26, 2018.

Recommendations: Ease Restrictions on Foreign-Trained Doctors

- The Department of Health and Human Services, in coordination with the Accreditation Council for Graduate Medical Education (GME), should identify foreign medical residency programs comparable in quality and rigor to American programs. Graduates of such equivalent programs should be granted “residency waivers,” allowing them to forgo completing an American residency and instead apply directly for state licensure.
- States should create an expedited pathway for highly qualified, foreign-trained doctors seeking licensure who have completed a residency program equivalent to an American GME program.

Federal Funding of Medical Education

Spending on physician services comprises approximately 20 percent of all healthcare expenditures in the United States, and prices for physician services tend to be substantially higher in the U.S. than in other wealthy countries.¹⁴⁶ As mentioned above, one option to reduce prices is to increase the supply of physicians. Physician supply in the United States, measured as physicians per 1,000 population, is well below the OECD median and is lower than 8 of 10 other OECD countries.¹⁴⁷ Unlike many other professions, in which market forces determine supply, the number of persons trained to be physicians is limited by organizations that are themselves often run by physicians, which creates natural conflict-of-interest concerns and raises questions concerning cartel-style rent seeking. Some barriers to entry in the physician sector (such as extensive educational, training and testing requirements, including state licensing and specialty board certification), may be justified to ensure professional competence. Nonetheless, this does not warrant non-market-based limits placed on the number of persons seeking to enter the medical field. Medical schools admit only a fraction of applicants, with many qualified individuals unable to enter due to the sharply limited spaces available.

Not only is the supply of potential physician practitioners limited, federal policy currently subsidizes medical training for an artificially low number of persons. The Department of Education administers loan programs that are available to medical school students, including private loans guaranteed by the federal government and direct loans from the

¹⁴⁶ Centers for Medicare and Medicaid Services. National Health Expenditure 2016 Highlights. 2016. <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/downloads/highlights.pdf>. Accessed September 21, 2018. One reason for lower foreign physician service prices, not discussed here, is the comparatively aggressive regulation of medical care delivery in other countries.

¹⁴⁷ Squires D, Anderson C. U.S. healthcare from a global perspective: spending, use of services, prices, and health in 13 countries. The Commonwealth Fund. October 2015. <http://johnegarven.com/blog/wp-content/uploads/2017/07/Spending-Use-of-Services-Prices-and-Health-in-13-Countries-The-Commonwealth-Fund.pdf>. Accessed September 21, 2018.

federal government through the students' schools. The Health Resources and Services Administration (HRSA), part of HHS, administers National Health Service Corps (NHSC) scholarships and loan repayment programs for health professionals who commit to practice in underserved areas and to train in primary care. An even larger amount of federal support is directed toward Graduate Medical Education (GME)—residency and fellowship programs that provide further training for medical school graduates. As of 2015, federal taxpayers paid \$287 million to support the NHSC, \$10.3 billion for Medicare GME, and \$2.4 billion for Medicaid GME, and \$265 million for the Children's Hospital Graduate Medical Education Payment Program.¹⁴⁸ Medical education is costly, but its estimated rate of financial return is high and clearly sufficient to entice many qualified individuals to seek admission to medical school. Current subsidies of medical education are generally regressive by reducing the cost to the very persons who can expect high financial returns to their valuable education and training.

The Structure of Medical Education

Medical education in the United States generally consists of four years of college education, followed by four years of medical school (undergraduate medical education), followed by graduate medical education (GME) consisting of three to six years of residency training in a medical specialty that is sometimes followed by a year or more of additional fellowship training. Medical school graduates must complete at least a year of residency training (often called an internship), depending on the state, to be licensed.

Medical students attend either allopathic medical schools (granting M.D. degrees) or osteopathic schools of medicine (granting D.O. degrees). The Liaison Committee on Medical Education (LCME), jointly sponsored by the Association of American Medical Colleges (AAMC) and the American Medical Association (AMA), is the United States Department of Education's recognized body for accrediting allopathic medical schools.¹⁴⁹ The American Osteopathic Association's (AOA) Commission on Osteopathic College Accreditation accredits osteopathic schools. In 2017-2018 there were 118,885 United States medical students including 46,315 men and 43,571 women at allopathic schools¹⁵⁰ and 15,904 men and 13,076 women at osteopathic schools.¹⁵¹ Residents and fellows train at programs accredited by the Accreditation Council for Graduate Medical Education (ACGME) or programs jointly accredited by the ACGME and the AOA. The Department

¹⁴⁸ Physician workforce: HHS needs better information to comprehensively evaluate graduate medical education funding. U.S. Government Accountability Office. GAO-18-240. March 9, 2018. <https://www.gao.gov/products/GAO-18-240>. Accessed August 23, 2018.

¹⁴⁹ Association of American Medical Colleges, Liaison Committee on Medical Education (LCME), April 22, 2018. https://www.aamc.org/members/osr/committees/48814/reports_lcme.html

¹⁵⁰ Table B-1.2: Total Enrollment at U.S. Medical School and Sex, 2013-2014 through 2017-2018. Association of American Medical Colleges. <https://www.aamc.org/download/321526/data/factstableb1-2.pdf>. Accessed August 23, 2018.

¹⁵¹ Table: Preliminary Enrollment Report Fall 2017. American Association of Colleges of Osteopathic Medicine. www.aacom.org/docs/default-source/data-and-trends/2017_fall_enrollment_report.pdf. Accessed August 23, 2018.

of Veterans Affairs, through affiliation agreements with medical schools and teaching hospitals, is the largest single provider of medical training in the United States, providing the site of training for medical students, residents and a small number of fellows.¹⁵²

To receive postgraduate training medical students must participate in a “match” process that determines where they receive residency training. This process is administered by the National Resident Matching Program that is sponsored in part by the AAMC. Applicants and training programs both submit rank-ordered preference lists, and then an algorithm matches applicants to programs to produce stable matchings as favorable as possible to applicants.¹⁵³ In 2004—in response to a lawsuit alleging that operating the match and accrediting residency programs was anti-competitive and violated the anti-trust statutes by limiting the number of residency positions and driving down resident choices and salaries—Congress granted the matching program an anti-trust exemption.¹⁵⁴

Graduate Medical Education (GME) Funding

Funding for GME subsidizes training for medical school graduates in hospitals and other teaching institutions in what are commonly known as residency and fellowship training programs. In 2015, federal agencies and state Medicaid programs provided \$16.3 billion to support GME. Five federal agencies (see Table 1) spent \$14.5 billion with the bulk of federal funding coming through Medicare (71 percent), Medicaid (16 percent), and the VA (10 percent); 45 state Medicaid agencies spent an additional \$1.8 billion on GME.¹⁵⁵

¹⁵² Heisler EJ, Panangala SV. The veterans health administration and medical education: in brief. Congressional Research Service. 7-5700. February 13, 2018. <https://fas.org/sgp/crs/misc/R43587.pdf>. Accessed August 23, 2018.

¹⁵³ Roth AE, Peranson E. The redesign of the matching market for American physicians: some engineering aspects of economic design.” *Am Econ Rev*. 1999;89(4):748-780.

¹⁵⁴ 15 U.S.C. § 37b [Pension Funding Equity Act of 2004].

¹⁵⁵ Physician workforce: HHS needs better information to comprehensively evaluate graduate medical education funding. U.S. Government Accountability Office. GAO-18-240. March 9, 2018. <https://www.gao.gov/products/GAO-18-240>. Accessed August 23, 2018.

Table 1. Federal Spending on Graduate Medical Education (GME) Training, 2015

Program	Total GME spending (dollars in millions)	Percent of total spending (percent)
HHS programs		
Medicare	10,335	71
Medicaid (federal share)	2,351	16
Children's Hospital GME Payment Program	249	2
Teaching Health Center GME Program	76	1
VA program	1,499	10
Total	14,509	100

Source: GAO analysis of departments of Health and Human Services (HHS) and Veterans Affairs (VA) data and GAO web-based survey administered to state Medicaid agencies. GAO-18-240.

About 30 percent of Medicare GME spending is for direct graduate medical education (DGME) to pay the salaries of residents and supervising physicians. Another 70 percent goes for indirect medical education (IME) to provide funding to hospitals that run training programs.¹⁵⁶ DGME payments are based on a per-resident amount and the number of full-time-equivalent (FTE) residents. IME Medicare payments are an add-on to the predetermined amount paid under the inpatient prospective payment system for each discharge with an adjustment for the number of FTE residents per hospital bed to represent the incremental care costs of providing GME training. DGME payments are also adjusted for the share of hospitals' patients covered by Medicare. The Balanced Budget Amendment of 1997 capped the number of FTE residents that programs may count for DGME and IME payment at the number of FTE residents working at the end of 1996.¹⁵⁷

While GME programs undoubtedly generate indirect costs, they also produce benefits for teaching institutions. Residents are an inexpensive source of labor. They work longer, more irregular hours than more experienced health professionals. They also increase attending

¹⁵⁶ Eden J, Berwich D, Wilensky G., eds. *Graduate Medical Education That Meets the Nation's Health Needs*. Washington, D.C.: The National Academies Press; 2014:9.

¹⁵⁷ Physician workforce: HHS needs better information to comprehensively evaluate graduate medical education funding. U.S. Government Accountability Office. GAO-18-240. March 9, 2018, at 10-12. <https://www.gao.gov/products/GAO-18-240>. Accessed August 23, 2018.

physicians' productivity by enabling them to increase the amount of patient services they can perform and for which they can bill.¹⁵⁸

The Medicare Payment Advisory Commission (MedPAC), an independent agency that advises Congress about Medicare, estimates that indirect graduate medical education payments are at least twice as high as actual costs, exceeding actual costs by \$3.5 billion each year.¹⁵⁹ Similarly, an HHS-sponsored study found that Medicare is overpaying for IME costs.¹⁶⁰ Some residency programs generate profits for hospitals. Hospitals value residency programs enough that they self-finance 12,000 residency positions.¹⁶¹

The current number of first year residency positions (30,232) exceeds the number of American medical school graduates (18,818 allopathic graduates and 4,617 osteopathic graduates) applying for them. The balance of positions are largely filled with foreign-born or U.S. citizen graduates of foreign medical schools, or in some cases, they go unfilled.¹⁶²

Physician Supply in the United States

There is likely an inadequate supply of physicians in the United States. Moreover, there is an uneven distribution in physician supply (both geographically and across specialties), GME training slots, and in government support for GME.¹⁶³ Yet there is inadequate information to assess overall physician needs, and for different specialties in different geographic areas.¹⁶⁴ GME slots are currently determined by the industry accrediting bodies and the hospitals or medical schools themselves. Similarly, medical school positions are accredited by physician industry groups.

¹⁵⁸ Physician workforce: HHS needs better information to comprehensively evaluate graduate medical education funding. U.S. Government Accountability Office. GAO-18-240. March 9, 2018, at 9.

<https://www.gao.gov/products/GAO-18-240>. Accessed August 23, 2018.

¹⁵⁹ Report to the Congress: aligning incentives in Medicare. Medicare Payment Advisory Commission (MedPAC). June 2010, at 109. http://www.medpac.gov/docs/default-source/congressional-testimony/20100623_EandC_Testimony_AligningIncentivesinMedicare.pdf?sfvrsn=0. Accessed August 23, 2018 ; see also Miller M. Graduate medical education payments. MedPAC. February 20, 2015.

https://www.nhpf.org/uploads/Handouts/Miller-slides_02-20-15.pdf. Accessed August 23, 2018; Wynn BO, Smalley R, Cordasco KM. Does It Cost More to Train Residents or to Replace Them? A Look at the Costs and Benefits of Operating Graduate Medical Education Programs. Santa Monica: Rand Corporation; 2013. https://www.rand.org/pubs/research_reports/RR324.html. Accessed August 23, 2018.

Report to the Congress: aligning incentives in Medicare. Medicare Payment Advisory Commission (MedPAC). June 2010, at 109.

http://www.medpac.gov/docs/default-source/congressional-testimony/20100623_EandC_Testimony_AligningIncentivesinMedicare.pdf?sfvrsn=0. Accessed August 23, 2018 ; see also Miller M.

Graduate medical education payments. MedPAC. February 20, 2015. https://www.nhpf.org/uploads/Handouts/Miller-slides_02-20-15.pdf. Accessed August 23, 2018; Wynn BO, Smalley R, Cordasco KM. Does It Cost More to Train Residents or to Replace Them? A Look at the Costs and Benefits of Operating Graduate Medical Education Programs. Santa Monica: Rand Corp.; 2013.

https://www.rand.org/pubs/research_reports/RR324.html. Accessed August 23, 2018.

[w.gao.gov/products/GAO-18-240](https://www.gao.gov/products/GAO-18-240). Accessed August 23, 2018.

¹⁶⁴ *Id.*

These findings suggest several areas for policy research and potential change. First, as requested in the FY 2019 President's Budget, the federal government should more efficiently spend taxpayer resources by streamlining federal Health and Human Services spending on graduate medical education into a single graduate medical education grant program. Under this Budget proposal, total funds available for graduate medical education in FY 2019 would equal the sum of Medicare's 2016 payments for DGME and IME, Medicaid's 2016 payments for GME, and the Children's Hospital GME Payment Program, adjusted for inflation. This amount would increase annually with inflation as measured by the consumer price index for all urban consumers (CPI-U) minus one percentage point per year. The new grant program would be funded out of the Treasury and jointly operated by the administrators of CMS and HRSA. This proposal is estimated to save \$48.1 billion between 2019 and 2028. The Budget proposal also provides the HHS Secretary with the authority to modify amounts distributed to hospitals based on the proportion of residents training in priority specialties or programs and based on other criteria identified by the Secretary, including addressing healthcare professional shortages and educational priorities. This flexibility will allow the federal government to more effectively target funding to those hospitals that are committed to building a strong medical workforce and to addressing medically underserved communities and health professional shortages.

Recommendations: Streamline Federal Funding of Medical Education

- As proposed in the FY 2019 President's Budget, the federal government should streamline federal Health and Human Services spending on graduate medical education into a single graduate medical education grant program. The budget proposal also provides the Secretary with the authority to modify amounts distributed to hospitals based on the proportion of residents training in priority specialties or programs and based on other criteria identified by the Secretary, including addressing healthcare professional shortages and educational priorities.
- The administration should continue the work done by the HRSA's National Center for Health Workforce Analysis, which studies U. S. physician supply needs across specialties and geographic areas. HRSA should launch a study that will also assess:
 - The administration's workforce development programs.
 - Gaps between existing programs and future workforce needs and identifying actions needed to address them.

Healthcare Provider Markets

Certificate of Need (CON) Requirements

State “certificate-of-need” (“CON”) laws require healthcare providers to obtain permission from a state (or state-authorized) agency to construct new healthcare facilities, expand existing ones, or offer certain healthcare services.¹⁶⁵ States initially adopted CON laws to further laudable policy goals, including cost control and access to care. The evidence to date, however, suggests that CON laws are frequently costly barriers to entry for healthcare providers rather than successful tools for controlling costs or improving healthcare quality. Based on that evidence and their enforcement experience, the two federal antitrust agencies—the FTC and the Antitrust Division of the Justice Department—have long suggested that states should repeal or retrench their CON laws.¹⁶⁶

Most states adopted CON programs in response to a since-repealed federal mandate, the National Health Planning and Resources Development Act of 1974,¹⁶⁷ which offered the states powerful incentives to adopt CON programs.¹⁶⁸ CON programs were supposed to control healthcare costs and mitigate incentives for an arms race in healthcare spending fostered by cost-based healthcare reimbursement systems.¹⁶⁹ Although both public and commercial reimbursement systems have changed significantly over time, many states have maintained substantial CON requirements. Congress repealed the 1974 Development Act in 1986, and a number of states have since repealed or revised their CON laws.¹⁷⁰

¹⁶⁵ Federal Trade Commission and U.S. Department of Justice. *Improving Health Care: A Dose of Competition*. July 2004, ch. 8, at 1-6. <http://www.ftc.gov/reports/healthcare/040723healthcarerpt.pdf>. Accessed August 23, 2018.

¹⁶⁶ See, e.g., *Joint Statement of the Fed. Trade Comm’n and the Antitrust Div. of the U.S. Dep’t Justice Regarding Certificate-of-Need (CON) Laws and Alaska Senate Bill 62, Which Would Repeal Alaska’s CON Program* (2017). <https://www.ftc.gov/policy/advocacy/advocacy-filings/2017/04/joint-statement-federal-trade-commission-antitrust-division>. Accessed August 23, 2018; *Joint Statement of the Federal Trade Commission and the Antitrust Division of the U.S. Department of Justice on Certificate-of-Need Laws and South Carolina House Bill 3250* (2016). <https://www.justice.gov/atr/file/812606/download>. Accessed August 23, 2018. For selected FTC and Division comments regarding state CON laws from 2008 -2016, see *Joint Statement of the Fed. Trade Comm’n and the Antitrust Div. of the U.S. Dep’t Justice Regarding Certificate-of-Need (CON) Laws and Alaska Senate Bill 62, Which Would Repeal Alaska’s CON Program* (2017). <https://www.ftc.gov/policy/advocacy/advocacy-filings/2017/04/joint-statement-federal-trade-commission-antitrust-division>. Accessed August 23, 2018.

¹⁶⁷ Pub. L. 93-641, 88 Stat. 2225 (1975) (codified at 42 U.S.C. §§ 300k-300n-5), *repealed*, Pub. L. 99-660, § 701, 100 Stat. 3799 (1986).

¹⁶⁸ See Miles JJ. *Health Care and Antitrust Laws: Principles and Practice*. Vol. 2. N.p.:Thomson Reuters; 2003: §16:1, at 16-2.

¹⁶⁹ See Federal Trade Commission and U.S. Department of Justice. *Improving Health Care: A Dose of Competition*. July 2004, ch. 8, at 2. ><http://www.ftc.gov/reports/healthcare/040723healthcarerpt.pdf><. Accessed August 23, 2018; CHRISTINE L. WHITE ET AL., *ANTITRUST AND HEALTHCARE: A COMPREHENSIVE GUIDE* 527 (2013).

¹⁷⁰ Regarding changes since 2011, see Koopman C, Philpot A. The state of certificate-of-need laws in 2016. *Mercatus Center*, George Mason Univ. September 27, 2016. <https://www.mercatus.org/publications/state-certificate-need-laws-2016>. Accessed August 23, 2018; cf. CON – Certificate of Need State Laws. National Conference of State Legislatures, August 17, 2018, <http://www.ncsl.org/research/health/con-certificate-of-need-state-laws.aspx>. Accessed September 26, 2018 (providing a table and an interactive map representing some of the variation in state CON laws.).

Fifteen states have eliminated their CON requirements altogether.¹⁷¹ Although most other states maintain CON programs,¹⁷² some remaining CON laws address only specific types of healthcare facilities (such as hospitals or nursing homes),¹⁷³ exempt certain types of healthcare facilities,¹⁷⁴ or apply only to facilities of a certain size.¹⁷⁵ Some CON laws are subject to sunset provisions.¹⁷⁶

CON proponents continue to raise cost control as a justification for CON programs; they also argue that CON laws improve the quality of healthcare services and assure access to healthcare services by disadvantaged citizens. However, available evidence suggests that CON laws have failed to produce cost savings, higher quality healthcare, or greater access to care, whether in underserved communities or in underserved areas.

CON Laws Impose Costs, Including Loss of Beneficial Competition

Empirical evidence on competition in healthcare markets generally demonstrates that consumers benefit from lower prices when provider markets are more competitive.¹⁷⁷ Scrutiny of hospital mergers by the FTC and the Antitrust Division has been particularly useful in understanding concentrated provider markets, and retrospective studies of the effects of provider consolidation by agency staff and independent scholars suggest that

¹⁷¹ Koopman C, Philpot A. The state of certificate-of-need laws in 2016. Mercatus Center, George Mason Univ. September 27, 2016. <https://www.mercatus.org/publications/state-certificate-need-laws-2016>. Accessed August 23, 2018. New Hampshire is the state that most recently rescinded its CON requirements, with the enactment of NH SB481 on June 6, 2016, effective July 1, 2016/ <https://legiscan.com/NH/bill/SB481/2016>. Accessed August 25, 2018.

¹⁷² Koopman C, Philpot A. The state of certificate-of-need laws in 2016. Mercatus Center, George Mason Univ. September 27, 2016. <https://www.mercatus.org/publications/state-certificate-need-laws-2016>. Accessed August 23, 2018; Miles JJ. *Health Care and Antitrust Laws: Principles and Practice*. Vol. 2. N.p.:Thomson Reuters; 2003: §16:2, at 16-9.

¹⁷³ Compare, e.g., OHIO ADMIN. CODE ANN. 3701-12-23, 23.2 (regarding certain activities by “long-term care” facilities in Ohio) with OR. REV. STAT. § 442.315(1) (2017) (regarding “any new hospital or new skilled nursing or intermediate care service or facility” in Oregon, subject to certain exclusions).

¹⁷⁴ For example, Connecticut generally requires a CON for establishment or acquisition of new healthcare facilities, Conn. Gen. Stat. § 19a-638(a), but exempts, e.g., residential care homes, nursing homes and rest homes, *ibid.* at § 19a-638(b)(4), outpatient chronic dialysis services, *id.* at § 19a-638(b)(9), and transplant services, *ibid.* at § 19a-638(b)(10), among others. See Conn. Gen. Stat. § 19a-638(b)(1)-(22) (exemptions).

¹⁷⁵ For example, Delaware requires a CON for a new facility, but only for capital expenditures by existing facilities in excess of \$5.8 million (or a higher amount based on inflation). See 16 Del. C. § 9304.

¹⁷⁶ For example, provisions of the Delaware Code requiring review, 16 Del. C. § 9304., are “[e]ffective until Dec. 31, 2020.”

¹⁷⁷ See, e.g., Gaynor M, Town R. The impact of hospital consolidation—update. Robert Wood Johnson Foundation, The Synthesis Project. Policy Brief No. 9. June 2012. http://www.rwjf.org/content/dam/farm/reports/issue_briefs/2012/rwjf73261. Accessed August 21, 2018 (synthesizing research on the impact of hospital mergers on prices, cost, and quality and finding that hospital consolidation generally results in higher prices, hospital competition improves quality of care, and physician-hospital consolidation has not led to either improved quality or reduced costs); Gaynor M, Town RJ. Competition in healthcare markets. In *Handbook of Health Economics*. Vol 2, 1st ed. Waltham, MA: North Holland; 2012:499, 637 (2012). Gaynor M, Ho K, Town R. The industrial organization of health-care markets. 53 *J Econ Lit*. 2015;53(2):235, 294, (201u5). https://www.researchgate.net/publication/278676719_The_Industrial_Organization_of_Health-Care_Markets. Accessed August 21, 2018 (critical review of empirical and theoretical literature regarding markets in healthcare services and insurance).

“increases in hospital market concentration lead to increases in the price of hospital care.”¹⁷⁸

FTC and Antitrust Division staff have examined the competitive impact of CON laws for several decades. For example, staff from the FTC's Bureau of Economics conducted several studies of CON laws in the late 1980s, both before and after repeal of the federal law that had encouraged their adoption.¹⁷⁹ In addition, the agencies jointly conducted 27 days of hearings on healthcare competition matters in 2003, receiving testimony about CON laws and market entry, hospital provider concentration, and other pertinent aspects of healthcare competition;¹⁸⁰ they jointly released a substantial report on healthcare competition issues, including those related to CON laws, in 2004.¹⁸¹ Finally, through their competition advocacy programs, the Agencies have reviewed numerous state CON laws and encouraged states to consider the competitive impact of those laws.¹⁸²

¹⁷⁸ Gaynor M, Town R. The impact of hospital consolidation—update. Robert Wood Johnson Foundation, The Synthesis Project. Policy Brief No. 9. June 2012, at 1. http://www.rwjf.org/content/dam/farm/reports/issue_briefs/2012/rwjf73261. Accessed August 21, 2018 (citing, e.g., Haas-Wilson D, Garmon C. *Hospital mergers and competitive effects: two retrospective analyses*. *Int J Econ Bus*. 2011;17, 30 (post-merger review of agency methods applied to two hospital mergers; data “strongly suggests” that large price increases in challenged merger be attributed to increased market power and bargaining leverage); Dafny L. Estimation and identification of merger effects: an application to hospital mergers. *J Law Econ*. 2009;52(3):523, 544 (“[H]ospitals increase price by roughly 40 percent following the merger of nearby rivals”); Capps C, Dranove D. Hospital consolidation and negotiated PPO Prices. *Health Aff*. 2004 Mar-Apr;23:175, 179 (“Overall, our results do not support the argument that efficiencies from consolidations among competing hospitals lead to lower prices. Instead, they are broadly consistent with the opposing view that consolidations among competing hospitals lead to higher prices.”); see also, e.g., Farrell J, Pautler P, Vita M. Economics at the FTC: retrospective merger analysis with a focus on hospitals. *Ref Indus Org* 2009;35(4):369 (Mergers between not-for-profit hospitals can result in substantial anti-competitive price increases).

