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Advancing Health in America

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May 23, 2025

The Honorable Andrew N. Ferguson
Chairman
Federal Trade Commission
600 Pennsylvania Ave. NW
Washington, DC 20580

Re: Request for Public Comment Regarding Reducing Anti-Competitive Regulatory Barriers (Dkt. ID FTC-2025-0028-0001)

Dear Chairman Ferguson:

On behalf of the American Hospital Association's (AHA) nearly 5,000 member hospitals, health systems and other health care organizations, and our clinician partners — including more than 270,000 affiliated physicians, 2 million nurses and other caregivers — and the 43,000 health care leaders who belong to our professional membership groups, we appreciate your invitation to submit comments identifying regulations that make health care markets less competitive.

The AHA shares the Trump administration's belief that the "ever-expanding morass of complicated Federal regulation imposes massive costs on the lives of millions of Americans, creates a substantial restraint on our economic growth and ability to build and innovate, and hampers our global competitiveness."[1] And we share the Federal Trade Commission's (FTC) belief that "[r]egulations that reduce competition, entrepreneurship, and innovation can hamper the American economy."[2] We therefore welcome the opportunity to comment on the laws and regulations that make it harder for hospitals and health systems to compete fairly in the health care.

As we submit these comments, we are mindful that this is, in many ways, well-trodden ground. In 2018, the first Trump administration issued a report entitled *Reforming America's Healthcare System Through Choice and Competition* (2018 Report), which correctly observed that "many government laws, regulations, guidance, requirements

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[1] Executive Order 14192, Unleashing Prosperity Through Deregulation (Jan. 31, 2025).
[2] Press Release, Request for Public Comment Regarding Reducing Anti-Competitive Regulatory Barriers (April 13, 2025).

and policies… 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."[3] Seven years later, the AHA starts from that exact premise. Many of the issues identified in that 2018 Report remain or have worsened, and many new challenges have emerged. Then, as now, the U.S. health care system imposes a bewildering array of regulations on hospitals and health systems, adding significant administrative costs, disincentivizing pro-competitive arrangements, and promoting vertical consolidation of large commercial insurers to the detriment of patients and providers across the country.

In this letter, we provide an overview of the key statutes and regulations that have impeded competition in the health care market and offer a series of recommendations to remedy these obstacles. We first outline the key areas of regulation that have permitted commercial insurers to limit market competition, narrow consumer choice and undermine access to health care for Americans — all while avoiding true accountability under the nation's antitrust laws. We then describe other categories of regulations that limit the ability of hospitals and health systems to compete in the market, including those that impose undue administrative burdens, inhibit the expansion of telehealth, limit growth within the health care workforce and generally inflict large costs on the health care industry without corresponding benefits.[4]

I. Regulations That Foster Anticompetitive Conduct by Insurers

The single greatest competition problems in the health care markets today are caused by large commercial health insurers. Laws and regulations contribute to those problems by shaping the environment in which commercial insurers operate, creating an unlevel playing field between providers and payors, and raising costs for patients without corresponding quality or access improvements. Commercial insurer consolidation, coupled with a statutory and regulatory setting that permits this unchecked expansion, has shaped market forces to severely limit the ability of health care providers to compete fairly. The 2018 Report puts it starkly, "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."[5]

UnitedHealth Group is perhaps the clearest example of this growing competition crisis. A Forbes 5 company ranked below only Walmart, Amazon and Apple in annual

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[3] U.S. Departments of Health and Human Services, Treasury, and Labor, *Reforming America's Healthcare System Through Choice and Competition* (2018) at 16-17.
[4] AHA separately submitted comments incorporating many of these suggestions to HHS, CMS, and OMB as part of the parallel effort to reduce burdensome regulations. May 12, 2025, Letter from AHA to Secretary Kennedy, Administrator Oz, and Director Vought re Request for Information: Deregulation (FR Doc. 2025-06316) https://www.aha.org/lettercomment/2025-05-12-aha-response-omb-deregulation-rfi
[5] Letter from Secretary Alex M. Azar, Secretary Steven T. Mnuchin, and Secretary Alexander Acosta to President Donald J. Trump (December 2018) introducing 2018 Report, *supra* note 3.

revenues, UnitedHealth Group owns the nation's largest commercial insurer, UnitedHealthcare, which controls 15% of the country's health insurance market.[6] But UnitedHealth has expanded its reach well beyond health insurance. UnitedHealth is now the single largest employer of physicians in the United States through its subsidiary Optum. And it doesn't stop there. Optum owns one of the country's largest insurance claim processing hubs, Change Healthcare, one of the largest pharmacy benefit managers (PBMs), OptumRx, and has acquired companies that operate ambulatory surgery centers and primary and urgent care service centers among other service providers.[7,8]

This vertical consolidation creates significant risk for Americans, as the country experienced in February 2024 in the wake of the cyberattack on Change Healthcare (Change). Nearly 900,000 physicians, 33,000 pharmacies and 5,500 hospitals relied on Change to facilitate their insurance company reimbursement or to access clinical protocols and prior authorization requirements through Change's product Interqual (notably, also owned by Change as a result of a recent acquisition). However, in the days and weeks following the Change cyberattack, many of these entities were forced to resort to paper and fax machines while they scrambled to find an alternative mechanism to get paid and keep their doors open.[9] And in the months following, it was reported that the data of 190 million Americans — more than half the nation — was compromised in the attack.[10] This degree of concentration not only harms Americans by limiting competition in the market, but also puts the country at greater risk of attack (with greater potential for large-scale harm) by creating a single point of vulnerability for an entire industry.

A recent report from Rep. Patrick Ryan, D-N.Y., indicates further reason for concern as it announced that an inquiry by his office into the state of Optum-owned medical