¹⁷⁹ Sherman D. The effect of state certificate-of-need laws on hospital costs: an economic policy analysis. Federal Trade Commission. January 1988. <https://www.ftc.gov/reports/effect-state-certificate-need-laws-hospital-costs-economic-policy-analysis>. Accessed August 23, 2018 (concluding, after empirical study of CON programs' effects on hospital costs using 1983-84 data on 3,708 hospitals, that strong CON programs do not lead to lower costs but may actually increase costs); Noether M. Competition among hospitals. Federal Trade Commission. May 1987. <https://www.ftc.gov/reports/competition-among-hospitals-0>. Accessed August 23, 2018 (empirical study concluding that CON regulation led to higher prices and expenditures); Anderson KB, Kass DI. Certificate of need regulation of entry into home healthcare: a multi-product cost function analysis. Federal Trade Commission. January 1986.

¹⁸⁰ *Health Care and Competition Law and Policy Hearings*. Federal Trade Commission. <https://www.ftc.gov/news-events/events-calendar/2003/02/health-care-competition-law-policy-hearings>. Accessed Dec. 2, 2015.

¹⁸¹ Federal Trade Commission and the U.S. Department of Justice. *Improving Health Care: A Dose of Competition*. July 2004, ch. 8, at 1-6. <http://www.ftc.gov/reports/healthcare/040723healthcarerpt.pdf>. Accessed August 23, 2018.

¹⁸² See, e.g., *Joint Statement of the Federal Trade Commission and the Antitrust Division of the U.S. Department of Justice to the Virginia Certificate of Public Need Work Group*. October 26, 2015. https://www.ftc.gov/system/files/documents/advocacy_documents/joint-statement-federal-trade-commission-antitrust-division-u.s.department-justice-virginia-certificate-public-need-work-group/151026ftc-dojstmtva_copn-1.pdf. Accessed August 23, 2018; Letter from Marina Lao, Director, Office of Policy Planning, Federal Trade Commission, et al., to The Honorable Marilyn W. Avila, N.C. House of Representatives. July 10, 2015. https://www.ftc.gov/system/files/documents/advocacy_documents/ftc-staff-comment-concurring-comment-commissioner-wright-regarding-north-carolina-house-bill-200/150113ncconadv.pdf. Accessed August 23, 2018; *Prepared Statement of the Federal Trade Commission Before the Florida State Senate*. April 2, 2008. https://www.ftc.gov/sites/default/files/documents/advocacy_documents/ftc-prepared-statement-florida-senate-

The best empirical evidence suggests that greater competition incentivizes providers to become more efficient. Recent work shows that hospitals faced with a more competitive environment have better management practices.¹⁸³ Consistent with this is evidence suggesting that repealing or narrowing CON laws can reduce the per-patient cost of healthcare.¹⁸⁴ Studies have found no empirical evidence that CON laws have restricted “over-investment.”¹⁸⁵ However, CON laws can restrict investments that would benefit consumers and lower costs in the long term and are likely to increase, rather than constrain, healthcare costs. This is because CON regimes impose the legal and regulatory costs of preparing an application, then seeing that application through an often-lengthy approval process and potential third-party challenges.¹⁸⁶ As a result, healthcare providers must spend resources on administrative processes rather than on constructing healthcare facilities or

[concerning-florida-certificate-need-laws/v080009florida.pdf](https://www.justice.gov/atr/press-releases/2018/082318). Accessed August 23, 2018; *Statement of the Antitrust Division, U.S. Department of Justice, Before the Florida Senate Committee on Health & Human Services*. March 25, 2008. <http://www.justice.gov/atr/comments-competition-healthcare-and-certificates-need>. Accessed August 23, 2018; *Joint Statement of the Fed. Trade Comm'n and the Antitrust Div. of the U.S. Dep't Justice Regarding Certificate-of-Need (CON) Laws and Alaska Senate Bill 62, Which Would Repeal Alaska's CON Program* (2017) <https://www.ftc.gov/policy/advocacy/advocacy-filings/2017/04/joint-statement-federal-trade-commission-antitrust-division>. Accessed August 23, 2018; *Statement of the Antitrust Division, U.S. Department of Justice, Before a Joint Session of the Health & Human Services Committee of the State Senate and the CON Special Committee of the State House of Representatives of the General Assembly of the State of Georgia*. February 23, 2007. <http://www.justice.gov/atr/competition-healthcare-and-certificates-need>. Accessed August 23, 2018.

¹⁸³ See, e.g., Bloom N, Propper C, Seiler S, Van Reenen JV. The impact of competition on management quality: evidence from public hospitals. *Rev Econ. Studies*. 2015 Apr 1;82(2):457, 457. (“We find that higher competition results in higher management quality.”)

¹⁸⁴ Vivian Ho & Meei-Hsiang Ku-Goto, *State Deregulation and Medicare Costs for Acute Cardiac Care*, 70 MED. CARE RES. & REV. 185, 202 (2012) (finding an association between the lifting of CON laws and a reduction in mean patient costs for coronary artery bypass graft surgery, and finding that these cost savings slightly exceed the fixed costs of new entrants); Patrick A. Rivers et al., *The Effects of Certificate of Need Regulation on Hospital Costs*, 36 J. HEALTH CARE FIN. 1, 11 (2010) (finding a positive relationship between the stringency of CON laws and healthcare costs per adjusted admission and concluding that the “results, as well as those of several previous studies, indicate that [CON] programs do not only fail to contain [hospital costs], but may actually increase costs as well” (emphasis in original)). While other studies evaluate the impact of repealing CON laws (with varying results), many of these studies are less persuasive because they do not account for preexisting cost differences between the states. Compare Michael D. Rosko & Ryan L. Mutter, *The Association of Hospital Cost-Inefficiency with Certificate-of-Need Regulation*, 71 MED. CARE RES. & REV. 1, 15 (2014) (finding “a plausible association between CON regulation and greater hospital cost-efficiency”), with Gerald Granderson, *The Impacts of Hospital Alliance Membership, Alliance Size, and Repealing Certificate of Need Regulation on Cost Efficiency of Non-profit Hospitals*, 32 MANAGE. DECIS. ECON. 159, 167-68 (2011) (“[R]epealing state CON programs contributed to an improvement in hospital cost efficiency.”).

¹⁸⁵ Some papers find that CON laws are associated with lower utilization of hospital beds. These studies, however, do not address the critical question of whether the lower bed utilization in states with CON laws is a result of preventing over-investment or restricting beneficial investment. See, e.g., Delamater PL, Messina JP, Grady SC, WinklerPrins V, Shortridge AM. Do more hospital beds lead to higher hospitalization rates? A spatial examination of Roemer's Law. *PLOS ONE*. 2013;8:13-14 (finding “a positive, significant association between hospital bed availability and hospital utilization rates”); Hellinger FJ. The effect of certificate-of-need laws on hospitals beds and healthcare expenditures: an empirical analysis. *Am J Man Care*. 2009;15:737 (finding that CON laws “have reduced the number of hospital beds by about 10%”).

¹⁸⁶ See, e.g., *Joint Statement of the Federal Trade Commission and the Antitrust Division of the U.S. Department of Justice on Certificate-of-Need Laws and South Carolina House Bill 3250* (2016), at text accompanying notes 14-25 (detailing lengthy application, hearing, and appeal process in South Carolina). <https://www.justice.gov/atr/file/812606/download>. Accessed August 23, 2018.

delivering healthcare services. In addition, those regulatory costs can be a barrier to entry, discouraging some would-be providers from entering certain healthcare markets, and discouraging some incumbent providers from expanding or innovating in ways that would make business sense but for the costs of the CON system. Even for providers willing to bear those regulatory costs, CON requirements may be hard barriers to entry if their applications are denied. Hence, CON laws can diminish the supply of healthcare facilities and services while exacerbating concentration in provider markets.

CON Laws Have Not Improved Healthcare Quality or Access

CON proponents have argued that CON laws support policy goals relating to healthcare quality and access. However, CON laws would be an indirect—and likely inefficient—way to achieve these goals. Moreover, the evidence suggests CON laws are ineffective. There is no compelling evidence suggesting that CON laws improve quality or access, inefficiently or otherwise.

Quality-based arguments on behalf of CON laws typically refer to evidence on volume/outcome relationships (i.e., the extent to which quality of care is related to how often a particular healthcare institution or provider performs a given procedure), rather than direct evidence of CON laws' impact on care quality. Even this volume/outcome evidence is mixed. Pronounced effects may be limited to certain relatively complicated procedures;¹⁸⁷ and even there, where certain studies have shown a volume/outcome relationship (e.g., coronary artery bypass graft surgery¹⁸⁸), evidence suggests that volume effects may not offset CON laws' larger negative impact on quality.¹⁸⁹ Studies that directly analyze the impact of changes in CON laws on health outcomes provide a more complete picture; the weight of that research has found that repealing or narrowing CON laws is generally unlikely to lower quality of care, and may improve the quality of certain types of care.¹⁹⁰ Moreover, CON programs can tend to foster or sustain undue provider

¹⁸⁷ See Halm EA, Lee C, Chassin MR. Is volume related to outcome in health care? A systematic review and methodological critique of the literature. *Ann Intern Med.* 2002 Sep 17;137(6):511, 514. ("We found the most consistent and striking differences in mortality rates between high- and low-volume providers for several high-risk procedures and conditions, including pancreatic cancer, esophageal cancer, abdominal aortic aneurysms, pediatric cardiac problems, and treatment of AIDS. The magnitude of volume-outcome relationships for more common procedures, such as [coronary artery bypass graft surgery], coronary angioplasty, and carotid endarterectomy, for which selective referral and regionalization policies have been proposed, was much more modest.")

¹⁸⁸ See Gaynor M, Seider H, Vogt WB. The volume-outcome effect, scale economies, and learning-by-doing. *Am Econ Rev.* 2005;95(2):243, 244.

¹⁸⁹ See, e.g., Ho V, Ku-Goto M, Jollis JG. Certificate of need (CON) for cardiac care: controversy over the contributions of CON. *Health Serv Res.* 2009 Apr;44(2 Pt 1):483, 483 (2009) ("States that dropped CON experienced lower [coronary artery bypass graft surgery] mortality rates relative to states that kept CON, although the differential is not permanent.")

¹⁹⁰ See Li S, Dor A. How do hospitals respond to market entry? Evidence from a deregulated market for cardiac revascularization. *Health Econ.* 2015;24:990, 1006 (finding that repeal of Pennsylvania's CON program improved "the match between underlying medical risk and treatment intensity"); Ho V, Ku-Goto M. State deregulation and Medicare costs for acute cardiac care. *Med Care Res Rev.* 2012;70:199 (finding association between lifting of CON laws and shorter lengths of stay and fewer strokes during admission for coronary artery bypass patients, finding no significant

concentration; and additional empirical evidence suggests that, “[a]t least for some procedures, hospital concentration reduces quality.”¹⁹¹

Evidence also fails to support the claim that CON programs would increase access to care for the indigent, or in medically underserved areas. The general argument has been that CON laws, by limiting competition, allow incumbent healthcare providers to earn greater profits—by charging higher prices and preserving their volume of lucrative procedures—than they would earn in a competitive environment. It is posited that those extra profits will be used to cross-subsidize care for the underserved. There are inherent weaknesses in this supposition. First, the charity-care rationale is at odds with the cost-control rationale. The notion that CON-protected incumbents would use their market power and profits to cross-subsidize charity care presumes that those providers will charge supra-competitive prices for non-charity care. Such supra-competitive pricing might harm many healthcare consumers, including low-income or under-insured patients who are ineligible for charity care. Second, because CON programs impede entry, expansion, and innovation, they can impede access to care for all patients, including low-income patients. Finally, the evidence does not show that CON laws promote charity care. Research suggests that safety-net hospitals are no stronger financially in CON states than in non-CON states.¹⁹² There is also empirical evidence contradicting the notion that dominant providers use their market power to cross-subsidize charity care, including an empirical study of the relationship between competition and charity care that found a “complete lack of support for the ‘cross-subsidization hypothesis.’”¹⁹³

CON Laws Can Foster Competition Problems Missed By Benefit/Cost Analysis

Not only may CON laws impose costly barriers to provider entry, but by interfering with market forces that normally determine the supply of facilities and services, they can

association between lifting CON laws and three other complications during admission for coronary artery bypass graft patients, and finding no significant associations between lifting of CON laws and length of stay or need for coronary artery bypass graft surgery for percutaneous coronary intervention patients); Cutler DM, Huckman RS, Kolstad JT. Input constraints and the efficiency of entry: lesson from cardiac surgery. *Am Econ J.: Econ Policy* 2010;2(1):51, 52 (finding that new entry after repeal of Pennsylvania’s CON program “had a salutary effect on the market for cardiac surgery by directing more volume to better doctors and increasing access to treatment”).

¹⁹¹ Gaynor M, Town R. The impact of hospital consolidation—update. Robert Wood Johnson Foundation, The Synthesis Project. Policy Brief No. 9. June 2012, at 3.

http://www.rwjf.org/content/dam/farm/reports/issue_briefs/2012/rwjf73261. Accessed August 21, 2018; see also Romano P, Balan DJ. A retrospective analysis of the clinical quality effects of the acquisition of Highland Park Hospital by Evanston Northwestern Health care. *Int J Econ Bus.* 2011;18:45, 64 (2011).

¹⁹² Cutler DM, Huckman RS, Kolstad JT. Input constraints and the efficiency of entry: lesson from cardiac surgery. *Am Econ J.: Econ Policy* 2010;2(1):63 (finding that, following repeal of Pennsylvania’s CON program, incumbent hospitals “were not put in a precarious position by the elimination of CON”); The Lewin Group. An evaluation of Illinois’ Certificate of Need Program: prepared for the State of Illinois Commission on Government Forecasting and Accountability. 2007 Feb 15;ii:27-28. <http://cgfa.ilga.gov/Upload/LewinGroupEvalCertOfNeed.pdf>. Accessed August 23, 2018. (“Through our research and analysis we could find no evidence that safety-net hospitals are financially stronger in CON states than other states.”)

¹⁹³ Garmon C. Hospital competition and charity care. *Forum Health Econ Policy.* 2009;12:1, 13.

suppress supply, misallocate resources, and shield incumbent healthcare providers from competition from new entrants.¹⁹⁴ In addition, incumbent firms may use CON laws to thwart or delay entry or expansion by new or existing competitors.¹⁹⁵ CON programs have also facilitated anti-competitive agreements among competitors. For example, in 2006, a hospital in Charleston, West Virginia, used the threat of objection during the CON process to keep a potentially competitive hospital from expanding.¹⁹⁶

Finally, as illustrated by the FTC's experience in the *Phoebe Putney* case, CON laws can entrench anti-competitive mergers by limiting the government's ability to implement effective structural remedies to consummated transactions. *Phoebe Putney* involved a challenge to the merger of two hospitals in Albany, Georgia.¹⁹⁷ Seeking a preliminary injunction in federal court, the FTC alleged that the merger would create a monopoly of inpatient general acute care hospital services sold to commercial health plans in Albany and surrounding areas. The district court dismissed the suit, finding that the merger was protected from antitrust scrutiny by the "state action doctrine."¹⁹⁸ The United States Court of Appeals for the Eleventh Circuit affirmed the district court's dismissal on state action grounds, although finding that "the joint operation of [the two hospitals] would substantially lessen competition or tend to create, if not create, a monopoly."¹⁹⁹ The Supreme Court reversed this decision, unanimously holding that "state action immunity" did not apply.²⁰⁰ However, the merging parties already had consummated the transaction while appeals were pending, and Georgia's CON regime precluded structural relief for the anticompetitive merger.²⁰¹ As the Commission explained, "[W]hile [divestiture] would

¹⁹⁴ See Federal Trade Commission and U.S. Department of Justice, *Improving Health Care: A Dose of Competition*, July 2004, ch. 8, at 4, http://www.ftc.gov/reports/health_care/040723health_carerpt.pdf. Accessed August 23, 2018 (discussing examples of how CON programs limited access to new cancer treatments and shielded incumbents from competition from innovative newcomers).

¹⁹⁵ See, e.g., *Joint Statement of the Federal Trade Commission and the Antitrust Div. of the U.S. Department of Justice Regarding Certificate-of-Need (CON) Laws and Alaska Senate Bill 62, Which Would Repeal Alaska's CON Program*, 6-7 (2017), <https://www.ftc.gov/policy/advocacy/advocacy-filings/2017/04/joint-statement-federal-trade-commission-antitrust-division>. Accessed August 23, 2018.

¹⁹⁶ *United States v. Charleston Area Med. Ctr., Inc.*, No. 2:06-0091 (S.D. W.Va. 2006). In a separate but similar case, informal suggestions by state CON officials led closely competing West Virginia hospitals to agree that one hospital would seek a CON for open heart surgery and the other for cancer treatment. *United States v. Bluefield Reg'l Med. Ctr., Inc.*, No. 1:05-0234 (S.D. W.Va. 2005). While the Division secured consent decrees prohibiting these agreements between competitors to allocate services and territories, such conduct indicates that CON laws can provide the opportunity for anti-competitive agreements. See, e.g., U.S. Department of Justice, Department of Justice Statement on the Closing of the Vermont Home Health Investigation. Press Release. November 23, 2005. http://www.justice.gov/archive/opa/pr/2005/November/05_at_629.html. Accessed August 23, 2018.

¹⁹⁷ See generally *In the Matter of Phoebe Putney Health Sys., Inc.*, Dkt. No. 9348 (March 31, 2015), <https://www.ftc.gov/enforcement/cases-proceedings/111-0067/phoebe-putney-health-system-inc-phoebe-putney-memorial>. Accessed August 23, 2018.

¹⁹⁸ *FTC v. Phoebe Putney Health Sys.*, 793 F. Supp. 2d 1356, 1361-1362 (M.D. Ga. 2011).

¹⁹⁹ *FTC v. Phoebe Putney Health Sys.*, 663 F.3d 1369 (11th Cir. 2011).

²⁰⁰ *FTC v. Phoebe Putney Health Sys.*, 133 S. Ct. 1003, 1007 (2013).

²⁰¹ The Eleventh Circuit had dissolved the stay that had prevented the parties from consummating the merger. With the stay dissolved, the parties had consummated their merger before the Supreme Court resolved the state-action question. *FTC v. Phoebe Putney Health Sys. Inc.*, 133 S. Ct. at 1011.

have been the most appropriate and effective remedy to restore the lost competition in Albany and the surrounding six-county area from this merger to monopoly, Georgia's [CON] laws and regulations unfortunately render a divestiture in this case virtually impossible."²⁰²

Certificates of Public Advantage

Certificate-of-public-advantage (COPA) regulations allow healthcare providers to enter into cooperative agreements that might otherwise be subject to antitrust scrutiny and can cover a wide range of provider collaboration and merger activity.²⁰³ COPA schemes displace competition in favor of state regulatory oversight and may, under the state action doctrine, immunize provider activity for conduct that might otherwise violate federal antitrust laws.²⁰⁴ Typically, states have the authority to approve COPA proposals if they determine that the likely benefits of the cooperative agreement outweigh any disadvantages attributable to a reduction in competition.²⁰⁵ In practical terms, COPAs significantly limit the ability of antitrust enforcement agencies to challenge collaborations and mergers that create or enhance provider market power, and therefore are likely to harm consumers.²⁰⁶

²⁰² *Statement of the Federal Trade Commission*, at 1, *In the Matter of Phoebe Putney Health Sys., Inc.*, Dkt. No. 9348, (March 31, 2015):1.

https://www.ftc.gov/system/files/documents/public_statements/634181/150331phoebeputneycommstmt.pdf. Accessed August 23, 2018.

²⁰³ Several states have passed COPA statutes since the 1990s, and there appears to be a recent resurgence in the implementation of COPA regulations. The following hospital mergers have been permitted to proceed pursuant to COPA oversight: HealthSpan Hospital System (Minnesota, 1994); Mission Health System (North Carolina, 1995); Benefis Health System (Montana, 1996); Palmetto Health System (South Carolina, 1998); Cabell Huntington Hospital/St. Mary's Medical Center (West Virginia, 2016); and Mountain States Health Alliance/Wellmont Health System (Tennessee and Virginia, 2017). In addition, the Staten Island Performing Provider System in New York recently received a COPA for certain collaborative activities (2016). See COPA Application #COPA-SIPPS Staten Island PPS. New York Department of Health, Public Health and Health Planning Council.

https://www.health.ny.gov/facilities/public_health_and_health_planning_council/meetings/2016-11-17/docs/copa-sipps_staten_island_pps.pdf. Accessed August 23, 2018.

²⁰⁴ To obtain antitrust immunity for conduct that might otherwise violate the federal antitrust laws, the state action doctrine requires both a clear articulation of the state's intent to displace competition in favor of regulation and that the state provide active supervision over the regulatory scheme or body. See *N.C. State Bd. of Dental Exam'rs v. FTC*, 135 S. Ct. 1101, 1114 (2015); *FTC v. Phoebe Putney Health Sys., Inc.*, 133 S. Ct. 1003, 1013 (2013).

²⁰⁵ Benefits typically considered by the states include cost efficiencies, quality improvements, population health improvements, preservation of hospital facilities and resources, and increased patient access to healthcare services. Disadvantages typically considered by the states include price increases, an inability of health plans to negotiate reasonable contract terms with providers, and reduced quality and access for healthcare services attributable to a reduction in competition.

²⁰⁶ For example, the Federal Trade Commission recently dismissed an administrative complaint filed in the matter of Cabell Huntington Hospital's proposed acquisition of St. Mary's Medical Center, after the West Virginia state legislature passed a COPA statute intended to shield the transaction from an antitrust challenge, and the West Virginia Health Care Authority approved the hospitals' COPA application. See *Statement of the Federal Trade Commission In the Matter of Cabell Huntington Hospital, Inc.*, Dkt. No. 9366 (Jul. 6, 2016).

https://www.ftc.gov/system/files/documents/public_statements/969783/160706cabellcommstmt.pdf. Accessed September 26, 2018.

Moreover, COPA review and oversight frequently are subject to the influence of special interests through state political processes.

As a condition for COPA approval, states often impose terms and conditions on the COPA recipient intended to mitigate the potential for anti-competitive harms. Such regimes may include rate regulation, prohibitions on certain contracting practices, and commitments to improve quality or return cost savings to the local community. These types of regulatory conditions are often difficult to implement and monitor and may not accomplish intended goals. In addition, some states that have approved COPA schemes have later repealed or revised the COPA statutes allowing them, effectively terminating the state regulatory oversight that was supposed to constrain the exercise of market power and potentially empowering an unrestrained monopolist.²⁰⁷ For these reasons, the FTC has raised concerns that COPAs may create or enhance provider market power without offering sufficient mechanisms for mitigating potential harms to competition and consumers.²⁰⁸

As discussed in Section 1, compelling empirical research suggests that market-based competition among healthcare providers yields positive results for consumers such as reduced prices and improved quality of care. Conversely, there is limited empirical research regarding the impact of COPA regulations. For this reason, FTC staff are currently

²⁰⁷ In 2015, the North Carolina legislature repealed the state's COPA statute, leaving no effective constraint on Mission Health System, which had operated under a COPA since 1995. See S.B. 698, Gen. Assemb., 2015-16 Session, Session Law 2015-288 (N.C. 2015), <http://www.ncleg.net/Sessions/2015/Bills/Senate/PDF/S698v5.pdf>. Accessed August 23, 2018 (ratified by General Assembly Sept. 29, 2015; signed into law by Governor Oct. 29, 2015, repealing Article 9A of Chapter 131E of the NC General Statutes, relating to Certificate of Public Advantage, effective Jan. 1, 2018); H.B. 1030, Gen. Assemb., 2015-2016 Session, Session Law 2016-94, at 93 (N.C. 2016), <http://www.ncga.state.nc.us/Sessions/2015/Bills/House/PDF/H1030v8.pdf>. Accessed August 23, 2018. (revising the effective date of repeal from January 1, 2018 to September 30, 2016). In 2007, the Montana state legislature revised the state's COPA statute to limit the duration of COPAs to ten years, effectively terminating the COPA that Benefis Health System had operated under since 1996. See Mont. Code Ann. § 50-4-603(5) (amended 2007). <http://leg.mt.gov/bills/mca/50/4/50-4-603.htm>. Accessed August 23, 2018 (limiting the duration of a COPA to no more than 10 years from the date of issuance).

²⁰⁸ See, e.g., FTC staff submissions regarding the proposed merger and COPA applications of Mountain States Health Alliance and Wellmont Health System. <https://www.ftc.gov/enforcement/cases-proceedings/151-0115/wellmont-healthmountain-states-health>. Accessed August 23, 2018; Submission of Amerigroup Tennessee Inc. to the Tennessee Department of Health on the review of the application for a Certificate of Public Advantage from Wellmont Health System and Mountain States Health Alliance (Nov. 18, 2016). November 18, 2016. https://www.tn.gov/content/dam/tn/health/documents/COPA_AmeriGroup_Submission_to_Tennessee_DOH_with_Exhibits_11.18.16.pdf. Accessed August 23, 2018; Written Comments of America's Health Insurance plans submitted to the Tennessee Department of Health – COPA Index Advisory Group. April 19, 2016. https://www.tn.gov/content/dam/tn/health/documents/AHIP_COPA_Comments_041819.pdf. Accessed August 23, 2018; Letter submitted by professors and academic economists to the Tennessee Department of Health. November 21, 2016. https://www.tn.gov/content/dam/tn/health/documents/Comment_on_Wellmont-MSHA_COPA_Application_by_Professors_and_Academic_Eco.pdf. Accessed August 23, 2018; Public comments submitted to the Virginia Department of Health regarding the cooperative agreement application of Mountain States Health Alliance and Wellmont Health System. <http://www.vdh.virginia.gov/licensure-and-certification/cooperative-agreement/public-comment/>. Accessed August 23, 2018.

assessing the potential benefits and disadvantages of COPAs and recently issued a notice requesting empirical research and public comments on these issues.²⁰⁹

The antitrust laws are intended to achieve the goals of reduced prices, improved quality, and greater innovation and access for healthcare services and not prevent procompetitive provider collaborations that would generate efficiencies and benefit consumers.²¹⁰ COPAs that immunize otherwise anti-competitive collaborations and mergers from antitrust scrutiny pose a substantial risk of consumer harm.

Recommendations: Repeal or Scale Back CON and COPA Requirements

- States should consider repeal of Certificate of Need (CON) statutes or, at a minimum, significantly scale back the scope of their CON regimes, for example by ensuring that competitors of CON applicants cannot weigh in on these applications.
- The FTC and its staff should make appropriate policy recommendations after completing ongoing research on the benefits and disadvantages of CON and COPA statutes and regimes.
- States should discontinue the use of COPAs to shield anti-competitive provider collaborations and mergers from antitrust scrutiny in the absence of any clear evidence that these regulatory schemes produce better results than market-based competition.

Nonprofit Exemption from Federal Trade Commission Jurisdiction

Currently, the FTC Act limits the FTC's jurisdiction over nonprofits. The FTC Act applies to "persons, partnerships, or corporations,"²¹¹ and the act defines "corporation" as an entity that "is organized to carry on business for its own profit or that of its members."²¹² In healthcare provider markets, where the FTC has particular expertise, the inability to regulate conduct by various nonprofit entities has prevented the agency from taking action

²⁰⁹ See FTC staff notice of COPA assessment: request for empirical research and public comments. November 1, 2017. https://www.ftc.gov/system/files/attachments/press-releases/ftc-staff-seeks-empirical-research-public-comments-regarding-impact-certificates-public-advantage/p181200_copa_assessment_comment_notice_11-1-17.pdf. Accessed August 23, 2018.

²¹⁰ See, e.g., *FTC Staff Comment to New York State Department of Health, Concerning Certificate of Public Advantage Applications, Intended to Exempt Performing Provider Systems from the Antitrust Laws* (April 22, 2015), at 3. https://www.ftc.gov/system/files/documents/advocacy_documents/ftc-staff-comment-center-health-care-policy-resource-development-office-primary-care-health-systems/150422newyorkhealth.pdf. Accessed August 23, 2018. ("The antitrust laws already recognize, and, indeed, have long stood for the proposition that competitor collaborations can be procompetitive. As explained in numerous sources of guidance issued by the federal antitrust agencies, this position extends to collaborations among competing healthcare providers.")

²¹¹ 15 U.S.C. § 45(a)(2).

²¹² 15 U.S.C. § 44.

against potentially anti-competitive behavior of nonprofits engaged in business.²¹³ Economic research suggests that antitrust law and policy could yield significant efficiency gains for nonprofit firms; therefore, the promotion of competition for both nonprofit and for-profit organizations would yield significant social value.²¹⁴ The FTC has jurisdiction over nonprofit entities for purposes of the Clayton Act, most notably Section 7, which prohibits mergers or acquisitions where “the effect of such acquisition may be substantially to lessen competition, or to tend to create a monopoly.”²¹⁵ The FTC has accordingly challenged a number of healthcare mergers involving a nonprofit entity,²¹⁶ and courts generally recognize that the nonprofit status of a healthcare provider does not mitigate the potential for anti-competitive harm arising from the merger.²¹⁷

Nonetheless, the jurisdictional limitation contained in the FTC Act creates an arbitrary and inefficient burden on the FTC's ability to enforce the antitrust laws to prevent anti-competitive conduct by certain nonprofit entities. For example, nonprofit healthcare entities may structure an affiliation that has the economic effect of a merger but is technically an agreement between competitors—thus subject to Section one of the Sherman Act rather than a merger subject to the Clayton Act. Similarly, while investigating a merger involving nonprofit healthcare providers, FTC staff may discover an anti-competitive agreement subject to the Sherman Act. In both instances, because the FTC's ability to enforce the Sherman Act through the FTC Act is limited to for-profit corporations, the FTC would have to refer these cases to the Antitrust Division at Justice, which has direct authority to enforce the Sherman Act without the limitations related to nonprofit

²¹³ For example, the Commission generally cannot challenge anti-competitive conduct, such as collusive behavior, by nonprofit hospitals. In three past enforcement actions, the Commission alleged that groups of physicians and hospitals had participated in unlawful price-fixing arrangements but was able to sue only the physicians and a for-profit hospital. See *Piedmont Health Alliance*, 138 F.T.C. 675 (2004) (consent order), <https://www.ftc.gov/enforcement/cases-proceedings/0210119/piedmont-health-alliance-inc-et-al-matter>. Accessed August 24, 2018; *Tenet Healthcare Corp./Frye Regional Medical Center*, 137 F.T.C. 219 (2004) (consent order), <https://www.ftc.gov/enforcement/cases-proceedings/0210119h/tenet-healthcare-corporation-frye-regional-medical-center-inc>. Accessed August 24, 2018; *Maine Health Alliance*, 136 F.T.C. 616 (2003) (consent order), <https://www.ftc.gov/enforcement/cases-proceedings/0210017/maine-health-alliance-william-r-diggins-matter>. Accessed August 24, 2018.

²¹⁴ Philipson TJ, Posner RA. Antitrust in the not-for-profit sector. *J Law Econ.* 2009 Feb;52(1): 1-18.

²¹⁵ 15 U.S.C. § 18.

²¹⁶ See, e.g., *Fed. Trade Comm'n v. Sanford Health*, No. 1:17 CV-133 (N.D. 2017); *Fed. Trade Comm'n v. Penn State Hershey Med. Ctr.*, 838 F.3d 327 (3d Cir. 2016); *Fed. Trade Comm'n v. Advocate Health Care Network*, 841 F.3d 460 (7th Cir. 2016); *ProMedica Health Sys., Inc. v. FTC*, 749 F.3d 559 (6th Cir. 2014), cert. denied, 135 S. Ct. 2049 (2015); *St. Alphonsus Med. Ctr.-Nampa Inc. v. St. Luke's Health Sys.*, 778 F.3d 775 (9th Cir. 2015).

²¹⁷ See, e.g., *Fed. Trade Comm'n v. OSF Health Care Sys.*, 852 F. Supp. 2d 1069, 1081 (N.D. Ill. 2012) (“[T]he evidence in this case reflects that nonprofit hospitals do seek to maximize the reimbursement rates they receive.”); *Fed. Trade Comm'n v. ProMedica*, No. 3:11 CV 47, 2011 WL 1219281, at *22 (N.D. Ohio Mar. 29, 2011) (finding that a nonprofit hospital entity “exercises its bargaining leverage to obtain the most favorable reimbursement rates possible from commercial health plans.”); *United States v. Rockford Mem'l Corp.*, 898 F.2d 1278, 1284-87 (7th Cir. 1990) (rejecting the contention that nonprofit hospitals would not seek to maximize profits by exercising their market power); *Fed. Trade Comm'n v. Univ. Health, Inc.*, 938 F.2d 1206, 1213-14 (11th Cir. 1991) (“[T]he district court's assumption that University Health, as a nonprofit entity, would not act anticompetitively was improper.”); *Hospital Corp. of America v. Fed. Trade Comm'n*, 807 F.2d 1381, 1390-91 (7th Cir. 1986) (rejecting the contention that nonprofit hospitals would not engage in anticompetitive behavior).

entities.²¹⁸ This referral process serves no public interest objective, but prevents the federal government from making the best use of the FTC's valuable institutional knowledge and experience. Removing the nonprofit limitation from the FTC Act would streamline the competition investigation and enforcement process.

Recommendations: Amend Federal Trade Commission (FTC) Jurisdiction Over Nonprofits

- Congress should amend the Federal Trade Commission Act to extend FTC's jurisdiction to nonprofit healthcare entities to prevent unfair methods of competition.

Employment Agreement Non-Compete Clauses

Non-compete clauses were first found to be anti-competitive in 1414.²¹⁹ Legal scholars suggest that the point of these clauses was “shoring up the crumbling values of the medieval economic system against enterprising master craftsmen,” aka entrepreneurs. These clauses can have dramatic economic consequences: California's public policy against enforcement of non-compete clauses, for example, is credited with fostering Silicon's Valley's rapid growth and innovation, outpacing the rival high-tech district around Boston.²²⁰

In the healthcare industry, some hospitals and physician groups continue to use these restrictive covenants to limit providers from practicing, typically in a certain geographical area for a given period after the provider leaves employment of the contracting hospital or physician group.²²¹ A survey of physicians found that roughly 45 percent of physicians in group practices were bound by non-compete agreements.²²² The AMA suggests that these contracts may disrupt competition and the continuity of care, and could constrain a patient's choice of provider. However, recent empirical analysis found evidence consistent with these agreements being used to prevent patients from being poached by departing doctors.²²³

²¹⁸ 15 U.S.C. § 4. See *United States v. Charleston Area Med. Ctr. et al.*, No. 2-16-cv-03664 (stipulated final judgment Oct. 21, 2016), which describes a Herman Act case involving an illegal agreement between two nonprofit hospitals to allocate marketing territories.

²¹⁹ Minda G. The common law, labor and antitrust. *Berk J Employ Labor Law*. 1989 Dec;11(4):461-539. <https://scholarship.law.berkeley.edu/cgi/viewcontent.cgi?referer=https://www.google.com/&httpsredir=1&article=1189&context=bjell>. Accessed August 24, 2018.

²²⁰ Gilson RJ. The legal infrastructure of high technology industrial districts: Silicon Valley, Route 128, and covenants not to compete. *NY Univ Law R*. 1999 Jun;74(3):575-629. <https://law.stanford.edu/index.php?webauth-document=publication/256234/doc/slspublic/NYULawReview-74-3-Gilson.pdf>. Accessed August 24, 2018.

²²¹ Goold SD. Report of the Council on Ethical and Judicial Affairs. CEJA Report 3-A-14. [https://www.ama-assn.org/sites/default/files/media-browser/public/about-ama/councils/Council Reports/council-on-ethics-and-judicial-affairs/ceja-3a14.pdf](https://www.ama-assn.org/sites/default/files/media-browser/public/about-ama/councils/Council%20Reports/council-on-ethics-and-judicial-affairs/ceja-3a14.pdf). Accessed August 24, 2018.

²²² Lavetti K, Simon C, and White WD. The Impacts of Restricting Mobility of Skilled Service Workers: Evidence from Physicians. Forthcoming *Journal of Human Resources*. http://kurtlavetti.com/UIPNC_vf.pdf. Accessed November 27, 2018.

²²³ *Ibid* at 41.

At least one case has viewed a non-compete clause in the healthcare industry with skepticism. The Tennessee Supreme Court opined on a non-compete clause between a physician and a private medical practice that had employed him in the 2005 case *Murfreesboro Medical Clinic (MMC) v. David Udom*.²²⁴ Here, the court ruled that certain provisions in non-compete clauses can be harmful to public policy and therefore unenforceable. The court indicated that the non-compete clause in question had been too broad and was not based on the extent to which MMC would compete with a provider (in this case, David Udom).

While there is not a large body of case law on non-compete clauses in the healthcare industry, cases in other industries also suggest that non-compete clauses that are unreasonable in scope and duration may not be enforceable. The enforceability of non-compete clauses, including those clauses and contractual provisions related to healthcare, is typically an issue of state law.

Legal experts have suggested that a non-compete clause may be defensible where it is reasonable in scope and duration and necessary to protect against a former employee who had access to trade secret information or closely-guarded customer relationships injuring a business by utilizing that information or those customer relationships upon leaving.^{225,226} Employers that invest in substantial training for their provider employees might also seek to protect the investment that they make in their human capital. However, it is not clear that healthcare industry non-compete clauses are always proportionate to or even based on these concerns. In fact, other experts suggest that these clauses reduce bargaining power for employees because they reduce worker mobility.²²⁷

Various reports on non-compete clauses have also suggested that they are overly burdensome and restrictive on providers. Further scrutiny of these and other restrictive covenants is warranted, particularly where they impede patient access to care and limit the supply of providers. By suppressing competition, these clauses may inflate healthcare prices, elevating patient and federal spending on healthcare goods and services.

²²⁴ *Murfreesboro Medical Clinic, P.A., v. David Udom*, S.C.T. M2003-00313-SC-CV (June 29, 2005).

<https://caselaw.findlaw.com/tn-supreme-court/1058188.html>. Accessed August 24, 2018.

²²⁵ *McRand, Inc. v. Van Beelen*, 138 Ill. App.3d 1045 (1985).

<https://www.leagle.com/decision/19851183138illapp3d104511046>. Accessed August 24, 2018.

²²⁶ Horton RW. Restrictive covenants in physician employment relationships. American Health Lawyers Association—Member Briefing. April 2013.

http://www.bassberry.com/~media/Files/Publications/2013/05/AHLA_Article_Horton_and_Padgett_April_2013.pdf. Accessed August 24, 2018.

²²⁷ Garmaise JM. Ties that truly bind: noncompetition agreements, executive compensation, and firm investment. *J Law Econ Org*. 2011 Aug;27(2):376-425. <https://academic.oup.com/jleo/article-abstract/27/2/376/2194339>. Accessed August 24, 2018.

Recommendations: Scrutinize Non-Compete Clauses and Other Restrictive Covenants

- States should scrutinize restrictive covenants such as non-compete clauses, particularly their impact on patient access to care and on the supply of providers.

Health Insurance Markets

“Any-Willing-Provider” (AWP) Laws

“Any-willing-provider” (AWP) laws, like related “freedom of choice” (FOC) laws, are restrictions on certain types of selective contracting practices by health plans or pharmacy benefit plans. AWP laws require plan sponsors—or sometimes intermediaries, such as pharmacy benefit managers (PBMs)—to contract with any healthcare provider willing to meet the terms of participation in that plan’s network agreements.²²⁸ FOC laws permit plan beneficiaries (or enrollees) to choose their providers, regardless of whether a chosen provider is part of their plan’s network.²²⁹ Research suggests that AWP (and, perhaps to a lesser extent, FOC) laws can suppress pro-competitive forms of health and pharmacy benefit plan contracting.²³⁰

Basic economic theory suggests that a buyer can obtain a negotiating advantage by contracting selectively with a subset of providers, or at least having a credible option to do so, because providers will compete aggressively to be included. For that reason, health plans and pharmacy benefit plans often seek to employ some form of selective contracting, entering into agreements with limited networks of providers. Commonly, plans also offer tiered benefits to incent the use of lower-cost (or otherwise more efficient) providers,

²²⁸ See, e.g., Federal Trade Commission and U.S. Department of Justice. *Improving Health Care: A Dose of Competition*. Ch. 6. July 2004: 29-30. <http://www.ftc.gov/reports/healthcare/040723healthcarerpt.pdf>. Accessed August 23, 2018; Vita MG, Regulatory restrictions on selective contracting: an empirical analysis of “any-willing-provider” regulations. *J Health Econ*. 2011;20:955, 956; Klick J, Wright JD. The effect of any willing provider and freedom of choice laws on healthcare expenditures. *Am Law Econ Rev*. 2015;17:192, 196-197.

²²⁹ *McRand, Inc. v. Van Beelen*, 138 Ill. App.3d 1045 (1985).
<https://www.legale.com/decision/19851183138illapp3d104511046>. Accessed August 24, 2018.

²³⁰ State AWP (and FOC) laws vary substantially in scope – e.g., applying to some types of plans but not others, or some types of providers but not others. They also vary in stringency and may impose greater or lesser restraints, via varied enforcement mechanisms, on plan contracting and benefits design. Vita MG, Regulatory restrictions on selective contracting: an empirical analysis of ‘any-willing-provider’ regulations. *J Health Econ*. 2011;20:959; Klick J, Wright JD. The effect of any willing provider and freedom of choice laws on healthcare expenditures. *Am Law Econ Rev*. 2015;17:198-200. For example, some states have adopted AWP laws for pharmacy services. See, e.g., Carroll A, Ambrose JM. Any-willing-provider laws: their financial effect on HMOs. *J Health Polit Policy Law*. 2002;27:928. Depending on these variables, AWP and FOC laws may have greater or lesser economic impact. See, e.g., Vita MG, Regulatory restrictions on selective contracting: an empirical analysis of “any-willing-provider” regulations. *J Health Econ*. 2011;20:959.

services, or prescription drugs by plan beneficiaries.²³¹ Incentives to use a preferred tier may include (a) lower copayments, (b) lower co-insurance percentages, or (c) lower deductibles.²³² In effect, such tools differentiate the out-of-pocket prices associated with different providers, services, or drugs—tier by tier—for the beneficiaries of plans that employ tiering.²³³

Selective contracting and tiered benefits are not always efficiency-enhancing or procompetitive. They can also limit consumer choice. To guard against such concerns and potential conflicts of interest,²³⁴ some states have enacted AWP or FOC laws, but, as will be explained below, these rules raise their own set of issues.

Medicare includes a type of AWP restriction—an “any willing pharmacy” provision—while also permitting selective contracting and tiered benefits. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. 173, 117 Stat. 2066, requires that Medicare part D plans “permit the participation of any pharmacy that meets the terms and conditions under the plan,” but permits them to, “notwithstanding... [that requirement] reduce coinsurance or copayments for part D eligible individuals enrolled in the plan below the level otherwise required.” That is, part D plans cannot wholly exclude participation by “willing” pharmacies but can engage in tiering—a form of selective contracting (and selective benefits).²³⁵ In 2018, the Centers for Medicare and Medicaid Services clarified the Part D AWP rules and their expectations regarding statutorily required AWP provisions, including the ability of plans to maintain preferred networks. CMS’s intent was “to ensure that Part D plan sponsors could continue to develop and maintain preferred networks while complying with the any willing pharmacy requirement, which applies to standard terms and conditions.”²³⁶

²³¹ See generally, e.g., Robinson JC. Applying value-based insurance design to high-cost health services. *Health Aff.* 2010;29(11):2009; Robinson JC. Hospital tiers in health insurance: balancing consumer choice with financial incentives. *Health Aff.* 2003 Jan-Jun Suppl Web Exclusives:W3-135; Yegian JM. Tiered hospital networks. *Health Aff.* 2003;147:W3. Coverage for the non-preferred tier is therefore lower – in some limiting cases, zero.

²³² See Robinson JC. Applying value-based insurance design to high-cost health services. *Health Aff.* 2010;29(11):2010.

²³³ Often—not always—drug benefits are designed to encourage substitution of lower-cost generic versions of branded products. See Robinson JC. Applying value-based insurance design to high-cost health services. *Health Aff.* 2010;29(11):2011.

²³⁴ Beneficiaries or subscribers might generally prefer more choice rather than less, all other things being equal. Providers might also have more self-interested reasons for favoring AWP or FOC laws to the extent that they suffer financially when excluded from preferred tiers of provider networks and/or to the extent that competitive bidding can otherwise diminish profits, say, in significantly concentrated provider markets. See, e.g., Vita MG, Regulatory restrictions on selective contracting: an empirical analysis of “any-willing-provider” regulations. *J Health Econ.* 2011;20:956.

²³⁵ 42 USCS § 1395w-104(b)(1). See, e.g., CMS. Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs. 79 *Fed Reg* 1918, 1978-1982 (Jan. 10, 2014) (discussing proposed “any-willing-pharmacy” rules).

²³⁶ See Medicare Program. Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program, 83 *Fed Reg.* 16440, 16440-16757 (Apr. 16, 2018).

AWP Laws are Costly Restraints on Plan Contracting

Although limited or “narrow” networks may limit patient choice and are not necessarily efficiency-enhancing or procompetitive, empirical evidence suggests that AWP and FOC laws broadening networks can make it more difficult for health insurers, health plans, or PBMs to negotiate discounts from providers, and that these laws tend to result in higher costs. Evidence also suggests that selective contracting—which AWP laws constrain—tends to lower healthcare costs and expenditures.²³⁷

Empirical Evidence on AWP

Several studies have analyzed state-by-state policy variation to measure the effects of AWP laws, finding that such laws undercut negotiating strategies whereby providers compete for inclusion in a network or a preferred tier. For example, one recent study examined state-level per capita health expenditure data from 1991-2009 and associated

AWP laws with approximately 5 percent higher per-capita drug expenditures.²³⁸ A 2009 study similarly examined variations in state AWP laws applicable to drug purchases. It found that AWP states have higher prescription drug spending than states without AWP laws. The conclusion was the same, even when using different econometric techniques to control for variations across the states, such as differences in demographics, market structure, and regulatory environment.²³⁹ An earlier study, looking at both the imposition and relative stringency of health plan AWP laws, found that AWP laws generally undermine the ability of managed care organizations to lower healthcare spending by extracting discounts in return for inclusion in a limited network. Specifically, the study found that per capita total healthcare expenditures are higher in states with relatively strong AWP laws, observing an impact on both hospital and physician expenditures.²⁴⁰

²³⁷ The limited literature on this issue tends to look at the effect of any-willing-provider laws on total spending, instead of prices. Because the quantity of healthcare is generally measured to have a negative, though small, relationship with healthcare prices, these studies likely understate the effect of AWP laws on prices. See, e.g., *Fed. Trade Comm'n Staff Comment to the Ctrs. for Medicare & Medicaid Servs.*, 8, n.15 (March 2014). https://www.ftc.gov/system/files/documents/advocacy_documents/federal-trade-commission-staff-comment-centers-medicare-medicaid-services-regarding-proposed-rule/140310cmscomment.pdf. Accessed August 24, 2018.