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[6] Bruce Gil, *The 7 biggest health insurance companies that control almost 75% of the market*, Quartz (Jan. 6, 2025) https://qz.com/unitedhealth-cvs-health-insurance-market-share-1851727627
[7] Alan Condon, *Optum spending spree continues, adding to 70k+ physicians*, Becker's Hospital Review (Apr. 11, 2023) https://www.beckershospitalreview.com/finance/optum-spending-spree-continues-adding-to-70k-physicians/; *see generally* Annika Kim Constantino & Ashley Capoot, *How UnitedHealthcare became the face of America's health insurance frustrations*, CNBC (May 22, 2025) https://www.cnbc.com/2025/05/22/unitedhealth-news-backlash-stockprice.html
[8] Natasha Murphy, *Trends and Consequences in Health Insurer Consolidation*, Center for American Progress (Dec. 4, 2024) https://www.americanprogress.org/article/trends-and-consequences-in-health-insurer-consolidation/
[9] Brittany Trang, Tara Bannow, Bob Herman, *Experts say scale of Change cyberattack shows risk of centralized claims processing*, STAT News (Feb. 27, 2024) https://www.statnews.com/2024/02/27/change-healthcare-cyber-attack-reveals-consolidation-risks/
[10] Alex Vakulov, *UnitedHealth Data Breach Escalates: 190 Million Americans Affected*, Forbes (Jan. 27, 2025) https://www.forbes.com/sites/alexvakulov/2025/01/27/unitedhealth-data-breach-escalates-190-million-americans-impacted/

practices in the Hudson Valley revealed an "avalanche of dysfunction."[11] The publicly disclosed details are alarming, ranging from issues of blocked access to diagnoses and care to poor triaging of urgent medical needs, inability to access needed medications, and a host of administrative and billing challenges. As Rep. Ryan reported, "The volume of responses, the specificity of issues, and the frankly heartbreaking stories involved are unlike anything I've seen in my time in Congress. I've heard from disabled children unable to get treatment. Mothers are waiting almost a year for a cancer diagnosis. Families sent into debt because of overcharges for treatments never even received."[12] We presume that the full set of data, provided to the Department of Justice (DOJ), the U.S. Department of Health and Human Services (HHS), and the FTC, paints an even more devastating picture of the impact of Optum's vertical consolidation.

While it is the largest of these behemoths, UnitedHealthcare is one of a cohort of big insurers that have aggressively consolidated in recent years. Just seven insurance companies control almost 75% of the health insurance market, with a total of four controlling 50% of the market.[13] And this control translates directly into dollars: just six insurers are responsible for 30% of the health care spending in the United States.[14] Commercial health insurer markets have grown increasingly concentrated over time, with particular growth over the last decade. One recent study reviewed data from markets across the country between 2014 and 2023 and found that in most major metropolitan cities across the United States, the major commercial health insurers have consolidated so significantly that they have driven out competition and left consumers with only limited coverage options.[15]

This is perhaps most apparent in the degree of consolidation between the largest PBMs — CVS Caremark, Optum Rx and Express Scripts — and commercial insurers, given that all three are owned by or aligned with major health plans. As the AHA reported to the FTC in May 2022, this health plan and PBM consolidation helps plans maximize their negotiating leverage; consolidate the use of pharmacies among a small, plan-owned or affiliated network; and increase plan profits through their role as an intermediary in the pharmacy supply chain. In addition, these maneuvers, achieved by manipulating insurance rules and benefit design, particularly with respect to specialty drug coverage, establish a clear motivation for steering patients in ways that may financially benefit the plan and PBM but are often not in the patients' best interest — clinically or financially. Increases in both PBM profits and health insurance premiums

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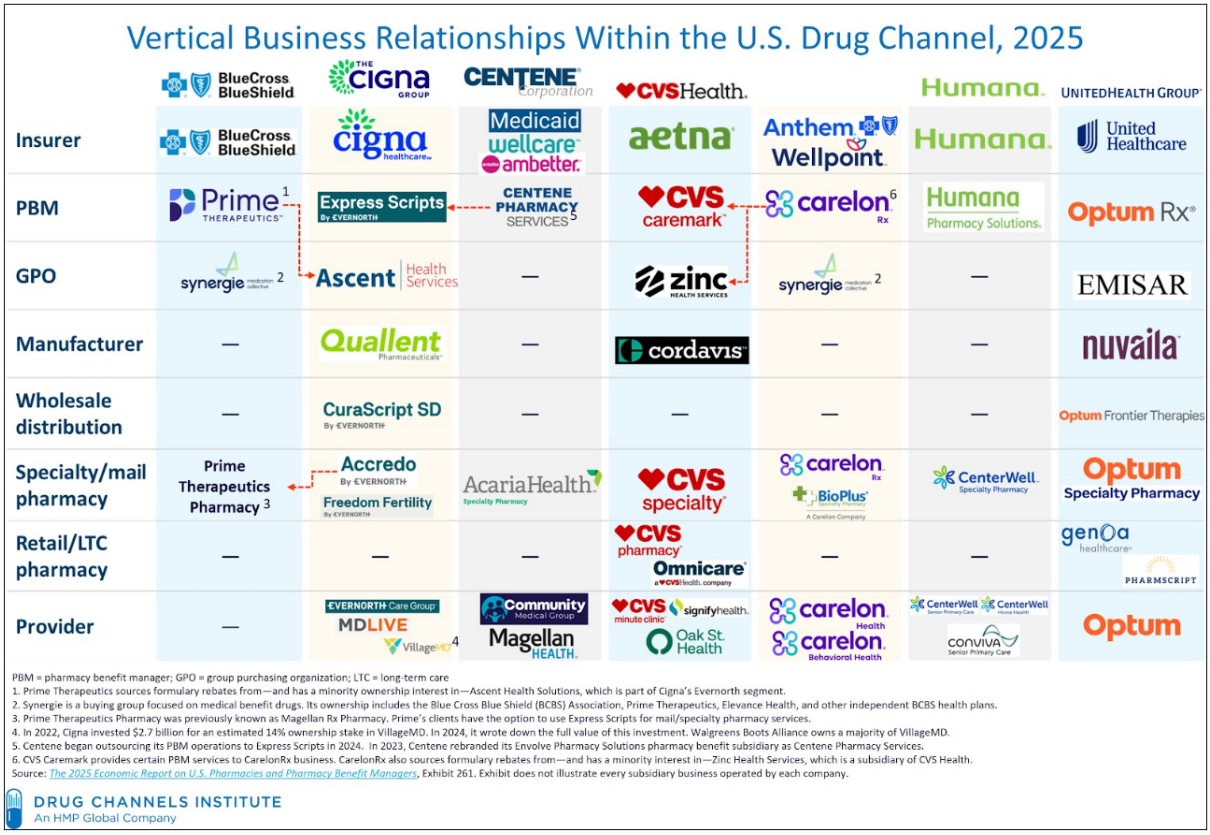
[11] Press Release, Congressman Pat Ryan Releases Shocking Results of Optum Community Inquiry, Submits Full Set of Data to the Department of Justice, Health and Human Services, and Federal Trade Commission for Further Investigation (Apr. 3, 2025) at https://patryan.house.gov/media/press-releases/congressman-pat-ryan-releases-shocking-results-optum-community-inquiry-submits.
[12] Id.
[13] Gil, *supra* note 6.
[14] Id.
[15] Jose R. Guardado, Ph.D., and Carol K. Kane, Ph.D., *Competition in Health Insurance: A comprehensive study of U.S. markets*, American Medical Association (2024) https://www.ama-assn.org/system/files/competition-health-insurance-us-markets.pdf

suggest that such arrangements are not increasing health system efficiencies but rather are contributing to increased spending across the health care system.[16] The FTC has recognized the harms of vertical consolidation in the PBM space, recently reporting on a host of abuses by the three largest PBMs, including significant price markups, disproportionately dispensing of the most profitable drugs, the use of spread pricing to generate additional income, and significant increases in both plan sponsor and patient drug spending.[17]

A chart from the Drug Channels Institute illustrates the extraordinary degree of vertical consolidation undertaken by the large commercial insurers.