²³⁸ Klick J, Wright JD. The effect of any-willing-provider and freedom-of-choice laws on healthcare expenditures. *Am Law Econ Rev.* 2015;17:204-05. Klick & Wright find smaller, and not statistically significant effects associated with FOC laws. That may be due, they suggest, to the commonly weaker restraints provided by FOC laws that, in effect, permit beneficiaries to leave the bounds of a network by forgoing the savings gleaned by selective contracting on an *ad hoc* basis, doing less general damage to selective contracting. *Ibid.*, at 194.

²³⁹ Durrance CP. The impact of pharmacy-specific any-willing-provider legislation on prescription drug expenditures. *Atlantic Econ J.* 2009;37:409.

²⁴⁰ Vita M. Regulatory restrictions on selective contracting: an empirical analysis of “any-willing-provider” regulations. *J Health Econ.* 2001;20:955, 960-66. Panel data show, e.g., that states with highly restrictive AWP/FOC laws spent approximately 2 percent more on healthcare than states without such policies.

Empirical research on these laws has focused on the impacts on costs, not prices.²⁴¹ A 2005 Maryland study, however, examined the impact of AWP/FOC types of restrictions on mail-order provision of, for example, maintenance drugs. The Maryland report estimated that greater use of mail-order maintenance drugs—enabled by liberalizing Maryland insurance law—would save Maryland consumers 2-to-6 percent on retail drug purchases overall, with 5-to-10 percent savings for third-party carriers.²⁴²

Empirical Evidence on Selective Contracting

Related research has examined the effect of selective contracting, more generally, in connection with healthcare provider markets. For example, a study of limited network health plans in Massachusetts found that large premium differences between broad and limited network plans were driven by real reductions in spending by those beneficiaries who switched from broad to narrow network plans; the study did not find reduced access to care or any adverse impact on beneficiary health.²⁴³ An earlier study of Massachusetts health plans, based on different data sources, also found savings associated with selective contracting.²⁴⁴ Another study concluded that Connecticut health plans' ability to negotiate discounts with hospitals increased with a plan's willingness and/or ability to channel patients to selected hospitals, consistent with the predictions of a theoretical model introduced in the same study.²⁴⁵ These studies show that buyers in health insurance markets can and do use selective contracting, harnessing the benefits of competition to negotiate lower prices.

More recently, CMS released two studies analyzing prescription drug data from March 2012 for Medicare Part D plans.²⁴⁶ In both studies, CMS found substantial savings on average associated with preferred pharmacies and mail-order pharmacies. It has been noted that those CMS studies do not control for product mix, which can vary substantially across

²⁴¹ Gaynor M, Mostashari F, Ginsburg PB. Making healthcare markets work: competition policy for healthcare. Brookings. April 13, 2017. ><https://www.brookings.edu/wp-content/uploads/2017/04/gaynor-et-al-final-report-v11.pdf>< at 24, n.34. Accessed September 26, 2018.

²⁴² See Maryland Health Care Commission and Maryland Insurance Administration. Mail order purchase of maintenance drugs: impact on consumers, payers, and retail pharmacies. (Dec. 23, 2005).

²⁴³ Gruber J, McKnight R. Controlling healthcare costs through limited network insurance plans: evidence from Massachusetts state employees. *Am Econ J: Econ Policy*. 2016;8(2):219, 221.

²⁴⁴ Wu VY. Managed care's price bargaining with hospitals. *J Health Econ*. 2009(28):350.

²⁴⁵ Sorensen AT. Insurer-hospital bargaining: negotiated discounts in post-deregulation Connecticut. *J. Indus Econ*. 2003;51:469 (building a simple theoretical model describing the dynamics of the bargaining effects and testing it with data on negotiated Connecticut hospital discounts).

²⁴⁶ Part D Claims Analysis: Negotiated Pricing Between Preferred and Non-Preferred Pharmacy Networks. April 30, 2013. <http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/Downloads/PharmacyNetwork.pdf>. Accessed August 24, 2018; Part D Claims Analysis: Negotiated Pricing Between General Mail Order and Retail Pharmacies. <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/Downloads/Negotiated-Pricing-Between-General-Mail-Order-and-Retail-PharmaciesDec92013.pdf>. Accessed August 24, 2018.

types of pharmacies.²⁴⁷ Acknowledging that limitation, the findings are generally consistent with the independent research on selective contracting discussed above.²⁴⁸

Recommendations: Scrutinize Any-Willing-Provider (AWP) Laws

- Federal and state policymakers should carefully scrutinize the impact on competition and consumers of AWP laws, rules, and proposals, along with other restraints on network formation and selective contracting.

Network Adequacy Requirements

Due to increased federal regulation of insurance through the ACA, premiums and deductibles have soared, forcing insurers to narrow provider networks to temper those prices. In 2017, 9 percent of firms with at least 200 employees offered their employees a health plan with a narrow network that included fewer providers than a typical Health Maintenance Organization,²⁴⁹ an increase of 2 percentage points from 2016.²⁵⁰ Among ACA-compliant individual market health plans offered on exchanges in 2016, nearly one-third had fewer than 25 percent of physicians within their service area participating as in-network providers.²⁵¹

Narrow network plans bolster competition among hospitals and physician groups vying to be included in networks to secure patient volume. Furthermore, narrow network plans offer lower premiums relative to broader network plans.²⁵² This feature is particularly beneficial to lower-income consumers, who tend to be extremely price sensitive,²⁵³ suggesting they

²⁴⁷ See, e.g., Fed. Trade Comm'n Staff Comment to the Ctrs. for Medicare & Medicaid Servs., (March 2014). https://www.ftc.gov/system/files/documents/advocacy_documents/federal-trade-commission-staff-comment-centers-medicare-medicaid-services-regarding-proposed-rule/140310cmscomment.pdf at 4-5 for a discussion of the CMS studies and their potential limitations. Accessed August 24, 2018.

²⁴⁸ See, e.g., Fed. Trade Comm'n Staff Comment to the Ctrs. for Medicare & Medicaid Servs., (March 2014). https://www.ftc.gov/system/files/documents/advocacy_documents/federal-trade-commission-staff-comment-centers-medicare-medicaid-services-regarding-proposed-rule/140310cmscomment.pdf at 10, n.34 (also noting that FTC staff had undertaken a literature review in conjunction with their comments to CMS and had not found any countervailing evidence suggesting increased costs). Accessed August 24, 2018.

²⁴⁹ 2017 Employer Health Benefits Survey. Menlo Park, California: Kaiser Family Foundation and Health Research and Education Trust. September 19, 2017. <https://www.kff.org/health-costs/report/2017-employer-health-benefits-survey/>. Accessed August 24, 2018.

²⁵⁰ Employer Health Benefits 2016 Annual Survey. Menlo Park, CA: Kaiser Family Foundation and Health Research and Education Trust; 2016. <https://www.kff.org/health-costs/report/2016-employer-health-benefits-survey/>. Accessed August 24, 2018.

²⁵¹ Polsky D, Zhang Y, Yasaitis L, Weinger J. Trends in physician networks in the marketplace in 2016. UPenn Leonard Davis Institute of Health Economics. December 6, 2016. <https://ldi.upenn.edu/brief/trends-physician-networks-marketplace-2016>. Accessed August 24, 2018.

²⁵² Polsky D, Cidav Z, Swanson A. Plans with narrow physician networks feature lower monthly premiums than plans with larger networks. *Health Aff.* 2016;35(10):1841-1848.

²⁵³ Finkelstein A, Hendren N, Shepard M. Subsidizing health insurance for low-income adults: evidence from Massachusetts. NBER Working Paper No. 23668. Cambridge, MA. August 2017. <http://www.nber.org/papers/w23668>. Accessed August 24, 2018.

are more interested in the size of the premium relative to the breadth of the provider network.

A potential concern regarding narrow networks is that enrollees may not have adequate choice or access to providers. Networks may lack the capacity to serve all enrollees within a health plan or lack specific specialists, leading some enrollees with only the option of more expensive care from out-of-network providers.²⁵⁴ These issues pertain to private insurance (group and individual markets) as well as Medicaid managed care and Medicare Advantage plans, where insurers generally contract with a limited number of providers. This discussion applies generally to issues across these markets except where noted.

Regulations, primarily through state authority, have attempted to achieve network adequacy by requiring health plans to show sufficient capacity and access, often defined by quantitative standards (e.g., physician-to-enrollee ratios, distance, and wait times). For example, CMS requires states to develop standards for travel time and distance from enrollees' homes to providers to regulate Medicaid managed care plans. In private markets, states are primarily responsible for the enforcement of network adequacy standards. CMS's 2017 market stabilization final rule relieved burden on issuers by relying on states to regulate network adequacy for qualified health plans in the individual and small-group markets. Across states, there is substantial variation in the number and types of network adequacy measures used.

Impact on Competition and Choice

Measures used to determine network adequacy may not align with a network's ability to meet enrollees' preferences, may discourage innovative ways to meet those preferences, and may ultimately limit consumers' choices. For example, using proximity measures to regulate network adequacy may discourage insurers and providers from developing telemedicine capabilities²⁵⁵ or utilizing regional or national centers of excellence outside the residency area.²⁵⁶ Relying on current measures may also restrict entry into the insurance market by insurers with innovative plan designs. For example, vertically integrated health

²⁵⁴ Hall MA, Ginsburg PB. A better approach to regulating provider network adequacy. USC Schaeffer Center for Health Policy and Economics and Brookings Center for Health Policy. September 2017.

<https://www.brookings.edu/wp-content/uploads/2017/09/regulatory-options-for-provider-network-adequacy.pdf>. Accessed August 24, 2018.

²⁵⁵ Ahn S, Corlette S, Lucia K. Can telemedicine help address concerns with network adequacy? Opportunities and challenges in six states. Urban Institute. April 6, 2016. <https://www.urban.org/research/publication/can-telemedicine-help-address-concerns-network-adequacy-opportunities-and-challenges-six-states>. Accessed August 24, 2018.

²⁵⁶ Hall MA, Ginsburg PB. A better approach to regulating provider network adequacy. USC Schaeffer Center for Health Policy and Economics and Brookings Center for Health Policy. September 2017.

<https://www.brookings.edu/wp-content/uploads/2017/09/regulatory-options-for-provider-network-adequacy.pdf>. Accessed August 24, 2018.

systems may be less likely to enter a market if network adequacy standards would force them to compete with other providers.²⁵⁷

Inadequate or erroneous provider directories in network plans may also discourage providers from competing on price or quality to attract patients. If consumers cannot accurately identify in-network providers, or compare networks of competing insurers, it is more difficult for them to make informed choices. In addition, without proper information, enrollees may be more likely to unknowingly receive care out of network, leading to instances of “surprise billing.” Of patients aged 18-64 who receive out-of-network care, nearly 70 percent are unaware that the provider is outside their plan’s network prior to receiving care.²⁵⁸

While CMS requires Medicare Advantage, Medicaid managed-care plans, and qualified health plans in the exchange to update and provide consumer-accessible provider directories, ensuring that enrollees receive accurate information in real-time may still be difficult. In a review of provider locations from online directories, CMS found errors in over half of the locations for Medicare Advantage providers, with 33 percent of errors due to the provider not working at or not accepting the plan at the listed location (CMS 2018).²⁵⁹

The provision of accurate and timely information would also bolster competition. To facilitate more competition and innovation, network adequacy standards should place greater emphasis on network outcomes while giving states flexibility to meet their specific needs. In 2015, the National Association of Insurance Commissioners opposed blanket federal network adequacy requirements in its Health Benefit Plan Network Access and Adequacy Model Act, especially as strict quantitative measure are unlikely to meet varying needs across states. Current quantitative standards could be less restrictive and used primarily as minimum thresholds to determine whether an insurer can enter a market or when a network has actually failed an enrollee.²⁶⁰ These standards should take into account alternative network designs and be used alongside external review by physicians when networks fail to provide adequate access to enrollees.²⁶¹ Insurers could be allowed to have more flexibility with provider contractors, such as “spot contracts,” to fill in network gaps as needed.²⁶²

²⁵⁷ Howard DH. Adverse effects of prohibiting narrow provider networks. *New Engl J Med* 2014;371:591-592.

²⁵⁸ The burden of medical debt: results from the Kaiser Family Foundation/New York Times Medical Bills Survey. January 5, 2016. <https://www.kff.org/health-costs/report/the-burden-of-medical-debt-results-from-the-kaiser-family-foundation-new-york-times-medical-bills-survey/>. Accessed August 24, 2018.

²⁵⁹ CMS. Online provider directory review report. 2018. https://www.cms.gov/Medicare/Health-Plans/ManagedCareMarketing/Downloads/Provider_Directory_Review_Industry_Report_Final_01-13-17.pdf. Accessed August 24, 2018.

²⁶⁰ Hall MA, Ginsburg PB. A better approach to regulating provider network adequacy. USC Schaeffer Center for Health Policy and Economics and Brookings Center for Health Policy. September 2017. <https://www.brookings.edu/wp-content/uploads/2017/09/regulatory-options-for-provider-network-adequacy.pdf>. Accessed August 24, 2018.

²⁶¹ *Id.*

²⁶² *Id.*

Recommendations: Loosen Network Adequacy Requirements

- The administration should continue to provide flexible network adequacy standards for Medicare Advantage and other federally sponsored programs and avoid stringent requirements that are not conducive to innovation and modern medicine and that do not allow states flexibility to meet their specific needs.
- Similarly, states should consider loosening network adequacy standards and avoid stringent requirements.

The ACA Rules Limit Choice

The Affordable Care Act introduced a number of mandates and burdensome requirements that significantly reduced choice and competition in insurance markets and caused premiums, particularly in the individual market, to soar. This occurred to a significant extent because government rules and price controls on health insurance premiums, designed to assist some people with higher anticipated health expenditures, inhibited the application of actuarially determined pricing and created an adverse selection spiral in the individual market. These requirements also produced a significant reduction in coverage options for most consumers. In addition to reducing consumer choice and competition between insurers, the higher administrative costs associated with the ACA mandates disproportionately hurt smaller employers, in part because smaller employers were unable to spread these costs as broadly as larger employers and in part because the large-group market is not bound by all of the ACA's mandates. Therefore, as a general matter, smaller employers that continued to offer coverage were forced to disproportionately raise premium contributions paid by covered workers, making them less competitive with larger employers and with other smaller employers that chose not to offer health coverage to their employees.²⁶³

ACA's Harmful Insurance Rules

The ACA forces insurers offering coverage in the individual and small-group markets to offer a mandated set of government-defined benefits.²⁶⁴ This mandate reduces consumer choice and represents a hidden cost on the majority of consumers by forcing them to pay for more coverage – and the corresponding expense – than many customers would

²⁶³ 2017 Employer Health Benefits Survey. Menlo Park, CA: Kaiser Family Foundation and Health Research and Education Trust. September 19, 2017. <https://www.kff.org/health-costs/report/2017-employer-health-benefits-survey/>. Accessed August 24, 2018.

²⁶⁴ The 10 required categories are: 1) ambulatory patient services, 2) emergency services, 3) hospitalization, 4) maternity and newborn care, 5) mental health and substance use disorder services, 6) prescription drugs, 7) rehabilitative and habilitative services and devices, 8) laboratory services, 9) preventive and wellness services and chronic disease management, and 10) pediatric services.

otherwise choose to buy voluntarily in insurance packages. Excessive mandates hinder innovation in plan design and greater access to coverage; they also limit public efforts to assure affordability without substantial government subsidies. This leaves significant swathes of consumers with coverage that includes numerous items they do not want or need and contributes to pricing others out of the market, including some of the 6.5 million people who paid the penalty for not having minimum essential coverage under the ACA.²⁶⁵ The ACA further restricts choice and competition through a prohibition on people over the age of 30 purchasing catastrophic insurance (unless they qualify for a hardship exemption).

The ACA also requires insurers to cover numerous preventive services without cost sharing under the premise that a government-imposed system-wide increase in “free” preventive care will lower overall healthcare costs.²⁶⁶ Under the ACA, the U. S. Preventive Services Task Force (USPSTF), the Advisory Committee on Immunization Practices of the CDC, and HRSA are tasked with determining the required preventive services.²⁶⁷ However, a New England Journal of Medicine study found that “sweeping statements about the cost-saving potential of prevention...are overreaching. Studies have concluded that preventing illness can in some cases save money but in other cases can add to healthcare costs.”²⁶⁸ Other research finds that 80 percent of preventive services add more to future expenditures than they save in healthcare costs.²⁶⁹ These findings suggest that the ACA’s coverage mandates, while certainly providing some benefit, increase premiums, as well as lead to unnecessary utilization. Atul Gawande, former adviser to President Bill Clinton and President Barack Obama, has warned about the risks of over-testing and over-treating.²⁷⁰ Over-testing leads to problems like additional radiation exposure and stress from the abundance of false positive results, and over-treating leads to problems like medical errors and hospital-acquired infections.

The Medical Loss Ratio (MLR) is an ACA mandate requiring that insurers in the individual and small-group markets spend at least 80 percent of premiums on healthcare costs,

²⁶⁵ Koskinen J. Letter updating members of Congress regarding 2016 tax filings related to ACA provisions. January 9, 2017, <https://www.irs.gov/pub/newsroom/commissionerletteracafilingseason.pdf>. Accessed August 24, 2018.

²⁶⁶ This requirement is distinct from proposals discussed elsewhere in this report concerning the ability of high-deductible health plans (HDHPs) that enable individuals to contribute to health savings accounts (HSAs) to cover preventive services before the patient pays the full deductible if it is cost efficient for them to do so.

²⁶⁷ The USPSTF is an independent, volunteer panel comprised of experts from the fields of preventive medicine and primary care. The Task Force does not consider the costs of a preventive service when determining what policies to recommend. USPSTF determines the services under Public Health Service Act (PHS Act) §2713(a)(1), while the CDC determines services under PHS Act §2713(a)(2), and HRSA determines services under PHS Act §2713(a)(3) and (4).

²⁶⁸ Cohen JT, Neumann PJ, Weinstein MC. Does preventive care save money? Health economics and the presidential candidates. *N England J Med*. 2018 Feb 13;358:661-663. <http://www.nejm.org/doi/full/10.1056/NEJMp0708558>. Accessed August 24, 2018.

²⁶⁹ Russell LB. Preventing chronic disease: an important investment, but do not count on cost savings. *Health Aff*. 2009 Jan-Feb;28(1):42-45. <https://www.healthaffairs.org/doi/full/10.1377/hlthaff.28.1.42>. Accessed August 24, 2018.

²⁷⁰ Gawande A. Overkill. *The New Yorker*. May 11, 2015. <https://www.newyorker.com/magazine/2015/05/11/overkill-atul-gawande>. Accessed September 20, 2018.

allowing 20 percent for administrative costs and profit.²⁷¹ The MLR was intended to provide a minimum guaranty of value to customers, as companies that fail to meet this ratio are obligated to pay a rebate to their customers.²⁷² However, the MLR may create a perverse incentive that encourages insurance companies, particularly in the absence of competition, to increase premiums.²⁷³ Some health policy experts also believe that the MLR regulations will harm the ability of some insurers, particularly smaller insurers, to compete, thus reducing consumer choices.²⁷⁴

A number of ACA rules have contributed to large increases in average premiums and have driven down choices in the individual and small-group markets. In 2013, the year before many of the ACA rules took effect, 395 insurers operated in the individual market.²⁷⁵ By 2017, this number had fallen to 218, and 70 percent of counties (including 36 percent of U. S. residents) had no more than two insurers selling individual plans in the exchange.²⁷⁶ In the exchanges in 2018, 29 percent of enrollees had only one issuer to choose from, up from 20 percent in 2017; 55 percent of enrollees had at most two insurers to choose from, up from 44 percent in 2017.²⁷⁷ This problem is most pronounced in rural counties. As a result of high and rising premiums, relatively young and healthy people, particularly those in the middle-class who earn too much to qualify for a premium subsidy, have largely avoided the exchanges. Moreover, the ACA's special enrollment periods created an incentive for people to wait until they need healthcare to seek insurance in the exchanges, an incentive that has exacerbated adverse selection and led to spikes in premiums.²⁷⁸ In an attempt to mitigate this problem, the Department of Health and Human Services issued an April 2017 rule aimed at significantly restricting peoples' ability to game the special enrollment periods.²⁷⁹

²⁷¹ The large-group market minimum MLR requirement is 85 percent. MLR requirements do not apply to insurers with fewer than 1,000 enrollees per state.

²⁷² Medical Loss Ratio (MLR). Healthcare.gov. <https://www.healthcare.gov/glossary/medical-loss-ratio-mlr/>. Accessed August 24, 2018.

²⁷³ Book R. How the medical loss ratio requirement could increase health insurance premiums and insurer profits at taxpayer expense. American Action Forum. April 2013. https://www.americanactionforum.org/wp-content/uploads/files/research/MLR_Paper_Final.pdf. Accessed August 24, 2018.

Roy, A. Obamacare's MLR 'Bomb' Will Create Private Insurance Monopolies and Drive Premiums Skyward. Hallelujah! Forbes. December 6, 2011.

²⁷⁵ Haislmaier E, Senger A. The 2017 health insurance exchanges: major decrease in competition and choice. The Heritage Foundation. January 30, 2018. <https://www.heritage.org/health-care-reform/report/the-2017-health-insurance-exchanges-major-decrease-competition-and-choice>. Accessed August 24, 2018.

²⁷⁶ *Id.*

²⁷⁷ Health plan choice and premiums in the 2018 federal health insurance exchange. ASPE. October 30, 2017. https://aspe.hhs.gov/system/files/pdf/258456/Landscape_Master2018_1.pdf. Accessed August 24, 2018.

²⁷⁸ Turner G. ACA rules allow people to game the system, contributing to premium spikes. Galen Institute. June 11, 2016. <http://galen.org/2016/aca-rules-allow-people-to-game-the-system-contributing-to-premium-spikes/>. Accessed August 24, 2018.

²⁷⁹ Centers for Medicare & Medicaid Services, HHS. Patient Protection and Affordable Care Act; market stabilization: final rule. *Fed Regist.* 2017;82(73):18346-18382.

The administration has taken two major actions to provide Americans, particularly middle-class Americans without employer-sponsored insurance, with additional and more affordable health insurance choices. In June, the Labor Department released a final rule expanding the ability of employers, including sole proprietors without common law employees, to join together to form an association health plan (AHP).²⁸⁰ In August, the departments of Health and Human Services, the Treasury, and Labor released a final rule expanding the ability of consumers to purchase short-term, limited-duration insurance—much more affordable products that can better serve many consumers' needs.²⁸¹ According to the Congressional Budget Office, about 6 million Americans will benefit from these actions and enroll in these plans within a few years.²⁸²

Recommendations: Loosen Insurance Rules and Mandates

- The administration should continue to work with Congress to enact legislation that remedies key problems resulting from the ACA, that promotes greater choice and competition in healthcare markets, and that produces a sustainable government healthcare financing structure.
- Similarly, the administration should provide states with the maximum ability to expand healthcare choice and competition and create a sustainable financing structure.
- States should allow maximum consumer choice and competition in their healthcare markets, including through Association Health Plans and short-term limited-duration insurance.
- Congress should repeal the ACA's employer mandate consistent with the FY 2019 President's Budget.

ACA Rules Restricting Physician-Owned Hospitals Reduce Competition

The ACA placed an effective moratorium on the opening and expansion of physician-owned hospitals.²⁸³ According to the Physician Hospitals of America, 37 planned hospitals have not been constructed, and over 30,000 planned healthcare jobs have gone uncreated

²⁸⁰ Employee Benefits Security Administration, Department of Labor. Definition of “employer” under section 3(5) of ERISA-association health plans: final rule. *Fed Regist.* 2018;83(120):28912-28964.

²⁸¹ Internal Revenue Service, Department of the Treasury; Employee Benefits Security Administration, Department of Labor; Centers for Medicare & Medicaid Services, Department of Health and Human Services. Short-term, limited-duration insurance: final rule. *Fed Regist.* 2018;83(150):38212-38243.

²⁸² Congressional Budget Office. Federal subsidies for health insurance coverage for people under age 65: 2018 to 2028. May 23, 2018. <https://www.cbo.gov/publication/53826>. Accessed September 27, 2018.

²⁸³ Bluey RB. Obamacare has a poison pill for doctor owned hospitals. The Heritage Foundation. May 4, 2010. <https://www.heritage.org/health-care-reform/commentary/obamacare-has-poison-pill-doctor-owned-hospitals>. Accessed August 24, 2018.

because of these ACA restrictions on physician-owned hospitals.²⁸⁴ These restrictions, which were favored by the American Hospital Association, were included to address potential financial conflicts of interest with doctors referring patients to their own hospitals and concerns that physicians may be referring the healthiest patients to their own hospitals.²⁸⁵ Those concerns may have been overstated, considering that many studies suggest physician-owned hospitals provide higher-quality care and that patients benefit when traditional hospitals have greater competition.

Physician-owned hospitals, furthermore, have been shown to provide patients with high-quality care. According to a study published by the Journal of the American College of Surgeons, physician-owned surgical hospitals outperform other hospitals in the Medicare value-based purchasing program.²⁸⁶ More than 40 percent of physician-owned hospitals received the top 5-star rating in a 2015 release by the Centers for Medicare and Medicaid Services (CMS), compared to only 5 percent of general hospitals.^{287, 288} Further, patients are 3-to-5 times less likely to experience complications at a physician-owned specialty hospital than at a general hospital.²⁸⁹

Recommendations: Replace Restrictions on Physician-Owned Hospitals

- Congress should consider repealing the ACA changes to physician self-referral law that limited physician-owned hospitals.

ACA Section 1557 (Nondiscrimination Requirements)

ACA Section 1557 has been implemented in such a way that creates a number of burdens on healthcare providers and payers. For example, current rules concerning persons with limited English proficiency require covered entities to include a notice of the right to translation services in 15 languages in nearly all “significant communications” that go to

²⁸⁴ Leonard K. Obamacare wounds doctor-owned hospitals. *Washington Examiner*. July 10, 2017. <http://www.washingtonexaminer.com/obamacare-wounds-doctor-owned-hospitals/article/2627880>. Accessed August 24, 2018.

²⁸⁵ Dickson V. Lifting restrictions on physician-owned hospitals could be key to widening access to care. *Modern Health Care*. June 27, 2017. <http://www.modernhealthcare.com/article/20170627/NEWS/170629899>. Accessed August 24, 2018.

²⁸⁶ Ramirez AG, Tracci MC, Stukenborg GJ, Turrentine FE, Kozower BD, Jones RS. Physician-owned surgical hospitals outperform other hospitals in Medicare value-based purchasing program. *J Am Coll Surg*. 2016 Oct;223(4):559-567. <https://www.sciencedirect.com/science/article/pii/S1072751516307207?via%3Dihub>. Accessed August 24, 2018.

²⁸⁷ Turner G. Lift the ban on physician-owned hospitals. *Forbes*. November 6, 2015. <https://www.forbes.com/sites/gracemarieturner/2015/11/06/lift-the-ban-on-physician-owned-hospitals/#5311bcd11531>. Accessed August 24, 2018.

²⁸⁸ Note CMS released an updated star rating approach in 2017 that expanded the number of hospitals that qualify for top 5-star ratings.

²⁸⁹ Turner G. Lift the ban on physician-owned hospitals. *Forbes*. November 6, 2015. <https://www.forbes.com/sites/gracemarieturner/2015/11/06/lift-the-ban-on-physician-owned-hospitals/#5311bcd11531>. Accessed August 24, 2018.

beneficiaries, enrollees, applicants, and members of the public.²⁹⁰ As a result, covered entities have printed and mailed additional “tagline” sheets they are required to include in documents they frequently mail to customers such as explanations of benefits.²⁹¹ Entities have not been permitted to have online translations alone without mailing “tagline” sheets. Entities covered by the Section 1557 regulation are required to repeatedly notify a population of primarily English and Spanish speakers in multiple languages that they have a right to request translations repeatedly.

It is critical to structure anti-discrimination provisions so they are not barriers to entry that favor larger entities who can better absorb these types of costs and thereby limit competition. However, these and other new requirements imposed on the healthcare industry by the Section 1557 regulations were estimated to cost covered entities \$637.5 million over the first two years.²⁹² This burden is especially hard for smaller entities to enact because unlike larger market players, they cannot take advantage of economies of scale by spreading the additional costs incurred over their larger enrollee population.

Recommendations: Reconsider Section 1557 of the ACA

- The administration should reconsider regulations authored under Section 1557 of the ACA to ensure they do not create undue administrative burdens and serve as unnecessary barriers to entry that inhibit competition.

Giving Americans Control over Their Healthcare Spending

The introduction to this report highlights how third-party payment distorts healthcare markets, increases spending and premiums, and reduces consumers' incentives to seek value from their healthcare decisions. Federal law currently favors third-party control and payment through the federal exclusion of employer-sponsored insurance (ESI) premiums, including employer contributions for self-insured plans, from both income and payroll taxes, the design of the Medicare and Medicaid programs, and the ACA premium tax credits. Easing restrictions on other types of arrangements available for this tax preference could put more control in the hands of consumers and could thus promote cost-conscious consumer behavior.

The primary vehicles that put more control in the hands of consumers and reduce the bias toward third-party payment are high deductible health plans (HDHPs) paired with HSAs

²⁹⁰ Translated resources for covered entities. U.S Department of Health & Human Services. September 7, 2016. <https://www.hhs.gov/civil-rights/for-individuals/section-1557/translated-resources/index.html>. Accessed August 24, 2018.

²⁹¹ *Id.*

²⁹² U.S. Department of Health & Human Services. Nondiscrimination in health programs and activities. *Federal Reg* 2015 Sep 8;80(173):54172-55221. <https://www.gpo.gov/fdsys/pkg/FR-2015-09-08/pdf/2015-22043.pdf>. Accessed August 24, 2018. See also Barlas S. Formulary policies a battleground in HHS proposal on nondiscrimination. *P T*. 2016 Mar;41(3):173-175, 193. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4771086/>. Accessed August 24, 2018.

and Health Reimbursement Arrangements (HRAs). Research demonstrates that consumer-directed health plans, such as these, can lower healthcare spending, largely through reductions in usage of outpatient care and pharmaceuticals.²⁹³

Benefits of Expanding Health Savings Accounts

Under tax provisions originally enacted in 2003, persons enrolled in certain HDHPs—which are generally referred to here as HSA-qualified plans— may contribute to savings accounts to pay for healthcare expenses on a tax-preferred basis. Contributions made by an individual's employer or by an individual through payroll deduction are excluded from wages for purposes of income and payroll taxes. Contributions made directly by an individual are deductible for income-tax purposes. Individuals must be enrolled in an HSA-qualified plan and generally cannot be enrolled in any health plan other than the HSA-qualified plan to be allowed to make HSA contributions. Annual HSA contributions are limited to \$3,450 for persons enrolled in single coverage under an HSA-qualified plan (\$6,900 for persons enrolled in family coverage) for 2018.²⁹⁴ HSA-qualified plans are required to meet the following requirements²⁹⁵:

1. Minimum deductibles (\$1,350 for self-only coverage or \$2,700 for family coverage in 2018).
2. An annual limit on the sum of the deductible and out-of-pocket expenses (\$6,550 for self-only coverage and \$13,300 for family coverage).
3. The out-of-pocket expense limits do not apply to any out-of-network benefits if the plan uses a network (that is, the out-of-pocket cap applies to the deductible and cost sharing only on in-network benefits).
4. Only preventive care benefits as defined in applicable guidance²⁹⁶ may be provided before the minimum deductible is met.
5. The health plan coverage must not be not limited to vision, dental, disability, workers compensation or other specified types of limited insurance coverage.

HSA funds not used to pay health expenses over the course of the year may be saved for future use, and any funds unspent when individuals turn 65 may be withdrawn for any use

²⁹³ Haviland AM, Eisenberg MD, Mehrotra A, Huckfeldt PJ, Sood N. Do “consumer-directed” health plans bend the cost curve over time? NBER Working Paper No. 21021. Issued March 2015, revised July 2015. <http://www.nber.org/papers/w21031>. Accessed September 21, 2018.

²⁹⁴ See 26 CFR 601.602: Tax forms and instructions. Also Part 1, §§ 1, 223. Rev. Proc. 2017-37. <https://www.irs.gov/pub/irs-drop/rp-17-37.pdf>. Accessed August 24, 2018; Also: Part I, § 223. Rev. Proc. 2018-27. <https://www.irs.gov/pub/irs-drop/rp-18-27.pdf>. Accessed August 24, 2018.

²⁹⁵ Note that short-term, limited-duration insurance plans that provide significant benefits and that meet these requirements may constitute an HSA-qualified plan.

²⁹⁶ Notice 2004-23, 2004-15 IRB 725, Notice 2004-50, 2004-33 IRB 196, and Notice 2013-57 2013-40 IRB 293.

without penalty.²⁹⁷ Thus, HSAs promote savings for later healthcare expenses, an extremely beneficial feature since healthcare expenditures tend to grow with age.

Unfortunately, many people—likely around 60 percent—who have deductibles exceeding the required minimum deductibles for HSA-qualified plans do not have HSA-qualified plans.²⁹⁸ Some of the common reasons that plans are not HSA-qualified plans are because of 1) separate drug coverage based on a tiered copayment structure with no or a low deductible, 2) coverage of generic drugs before the deductible is met, or 3) coverage of primary care visits (for free or with a copayment) before the deductible is met. Thus, certain innovative insurance products, which attempt to incentivize cost-effective health treatments and health behaviors, cannot be coupled with HSAs.

For example, an insurer looking to prudently manage the costs of diabetes by offering insulin coverage before the deductible with the goal of reducing much larger future costs that might occur from mismanagement of the disease could preclude its enrollees from contributing to an HSA. Alternatively, an insurer might offer a plan with an actuarial value²⁹⁹ similar to that of an HSA-qualified plan, but with a low deductible combined with higher copays. This plan could provide even more of an incentive for individuals to be as cost-conscious as the HSA-qualified plan requirements provide but would not be an HSA-qualified plan.

A third example of an arrangement that might not meet the current HSA requirements is a fixed-fee arrangement between providers and consumers, such as a direct primary care arrangement with a primary care physician where the patient pays a monthly fee in exchange for a set number of visits as well as basic treatments. Some or all fees under such fixed-fee arrangements might not be healthcare expenses under section 213(d) of the Internal Revenue Code (the “Code”). If so, HSA funds used for paying these fees could be subject to income taxes and a penalty.³⁰⁰ Also, if the fixed-fee arrangement is determined to be insurance for tax purposes, the arrangement would likely be considered a health plan and preclude the individual from contributing to an HSA during the year because

²⁹⁷ Withdrawals prior to age 65 not spent on qualified medical expenses are subject to income taxes plus a 20 percent penalty. Withdrawals after age 65 not spent on qualified medical expenses are subject to income taxes but are not subject to a penalty, resulting in tax-free return on investment, similar to the tax treatment of 401(k) retirement plans. Withdrawals for medical care are not subject to income taxes or the penalty. Therefore, HSA funds used for future medical care receive both tax-free return on investment and the exclusion of the contribution from income (and payroll taxes if contributed through an employer plan). This is like adding the tax preference for 401(k)'s to the tax exclusion for employer sponsored health benefits.

²⁹⁸ Cohen RA, Martinez ME, Zammitti EP. Health insurance coverage: early release of estimates from the National Health Interview Survey. January-March 2017. National Center for Health Statistics. <https://www.cdc.gov/nchs/data/nhis/earlyrelease/insur201708.pdf>. Accessed August 24, 2018

²⁹⁹ The actuarial value measures the fraction of covered benefits paid by the plan for a standard population. Hence, it measures the expected generosity of the plan.

³⁰⁰ Internal Revenue Code §§ 223(f)(1), (2) and (4).

individuals who have a health plan in addition to an HSA-qualified plan cannot contribute to an HSA.³⁰¹

These constraints on HSA-qualified plans and the requirement that prevents an HSA contributor from having any health plan other than an HSA-qualified plan, limit the popularity of HSAs, reduce choice, and potentially increase healthcare spending as people eschew HSA-qualified plans and instead choose plans with greater third-party payment. An alternative standard for determining HSA-qualified plans would allow individuals with certain cost-conscious plan features to benefit from HSAs.

One such proposal would be to allow anyone enrolled in a health insurance plan with a 70 percent actuarial value (AV) or below to contribute to an HSA. This will incentivize employers whose current plans have an actuarial value above the threshold to switch to offer a plan or plans with a somewhat higher deductible and copayments (and a lower actuarial value) because their workers could then newly participate in an HSA. Economic theory suggests employers would fund employees' HSAs with premium savings. Expanding HSAs and the corresponding incentive to obtain greater value from healthcare spending could lead to less consumption of healthcare, particularly lower-value services and treatments, and further premium reductions.

Individuals whose current plans are at or below 70 percent AV that are not currently paired with HSAs would have an expanded tax-preference for out-of-pocket spending causing some of them to spend more although this incentive is limited since unspent HSA amounts roll over from one year to the next. However, some, but not all, of those whose current plans are above 70 percent AV and who switch to 70 percent or lower AV plans would bear higher after-tax, out-of-pocket costs for services and therefore have an increased incentive to seek value for their healthcare spending. In these situations, providers would be subject to more pressure to set transparent prices and to compete for customer business by lowering prices and improving quality. In addition, unlike with current HSA-qualified plans, insurers would have flexibility to include highly cost-effective care before the deductible is met.³⁰²

As noted above, an additional constraint on the availability and use of HSAs is the requirement that HSA-qualified plans can only provide certain preventive care benefits before the minimum deductible is met. Reconsideration of the scope of care that qualifies as preventive could make HSA-qualified plans more attractive and thus enhance access to HSAs. Short of creating a new statutory standard for HSA-qualified plans, the existing regulatory definition of preventive care could reasonably be interpreted more expansively for purposes of the HSA and related HSA-qualified plan rules. A broader interpretation could improve cost-effectiveness and give consumers greater options for financing their

³⁰¹ It is unclear whether, under current rules, consumer-provider fixed-fee arrangements, such as direct primary-care arrangements, should be considered health plans and thus be prohibited from being coupled with HSA-qualified plans.

³⁰² The direct immediate budgetary cost of deeming 70 percent AV plans as HSA-qualified plans could be relatively small. This is because among individuals in employer-sponsored plans much of the cost of tax-preferred HSA spending would be offset by reduced tax-preferred premiums.

healthcare. One reasonable approach would be to consider treatments preventive if they are highly cost-effective and treat a chronic condition that would, in a relatively high share of cases, become more severe or develop into a new condition that is considerably more expensive to treat, if the original condition were left untreated.

Another HSA reform that would reduce the bias in favor of comprehensive, employer-sponsored coverage would be allowing people with an HSA-qualified plan who also choose consumer-provider, fixed-fee arrangements, such as direct primary care arrangements, to contribute to an HSA. Doing so would provide another avenue for first-party payment of healthcare services, thereby expanding choice and making HSA-qualified plans more attractive relative to comprehensive insurance. Some of these types of arrangements are simply pre-payment, outside of traditional insurance arrangements with all the corresponding administrative costs, for certain healthcare services that are known and regular in nature. For example, a patient with diabetes might purchase a fixed-fee arrangement that supplied insulin, testing equipment, and a quarterly visit with a healthcare provider specializing in treating diabetes patients. Healthcare providers would then have an incentive to compete with respect to price and quality to attract patients with HSAs.

Another limitation of current law is that Medicare beneficiaries in HDHPs are not allowed to make tax-deductible contributions to their HSAs or Medicare Savings Accounts (MSAs) even if Medicare serves as their secondary coverage. This limitation reduces the ability of working seniors to save for future healthcare expenses and leads them to rely more upon third-party payment for healthcare services in retirement. The FY2019 President's Budget proposed to give Medicare beneficiaries greater flexibility to take control of their healthcare. The Budget proposal would allow beneficiaries enrolled in Medicare MSA Plans to contribute to their MSAs. Beneficiaries would also have a one-time opportunity to roll over the funds from their private HSAs to their Medicare MSAs. These beneficiaries who elect this plan option would not be allowed to purchase Medigap or other supplemental insurance. Medicare beneficiaries who have an employer-sponsored HDHP would be allowed to make contributions to their HSAs, although Medicare would not cover any expenses before the HDHP deductible is met. The Budget estimated that this proposal would reduce government revenue by about \$11 billion, over 10 years.

Although the premiums for employer-sponsored coverage—both the premiums paid by the employer and employee—are generally excluded from federal income and payroll taxes, the premiums paid for non-group coverage do not receive this same tax treatment. The ACA's premium tax credits provide assistance for the purchase of individual market plans, but this assistance declines rapidly as household income rises and does not extend to people in households with income above 400 percent of the federal poverty line. As part of its proposal to replace the ACA, the President's FY2019 Budget recommended increasing HSA contribution limits and allowing the use of tax-preferred HSA funds to pay HDHP premiums. The Treasury Department's budget estimates suggest that, as part of ACA repeal, raising the HSA contribution limits to the out-of-pocket maximums and allowing

the purchase of HDHP premiums from HSAs would reduce government revenue by \$28 billion over 10 years.

Another option to increase consumer control through HSA expansion would be to allow persons enrolled in Healthcare Sharing Ministries as defined in Code section 5000A(d)(2)(B)(ii) to contribute to HSAs. Healthcare Sharing Ministries are organizations in which people with shared religious or ethical beliefs help pay each other's medical costs. Contributions to HSAs by participants in Health Sharing Ministries would be permissible provided that the individuals (1) remain responsible for an amount of their own (or their family's own) healthcare expenses equal to the applicable annual deductible for an HSA-qualified plan, and (2) with respect to any particular medical expense, are not eligible for payment, sharing, or reimbursement of the expense in any manner by both the Healthcare Sharing Ministry and the HSA. In other words, the HSA-qualified plan deductible would still apply and a medical expense could not be reimbursed twice. These arrangements would encourage individuals to keep medical spending low by encouraging less costly behaviors and greater negotiation with medical providers. In expanding the flexibility of these arrangements, however, distinguishing genuine Healthcare Sharing Ministries from plans and organizations that mischaracterize themselves as such would be essential.

Benefit of Expanding Health Reimbursement Arrangements

Since HSAs are the property of the individual, increasing consumers' ability to use HSAs is likely the best way to encourage first-party payment. Expanding HRAs could also encourage more efficiency through greater consumer control over their healthcare and somewhat reduced third-party payment.

Originally described in IRS guidance in 2002,³⁰³ HRAs allow employers to reimburse their employees' medical expenses. An HRA is an arrangement that is funded solely by an employer and that reimburses an employee for medical expenses incurred by the employee or his or her family up to a maximum dollar amount for a period. Historically, HRAs have often been used by employers that did not choose to offer group insurance to their workers, as well as to supplement group coverage.

As a result of the interpretation of some ACA provisions, HRAs can currently only be offered if employers also offer ACA-compliant group health insurance plans. In implementing the ACA, the Obama administration determined that standalone HRAs violated the ACA prohibition on annual dollar limits and the requirement that group health plans provide certain preventive care without cost sharing. Although the Obama administration issued regulations allowing HRAs to be offered as long as the employee had other group health insurance coverage, the Obama administration restricted individuals' ability to use an HRA to purchase individual market insurance of their own choosing, even

³⁰³ IRS Notice 2002-45, 2002-02 CB 93; Revenue Ruling 2002-41, 2002-2 CB 75.

if the insurance did not have annual and lifetime dollar limits and covered preventive care without cost sharing.

The following two expansions of HRAs, both proposed in a notice of proposed rule-making issue on October 23, 2018, would increase their usability and provide employers, and their employees, with a greater set of alternatives for financing health coverage. First, reversing the Obama administration restriction on HRAs for individuals with individual market insurance would encourage more employers to offer HRAs, increase consumer choice, and provide equal tax treatment for employee-selected coverage in the individual market as for traditional employer-selected group coverage.³⁰⁴ In essence, allowing HRAs to be integrated with non-group coverage that does not have annual dollar limits and that covers the necessary preventive care without cost sharing would allow employers to provide a tax-advantaged, defined contribution arrangement for each employee to select the health insurance that best works for his or her circumstances. In addition to the benefit for workers, the proposed rule would better enable businesses to focus on what they do best—serve their customers—and not on navigating and managing complex health benefit designs.

This proposed rule is increasingly important as fewer employees at small and mid-sized firms are enrolled in employer coverage and most employers that do offer a plan only provide their workers a single option. For firms that employ 3-24 workers, the percentage of workers covered by employer health benefits has fallen from 44% in 2010 to 30% in 2018. For firms that employ 25-49 workers, the percentage of workers covered by employer health benefits has fallen from 59 percent in 2010 to 44 percent in 2018. 81 percent of small to midsized employers (fewer than 200 employees), and even 42 percent of larger employers (at least 200 employees), offering health benefits only provide a single coverage option for their employees. Economists have found that increasing plans available to employees is extremely valuable, providing the median consumer equivalent benefit as a 13 percent premium reduction.³⁰⁵

An additional way to expand the use of HRAs is to allow a limited “excepted benefit” HRA that, as with all excepted benefits, would not be subject to the ACA’s market rules (such as the prohibition on annual dollar limits and the requirement to cover preventive care without cost sharing) or certain other requirements for group health plans under the Code and the Employee Retirement Income Security Act of 1974 (ERISA). Providing an excepted benefit HRA would reduce the bias toward comprehensive ESI and allow employees another tax-advantaged arrangement to finance limited healthcare expenses. The proposed regulation would permit employers that offer traditional group coverage to

³⁰⁴ 83 FR 54420. *Federal Register*. A Proposed Rule by the Internal Revenue Service, the Employee Benefits Security Administration, and the Health and Human Services Department on October 29, 2018. <https://www.federalregister.gov/documents/2018/10/29/2018-23183/health-reimbursement-arrangements-and-other-account-based-group-health-plans>

³⁰⁵ Dafny, L., Ho, K., and Varela, M. Let Them Have Choice: Gains from Shifting Away from Employer-Sponsored Health Insurance and Toward an Individual Exchange. *American Economic Journal: Economic Policy*. 2013 February; 5(1): 32-58. https://www.jstor.org/stable/23358336?seq=1#metadata_info_tab_contents

provide an HRA of up to \$1,800 per year (indexed to inflation) to reimburse an employee for certain qualified medical expenses, including standalone dental benefits and premiums for a short-term health insurance plan.

According to preliminary estimates from the Treasury Department, once fully phased in, roughly 800,000 employers are expected to provide HRAs to pay for individual health insurance coverage to over 10 million employees. Some experts, such as Harvard Business School professor Regina Herzlinger, suggest the effect could be larger since expanded HRAs will create a more efficient healthcare system as consumerism will be unleashed.³⁰⁶ This phenomenon could lead to increased workforce investment and higher wages as less is spent on health insurance and could spur innovation among providers and insurers as they directly compete for consumer dollars.

Recommendations: Realign Incentives

- Congress should expand consumers' abilities to benefit from Health Savings Accounts (HSAs), including by allowing a greater number of plans (e.g. any plan with an actuarial value below 70 percent) to be HSA-qualified plans, raising the contribution limit on HSAs, allowing people to use their HSA to pay HSA-qualified non-group premiums, allowing Medicare beneficiaries in enrolled high-deductible health plans to contribute to an HSA, and enabling consumers with HSAs to enter into provider-consumer fixed-fee arrangements, including direct primary-care arrangements.
- The administration should explore ways to administratively expand consumers' abilities to benefit from HSAs, including by interpreting preventive services to allow HSA-qualified plans greater ability to cover preventive low-cost treatments for chronic conditions.
- Consistent with Executive Order 13813, the administration should work through the regulatory process to increase the usability of HRAs, to expand employers' ability to offer HRAs to their employees, and to allow HRAs to be used in conjunction with non-group coverage.