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Other research has put an even finer point on the astonishing degree of commercial insurer consolidation in comparison to other kinds of consolidation in the health care

[16] Letter from AHA to FTC Chair Lina Khan (May 24, 2022) re Request for Public Comment on the Impact of Pharmacy Benefit Managers' Practice
[17] Press Release, FTC Releases Second Interim Staff Report on Prescription Drug Middlemen (Jan. 14, 2025) at https://www.ftc.gov/news-events/news/press-releases/2025/01/ftc-releases-second-interim-staff-report-prescription-drug-middlemen.
[18] Vertical Business Relationships Within the U.S. Drug Channel, 2025, Drug Channels Institute, https://www.drugchannels.net/2025/04/mapping-vertical-integration-of.html

environment. A 2024 study found that, on average, the largest health insurers hold an average of 82.2% of the market share in each state, while, in contrast, the largest health systems in a given state hold on average a combined 43.1% of the market share.[19] This dramatic differential can have severe anticompetitive effects. The study found that when the market share of a particular insurer is significantly greater than the market share of an individual health system in a particular market, there can be a negative impact on the amount insurers are willing to pay hospitals and health systems, generating further negative downstream impacts in the health care market.[20] The Trump administration's 2018 Report points to examples of the ways in which health insurer market concentration increases premiums and limits choice, while increasing market options puts downward pressure on insurance premiums.[21] Those problems have only worsened in the past four years.

Commercial insurers often claim that consolidation helps them to negotiate better prices and improve care coordination and data tracking and trending, but the data show that in fact the primary beneficiary of insurer consolidation is the insurer itself.[22] **Market power may enable big commercial insurers to put downward pressure on prices, but in general, they do not pass on those savings to patients in the form of lower premiums or out-of-pocket costs**.[23] Rather, because they have so much market power, they can increase premiums higher without the fear that participants will opt for a different insurance provider.[24] Insurer consolidation — and continued absorption of a range of health care providers — further limits consumer choice because insurers increasingly restrict beneficiaries to their own provider networks and impose added costs when beneficiaries seek care elsewhere.[25] The costs imposed by this anticompetitive conduct are not only financial: insurers routinely impose administrative burdens such as prior authorization and "white bagging" requirements that can hamper access to health care, hinder health care outcomes, and even implicate patient safety.[26,27] Insurer consolidation practices also hurt provider compensation, worsening the existing workforce challenges faced by hospitals and health systems across the country.[28] This is the essence of anticompetitive conduct.

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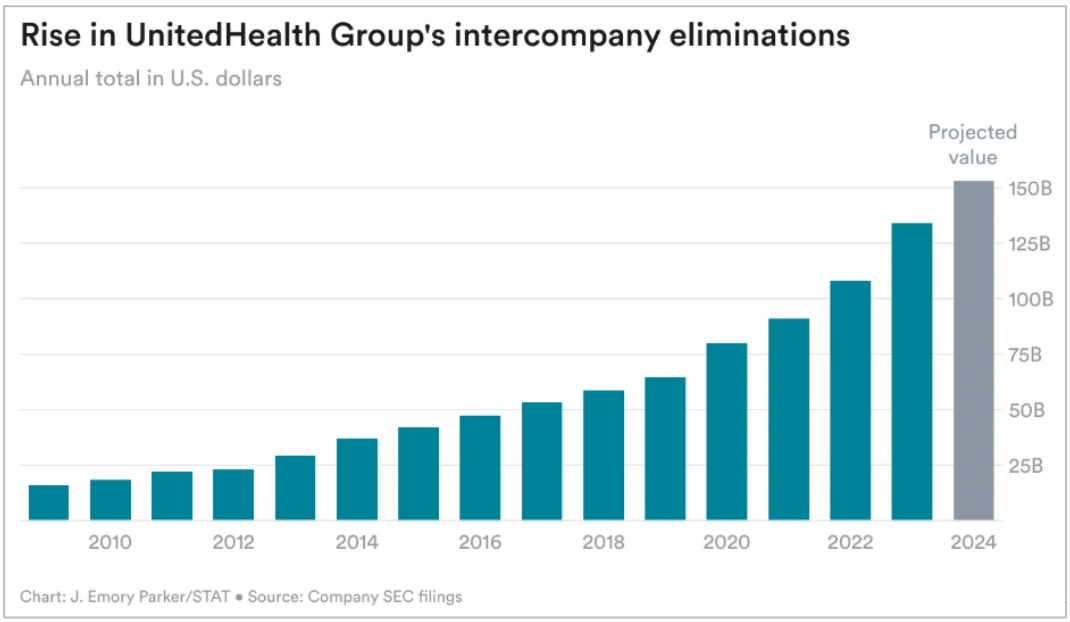
[19] Atul Grover, M.D., et al, *Why Market Power Matters for Patients, Insurers, and Hospitals*, AAMC Research and Action Institute (May 1, 2024) https://www.aamcresearchinstitute.org/our-work/data-snapshot/why-market-power-matters
[20] Id.
[21] 2018 Report, *supra* note 3, at 7
[22] Murphy, *supra* note 8.
[23] Id.
[24] Id.
[25] Id.
[26] "White bagging" is a practice whereby insurers require beneficiaries to obtain medically necessary drugs that would ordinarily be obtained from and administered in a clinic or hospital setting from specialty pharmacies unrelated to (and far from the oversight of) their health care providers because of a favorable arrangement between the health insurer and that specialty pharmacy.
[27] AHA Letter, *supra* note 16.
[28] Murphy, *supra* note 8.

A. Medical Loss Ratio Requirements Incentivize Insurers to Vertically Consolidate So They Can Direct Health Care Spend to Themselves Via Intercompany Eliminations

The Affordable Care Act requires health insurers to spend a specified percentage (80-85%, depending on the market) of premium dollars on medical care or else provide a rebate to their customers if they fail to meet that threshold. This is known as the Medical Loss Ratio (MLR). But as the Trump administration's 2018 Report noted, experts have raised concerns that the current MLR framework risks incentivizing insurers to raise premiums, enabling them to pay higher rebates but also to keep larger profits to the detriment of both consumers and the federal government.[29]

These MLR requirements, aimed at limiting the amount of money insurers direct to themselves, have further prompted insurers to vertically integrate with other kinds of health care entities, like health care providers, to facilitate "intercompany eliminations," that is, to keep more of those medical expense dollars on their books by directing that health care spend toward providers and entities the insurer owns rather than paying service providers outside of the insurer's umbrella. STAT News has published charts illustrating the extraordinary increase in these intercompany eliminations by large insurers such as UnitedHealth Group and Elevance Health, which owns a number of Blue Cross Blue Shield-branded and non-Blue Cross Blue Shield-branded insurance subsidiaries licensed in a number of states.