The Unintended Consequences of Federal Policies

Delivery System Reform

Policymakers generally agree that the U. S. healthcare system's reliance on fee-for-service, third-party financing has contributed to a system that produces high costs with uneven quality. The increasing recognition among policymakers of this dynamic has led to recent

³⁰⁶ Herzlinger, Regina and Klein, Joel. The IRS can save American health care. *Wall Street Journal*. July 1, 2018. <https://www.wsj.com/articles/the-irs-can-save-american-health-care-1530477705> See also: https://www.researchgate.net/profile/Barak_Richman/publication/316282783_Changing_the_Tax_Code_to_Create_Consumer-Driven_Health_Insurance_Competition/links/594aa2b7458515225a830ab4/Changing-the-Tax-Code-to-Create-Consumer-Driven-Health-Insurance-Competition.pdf

reimbursement policies that attempt to move away from rewarding volume (fee-for-service) to rewarding value. Many delivery system reform efforts to date have sought to transfer risk to entities with better incentives for managing costs and delivering value to patients. One of the most successful examples of this has been Medicare Advantage, which has moved away from a fee-for-service model, improved incentives, and has generally produced higher value (better care per unit of cost) for patients. The success of Medicare Advantage is based on better empowering consumers—letting them determine what constitutes value, as opposed to deferring the judgement to Washington. As HHS Secretary Azar has stated, if the government writes the equation for value, the answer is never going to be cheap or simple, and special interests will find a way to manipulate it. Relying on the free exchange of information between buyers and sellers, among competing interests, can deliver better outcomes from our healthcare system at a lower cost with patients, not the government, in charge.³⁰⁷

ACOs

Various structures have been tried in different settings by the prior administration. However, they have often relied on the government (rather than patients and the private sector) to define value, rather than allowing patient choice. One such approach has been the development of Accountable Care Organizations (ACOs), groups of doctors, hospitals and other providers that work together to manage and coordinate care for Medicare fee-for-service beneficiaries through an accountable care organization, whose performance is evaluated according to quality standards established by the government. ACOs were intended to improve coordination of care between primary care providers, specialists, and hospitals by holding providers accountable for patient outcomes and total costs. When considering the future of ACOs and broader delivery system reform efforts, it is critical to understand the history of ACOs and their effect on provider competition.

The largest Medicare ACO program is the Medicare Shared Savings Program (MSSP), in which Medicare shares in the financial savings and losses generated by ACOs. In 2018, there were 561 MSSP ACOs, which enrolled 10.5 million beneficiaries.³⁰⁸ Importantly, most MSSP participants are not responsible for financial risk if their spending is above established targets (i.e., one-sided financial risk). New payment models such as Medicare's Next Generation ACOs require providers to take on both shared savings and shared

³⁰⁷ Azar AM. Remarks to the Heritage Foundation. U.S. Department of Health & Human Services. <https://www.hhs.gov/about/leadership/secretary/speeches/2018-speeches/remarks-to-the-heritage-foundation.html>. Accessed September 21, 2018.

³⁰⁸ Medicare shared savings program fast facts. Centers for Medicare and Medicaid Services (CMS). January 2018. <https://www.cms.gov/Medicare/Fee-for-Service-Payment/sharedsavingsprogram/Downloads/SSP-2018-Fast-Facts.pdf>. Accessed August 24, 2018.

losses³⁰⁹ (i.e., two-sided financial risk).³¹⁰ These models may offer important learning opportunities to test public-private initiatives that aim to increase value since two-sided financial risk represents better incentives to achieve value than one-sided financial risk. Over time, two-sided financial risk should be paired with some control over the inputs to match outcome accountability.

ACO Impact on Provider Competition

While changes such as ACOs and other alternative payment models (APMs) may hold the promise of improved care coordination and better aligned financial incentives, they may also encourage provider consolidation that increases market concentration, drives up prices, and decreases competition between providers. This may occur as hospitals purchase physician practices (vertical integration), or through mergers between hospitals or between physician practices (horizontal integration). Although a causal link has not yet been identified, some studies have found that vertical integration has been associated with higher prices and spending in some markets and for some providers.³¹¹ In California, hospital-owned physician practices have higher per-patient spending than physician-owned practices.³¹² Most economists believe that horizontal integration threatens consumers with higher prices as well as reduced options.

Some experts have suggested that hospital-acquired practices increase the use of evidence-based care such as disease registries, nurse care managers, and reminders to patients that can improve quality of care and outcomes more than physician-owned practices that do not use such care management practices.³¹³ However, hospital-owned practices may have higher rates of emergency department visits and higher Medicare spending per patient.³¹⁴

³⁰⁹ Shared savings and losses are determined against a benchmark based on baseline and national and regional trends.

³¹⁰ A patient-centered medical home is a model of care coordination in which care is comprehensive and coordinated across multiple resources within the healthcare system as well as the broader community. More information can be found at Defining the PCMH. U.S. Department of Health & Human Services AHRQ. <https://pcmh.ahrq.gov/page/defining-pcmh>. Accessed August 25, 2018.

³¹¹ Baker LC, Bundorf MK, Kessler DP. Vertical integration: hospital ownership of physician practices is associated with higher prices and spending. *Health Aff (Millwood)*. 2014 May;33(5):756-763.

³¹² Robinson JC, Miller K. Total expenditures per patient in hospital-owned and physician-owned physician organizations in California. *JAMA*. 2014;312(16):1663–1669.

³¹³ Bishop TF, Shortell SM, Ramsay PP, Copeland KR, Casalino LP. Trends in hospital ownership of physician practices and the effect on processes to improve quality. *Am J Manag Care*. 2016 Mar;22(3):172-176; Rodriguez HP, McClellan SR, Bibi S, Casalino LP, Ramsay PP, Shortell SM. Increased use of care management processes and expanded health information technology functions by practice ownership and Medicaid revenue. *Med Care Res Rev*. 2016 Jun;73(3):308-328.

³¹⁴ Pesko MF, Ryan AM, Shortell SM, et al. Spending per Medicare beneficiary is higher in hospital-owned small- and medium-sized physician practices. *Health Serv Res*. 2017 Sep 21. doi: 10.1111/1475-6773.12765.

This may be why greater physician-hospital integration has been linked to higher commercial prices for outpatient care³¹⁵ and hospital prices.³¹⁶

The FTC and the Justice Department worked closely with CMS to develop ACO eligibility criteria so Medicare Shared Savings Program ACO applicants meet clinical integration requirements, avoiding antitrust concerns.³¹⁷ In order to facilitate compliance with antitrust rules, the FTC and DOJ developed antitrust guidance and policy for ACOs,³¹⁸ defining antitrust safety zones as well as areas of potential concern where providers have high market power based on their share of the primary service area. The antitrust authorities continue to monitor ACOs for potential antitrust violations.

Research to date indicates that ACOs tend to develop in competitive markets; and only in a minority of markets have ACOs increased physician concentration.³¹⁹ One recent study found that markets with higher ACO penetration did not experience differential changes in physician-hospital integration, practice size, or market concentration of physicians or hospitals from 2008 to 2013.³²⁰ The study also found high ACO penetration markets had more competitive hospital and insurance markets and higher commercial HMO penetration. The authors did note that continued consolidation might be a defensive response to the potential threat from new payment models, as larger health systems may be able to resist payer pressures to enter into risk contracts.

Importantly, provider consolidation began prior to the start of delivery system reform efforts. In one study of hospital acquisition of practices between 2006 and 2013, vertical integration peaked in 2011. Hospitals mostly bought small primary care, multi-specialty, or cardiology practices; case studies of hospitals indicated the primary motivation was to increase referrals and negotiate higher payment rates with insurers.³²¹

³¹⁵ Neprash HT, Chernew ME, Hicks AL, Gibson T, McWilliams JM. Association of financial integration between physicians and hospitals with commercial health care prices. *JAMA Intern Med*. 2015 Dec;175(12):1932-1939.

³¹⁶ Baker LC, Bundorf MK, Kessler DP. Vertical integration: hospital ownership of physician practices is associated with higher prices and spending. *Health Aff (Millwood)*. 2014 May;33(5):756-763.

³¹⁷ Federal Trade Commission and Department of Justice. Statement of antitrust enforcement policy regarding accountable care organizations participating in the Medicare Shared Savings Program. *Fed Register*. 2011 Oct 28;76(209):67026-67032. <https://www.gpo.gov/fdsys/pkg/FR-2011-10-28/pdf/2011-27944.pdf>. Accessed August 24, 2018.

³¹⁸ Accountable care organizations. FTC. <https://www.ftc.gov/tips-advice/competition-guidance/industry-guidance/health-care/accountable-care-organizations>. Accessed August 24, 2018; Federal Trade Commission and Department of Justice. Statement of antitrust enforcement policy regarding accountable care organizations participating in the Medicare Shared Savings Program. *Fed Register*. 2011 Oct 28;76(209):67026-67032. <https://www.gpo.gov/fdsys/pkg/FR-2011-10-28/pdf/2011-27944.pdf>. Accessed August 24, 2018.

³¹⁹ Richards MR, Smith CT, Graves AJ, Buntin MB, Resnick MJ. Physician competition in the era of accountable care organizations. *Health Serv Res*. 2018 Apr;53(2):1272-1285.

³²⁰ Neprash HT, Chernew ME, McWilliams JM. Little evidence exists to support the expectation that providers would consolidate to enter new payment models. *Health Aff (Millwood)*. 2017 Feb 1;36(2):346-354.

³²¹ West J, Johnson G, Jha AK. Trends in acquisitions of physician practices and subsequent clinical integration: a mixed methods study. *J Eval Clin Pract*. 2017 Dec;23(6):1444-1450.

A Robert Wood Johnson Foundation project on the impact of hospital consolidation concluded that early trends in consolidation were primarily to improve bargaining power and did not necessarily involve clinical integration.³²² Some potential factors related to delivery-system reform that may be contributing to provider consolidation include large health system economies of scale and ability to handle increasing quality and cost measurement reporting. The capital and resource requirements to transform a primary care practice, even within a practice, are substantial. The financial and administrative demands of delivery system reform may incentivize small practices and solo practitioners to accept buy-outs by hospitals and health systems or leave the profession prematurely. The trend toward large systems is likely not be better for patients. A 2013 study found that larger health systems participating in payment reform have not shown better patient outcomes or lower spending,³²³ whereas small practices have seen lower rates of preventable admissions.³²⁴ Thus, it is important that delivery system reform efforts do not harm smaller practices that lack economies of scale to satisfy new rules and requirements accompanying delivery system reform more easily.

Recommendations: Delivery System Reform

- The administration should focus on identifying alternative payment models that allow free markets and patients to define value, rather than rely on technical and burdensome definitions invented in Washington.
- The administration should evaluate the best metrics for measuring value and quality in the healthcare sector, eliminating unnecessary and potentially counterproductive measures and reducing the burden on providers.
- The administration should ensure that smaller physician and provider practices are not unduly harmed by delivery system reform and corresponding requirements.
- The administration should ensure that these delivery system reform models, which aim to hold providers accountable to a set of population-based metrics and total spending, foster collaboration across systems within a geographic area and do not produce harmful consolidation, particularly horizontal consolidation.
- The Administration should pursue policies and programs that encourage value, competition, and choice, such as Medicare Advantage, and move away from a fee-for-service model.

³²² Gaynor M, Town R. The impact of hospital consolidation—update. Robert Wood Johnson Foundation, The Synthesis Project, Policy Brief No. 9, June 2012.

http://www.rwjf.org/content/dam/farm/reports/issue_briefs/2012/rwjf73261. Accessed August 21, 2018.

³²³ McWilliams JM, Chernew ME, Zaslavsky AM, Hamed P, Landon BE. Delivery system integration and health care spending and quality for Medicare beneficiaries. *JAMA Intern Med.* 2013 Aug 12;173(15):1447-1456.

³²⁴ Casalino LP, Pesko MF, Ryan AM, et al. Small primary care physician practices have low rates of preventable hospital admissions. *Health Aff (Millwood).* 2014 Sep;33(9):1680-1688.

Positively Realigning Incentives through Payment Reform

Patients with certain clinical needs can often seek care in one of a variety of settings. Medicare fee-for-service (FFS) reimbursement is often based predominately on the setting of care and not the patient's underlying medical need. This can create incentives for providers to refer patients selectively to more highly reimbursed care settings, unjustifiably increasing concentration and spending. Two examples of service types with multiple venue options are post-acute care (PAC) and certain physician services furnished in hospital outpatient departments (HOPD).

Post-Acute Care

Medicare post-acute care (PAC) providers are primarily used for recuperation and rehabilitation. These providers include home health agencies (HHAs), skilled nursing facilities (SNFs), inpatient rehabilitation facilities (IRFs), and long-term care hospitals (LTCHs). In 2016, Medicare spent approximately \$60 billion on Medicare PAC services. Per statute, separate Medicare prospective payment systems (PPSs) were developed for each Medicare PAC setting. Base PPS payments for each of these settings differs considerably, even though the clinical characteristics of patients and the services delivered at any of the four PAC settings may be similar. The 2018 base PAC PPS payments (i.e., base payments prior to adjustments such as case mix) are about \$15,000 per discharge for IRF, about \$400 per diem for SNF (up to 100 days in a covered spell of illness), about \$3,000 per 60-day episode for an HHA, and about \$41,000 per discharge for a standard LTCH stay or an inpatient hospital with comparable payment rate for patients who meet statutorily specified LTCH eligibility criteria. A unified or site-neutral PAC prospective payment system would base Medicare payment on the clinical characteristics of the patient instead of the provider setting.

Hospital Outpatient Departments

Many of the services delivered by hospital outpatient departments (HOPDs), such as evaluation and management visits, endoscopies, and imaging services, are also delivered in physician offices and ambulatory surgical centers (ASCs). Medicare FFS benefit payments are projected to be \$50 billion in 2018 and \$100 billion in 2027 for these services.³²⁵ Conceptually, physician reimbursement for ambulatory services has two components: the professional component, which covers the physician time, and the technical (also called facility) component, which covers the cost of the office, equipment, and auxiliary staff's time. The professional component is paid under the Medicare Physicians Fee Schedule (PFS) regardless of the place of service. However, the technical component is typically higher in the HOPD than in a physician's office or ambulatory surgical center.

³²⁵ CBO Baseline, 2017. These figures include some services that are not paid under OPFS. Some of these HOPD payments are copayments and some are paid via Part B premium. Also, these figures pertain to FFS enrollees only. Any change in payment rates will yield savings on the Medicare Advantage side.

Sec. 603 of the Bipartisan Budget Act of 2015 (BBA) modified how off campus outpatient services are paid. Prior to enactment of the BBA, hospitals were able to purchase freestanding clinics and bill for outpatient services under the Outpatient Prospective Payment System (OPPS) for the services furnished at these off-campus provider based departments. Sec. 603 changed the incentives so that after January 1, 2017, services furnished by certain off-campus provider based departments would no longer be payable under the OPPS (and would generally instead be paid lower rates under the Physician Fee Schedule), effectively decreasing payments for these services and eliminating an incentive for hospitals to purchase these freestanding clinics. Clinics purchased by the hospitals prior to November 2, 2015 or which were located less than 250 yards away from a remote location of the hospital were “grandfathered,” and continue to have services rendered paid under OPPS. Elimination of this incentive to consolidate will hopefully serve to maintain market competition and slow increases in Medicare and private insurance sending.

Recommendations: Positively Realigning Incentives through Payment Reform

- Congress should establish site neutral payment policies based on the anticipated clinical needs and risk factors of the patient, rather than the site of service. In delivering these reforms, Congress should account for differing levels of patient acuity.
- State Medicaid programs should embrace site neutrality as a goal and reform their payment systems to pay for the value delivered where value is defined according to a relatively limited, straightforward, and non-gameable set of metrics. Additionally, metrics should not be designed and proposed solely by the entities to which they will ultimately apply.

Quality Improvement and the Measurement and Reporting of Quality

One of the earliest experiences with quality reporting was the publication of “report cards” in New York and Pennsylvania, which started reporting physician and hospital coronary artery bypass graft (CABG) surgery mortality rates in the 1990s. These efforts led to some early successes, including a 41 percent decline in risk-adjusted mortality rates³²⁶ and 27 surgeons with low volume and high mortality rates ceasing performing CABG surgeries.³²⁷ Potential drawbacks are that report cards may have produced some “cherry picking” by providers, so that fewer severely ill patients received CABG and health outcomes for

³²⁶ Hannan EL, Kilburn H, Racz M, Shields E, Chassin MR. Improving the outcomes of coronary artery bypass surgery in New York State. *JAMA*. 1994;271(10):761-766.

³²⁷ Chassin MR, Hannan EL, DeBuono, BA. Benefits and hazards of reporting medical outcomes publicly. *N Engl J Med*. 1996;334(6):394-398.

severely ill patients worsened.³²⁸ Several other studies have demonstrated positive results from measuring quality outcomes and publishing the results.³²⁹

While value is best determined by private sector interactions, the government can play a productive role in collecting and making available data that patients and insurance companies can use to make more informed decisions. In the past, the government has often failed to establish sensible metrics, creating significant reporting burdens for providers and metrics that are not informative for patients or industry and can easily be gamed when reimbursement is tied to them.

Quality Reporting History

Following the publication of the landmark reports, *To Err is Human* and *Crossing the Quality Chasm* by the Institute of Medicine in 1999 and 2001 respectively, numerous quality-reporting requirements have been imposed on providers. The premise of quality reporting is that it will motivate providers to improve the quality of healthcare they deliver and provide patients with the information they need to make informed choices about their

³²⁸ Dranov D, Kessler D, McClellan M, Satterthwaite M. Is more information better? The effects of 'Report Cards' on health care providers. *J Polit Econ*. 2003;111(3):555-588.

³²⁹ In 1997, for example, the Cleveland Health Quality Choice project began a regional initiative to disseminate data to profile hospital performance and found improved outcomes in risk-adjusted mortality for six medical and two surgical procedures. (Rosenthal GE, Quinn L, Harper DL. Declines in hospital mortality associated with a regional initiative to measure hospital performance. *Am J Med Qual*. 1997 Summer;12(2):103-112. PMID: 9161057). In addition, a 2008 Pennsylvania study showed significantly lower odds of in-hospital mortality associated with intensive public reporting (OR=0.59-0.79, p<0.01). (Hollenbeak CS, Gorton CP, Tabak YP, et al. Reductions in mortality associated with intensive public reporting of hospital outcomes. *Am J Med Qual*. 2008;23:279-286). The CABG Outcomes Public Reporting Program (CCORP), mandated by the California legislature in 2003, also generates annual report cards, including risk-adjusted operative mortality rates, for all nonfederal hospitals and surgeons who perform the procedure. The program reported observed mortality decreased statewide (2.90% to 2.22%, p<0.01) and no evidence that high-risk patients denied CABG because of public reporting. (Li Z, Carlisle DM, Marcin JP, et al. Impact of public reporting on access to coronary artery bypass surgery: the California Outcomes Reporting Program. *Ann Thorac Surg*. 2010 Apr;89(4):1131-1138. PMID: 20338320). In addition, in 2016 a systematic review and meta-analysis of impact of public reporting on clinical outcomes, showed positive impact of public reporting on overall mortality (RR=0.85 [95% CI, 0.79-0.92]). (Campanella P, Vukovic V, Parente P, et al. The impact of public reporting on clinical outcomes: a systematic review and meta-analysis. *BMC Health Serv Res*. 2016 Jul 22;16:296.) Finally, an evaluation of state-mandated health-care-associated infection reporting laws on central-line associated bloodstream infection rates at the hospital/ICU level found that states with such laws had lower CLABSI rates beginning approximately six months prior to the law's effective date (IRR = 0.66; p < .001). This effect has persisted for > 6.5 years. (Liu H, Herzig CTA, Dick AW, et al. Impact of state reporting laws on central line-associated bloodstream infection rates in U.S. adult intensive care units. *Health Serv Res*. 2017 Jun;52(3):1079-1098). See also Hannan EL, Kumar D, Racz M, et al. New York State's Cardiac Surgery Reporting System: four years later. *Ann Thorac Surg*. 1994 Dec;58(6):1852-1857. PMID: 7979781; Chassin MR, Hannan EL, DeBuono BA. Benefits and hazards of reporting medical outcomes publicly. *N Engl J Med*. 1996 Feb 8;334(6):394-398. PMID: 8538714; Dehmer GJ, Drozda JP Jr, Brindis RG, et al. Public reporting of clinical quality data: an update for cardiovascular specialists. *J Am Coll Cardiol*. 2014 Apr 8;63(13):1239-1245. Review. PMID: 24509280.

care. Early quality public reporting initiatives centered around hospital mortality rates,³³⁰ and required many providers to abstract data manually from patient charts.

The Deficit Reduction Act of 2005 mandated that HHS develop a plan for value-based purchasing for Medicare hospitals starting in 2009, which led to Medicare's first pay-for-reporting programs for hospitals and physicians.³³¹ Medicare tested the first hospital pay-for-performance program through a partnership with Premier, an alliance of hospitals, in the Hospital Quality Incentive Demonstration,³³² a six-year program that awarded top-performing hospitals with bonuses based on evidence-based quality measures for five clinical conditions. This demonstration showed improvements in quality for participants and those who publicly reported quality.³³³ Refinements to Premier's methodology, rewarding both achievement and improvement as a means to address disparities,³³⁴ have led to implementation of similar features in Medicare's current value-based purchasing programs.

Since 2003, HHS has published a national report on quality and disparities through national databases in the Agency for Healthcare Research and Quality (AHRQ). The data show continued disparities among providers alongside overall improvements. The National Quality Forum is now looking at methodologies to display this data to providers to help improve care for disadvantaged populations (including poor, rural, and vulnerable populations) by reporting potentially preventable admissions that reflect the quality of primary care or higher rates of delayed care due to affordability.³³⁵

Medicare's Physician Value-Modifier (VM) program, a physician pay-for-performance program, sought to extend the goals of quality improvement in the ambulatory care setting and assess population outcomes such as preventable admissions, using Medicare claims

³³⁰ These early quality measures relied on manual abstraction from medical records. The below support the claim this was a burden: General Accounting Office. Report cards: a useful concept but significant issues need to be addressed. Washington, D.C.: Government Printing Office, 1994.

See also: Epstein A. Performance reports on quality--prototypes, problems, and prospects. *N Engl J Med*. 1995 Jul 6;333(1):57-61.

³³¹ Damberg CL, Sorbero M, Mehrotra A, Teleki S, Lovejoy S, Bradley L. An environmental scan of pay for performance in the hospital setting: final report. Working paper prepared by RAND. Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services. November 2007. <https://aspe.hhs.gov/system/files/pdf/75266/PayPerform07.pdf>. Accessed August 25, 2018.

³³² Premier Hospital Quality Incentive Demonstration. <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Downloads/HospitalPremierPressRelease-FactSheet.pdf>. Accessed August 25, 2018.

³³³ Centers for Medicare and Medicaid Services, Evaluation of the Premier Hospital Quality Incentive Demonstration. Executive Summary. March 3, 2009. https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Reports/downloads/Premier_ExecSum_2010.pdf. Accessed August 25, 2018.

³³⁴ Ryan AM, Blustein J, Doran T, Michelow MD, Casalino LP. The effect of Phase 2 of the Premier Hospital Quality Incentive Demonstration on incentive payments to hospitals caring for disadvantaged patients. *Health Serv Res*. 2012;47(4):1418-1436.