[29] Robert Book, *How the Medical Loss Ratio Requirement Could Increase Health Insurance Premiums and Insurer Profits at Taxpayer Expense*, American Action Forum (April 2013) at https://www.americanactionforum.org/wp-content/uploads/files/research/MLR_Paper_Final.pdf



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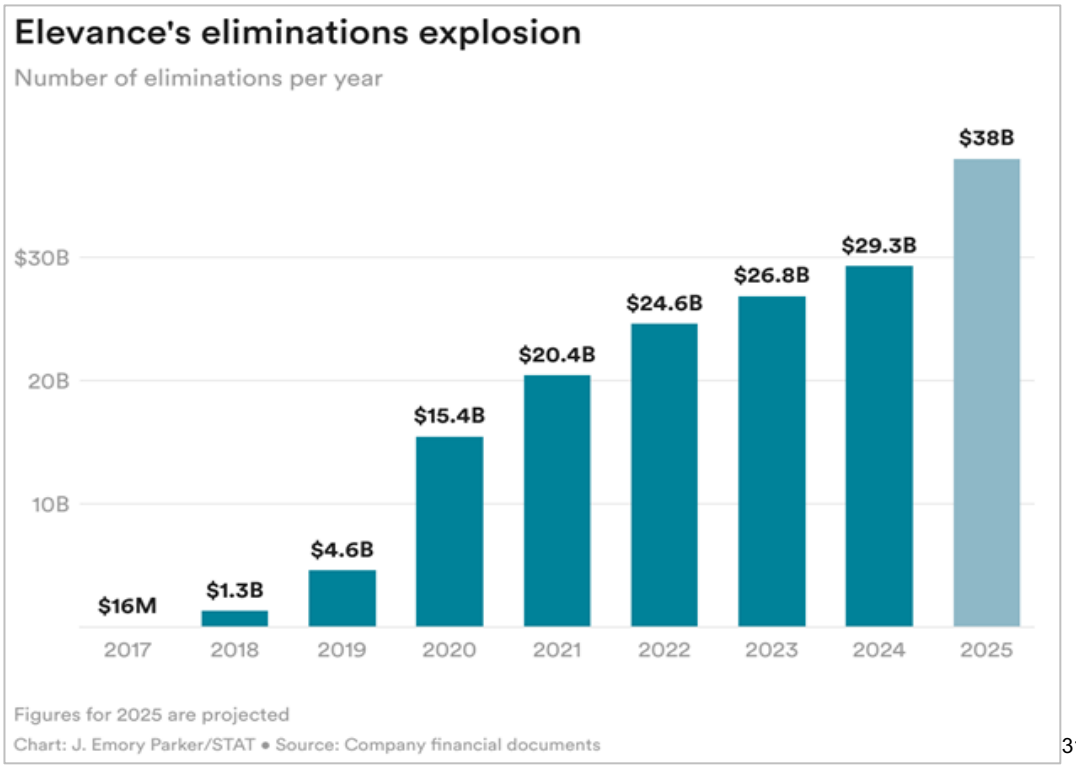

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[30] Bob Herman, STAT Health Care Inc. Newsletter (Dec. 4, 2023) at https://marketing.statnews.com/hca-mission-north-carolina-cigna-humana-merger-unh-eliminations
[31] Bob Herman, STAT Health Care Inc. Newsletter (April 28, 2025) at https://www.statnews.com/2025/04/28/tariffs-medical-devices-medicare-advantage-elevance-expansion-mpt-steward-health-care-inc/

Integration across providers and insurers is not necessarily problematic if the result is improved quality of care and coverage provided to patients, such as through enhanced care coordination and access to care. However, these large, for-profit insurers are disaggregating care, restricting consumer choice of providers and decreasing access to care — all while failing to pass along the financial benefits of these relationships to consumers. Thus, these acquisitions are simply part of an MLR gamesmanship strategy.

Indeed, this MLR gamesmanship is an issue recently raised by members of Congress. They wrote to the Government Accountability Office (GAO) to express their concerns about the ways in which Medicare Advantage Organizations (MAOs) circumvent MLR requirements by acquiring related health care businesses — like health care providers — and allocating payments for medical expenses to providers and other companies the MAO owns, ultimately benefiting the MAO's bottom line.[32] The members requested that the GAO perform a detailed review of the ways in which these requirements are currently operating, including the degree to which insurers are complying with these requirements or seeking to circumvent them. While the GAO report might provide more details, hospitals already know the bottom line: large commercial insurers are manipulating the regulatory environment to vertically consolidate.

A key example that we have observed is the large-scale purchase of medical practices by insurers. We have strong reason to believe that insurers are paying far more than hospitals and health systems can to acquire these practices both because they can afford to do so — it is profitable for them to acquire practices to facilitate intercompany eliminations and circumvent MLR requirements — *and* because they are not regulatorily prevented from buying practices in excess of fair market value, as we discuss further in Section I.B., below.

A similar practice has been identified with respect to PBMs. As reported last fall, insurer-owned PBMs routinely underpay independent drugstores for medications while funneling patient prescriptions to their own affiliated mail-order pharmacies and frequently paying those affiliated pharmacies more than they pay independent drugstores for the same drugs.[33] The costs of these insurer practices are borne not only by consumers and employers who pay increasingly higher premiums and drug costs, but also by the local drugstores and providers who are being put out of business and the communities that rely on them as a vital (and often the only) health care resource.[34] As outlined further below, several key factors contributing to the dramatic rise in these practices can be remedied readily via regulatory reform. **As the administration**

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[32] Letter from Rep. Lloyd Doggett and Rep. Gregory F. Murphy, M.D., to the Honorable Gene L. Dodaro, Comptroller General of the United States (April 16, 2025).
[33] Reed Abelson and Rebecca Robbins, New York Times, *The Powerful Companies Driving Local Drugstores Out of Business* (Oct. 19, 2024).
[34] *Id.*

reviews its regulatory reform agenda, preventing MLR abuse should be a top priority.