³³⁵ Compendium of U.S. Health Systems, 2016. U.S. Department of Health and Human Services, AHRQ. <https://www.ahrq.gov/chsp/compendium/index.html>. Accessed August 25, 2018.

data. In addition, the Quality Payment Program, enacted in 2015 through MACRA, has created another requirement for physicians to report on measures. Like the Value Modifier Program, the Quality Payment Program also assesses clinicians and group practices on population level outcomes including all-cause readmissions and avoidable ER visits.

Quality metrics have a greater effect on providers than on patients. Many of the patients did not consult the report cards, and of those who did, many reported that they did not affect their choice of hospitals or surgeons.³³⁶ However, the quality metrics certainly affect providers who do not wish to be publicly identified as potentially harming patients, and this seemingly drives many providers to improve. Although measuring quality has generally produced positive results, the proliferation of measures produces a burden that discourages providers and likely takes away from patient care. Moreover, many providers have learned to game certain measures or have become sophisticated in explaining away bad results as attributable to improper risk adjustment.

The shift to value-based payment, the large number of quality measures, and the potential lack of alignment in measures required by different payers (e.g., Medicare, state Medicaid agencies, and health insurers) further increases the burden of quality reporting on providers. Each year physicians and their staff in four common practice areas (cardiology, orthopedics, primary care, and multispecialty) spend 15.1 hours per week per physician on reporting quality measures—about 785 hours per physician per year—at an estimated average annual cost of \$40,069 per physician or \$15.4 billion per year for these specialties.³³⁷ This is clearly too much, especially given the problems intrinsic to many of the metrics being recorded. CMS estimated the total costs burden of MIPS in the first year to be \$1.3 billion in 2017, decreasing to \$694 million by 2018 due to fewer clinicians being eligible under revised volume requirements.

Half of physicians and 38 percent of nurse practitioners and physician assistants report that quality reporting requirements have a negative impact on the quality of care.³³⁸ This stands out as another example of well-intentioned government action having unintended consequences. To address this issue, the National Quality Forum (NQF) has endorsed a set of common quality reporting measures for use by public and private payers. Under current

³³⁶ Marshall MN, Shekelle PG, Leatherman S, Brook RH. The public release of performance data: what can we expect to gain. A review of the evidence. *JAMA*. 2000;283:1866-1874; Schneider EC, Epstein AM. Use of public performance reports: a survey of patients undergoing cardiac surgery. *JAMA*. 1998;279:1638-1642.

³³⁷ Casalino LP, Gans D, Weber R, et al. US physician practices spend more than \$15.4 billion annually to report quality measures. *Health Aff (Millwood)*. 2016 Mar;35(3):401-406.

³³⁸ Ryan J, Doty MM, Hamel L, Norton M, Abrams MK, Brodie M. Primary care providers' views of recent trends in healthcare delivery and payment: findings from the Commonwealth/Kaiser Family Foundation 2015 National Survey of Primary Care Providers. Commonwealth Fund/Kaiser Family Foundation. Issue Brief. August 5, 2015. <https://www.commonwealthfund.org/publications/issue-briefs/2015/aug/primary-care-providers-views-recent-trends-health-care-delivery>. Accessed August 25, 2018.

law, NQF endorsement is required to ensure standardization and stakeholder input in measures used for quality reporting and performance-based payment.

Another recent private-public effort, Core Quality Measures Collaborative,³³⁹ has worked to align measure specifications across payers including Medicare and Medicaid. In addition, CMS's Meaningful Measures Initiative removed 18 hospital reporting measures and is proposing removal of 36 measures from the MIPS program that have showed no variation and are topped-out (i.e. already showing high level of performance with minimal to no variation).

Impact of Quality Reporting on Competition

A recent report by the Government Accountability Office (GAO) predicts that many small practices will be unable to transition to MIPS due to lack of financial resources.³⁴⁰ The new requirements potentially disadvantage small, independent practices or solo practitioners who, unlike large health systems, are less likely to have the administrative infrastructure and staffing resources (e.g., a practice manager or other administrative staff) to report efficiently on quality and conduct regular quality improvement activities to improve performance. One potential concern is that practices that participate in these programs may harm patient care if they need to divert limited resources to reports and bureaucracy and away from actual quality improvement and patient care. The financial effects from penalties, diverted resources, and poor performance results could affect their ability to stay in business, force them to merge with larger systems, or lead to early retirement.

The GAO also suggests that small practices could work with partners to share in financial risk and help coordinate services, as well as work with non-partners in order to support quality reporting, patient surveys, and EHR requirements. Since many practices would like to remain independent and there is increasing evidence that small independent practices provide higher quality of care, such as fewer preventable hospital admissions, at lower cost,³⁴¹ enabling them to achieve these benefits while remaining independent is important.

Recommendations: Quality Improvement and the Measurement and Reporting of Quality

- As proposed by the Centers for Medicare and Medicaid Services' Patients over Paperwork initiative, the administration should streamline and standardize quality measures across programs to avoid duplicative reporting requirements and limit the number of measures where the expected cost of collecting the measure

³³⁹ Core measures. CMS. <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityMeasures/Core-Measures.html>. Accessed August 25, 2018.

³⁴⁰ Medicare value-based payment models: participation challenges and available assistance for small and rural practices. U.S. Government Accountability Office (GAO). Report to Congressional Committees. December 2016. <https://www.gao.gov/assets/690/681541.pdf>. Accessed August 25, 2018.

³⁴¹ Casalino LP, Pesko MF, Ryan AM, et al. Small primary care physician practices have low rates of preventable hospital admissions. *Health Aff (Millwood)*. 2014 Sep;33(9):1680-1688.

exceeds the expected benefit. In addition, the administration should collaborate with state Medicaid programs, private payers, and other government payers to align and streamline quality measures and reporting structures to reduce physician burden.

- The administration should seek to develop measures that are meaningful to providers and patients, and help them assess quality and value.
- The administration should focus on providing a framework for quality reporting in plain language that is more accessible and appealing to consumers.
- The administration should consider providing incentives and technical assistance to support the development of virtual provider groups (e.g., independent practice associations, alternative payment models, or regional quality collaboratives) that can increase the competitiveness of small practices through access to shared resources and help build capacity for care management.
- HHS should explore opportunities to initiate research into machine learning techniques that can directly access data on CMS beneficiaries from the provider Electronic Medical Records (EMRs) using open application program interfaces in order to enable quality analysis and payments based on value while reducing burden and cost and benefitting the public.

Section Four:

Enabling Consumer-Driven Healthcare

Rising healthcare spending is partly attributable to consumers' insulation from the true market price of healthcare services through the presence of third-party payment. Historically, consumers have had little reason to seek out, or price shop for, lower-cost or higher-value providers and services due to the abundance of third-party payment. Instead, reimbursement rates are negotiated between third-party payers, generally the government or insurers, and providers. And consumers generally are provided with little information on the prices of healthcare products and services.

Perhaps not surprisingly, there is a wide variation in prices charged across providers, even within a geographic area.³⁴² Substantial savings could be achieved if consumers actively shopped and selected lower-cost providers. For example, Table 2 demonstrates the potential savings for people who self-pay relative to the insurance rate. Unlike most industries, which typically offer relatively uniform prices to most consumers, the reimbursement of a specific service will vary significantly based on the third-party payer with which a consumer is aligned. It is also worth noting that consumers may receive a lower price by paying cash for services.³⁴³ Yet it can be difficult for consumers to find price information.

Table 2

³⁴² Newman D, Parente S, Barrette E, Kennedy K. DATAWATCH: Prices for common medical services vary substantially among the commercially insured. *Health Aff.* 2016;35:5923-5927. doi:10.1377/hlthaff.2015.1379.

³⁴³ Beck M. How to cut your health-care bill: pay cash. *Wall Street Journal*. February 15, 2016. <https://www.wsj.com/articles/how-to-cut-your-health-care-bill-pay-cash-1455592277>. Accessed August 25, 2018.

The Cash Advantage

Patients who pay cash upfront for medical services can sometimes make out better than they would by using their insurance, especially if they have high-deductible plans and pay the insured rate in full. Some examples:

PROCEDURE	FACILITY CITY	SELF-PAY RATE	INSURANCE RATE	INSURANCE COMPANY
MRI of the foot	Regional Medical Imaging Flint, Mich.	\$379	\$445	Aetna
Tonsillectomy	Banner Desert Medical Center Mesa, Ariz.	\$2,858*	\$5,442	Arizona Blue Cross Blue Shield
MRI of the knee	Boulder Community Hospital Boulder, Colo.	\$600	\$1,100	Arizona Blue Cross Blue Shield

Note: Insurers' rates may vary by plan. *Not including physicians' fees, typically \$1,000 to \$1,400.

Sources: the providers; insurers' cost-estimator tools

TABLE: WALL STREET JOURNAL

In sum, the abundance of third-party payment creates a system in which consumers generally do not shop on price and providers lack incentives to compete on price and quality to attract and retain patients. Of note, while the third-party payers have knowledge of the reimbursement schedule, price transparency at this level is inefficient for two reasons: (1) Insurers may lack incentives to obtain lower prices especially if profits are capped at a percentage of spending, and (2) Insurance introduces moral hazard and waste.

Despite the current foundational impediments to establishing a consumer-driven market, some examples provide insight into the results that might be achievable if consumers had greater incentives and ability to make informed decisions about their healthcare consumption.

Some government tax policies and payers' benefit design strategies have sought to encourage consumers to become more actively engaged in purchase decisions. As discussed earlier, consumer-directed models, such HDHP linked to HSAs, hold the promise of increasing consumer engagement in their healthcare decisions. So do initiatives that leverage the power of consumer shopping, like reference pricing. As of 2017, more than 20 million people were enrolled in an HSA-qualified plan, although only about 40 percent

of these enrollees contributed to an HSA.³⁴⁴ One study found that HDHPs produce lower spending, primarily due to less utilization.³⁴⁵ Combining HDHPs with consumer-driven HSAs could create more effective incentive structures than existing third-party arrangements, incentivizing patients to shop for higher-value care without forgoing necessary treatments. However, patients cannot make fully informed decisions about where to receive care without information about the cost and quality of providers. Unfortunately, consumers often lack meaningful and understandable price information.

Payers Can Improve Incentives

Empowering consumers with price information and realigning financial incentives to give consumers a greater stake in their healthcare decisions has been shown to lower prices without affecting quality. One model for increasing consumer engagement is the use of reference-based pricing. Reference pricing places an upper limit on the amount of reimbursement a payer will pay for a medical service. Generally, the reference price is set to a specific percentile of the distribution of provider reimbursements in a market, such as the median reimbursement. If an enrollee receives care from a provider that charges above the reference price, then the enrollee is responsible for the difference.

Reference pricing has been shown to reduce the variation in prices across providers, as providers increasingly compete on price. When the California Public Employees' Retirement System (CalPERS), which provides benefits to over 1.4 million enrollees, started using reference pricing, higher-cost providers soon responded by lowering their prices to attract these enrollees (Robinson 2017).³⁴⁶ CalPERS distributed lists of hospitals that exceeded a certain quality threshold and had different prices for its enrollees. Consumers increasingly used lower-cost providers with no negative impact on quality.³⁴⁷

Price Transparency in Action: in CalPERS PPO plans

Since 2011, CalPERS has used reference pricing for its PPO enrollees. Services that use reference pricing include joint replacement, arthroscopy, cataract removal, and colonoscopy.

Results:

- 9-14 percentage point increase in the use of low-price facilities.
- Reduction in prices 17-21%.

³⁴⁴ Fronstin, P. Has enrollment in HSA-eligible plans stalled? Washington, D.C. Employee Benefit Research Institute. February 16, 2018 [cited 2018 May 7]. https://www.ebri.org/pdf/briefspdf/EBRI_IB_441.pdf. Accessed August 25, 2018.

³⁴⁵ Brot-Goldberg ZC, Chandra A, Handel BR, Kolstad JT. What does a deductible do? The impact of cost sharing on healthcare prices, quantities, and spending dynamics *The Quarterly Journal of Economics*. 2017;132(3):1261-1318.

³⁴⁶ Robinson CR, Brown TT, Whaley C. Reference pricing changes "choice architecture" of healthcare for consumers. *Health Aff*. 2017;35:524-530. doi: 10.1377/hlthaff.2016.1256.

³⁴⁷ *Id.*

(See Figure 2.) CalPERS' experience highlights the potential for realigning incentives using reference-based pricing, to lower cost and increase value in the healthcare system.

The Centers of Excellence contracting approach is another method that many payers use to obtain value for employees. Under this approach, an employer or insurer contracts with specific high-value providers for particular services or procedures and offers its health plan enrollees lower cost sharing for using those providers. Often these arrangements rely on bundled payments, in which the payer reimburses the provider a set amount for a pre-defined episode of care.³⁴⁸ Centers of Excellence contracting is often used in non-emergency situations in which a consumer can travel to

obtain care from a nationally recognized physician or hospital. For example, Walmart covers its health plan enrollees at zero-cost sharing if they travel to the Mayo Clinic, Cleveland Clinic, or another select high-quality provider for cardiac, spine, and transplant surgeries.³⁴⁹ In addition, Walmart covers travel and lodging costs for the patient and a caregiver.

Price Transparency in Action:

Finding Value in Imaging

In 2010, AIM Health started calling patients referred to MRI providers with substantially higher cost (\$400+) or poorer quality than other sites. Patients were notified of a higher value site, but were not forced to switch.

Results:

Reduced Patient Costs

- Saved patients \$220 (18.7%) per scan relative to patients in other cities.

Promoted Site Neutrality

- 30% decline in hospital price premium for MRIs
- Use of hospital-based facilities fell from 53% to 45%, 2010-2012

Current State of Price-Transparency Efforts

Meaningful and timely consumer access to prices can supplement benefit designs to help consumers choose lower-cost, higher-value providers. In a competitive, functioning insurance market, insurers would have an incentive to use such approaches.

³⁴⁸ Delbanco SF, Murray R, Berenson RA, Upadhyay, DK. Centers of Excellence. Payment methods and benefit designs: how they work and how they work together to improve healthcare. Urban Institute. April 2016. https://www.urban.org/sites/default/files/06_centers_of_excellence.pdf. Accessed September 21, 2018.

³⁴⁹ Welborn S. The right care at the right time: expanding our Centers of Excellence network. Walmart. <https://news.walmart.com/2016/10/10/the-right-care-at-the-right-time-expanding-our-centers-of-excellence-network>. Accessed August 25, 2018.

To be effective, price transparency efforts must distinguish between the charges a provider bills and the rate negotiated between payers and each provider. Some health plans and self-insured employers have developed price transparency tools for their enrollees. CalPERS uses a price transparency platform that allows patients to see providers' prices along with out-of-pocket costs. Over 90 percent of enrollees in Aetna commercial health plans have access to Aetna's Member Payment Estimator which provides personalized out-of-pocket costs for more than 600 medical services—a helpful resource because it uses negotiated plan prices instead of relatively meaningless charges,³⁵⁰ and takes into account cost-sharing responsibilities such as any remaining deductible amount.

State governments purchase significant volumes of healthcare goods and services through Medicaid, departments of corrections, and public sector employees' pension and health benefit funds.³⁵¹ In this capacity, states have an incentive to reduce their healthcare spending. Realigning incentives and promoting price transparency may help states do so. Most states have some laws related to price transparency; however, states may be able to do more.³⁵²

At the federal level, the ACA requires hospitals to report annually and make public a list of hospital charges for items and services. Starting in 2013, CMS publicly released average hospital-specific charges per patient and average Medicare payments for common diagnosis-related groups and ambulatory procedures. As part of the FY 2019 Inpatient Prospective Payment System Proposed Rule, CMS updated its guidelines to require hospitals to make available a list of their current standard charges via the internet in a machine readable format and to update this information at least annually, or more often as appropriate, which may make it easier for consumers to find charges and for third parties to collect and analyze data when developing value and price transparency tools or reports. This data may show the very high rates that many hospitals charge for certain services and treatments. The agency also sought comment on how to make this information available in a consumer-friendly interface.

Boosting price transparency will likely have limited utility unless the dampening effect of third-party payment on consumer engagement is also addressed. One study classified 43 percent of healthcare spending as shoppable;³⁵³ however, third-party payment reduces the

³⁵⁰ Charges are defined as the prices of a service, diagnostic test, medical procedure, and other items for which a hospital bills a patient or insurer before any discount is applied. For the most part, charges do not reflect the actual price a consumer pays, as charges do not take into account any discount received through insurance or discount the hospital applies for paying in cash.

³⁵¹ Sinaiko AD, Chien AT, Rosenthal MB. The role of states in improving price transparency. *JAMA Int Med*. 2015. 175(6):886-887.

³⁵² Delbanco S, de Brantes F. States must step up to help consumers gain access to health care prices. *The Health Care Blog*. March 18, 2013. www.thehealthcareblog.com/blog/2013/03/18/states-must-step-up-to-help-consumers-gain-access-to-health-care-prices/. Accessed June 2013.

incentive to shop, resulting in low utilization of price transparency tools. Studies have found that only between 1 percent and 20 percent of patients use price transparency tools when they are available.³⁵⁴ The most promising results for price transparency tools have been for services that rely less on the established physician-patient relationship and are relatively fungible and shoppable, such as imaging and laboratory tests. Price shopping for imaging services is associated with savings of up to 19 percent.³⁵⁵ In addition, some evidence suggests this shopping is associated with increased price competition among providers offering these services.³⁵⁶

Further development of a consumer market for healthcare, anchored around readily available healthcare prices will likely require reforms to the third-party payment system. Research suggests that without strong financial incentives and accessible data on value (like those present in the CalPERS reference pricing example) consumers are often unwilling to change providers, overly rely on current providers for referrals, and conflate high prices with perceived quality regardless of actual outcomes. Many patients also naturally lose interest in the cost of healthcare once they meet their insurance deductible.³⁵⁷

Importantly, price information may be less useful to consumers if price comparisons do not group, or bundle, services into common episodes of care. An episode of care can include multiple services and fees, which makes it difficult for consumers to obtain accurate price estimates. Consumers may be unaware, for example, of separate physician and facility fees, resulting in higher than expected prices and surprise medical bills. By developing a standardized set of services, such as those used in bundled payment approaches, price transparency efforts could better help consumers compare providers.

Not surprisingly, many insurers and providers do not wish to publicize price information, which inhibits price transparency efforts. Employers may lack access to healthcare pricing information if providers or insurers are unwilling to release their prices. In some instances, even self-insured employers lack access to pricing data that their administrator deems

³⁵⁴Mehrotra MD, Brannen T, Sinaiko, AD. Use patterns of a state healthcare price transparency web site: what do patients shop for? *Inquiry*. 201; 51:1-3. and Desai S, Hatfield LA, Hicks AL, Sinaiko AD, Chernew ME, Cowling D, et al. Offering a price transparency tool did not reduce overall spending among California public employees and retirees. *Health Aff (Millwood)*. 2017;36(7):1401–07 among others.

³⁵⁵ Whaley C, Schneider Chafen J, Pinkard S, Kellerman G, Bravata D, Kocher R, et al. Association between availability of health service prices and payments for these services. *JAMA*. 2014;312(16):1670–6 and Wu S, Sylwestrzak G, Shah C, DeVries A. Price transparency for MRIs increased use of less costly providers and triggered provider competition. *Health Affairs*. 2014. 33(8):1391-8.

³⁵⁶ Wu S, Sylwestrzak G, Shah C, DeVries A. Price transparency for MRIs increased use of less costly providers and triggered provider competition. *Health Affairs*. 2014. 33(8):1391-8.

³⁵⁷ (Semigran HL, Gourevitch R, Sinaiko AD, et al. Patients' Views on Price Shopping and Price Transparency. *AM J Manag Care*. 2017;23(6):e186-92., Sinaiko AD, Rosenthal MB. Examining a healthcare price transparency tool: who uses it, and how they shop for care. *Health Aff (Millwood)*. 2016;35(4):662–70, and Volpp, KG. Price transparency: Not a panacea for healthcare costs. *JAMA* 2016;315(17): 1842-3.

proprietary information,³⁵⁸ even though the employer is paying for much of their employees' healthcare. The Labor Department has finalized a rule that enhances small employers' and sole proprietors' options for banding together to form Association Health Plans under Title I of the Employee Retirement Income Security Act.³⁵⁹ Small employers and sole proprietors that form these plans may be able to gain the market power necessary to leverage providers into these pricing arrangements.

Recommendations: Facilitate Price Transparency

- It should be a priority of this administration to ensure that patients are engaged with their healthcare decisions, and have the information they need to be savvy consumers of healthcare. Federal agencies should eliminate any federal rules or policies that create unnecessary barriers to state, federal or private sector initiatives that provide price transparency.
- The administration should consider legislative proposals to empower patients as they shop for healthcare by making it easier to pay directly.
- Congress should seek to empower patients as they shop around for healthcare by making it easier to pay for their healthcare directly. Actions might include:
 - Allowing all Americans, including Medicare beneficiaries, to maintain and contribute to a Health Savings Account, not only those enrolled in high deductible health plans.
 - Increasing flexibility for beneficiaries and providers in the Medicare program by allowing for direct negotiations between these parties so that beneficiaries can access services at a price or under a payment plan that works for them.
- Congress, federal agencies and states should incentivize providers to compete on price, including right to shop modeled on successful state efforts as well as understandable reference pricing models.

Empowering Patients: Using Choice to Bring a Longer-Term View to Healthcare

Difficulty accessing price and use data is a barrier to choice and competition in healthcare. Without ready access to such data, consumers, even those with properly aligned incentives, struggle to shop for value. While a wealth of data exists in the healthcare sector, patients

³⁵⁸ Delbanco S, de Brantes F. States must step up to help consumers gain access to healthcare prices. *The Health Care Blog*. March 18, 2013. www.thehealthcareblog.com/blog/2013/03/18/states-must-step-up-to-help-consumers-gain-access-to-health-care-prices/. Accessed June 2013.

³⁵⁹ Definition of "employer" under section 3(5) of ERISA-association health plans. *Federal Register*. A final rule by the Employee Benefits Security Administration on June 21, 2018. <https://www.federalregister.gov/documents/2018/06/21/2018-12992/definition-of-employer-under-section-35-of-erisa-association-health-plans>. Accessed October 5, 2018.

are often least able to benefit from it. By realigning incentives and better leveraging health data, providers, payers and researchers can help consumers choose more effective treatment options, cut down on wasteful spending, and reduce the growth in their own spending on unnecessary services or treatments.

Claims data captures information on diagnoses, procedures and therapies administered, and retail and outpatient drug dispensing, as well as site of care (provider office, hospital, etc.). When available to payers, researchers and others, such data can fuel insightful comparisons of long-term patient outcomes using different treatment options.³⁶⁰ While any one data set (claims, clinical, etc.) may not contain all facets of a patient's experience, each can add value. For example, claims data have been increasingly recognized as central to studying long-term patient outcomes and some payers already use it to monitor the effectiveness of patient management.³⁶¹ Claims data can also be used to compare population-level outcomes between different payment models and delivery systems, allowing the healthcare system to optimize patient care.³⁶² The healthcare system has generated claims data over decades, providing a low-cost means to shed light on long-term cost, use and outcomes, across therapeutic options.³⁶³ Today's more advanced technology can now connect claims data across time and location in a secure manner.³⁶⁴

To better inform their healthcare decisions and allow patients and providers alike to take a holistic view of patient health, longitudinal studies will be important. These studies are more challenging if patients move across multiple payers over time, and making best use of such data would likely require cooperation among payers and providers. Of course, this data can and should be readily accessible for enrollees in Medicare and Medicaid.

Twenty-five states, in an attempt to support price transparency efforts and make information more accessible for consumers, employers, researchers and others, have established All-Payer Claims Databases (APCDs). Research on this data may generate useful findings, up-to-date price transparency tools, or other patient engagement applications, as well as allow self-insured employers to manage their own costs better. These efforts have had mixed results to date.

³⁶⁰ Hilton RP, Serban N, Zheng RY. Uncovering longitudinal healthcare utilization from patient-level medical claims data. March 4, 2016. <https://arxiv.org/pdf/1603.00896.pdf>. Accessed August 25, 2018.

³⁶¹ Research Action for Health Network (REACHnet): an overview and implications for clinical research. REACHnet. October 19, 2016. Page 8. <https://pcornetcommons.org/wp-content/uploads/2017/02/REACHnet-Technical-Paper.pdf>. Accessed August 25, 2018.

³⁶² Hilton RP, Serban N, Zheng RY. Uncovering longitudinal healthcare utilization from patient-level medical claims data. March 4, 2016. <https://arxiv.org/pdf/1603.00896.pdf>. Accessed August 25, 2018.

³⁶³ Porter J. State innovations in the use of APCD data. APCD Council. <https://nashp.org/wp-content/uploads/2015/01/j.porter.24.drilling.claims.data.pdf>. Accessed August 25, 2018

³⁶⁴ Hammill BG, Hernandez AF, Peterson ED, Fonarow GC, Schulman KA, Curtis LH. Linking inpatient clinical registry data to Medicare claims data using indirect identifiers. *Am Heart J*. 2009 Jun;157(6):995-1000. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2732025/>. Accessed August 25, 2018.

The eventual hope is that this data will allow payers, employers and researchers to better identify variations in pricing and quality across providers and payers. This in turn would help employers and others develop reference-pricing or center-of-excellence payment arrangements. In addition, states, academics and third parties could use these databases to develop price transparency tools, as well as research patient outcomes across providers, services and therapies. These tools may help patients find providers that offer services they value – supplementing often-outdated provider directories. They may also fill in gaps for consumers who lack access to a price transparency tool through their provider, and give employers a tool to compare prices of services across insurers.³⁶⁵ Leveraging claims data may also help reduce the overuse of unnecessary or wasteful care, likely saving money for consumers, employers and taxpayers.³⁶⁶

Once claims data are accessible in a secure manner, any value-added analyses, presentations or tools built from it could be commercialized. This would leverage market forces to boost availability of insights about population health. Consumers could also access user-friendly information comparing price or value at potential sites of care.

Recommendations: Using Choice to Bring a Longer-Term View to Healthcare

- The administration should continue to publicly release and increase access to claims data from taxpayer-funded federal healthcare programs and encourage the private sector and states to build consumer-friendly websites capable of displaying price information for the most common transactions. The administration should work to ensure that such data are technically and financially accessible for third-party transparency advocates, vendors, developers, researchers, employers, state and local governments, and the general public.
- States should coordinate their efforts on maximizing the utility of claims data (consistent with all relevant federal and state privacy protections), including simplifying the process for reporting data and using a standard reporting format.

Healthcare Information Technology and Non-Competitive Healthcare Markets

Modern Computing and Non-Healthcare Markets

In the last two decades, we have seen transformations of many major markets, including airlines, autos, banking, brokerage, entertainment, lodging, music, printing, publishing,

³⁶⁵ These tools should use paid claims amounts (rather than charges) to develop more accurate measures of cost. See Delbanco S, de Brantes F. States must step up to help consumers gain access to health care prices. *The Health Care Blog*. March 18, 2013. www.thehealthcareblog.com/blog/2013/03/18/states-must-step-up-to-help-consumers-gain-access-to-health-care-prices/. Accessed June 2013.

³⁶⁶ Sinaiko AD, Chien AT, Rosenthal MB. The role of states in improving price transparency. *JAMA Int Med*. 2015. 175(6):886-887.

shipping, taxi and telephone industries driven, in part, through the availability of massive volumes of real-time price and service data. Information technology offers intriguing possibilities to transform healthcare markets as well by injecting information and competition into many points in the healthcare industry. With most American adults carrying smartphones, both the hardware and software required to assemble new combinations of real-time medical information—including data on care, nature of services, and provider prices—is widely available.

Current State of Healthcare Information Technology

Historically, healthcare IT systems have focused on revenue optimization, typically through support for large amounts of billing documentation required to maximize fee for service revenues from federal and private payers. In contrast to sectors of the economy with competitive markets where there is great focus on automation, hospitals and providers employ almost no automation. It is worthwhile to examine which non-market incentives and disincentives have driven the apparent disinterest in automation. Similarly, consumers also have very limited software tools to understand, shop for, purchase or participate in their healthcare. The limited consumer access to healthcare information has been largely limited to federally mandated portals.

A common theme throughout healthcare is the limited state of interoperability. Patients have very limited ability to obtain or move their records. Providers similarly have significant barriers to get healthcare information from other providers, including systems that cannot communicate with each other. Payers have effectively no access to electronic clinical data about their patients.

Currently, health information technology (health IT) too often facilitates anti-competitive practices. These practices include blocking clinical information exchange between providers, as well as selectively providing minimal support for regional information sharing. Another practice common to the highest-priced delivery systems is using a single health IT vendor that systematically and preferentially shares clinical data with other high-priced providers to the exclusion of competitors.³⁶⁷ At least one health IT vendor has also engaged in policies where it effectively forced smaller hospitals to buy their software installs from larger local competitors³⁶⁸.

³⁶⁷ Mandl KD, Mandel JC, Kohane IS. Driving innovation in health systems through an apps-based information economy. *Cell Sys*. 2015 July 29;1(1):8-13. <https://www.sciencedirect.com/science/article/pii/S2405471215000046>. Accessed August 25, 2018.

³⁶⁸ Epic helps convert its large hospital customers into Epic hosting sites/consultants. *Lab Soft News*. http://labsoftnews.typepad.com/lab_soft_news/2011/03/the-epic-converts-its-academic-health-system-customer-into-franchisees.html. Accessed September 21, 2018.

Importance of Interoperability

The ability to move the patient's clinical information from incumbent providers to competing providers is a key goal of interoperability and can promote competition and the growth of new and disruptive business models. Today this is the capability typically labeled as "interoperability." A broader model of interoperability that includes a network of patients and payers would also allow them to identify providers with best outcomes for specific procedures and treatments. It would also allow prescribers to see cost information about drugs prior to prescribing. Such interoperability would accelerate the development of consumer-facing apps that integrate medical healthcare, cost, and wellness data to help consumers make decisions about their care. Increasing interoperability may also empower consumers by lowering the switching costs that patients experience when moving from one provider to another. In its absence, providers can use the switching costs and barriers to entry associated with incompatible health information systems to impede patient mobility and competition between providers.

Barriers to Interoperability

Medical Complexity

The vast biologic complexity underlying human health is an intrinsic barrier to interoperability. This complexity means that a given diagnosis, treatment or procedure in medical records can be recorded in many different ways. Sharing the underlying biological, microbial, genetic and protein data is even harder.

Lack of Business Drivers

Most of United States healthcare employs a fee-for-service model, where clinicians and health systems bill patients or their payers for each service (test or procedure) used rather than for the value of that service. Under this model, a hospital can generate more revenue by ordering its own imaging or lab tests rather than using results previously gathered by another provider. The fee-for-service model provides little incentive to connect with other clinicians or service providers and leads to significant disconnects across the care continuum, including among long-term and post-acute care facilities, outpatient services and support providers, behavioral health providers, free-standing imaging centers, and emergency medical services.

Not surprising, health IT installations interoperate more readily with other sites under the same ownership. Across the country, large health systems are acquiring small hospitals and provider practices, and limiting communications outside of their own network. This network effect can raise barriers to entry and provider competition. These acquisitions are designed to allow the systems to dictate prices to insurers and to craft narrow referral networks that also result in higher prices and difficult or disproportionately costly access for out-of-network services. In cases where there are less-expensive local competitors,

health systems have reportedly blocked use of those services by refusing to allow electronic orders for those services, such as imaging tests, to be sent outside of their system.

Lack of Accessible Application Programming Interfaces

The consumer app economy has blossomed in recent years, due in great part to data holders publishing application programming interfaces (APIs) that open their databases to third-party software developers. For example, ride-sharing apps rely on many different APIs to offer their service (i.e., mapping APIs for location, banking APIs for payments). In contrast, most medical data captured in electronic health records (EHRs) today is not readily accessible through APIs. Typically, EHR developers have either not published their APIs, charged prohibitively high fees, or set onerous contractual conditions to use their APIs. Lack of API access discourages new market entrants and new business models. Even if API access were opened, however, different classification ontologies would limit their utility. Accordingly, this would need to be addressed as well.

Lack of Network Exchange

Most systems do not or cannot communicate with one another. There are currently more than 100 regional and state health-information networks. Additionally, some EHR developers have their own networks for their customers. Limited interoperability often affects patients who may be traveling and cannot retrieve their records from home. Typically, today's health information networks prohibit flow of information to non-providers who may also have important HIPAA-compliant³⁶⁹ interests in that data, specifically insurers paying for those services.³⁷⁰

Therefore, it is often impracticable to query for information across networks for even one patient. Importantly there are also no standards-based APIs to allow payers to query provider EMR databases to get information about more than one of their patients at a time. Thus, payers have almost no computational way to get clinical data and have to rely on inference from claims data. Payers have a difficult time measuring and paying for care based on provider clinical performance and must rely on narrow quality measures or one-off data extracts to contract intelligently.

Overcoming Interoperability Barriers and the 21st Century Cures Act

Congress passed the 21st Century Cures Act in December 2016. Provisions in the act calling for usability and interoperability reflect the broad national consensus that the 2009 HITECH Act's \$30 billion- plus EHR stimulus program did not materially address either usability or interoperability despite leading to widespread EHR purchases.

³⁶⁹ HIPAA refers to the Health Insurance Portability and Accountability Act.

³⁷⁰ Samal L, Dykes PC, Greenberg JO, et al. Care coordination gaps due to lack of interoperability in the United States: a qualitative study and literature review. *BMC Health Serv Res*. 2016 April 22;16:143. <https://bmchealthservres.biomedcentral.com/articles/10.1186/s12913-016-1373-y>. Accessed August 25, 2018.

The 21st Century Cures Act provides powerful tools to increase the interoperability of health data and, by extension, market competition. Three pro-competitive provisions are worth noting specifically. First, the Cures Act defines information blocking broadly and outlaws it. In doing so, the Cures Act bans the practice of providers blocking access to an individual's health data. This will ease patients' ability to seek alternative providers or types of care. The legislation charged HHS with crafting a narrow set of exceptions to adequately address any concerns about privacy, security and appropriate patient care that might arise by enacting this provision.

A second major health IT provision of the Cures Act is the mandate to create a "Trusted Exchange Framework" and a "Common Agreement" to get the various health information networks to share data. ONC supervision here is needed to expand the "permitted purposes" of data sharing to facilitate data flow and more competitive markets.

The third key provision is the requirement that developers of certified electronic health records publish application programming interfaces and allow "health information from such technology to be accessed, exchanged, and used without special effort through the use of application programming interfaces." This "open API" requirement is designed to foster plug-and-play capability with apps. The "without special effort" provision means the API must use modern industry software design and healthcare interoperability standards. Importantly, the availability of an open API should allow for population-level queries of batch data. Today there is no reasonable data standard for an insurer to get easily computable data across the population of patients a provider sees. Moreover, American healthcare providers have almost no computational accountability for the care they provide. The national discussions about "learning health systems," "big data," and machine learning are meaningless without computational access to clinical data sets. That is why many large American payers are working in conjunction with ONC and the Health Level Seven International (HL7) FHIR standards group to build out these computational accountability standards.

CMS proposed requirements that promote interoperability of health data in their 2019 payment rules and is overhauling the EHR Incentive Program (formerly known as "Meaningful Use") to an interoperability-focused program now renamed "Promoting Interoperability." In the 2019 IPPS (Inpatient Prospective Payment System) rule, CMS has incentivized a number of interoperability measures including closing the referral loop through health information exchange and providing patients electronic access to view, download and transmit their data. The IPPS and other CMS payment rules in the public comment period also provide incentives to use the electronic health records certified to the 2015 standards (which support APIs). CMS' Blue Button 2.0 initiative allows Medicare beneficiaries complete access to their Medicare claims data and will significantly improve beneficiary experience by providing this data in a universal and secure digital format that patients can share with the care provider of their choosing. Giving patients complete access to their claims data will break down barriers to interoperability by allowing patients to see a full picture of their care encounters and prescriptions on the device of their choosing as

they share it with their care team. CMS is also calling on all health insurers to release their claims data in a similar fashion to the Blue Button 2.0 initiative so that all patients have the same benefits as Medicare beneficiaries.

To promote data sharing and care coordination further, CMS is ensuring that patients have access to their healthcare data after a hospital discharge, and that their data are transferred with them to their next care setting. ONC and CMS are working on identifying the key provider burdens generated by using current electronic medical records and working on strategies to address these burdens.

Recommendations: Improve Health IT

- The administration should expeditiously implement provisions of 21st Century Cures Act to prevent information blocking, make it easier for patients anywhere to get their core health information, support “Open Application Programming Interfaces” to allow patients to get data on their smart phones, and encourage support of population-level data queries to allow payers electronic access to clinical data.
- CMS and ONC should continue work on documentation burden reduction to allow EHRs to provide informative medical records rather than boilerplate text for providers and patients.
- CMS should continue its emphasis on fostering interoperability across the healthcare sector.
- CMS should continue its efforts to make data available to patients through efforts such as “MyHealthEData” and Blue Button 2.0.
- ONC should continue making standards more comprehensive and robust.

Appendix: Recommendations to Restore Choice and Competition to the Healthcare Sector

Recommendations: Address Potential Antitrust and Provider Consolidation

- The administration should continue monitoring market competition, especially in areas that may be less competitive and thus more likely to be affected by alternative payment models.
- The administration should ascertain the impact of horizontal and vertical integration among provider practices on competition and prices.

Recommendations: Broaden Scope of Practice

- States should consider changes to their scope-of-practice statutes to allow all healthcare providers to practice to the top of their license, utilizing their full skill set.
- The federal government and states should consider accompanying legislative and administrative proposals to allow non-physician and non-dentist providers to be paid directly for their services where evidence supports that the provider can safely and effectively provide that care.
- States should consider eliminating requirements for rigid collaborative practice and supervision agreements between physicians and dentists and their care extenders (e.g., physician assistants, hygienists) that are not justified by legitimate health and safety concerns.
- States should evaluate emerging healthcare occupations, such as dental therapy, and consider ways in which their licensure and scope of practice can increase access and drive down consumer costs while still ensuring safe, effective care.

Recommendations: Improve Workforce Mobility

- States should consider adopting interstate compacts and model laws that improve license portability, either by granting practitioners licensed in one state a privilege to practice elsewhere, or by expediting the process for obtaining licensure in multiple states.
- The federal government should consider legislative and administrative proposals to encourage the formation of interstate compacts or model laws that would allow practitioners to more easily move across state lines, thereby encouraging greater mobility of healthcare service providers.

Recommendations: Facilitate Telehealth to Improve Patient Access

- States should consider adopting licensure compacts or model laws that improve license portability by allowing healthcare providers to more easily practice in multiple states, thereby creating additional opportunities for telehealth practice. Interstate licensure compacts and model laws should foster the harmonization of state licensure standards and approaches to telehealth.
- States and the federal government should explore legislative and administrative proposals modifying reimbursement policies that prohibit or impede alternatives to in-person services, including covering telehealth services when they are an appropriate form of care delivery. In particular, Congress should consider proposals modifying geographic location and originating site requirements in Medicare fee-for-service that restrict the availability of telehealth services to Medicare beneficiaries in their homes and in most geographic areas.

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- States generally should consider allowing individual healthcare providers and payers to mutually determine whether and when it is safe and appropriate to provide telehealth services, including when there has not been a prior in-person visit.
- Congress and other policymakers should increase opportunities for license portability through policies that maintain accountability and disciplinary mechanisms, including permitting licensed professionals to provide telehealth service to out-of-state patients.

Recommendations: Ease Restrictions on Foreign-Trained Doctors

- The Department of Health and Human Services, in coordination with the Accreditation Council for Graduate Medical Education (GME), should identify foreign medical residency programs comparable in quality and rigor to American programs. Graduates of such equivalent programs should be granted “residency waivers,” allowing them to forgo completing an American residency and instead apply directly for state licensure.
- States should create an expedited pathway for highly qualified, foreign-trained doctors seeking licensure who have completed a residency program equivalent to an American GME program.

Recommendations: Streamline Federal Funding of Medical Education

- As proposed in the FY 2019 President's Budget, the federal government should streamline federal Health and Human Services spending on graduate medical education into a single graduate medical education grant program. The budget proposal also provides the Secretary with the authority to modify amounts distributed to hospitals based on the proportion of residents training in priority specialties or programs and based on other criteria identified by the Secretary, including addressing healthcare professional shortages and educational priorities.
- The administration should continue the work done by the HRSA's National Center for Health Workforce Analysis, which studies U. S. physician supply needs across specialties and geographic areas. HRSA should launch a study that will also assess:
 - The administration's workforce development programs.
 - Gaps between existing programs and future workforce needs and identifying actions needed to address them.

Recommendations: Repeal or Scale Back CON and COPA Requirements

- States should consider repeal of Certificate of Need (CON) statutes or, at a minimum, significantly scale back the scope of their CON regimes, for example

- by ensuring that competitors of CON applicants cannot weigh in on these applications.
- The FTC and its staff should make appropriate policy recommendations after completing ongoing research on the benefits and disadvantages of CON and COPA statutes and regimes.
 - States should discontinue the use of COPAs to shield anti-competitive provider collaborations and mergers from antitrust scrutiny in the absence of any clear evidence that these regulatory schemes produce better results than market-based competition.

Recommendations: Amend Federal Trade Commission (FTC) Jurisdiction Over Nonprofits

- Congress should amend the Federal Trade Commission Act to extend FTC's jurisdiction to nonprofit healthcare entities to prevent unfair methods of competition.

Recommendations: Scrutinize Non-Compete Clauses and Other Restrictive Covenants

- States should scrutinize restrictive covenants such as non-compete clauses, particularly their impact on patient access to care and on the supply of providers.

Recommendations: Scrutinize Any-Willing-Provider (AWP) Laws

- Federal and state policymakers should carefully scrutinize the impact on competition and consumers of AWP laws, rules, and proposals, along with other restraints on network formation and selective contracting.

Recommendations: Loosen Network Adequacy Requirements

- The administration should continue to provide flexible network adequacy standards for Medicare Advantage and other federally sponsored programs and avoid stringent requirements that are not conducive to innovation and modern medicine and that do not allow states flexibility to meet their specific needs.
- Similarly, states should consider loosening network adequacy standards and avoid stringent requirements.

Recommendations: Loosen Insurance Rules and Mandates

- The administration should continue to work with Congress to enact legislation that remedies key problems resulting from the ACA, that promotes greater choice and competition in healthcare markets, and that produces a sustainable government healthcare financing structure.

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- Similarly, the administration should provide states with the maximum ability to expand healthcare choice and competition and create a sustainable financing structure.
- States should allow maximum consumer choice and competition in their healthcare markets, including through Association Health Plans and short-term limited-duration insurance.
- Congress should repeal the ACA's employer mandate consistent with the FY 2019 President's Budget.

Recommendations: Replace Restrictions on Physician-Owned Hospitals

- Congress should consider repealing the ACA changes to physician self-referral law that limited physician-owned hospitals.

Recommendations: Reconsider Section 1557 of the ACA

- The administration should reconsider regulations authored under Section 1557 of the ACA to ensure they do not create undue administrative burdens and serve as unnecessary barriers to entry that inhibit competition.

Recommendations: Realign Incentives

- Congress should expand consumers' abilities to benefit from Health Savings Accounts (HSAs), including by allowing a greater number of plans (e.g. any plan with an actuarial value below 70 percent) to be HSA-qualified plans, raising the contribution limit on HSAs, allowing people to use their HSA to pay HSA-qualified non-group premiums, allowing Medicare beneficiaries in enrolled high-deductible health plans to contribute to an HSA, and enabling consumers with HSAs to enter into provider-consumer fixed-fee arrangements, including direct primary-care arrangements.
- The administration should explore ways to administratively expand consumers' abilities to benefit from HSAs, including by interpreting preventive services to allow HSA-qualified plans greater ability to cover preventive low-cost treatments for chronic conditions.
- Consistent with Executive Order 13813, the administration should work through the regulatory process to increase the usability of HRAs, to expand employers' ability to offer HRAs to their employees, and to allow HRAs to be used in conjunction with non-group coverage.

Recommendations: Delivery System Reform

- The administration should focus on identifying alternative payment models that allow free markets and patients to define value, rather than rely on technical and burdensome definitions invented in Washington.

- The administration should evaluate the best metrics for measuring value and quality in the healthcare sector, eliminating unnecessary and potentially counterproductive measures and reducing the burden on providers.
- The administration should ensure that smaller physician and provider practices are not unduly harmed by delivery system reform and corresponding requirements.
- The administration should ensure that these delivery system reform models, which aim to hold providers accountable to a set of population-based metrics and total spending, foster collaboration across systems within a geographic area and do not produce harmful consolidation, particularly horizontal consolidation.
- The Administration should pursue policies and programs that encourage value, competition, and choice, such as Medicare Advantage, and move away from a fee-for-service model.

Recommendations: Positively Realigning Incentives through Payment Reform

- Congress should establish site neutral payment policies based on the anticipated clinical needs and risk factors of the patient, rather than the site of service. In delivering these reforms, Congress should account for differing levels of patient acuity.
- State Medicaid programs should embrace site neutrality as a goal and reform their payment systems to pay for the value delivered where value is defined according to a relatively limited, straightforward, and non-gameable set of metrics. Additionally, metrics should not be designed and proposed solely by the entities to which they will ultimately apply.

Recommendations: Quality Improvement and the Measurement and Reporting of Quality

- As proposed by the Centers for Medicare and Medicaid Services' Patients over Paperwork initiative, the administration should streamline and standardize quality measures across programs to avoid duplicative reporting requirements and limit the number of measures where the expected cost of collecting the measure exceeds the expected benefit. In addition, the administration should collaborate with state Medicaid programs, private payers, and other government payers to align and streamline quality measures and reporting structures to reduce physician burden.
- The administration should seek to develop measures that are meaningful to providers and patients, and help them assess quality and value.
- The administration should focus on providing a framework for quality reporting in plain language that is more accessible and appealing to consumers.
- The administration should consider providing incentives and technical assistance to support the development of virtual provider groups (e.g., independent practice associations, alternative payment models, or regional quality collaboratives) that

can increase the competitiveness of small practices through access to shared resources and help build capacity for care management.

- HHS should explore opportunities to initiate research into machine learning techniques that can directly access data on CMS beneficiaries from the provider Electronic Medical Records (EMRs) using open application program interfaces in order to enable quality analysis and payments based on value while reducing burden and cost and benefitting the public.

Recommendations: Facilitate Price Transparency

- It should be a priority of this administration to ensure that patients are engaged with their healthcare decisions, and have the information they need to be savvy consumers of healthcare. Federal agencies should eliminate any federal rules or policies that create unnecessary barriers to state, federal or private sector initiatives that provide price transparency.
- The administration should consider legislative proposals to empower patients as they shop for healthcare by making it easier to pay directly.
- Congress should seek to empower patients as they shop around for healthcare by making it easier to pay for their healthcare directly. Actions might include:
 - Allowing all Americans, including Medicare beneficiaries, to maintain and contribute to a Health Savings Account, not only those enrolled in high deductible health plans.
 - Increasing flexibility for beneficiaries and providers in the Medicare program by allowing for direct negotiations between these parties so that beneficiaries can access services at a price or under a payment plan that works for them.
- Congress, federal agencies and states should incentivize providers to compete on price, including right to shop modeled on successful state efforts as well as understandable reference pricing models.

Recommendations: Using Choice to Bring a Longer-Term View to Healthcare

- The administration should continue to publicly release and increase access to claims data from taxpayer-funded federal healthcare programs and encourage the private sector and states to build consumer-friendly websites capable of displaying price information for the most common transactions. The administration should work to ensure that such data are technically and financially accessible for third-party transparency advocates, vendors, developers, researchers, employers, state and local governments, and the general public.
- States should coordinate their efforts on maximizing the utility of claims data (consistent with all relevant federal and state privacy protections), including simplifying the process for reporting data and using a standard reporting format.

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