B. Key Stark Law Exceptions Promote Anticompetitive Conduct by Insurers and Should Be Revisited

The framework established by the Physician Self-Referral Law (Stark Law) has limited the ability of hospitals and health systems to grow and compete, while permitting commercial insurers to operate unchecked to acquire physician practices and other health care entities at prices far exceeding the fair market value prices that hospitals and health systems are permitted to pay. The Stark Law was passed with the general aim of ensuring that government health care program expenditures were based upon clinical need, rather than a referrer's pecuniary or other self-interest. **Consistent with that aim, regulators have historically viewed hospital acquisitions of physician practices as suspect, particularly where the hospitals continue to employ the physicians in some capacity. In contrast, acquisitions by insurers or other non-hospital players have largely avoided the same regulatory scrutiny.** This is even more notable given a new AHA analysis of LevinPro HC data of nearly 800 physician practice acquisitions from 2019 to 2024, which found that hospitals tend to acquire practices in lower-margin specialties such as family or pediatric medicine that ensure access to essential services for communities, while commercial insurers (who acquired 40% more physicians than hospitals did during the studied period) typically focus on higher-margin specialties in densely populated markets. **The regulatory environment has provided insurers with ample runway to expand and vertically integrate, unconstrained by the extensive legal barriers that prevent hospitals from similar efforts.**

The paradigm of insurers as merely providing health insurance to beneficiaries — rather than vertically integrated giants in the business of referring or seeking referrals in support of a profit motive — no longer applies where insurers have dramatically expanded their role in the health care universe. Indeed, as recent cases brought by the Department of Justice illustrate — most notably, the recently filed complaint in *U.S. ex rel. Shea v. eHealth, Inc. et al.* alleging violations of the Anti-Kickback Statute and False Claims Act in connection with a variety of alleged MAO and MA broker kickback arrangements to steer MA beneficiaries to certain plans — insurers are increasingly occupying health care provider spaces and ought to be subject to the same regulatory limitations that have been historically imposed on providers.[35]

The Stark Law is a strict liability statute prohibiting physicians from referring Medicare (and Medicaid, under certain interpretations) patients to entities with which they have a financial relationship for the provision of designated health services (DHS), unless an exception applies. DHS includes clinical laboratory services, radiology and imaging

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[35] *See* Compl., *U.S. ex rel. Shea v. eHealth, Inc. et al.*, No. 21-CV-11777 (D. Mass. May 1, 2025).

services, home health services, and outpatient prescription drugs, among other frequently accessed health care services and items. The law provides for severe civil penalties, including fines or potential exclusion from federal health care programs — and depending on the underlying facts, violations may further entail potential False Claims Act liability. Given the stakes, hospitals and health systems go to great lengths to ensure compliance with this law and its corresponding regulations, often incurring large costs, as we discuss further in section II of this letter. **Yet, in its current state, the Stark Law makes numerous concessions to insurers that further promote the growth of commercial insurers (and their Medicare Advantage businesses) over that of hospitals and health systems.**

First and foremost, the Stark regulations altogether exclude many categories of insurance plans from the statutory prohibition. See, for example, 42 C.F.R. § 411.351, which defines DHS "entity" as excluding health plans and managed care organizations.[36] The Stark Law is therefore less likely to be implicated in arrangements between payor organizations and their corporate subsidiaries because it applies only where there is both a referring physician and a DHS entity. This removes a significant barrier for health insurers otherwise faced by other types of providers of designated health services, shifting the playing field in favor of health plans, which have proceeded to purchase providers of many of these services and, in fact, direct their beneficiaries to those service providers. This threshold definition warrants a closer look, its own comment period, and revision in light of the current health care market. That is not all. There are many other Stark exceptions that provide unique flexibilities to insurers. These, too, would benefit from revisiting to address the growing problem of vertical consolidation by commercial insurers.

First, the Stark Law excepts from liability physician referrals for services furnished to enrollees by an organization that offers certain kinds of prepaid health plans, such as HMOs and MCOs.[37] CMS has historically interpreted this as maximally flexible, "to cover not only services furnished by the organizations themselves, but also those furnished to the organization's enrollees by outside physicians, providers, or suppliers under contract with these organizations."[38] This directly promotes the vertical integration that insurers have been so eager to undertake, protecting physician referral relationships by removing roadblocks for insurers to operate in ways that hospitals and health systems are not permitted to do.

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[36] Defining an "entity" as "the person or entity that has presented a claim to Medicare for the DHS … other than a health care delivery system that is a health plan (as defined at § 1001.952(l) of this title), and other than any managed care organization (MCO), provider-sponsored organization (PSO), or independent practice association (IPA) with which a health plan contracts for services provided to plan enrollees)."
[37] 42 C.F.R. § 411.355(c), 42 U.S. Code § 1395nn(b)(3).
[38] Medicare and Medicaid Programs; Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships, 63 Fed. Reg. 1659, 1697 (Jan. 9, 1998).

Second, there is an exception protecting compensation paid directly or indirectly by an MCO or IPA to a physician pursuant to a risk-sharing arrangement.[39] This, too, should be revisited, as it similarly promotes expansion and growth in all directions by insurance companies, giving them an unfair competitive advantage in an otherwise regulatorily constrained market.

While hospitals and health systems are limited by these legal frameworks with respect to what they can pay for physician practices or other health care service providers, insurers have been viewed as exempt. The AHA's members cannot compete in such an artificially imbalanced marketplace. Hospitals that seek to bring a service or provider in-house to maximize efficiency and cost savings frequently lose out to an insurer that paid far more than the hospital's fair market valuation limitations under Stark would permit. This is an unsustainable market reality that ultimately harms consumers.

C. Additional Anticompetitive Regulations Promote Insurer Self-interest to the Detriment of Beneficiaries and Other Market Participants

In addition to the issues detailed above, we have identified other categories of insurance-related regulations for reconsideration as part of this effort, given their anticompetitive impact.

First, given the market dominance of the big insurers, each has imposed its own processes for administrative transactions, like prior authorizations, generating unnecessary added costs and administrative burden for hospitals and health systems. According to a recent report, 99% of Medicare Advantage beneficiaries have some form of prior authorization requirements in their plans.[40] Many of these prior authorization requirements are unduly burdensome, taking providers away from the bedside and hampering care access and patient outcomes by unnecessarily extending care timelines. **It is critical to ensure that prior authorization processes and other utilization management practices used by insurers are streamlined to maximize efficiency and conserve scarce provider resources.** We recommend further standardizing insurance-related administrative transactions to promote efficiency, starting by operationalizing the Interoperability and Prior Authorization Final Rule which will streamline electronic prior authorization processes across many payers.

Second, hospitals and health systems incur significant costs to develop and maintain billing and collections infrastructure to collect cost-sharing payments from patients and chase payment by insurers, the burden of which ought to be borne by the insurers themselves. We recommend eliminating this duplicative and costly billing infrastructure within hospitals, health systems and other providers by **shifting cost-sharing collection responsibilities to insurers — the entities that set co-pay, deductible**

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[39] 42 C.F.R. 411.357(n).
[40] Jeannie Fugelstein Biniek et al., Medicare Advantage Insurers Made Nearly 50 Million Prior Authorization Determinations in 2023, KFF (Jan. 28, 2025)

and co-insurance amounts in the first instance. Relatedly, we recommend eliminating billions in excess health care system costs resulting from providers chasing payment from insurers by **establishing prompt pay requirements in all forms of health care coverage, including Medicare Advantage.**

Finally, we have observed that the current requirements that payers and plans maintain separate credentialing processes impose unnecessary costs and recommend removing those requirements in favor of **permitting payers to instead recognize hospital credentialing as sufficient.**

D. Current Antitrust Enforcement Frameworks Generate Inconsistency

As a final note, we have observed that the current health care antitrust enforcement framework makes it difficult for enforcement agencies to undertake actions with the full marketplace in mind. Specifically, the FTC has historically been responsible for enforcement actions against hospital mergers, while the DOJ has been responsible for enforcement actions against insurers and drug companies. This separate treatment of hospitals is illogical and fails to account for the broader market interactions and realities that exist today, as well as generates inconsistency in enforcement for different types of health care players. Consistency is particularly critical today, as insurers increasingly acquire components of the health care market that traditionally would have been part of hospitals or otherwise independent health care practices. We recommend reevaluating that artificial split and instead centralizing oversight of health care antitrust enforcement. Notably, this would not require any statutory change. The historic division of labor between the DOJ and the FTC emerged over time informally. But with the massive changes in how the health care marketplace operates, it is far past time to give a single agency informal authority over *all* participants.

II. Regulations that Limit the Ability of Hospitals and Health Systems to Thrive in a Competitive Free Market

A. Stark Law and Anti-Kickback Statute Limitations on Hospitals and Health Systems

The Stark Law and Anti-Kickback Statute (AKS) in their current iteration not only facilitate the growth of big insurers as discussed in Section I, above, but also can limit desirable hospital and health system market activity to the detriment of patients and communities. Historically, these laws have had the effect of impeding value-based arrangements involving care coordination and/or collaborative electronic platforms, by making many of them difficult to undertake without running afoul of either or both laws.

The first Trump administration recognized the challenges imposed by these legal frameworks and undertook a comprehensive effort as part of the Regulatory Sprint to Coordinated Care to encourage value-based arrangements among providers, payors and others to more effectively coordinate and deliver care. The Regulatory Sprint

resulted in key updates advocated by AHA, including value-based arrangement exceptions and further clarifications for key standards such as "commercial reasonableness" and "takes into account the volume or value of referrals." But even with these reforms, Stark and AKS-based challenges remain for hospitals and health systems that wish to undertake certain types of transactions.

At the highest level, it is costly to comply with these laws, given the expensive legal advice and fair market value analyses hospitals and health systems routinely undertake. These regulatory hurdles can slow and even prevent beneficial arrangements. With the Stark Law in particular, to the extent that hospitals and health systems are required to comply with requirements that insurers are not, it disadvantages them and limits the functioning of a healthy free market. Notably, even the law's original sponsor, former Congressman Fortney "Pete" Stark, has criticized the regulatory complexity that evolved from the original Stark Law and advocated a return to a simplified version of the law.[41] The added potential for False Claims Act liability — which entails treble damages and per-claim penalties — further dramatically increases the stakes for noncompliance with Stark, making parties ever more cautious in undertaking even pro-competitive and beneficial transactions. Below, we make recommendations for regulatory revision that would help to remove or mitigate some of these obstacles.

We recommend further revision of the Stark exceptions to address concerns that still remain.[42]

- Revise the existing Personal Services Arrangement exception by removing the limitation to commercial plans to expand its application to Medicare, Medicare Advantage and Medicaid plans and beneficiaries. Further, affirm that the exception may protect non-monetary compensation provided by a hospital to a physician to implement a new payment model (including software or other infrastructure).
- Similarly, revise the existing Risk-Sharing exception to expand application to Medicare, Medicare Advantage, and Medicaid plans and beneficiaries.
- Revise the existing Employment exception to make clear that physician incentive plans are available for employees (not just independent contractors).

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[41] Joe Carlson, *Pete Stark: Repeal the Stark Law*, Modern Healthcare (Aug. 2, 2013), https://www.modernhealthcare.com/article/20130802/BLOG/308029995/pete-stark-repeal-the-stark-law

[42] Although outside the scope of this letter, the AHA also recommends that the government conduct a thorough review of certain overly broad theories of causation, which OIG and DOJ have historically relied on when enforcing the anti-inducement laws. Hospitals and health systems often find themselves the subject of enforcement actions for lawful arrangements based on open-ended theories of liability or causation (*e.g.*, the theory that any claim resulting from a violative transaction is "tainted" and therefore false; the "one-purpose test," which holds that if even one purpose of many was to induce referrals, a transaction violates the Anti-Kickback Statute). This, in turn, means that hospitals and health systems often hesitate to pursue lawful arrangements because the risk of enforcement exposure is simply too high if they run afoul of an overly broad interpretation of the law. Accordingly, a review of these theories would yield more beneficial transactions and thus have pro-competitive results.

- Revise existing regulatory language (e.g., "fair market value," "referral") because hospitals are now forced to expend resources attempting to comply with unclear provisions. For example:
    - We recommend that the definition of "fair market value" be returned to the statutory definition, the same as was adopted in the original rulemaking in 1995. The poorly worded definition of "general market value," changed in 2001, continues to cause confusion among both the regulators and the regulated. It caused at least one court to incorrectly conflate the determination of "fair market value" with the determination of whether the methodology for payment took into account the volume or value of referrals (a separate and independent prohibition). The 2001 insertion should be deleted.
    - We recommend that the definition of a referral in the regulations be modified to clarify that a "referral" under Stark must result in either an additional payment or an increase in payment.
- Eliminate/revise provisions of the law that do not address the key issue of overutilization and instead add complexity and ambiguity. For example, we recommend revisions to provide that parties can look to state contract law to meet writing and signature requirements and to prescribe the end-date of a non-compliant arrangement to avoid disproportionate disallowances that stem from assuming one problematic contract taints claims far into the future.
- Rescind the 2021 changes to the Stark Law isolated financial transactions exception to permit hospitals to rely upon the exception to pay for services already rendered where documentation does not exist but the compensation does not take into account the volume or value of referrals.
- Improve the advisory opinion process to review questions of interpretation and hypotheticals more efficiently and quickly. The process should provide that if an opinion is not issued within 90 days, the proposal should be deemed favorable.

Unlike the Stark Law, which imposes liability regardless of intent, the AKS is a criminal law that does require intent to induce referrals, but also imposes more significant penalties. We continue to support the value-based safe harbors issued as part of the Regulatory Sprint and recommend that they be maintained in their current form. We would, however, encourage the adoption of a broad AKS safe harbor akin to the "access to care/low risk of harm" exception to the Civil Monetary Penalties Law, to immunize arrangements that promote access to healthcare items or services and present a low risk of harm to patients and Federal health care programs.[43] This would more effectively protect (and therefore promote) beneficial arrangements that clearly improve patient access to healthcare items or services, maximizing efficiency in the delivery of healthcare services and thereby promoting competition.

[43] 42 U.S. Code § 1320a-7a(i)(6)(F); 42 CFR § 1003.110

B. Telehealth Regulations

As the Trump administration's 2018 Report advises, the advancement of telehealth is a "significant innovation in health care delivery" with "great potential to improve access in underserved locations, reduce costs, and generate improved short- and long-term health outcomes."[44] But the expansion of telehealth has faced "a variety of regulatory barriers [that] have kept telehealth from reaching its full potential to increase competition and access."[45] The AHA agrees.

The recommendations below, several of which are also referenced in the 2018 Report, will mitigate many of the regulatory challenges that have kept telehealth from expanding to its fullest potential.

- Remove telehealth originating site restrictions within the Medicare program to enable patients to receive telehealth in their homes.
- Remove telehealth geographic site restrictions to enable beneficiaries in non-rural areas to have the same access to virtual care as those in rural areas.
- Remove the in-person visit requirements for behavioral health telehealth.
- Remove requirements for hospice recertification to be completed in person to allow for telehealth-based recertification.
- Eliminate the telehealth physician home address reporting requirement, which compromises workforce safety.

C. Workforce-Related Regulations

Workforce challenges continue to drive costs for hospitals and health systems, generating competition challenges and market inefficiencies. These challenges are driven by a host of factors, such as growing administrative and regulatory burdens imposed on providers, scope of practice limitations, and other market-distorting policies, many of which can be mitigated through the kind of reform the administration is currently pursuing. As the Trump administration's 2018 Report noted, "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."[46]

Below, we propose recommendations that will help mitigate some of the challenges and generate improvements, several of which are also raised in the 2018 Report.

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[44] 2018 Report, *supra* note 3 at 39-41
[45] Id.
[46] 2018 Report, *supra* note 3, at 30

- Remove requirements for outpatient physical therapy plans of care to be signed off by a physician or nurse practitioner every 90 days.
- Reform nursing and allied health education payments to relax the CMS interpretation of "director control."
- Eliminate nurse practitioner practice limitations that are more restrictive under CMS rules than under state licensure.
- Promote medical licensure reciprocity to allow practitioners to work across state lines.
- Eliminate or raise the tax-free limit of $5,250 on employer-provided funds spent to train employees in high-demand services like radiology.

Other regulatory efforts risk further aggravating the challenging workforce realities and would benefit from reconsideration. Most notably, the nursing home staffing rule promulgated by CMS in May 2024[47] imposes an arbitrary staffing requirement that is impossible for nursing homes and the broader health care market to sustain. **The AHA recommends repealing the nursing home staffing rule that would require nearly 80% of all nursing homes — including those with 5 stars — to increase staffing**.[48] Staffing can be more appropriately managed by existing safety and quality frameworks in conjunction with the free market.

D. Quality and Patient Safety Requirements

A number of regulatory requirements have been developed and issued with the important goal of advancing care quality and patient safety, but have either outgrown their usefulness or been later shown to be less valuable or useful than initially anticipated. Maintaining these regulations imposes great cost on hospitals and health systems without commensurate benefit, and we recommend they be withdrawn.

Below, we provide a list of recommendations regulations for consideration as part of this effort.

- Repeal the onerous and now outdated Conditions of Participation (CoPs) that requires hospitals to report data on acute respiratory illnesses, including influenza, COVID-19 and RSV, once per week, with more frequent and extensive data reporting required during a public health emergency.
- Reduce administrative burden by eliminating the outdated requirement for post-acute care providers to report COVID-19 and influenza vaccine rates for

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[47] Medicare and Medicaid Programs; Minimum Staffing Standards for Long-Term Care Facilities and Medicaid Institutional Payment Transparency Reporting, 89 Fed. Reg. 40876, 40883 (May 10, 2024).
[48] The U.S. District Court for the Northern District of Texas vacated the 24/7 and HPRD Requirements of the rule on April 7, 2025, (*American Health Care Association v. Kennedy*, Nos. 2:24-CV-114, 171, ECF No. 101 (Mem. Op. Apr. 7, 2025)). The AHA filed an amicus brief in the case on October 29, 2024, see ECF No. 67.

patients/residents and staff. Similarly, remove the outdated requirement for hospitals to report staff vaccination rates.
- Remove the sepsis bundle measure, which evidence shows has not led to better outcomes but entails an enormous administrative burden, from all hospital quality reporting and value programs, replacing it with a measure of sepsis outcomes.
- Permanently adopt concurrent validation surveys for CMS accrediting organizations, eliminating duplicative "lookback" surveys that require a full re-survey of hospital compliance with CoPs.
- Minimize in-person hospital surveys for low-risk complaints and resume them virtually.
- Eliminate 42 CFR Part 2 requirements providing special privacy protections for behavioral health patients and protect their privacy under HIPAA.

E. Antitrust Rules

The FTC has recently promulgated regulations that will adversely impact competition in the health care space, particularly for hospitals and health systems. As described further below, each of the rules will interfere with healthy and desirable market activity, ultimately raising costs and disincentivizing valuable arrangements.

1. FTC Premerger Notification Requirements

Mergers are a critical mechanism for hospitals, particularly those in rural or underserved areas, to access the needed resources to remain open and provide vital health care services to their communities. They can produce economies of scale, resulting in vital reductions to operating expenses, improvements to the standard of care, and decreases in patient mortality. And they can preserve and even enhance competition by ensuring that multiple health care providers in a given geographic area are able to remain in operation and continue serving their communities.

Unfortunately, the FTC updated its premerger notification reporting and waiting requirements in November 2024, a sudden overhaul that imposes significant additional costs without corresponding benefits.[49] The FTC's existing notification process has functioned well for decades. But the FTC's new protocol demands substantial additional information at the initial step of its review of a merger — including lengthy and contestable "descriptions" about a merger's impact on competition — while threatening penalties for giving the agency a purportedly "wrong" answer. This significantly increases the costs of desirable mergers without benefiting the public or the FTC and will inevitably make it even more difficult for struggling hospitals to keep their doors open. The anticompetitive nature of this new rule is particularly profound when contrasted with the friendly regulatory environment enjoyed by big insurers. We

[49] *Premerger Notification; Reporting and Waiting Period Requirements*, 89 Fed. Reg. 89,216, 89,310/1 (Nov. 12, 2024) (Final Rule).

strongly recommend that the FTC withdraw, or at least revise, this new rule to preserve the efficiency and efficacy of the existing process.

2. FTC Rule Prohibiting Non-compete Agreements

In May 2024, the FTC issued a new rule prohibiting non-compete clauses.[50] As the AHA stated in a public comment in response to the Rule, while "[t]he AHA respects the FTC's efforts to address issues of genuine unequal bargaining power between certain employers and certain types of workers . . . the proposed rule would profoundly transform the health care labor market — particularly for physicians and senior hospital executives."[51] The non-compete rule "would instantly invalidate millions of dollars of existing contracts, while exacerbating problems of health care labor scarcity, especially for medically underserved areas like rural communities."[52]

This rule has the potential to not only chill valuable activity — for example, by imposing new limitations on hospitals and physicians seeking to negotiate mutually beneficial employment or contractual relationships — but also risks disturbing the competitive playing field for hospital labor by treating tax-paying hospitals (covered by the FTC rule) differently from non-profit ones (exempt from the FTC rule).[53] As the AHA explained, "this disequilibrium could reduce the available supply of highly-trained, highly-skilled labor for for-profit hospitals in particular markets, driving up the price for such labor or at least creating serious instability in those markets. Market distortions of this kind would arise in the context of an already-challenging workforce shortage for America's hospitals."[54] The AHA filed public comments urging the FTC to tailor its non-compete rule more narrowly, by exempting the health care industry or even highly-skilled, highly-compensated physicians and the hospitals' executives who have greater bargaining power.[55] As the AHA concluded: "[T]he proposed regulation errs by seeking to create a one-size-fits all rule for *all* employees across *all* industries, especially because Congress has not granted the FTC the authority to act in such a sweeping manner." We reiterated these concerns in an amicus brief we filed in July 2024 in *Ryan LLC v. Federal Trade Commission* (No. 3:24-CV-986) and do so again here. We urge the FTC to withdraw or revise this rule.

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[50] 89 Fed. Reg. 38,342 (May 7, 2024)
[51] AHA, Comment Letter re Proposed Non-Compete Clause Rule (Feb. 22, 2023), at 1–2, available at https://www.regulations.gov/comment/FTC-2023-0007-8138.
[52] Id.
[53] The FTC lacks statutory authority to regulate nonprofit entities that are exempt under Section 501(c)(3) of the Internal Revenue Code, including nonprofit hospitals and health systems. *See* 15 U.S. Code § 44.
[54] AHA Comment, *supra* note 51, at 16.
[55] See id. at 7–17.

F. Other Administrative Burdens

In addition to the categories outlined above, we have identified other examples of unnecessarily burdensome regulations. Overregulation imposes costs on hospitals and health systems, forcing them to divert valuable resources away from direct patient care and research and ultimately raising costs and stifling innovation.

In that vein, we provide some additional examples below of these regulations for review and reconsideration. These were also submitted to HHS, CMS, and the Office of Management and Budget this month as part of the parallel effort to reduce burdensome and unnecessary regulations.[56]

- Strengthen Medicare-dependent and Sole Community Hospitals by allowing participating hospitals to choose from an additional base year when calculating payments.
- Modify the HIPAA cybersecurity rule of December 2024 to make the requirements voluntary.
- Modify the HIPAA Breach Notification Rule to remove the requirement to report breaches affecting fewer than 500 individuals.
- Repeal the Food and Drug Administration Laboratory Developed Tests final rule that will hamper hospital labs' ability to continue developing high-quality in-vitro tests that have increased access to care and reduced costs.
- Eliminate the skilled nursing facility three-day length of stay requirement that often delays patients from transitioning to the most appropriate site of care.
- Eliminate the requirement that a hospital operate for at least six months under the prospective payment system before converting to Critical Access Hospital status.
- Allow for exceptions to the requirement that Medicare overpayments are returned in 180 days, given that providers may need additional time to complete investigations.
- Allow Medicare bad debts to be written off as contractual allowances, which is consistent with standard accounting practices and was permitted under prior policies.
- Streamline Medicare mandatory notices to patients, including eliminating where applicable rules require providers to give notice both in-person and via paper notices. Examples of such notices include the Important Message from Medicare, Advance Beneficiary Notice of Non-coverage, Medicare Outpatient Observation Notice, the Notice of Medicare Non-coverage and Medicare Change of Status Notice.
- Eliminate (or, at a minimum, significantly streamline) the onerous Hospital Consumer Assessment of Healthcare Providers and Systems (patient

[56] Letter from AHA to Secretary Kennedy, Administrator Oz, and Director Vought, *supra* note 4.

satisfaction) survey of hospitals, as the quality of the instrument and use of the results have degraded due to low response rates.
- Eliminate the Hospital Readmission Reduction Program, as performance has topped out.
- Suspend the Medicare hospital star ratings program as the methodology is inadequate, including distorted comparisons of hospital performance and a significant time lag.
- Support providers' access to cheaper drugs by enforcing rules to prevent gaming of patents and other policies that stifle pharmaceutical competition.
- Make voluntary all Center for Medicare and Medicaid models, with particular focus on the recently announced Transforming Episode Accountability Model, which will mandate that some of the most vulnerable hospitals transition to bundled payments for five types of surgical episodes.
- Repeal the excessive and confusing "information blocking" rule that would impose unjustified penalties on providers.

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As President Trump correctly explained in his Joint Address to Congress, "[t]he nation founded by pioneers and risk-takers now drowns under millions and millions of pages of regulations."[57] That is especially true for hospitals and health systems. Overregulation not only inflicts anti-competitive costs on the AHA's members, but it forces them to compete with the commercial insurance industry on a severely imbalanced playing field. We are therefore grateful for the FTC's effort to review and redress these anticompetitive regulatory frameworks.

We are eager to provide continued support in this critical project and welcome the opportunity to discuss these recommendations with you in greater detail. Please contact me at (202) 626-2303 or jschenker@aha.org with any questions.

Sincerely,

/s/

Julie Rapoport Schenker
Vice President and Deputy General Counsel

[57] Remarks by President Trump in Joint Address to Congress (March 6, 2025) https://www.whitehouse.gov/remarks/2025/03/remarks-by-president-trump-in-joint-address-to-congress/