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American Independent Medical Practice Association[®]

May 27, 2025

The Honorable Abigail Slater Assistant Attorney General Antitrust Division U.S. Department of Justice 950 Pennsylvania Ave. NW Washington, DC 20530

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

Re: Reducing Anticompetitive Regulatory Barriers

Dear Assistant Attorney General Slater and Chair Ferguson:

On behalf of the <u>American Independent Medical Practice Association</u> (AIMPA), we thank you for your leadership—and the leadership of the Trump Administration as a whole—in striving to eliminate anticompetitive state and federal laws and regulations that undermine freemarket competition and harm consumers, workers, and businesses. AIMPA appreciates the important work the Department of Justice (DOJ) and the Federal Trade Commission (FTC) are doing to coordinate efforts across federal agencies in response to President Trump's Executive Order 14267, issued on April 9, 2025, entitled "Reducing Anticompetitive Regulatory Barriers."

As the country's first national, multi-specialty advocacy organization representing physicians in independent medical practices, <u>AIMPA</u> focuses our comments on how specific anticompetitive laws and regulations are making it more difficult for millions of Americans to access high-quality, cost-efficient health care services. AIMPA represents more than 10,000 physicians who care for over 24 million patients in 45 states and so brings a unique perspective to this important topic.

The President's Executive Order and the solicitation of public comment by the DOJ and FTC recognize that eliminating anticompetitive laws and regulations will require collaboration not only among federal agencies but also between the Administration and Congress.

We divide our comments into three parts:



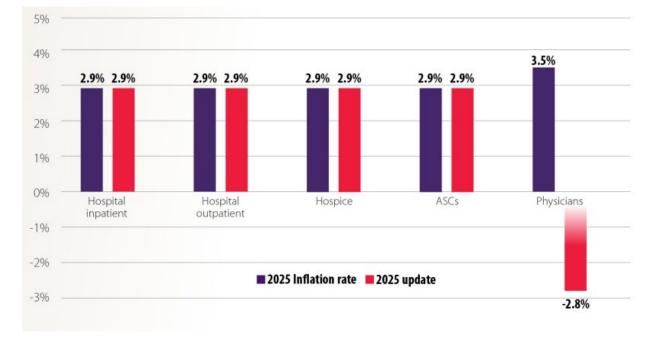
- First, we address the most significant barrier to competition in our health care system—the flawed Medicare payment system that is causing independent medical practices to disappear across the country and triggering the consolidation of care in the higher-cost hospital and health system setting.
- Second, we focus on three other anticompetitive federal laws and regulations that need to be changed to level the playing field in our healthcare delivery system. Specifically, we urge action by the Trump Administration to (i) take action in fulfilment of President Trump's April 15, 2025, <u>Executive Order</u> to lower drug and drug-related prices through site-neutral payment regulations—and then to expand these regulations to apply across dozens of other payment classifications for healthcare services; (ii) reform the anticompetitive 340B Drug Pricing Program that has accelerated hospital consolidation and costs the Medicare program and taxpayers billions of dollars; and (iii) eliminate regulations under the federal physician self-referral (Stark) law that have perpetuated an uneven playing field for healthcare delivery in the hospital versus the independent medical practice setting.
- Third, we identify a specific form of anticompetitive state laws—Certificate of Need (CON) programs—that fuel healthcare consolidation and undermine patient access to lower-cost, high-quality care. CON laws are inherently anticompetitive. They stand as barriers to market entry and thereby restrict the supply of care. They increase healthcare costs without any resultant improvement in the quality of care available on the market. As DOJ recognized in its solicitation of comments, the Antitrust Division routinely files *amicus curiae* briefs and statements of interest in private-party litigation and provides comments on proposed legislation in states at the request of state legislators. Flawed and arguably illegal CON laws are worthy of engagement by the Trump Administration.

I. The Flawed Medicare Payment System Driving Independent Medical Practices Out of Business

In 2012, roughly <u>one-fourth of physicians</u> were employed by hospitals or health systems. By 2024, the share of physicians employed by hospitals had more than doubled, to <u>55%</u>. This shift is not because hospital employment is better for patient care. Rather, it is the consequence of a flawed reimbursement methodology in which hospitals are reimbursed for outpatient care at significantly higher rates than when the same healthcare services are provided in independent practices or ambulatory surgery centers (ASCs).

This year, Medicare reimbursement increased for inpatient and outpatient hospital facilities, hospice providers, and nearly all other healthcare providers. Physicians, on the other hand, received a <u>pay cut</u>.





Credit: American Medical Association

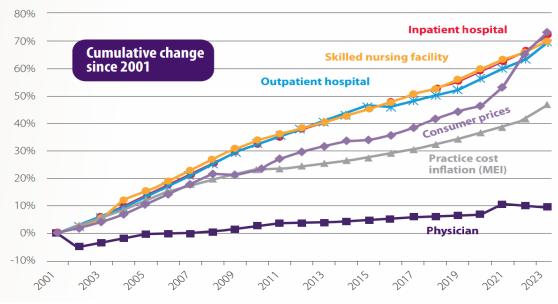
This payment cut is no anomaly. During the four years of the prior Administration, physicians received pay cuts from Medicare each year despite persistent inflation. The Medicare Economic Index, a measure of inflation in medical practice costs, increased 4.6% in 2024 and is set to increase 3.5% in 2025. Independent medical practices cannot continue to absorb reimbursement cuts from Medicare as their operational costs surge—especially when their competitors in the hospital setting are receiving payment increases to counter inflationary pressures.

Medicare's structural bias against independent medical practices is driving an ongoing wave of consolidation. In 2022 and 2023 alone, hospitals acquired <u>2,800 additional physician practices</u>. Hospitals owned nearly <u>70,000 physician practices</u> as of January 2024. That number has grown <u>12%</u> since 2019.

Since 2001, Medicare reimbursement rates for inpatient hospital services, hospital outpatient services, and services at skilled nursing facilities <u>have increased by around 70%</u>. Reimbursement for physicians has increased at a fraction of that rate—less than 10%.

The costs associated with operating a physician practice have increased <u>by nearly 50%</u> over that same period. Overall consumer prices have <u>surged even more</u>. After accounting for inflation, Medicare payments to physicians have <u>declined roughly 30%</u>. The following graphic depicts the trend:





Credit: American Medical Association

Given these economic realities, it is no wonder that independent medical practices continue to accede to buyout offers from hospitals, health systems, and insurance companies. Medicare reimbursement simply has not kept up with the cost of staffing, rent, insurance, and other operational expenses associated with running an independent practice.

The shift away from independent medical practice has had—and absent changes in federal law will continue to have—serious ramifications for patients and the healthcare system. This anticompetitive payment system is driving up healthcare costs. According to a 2024 study of five specialties conducted by healthcare consulting firm Avalere, total Medicare expenditures per beneficiary per year increased an average of more than \$1,300 in the 12 months after the physician caring for a beneficiary moved from an unaffiliated private practice to a hospital affiliation.

This anticompetitive payment structure has practical implications for ordinary Americans, who foot the bill in the form of higher taxes and insurance premiums. <u>Millions of Americans</u> are struggling with medical debt. That problem will grow worse if patients lose access to lower-cost independent medical practices. For patients in underserved and less populous communities, losing a neighborhood practice could mean having to drive hours to see a provider. Moreover, the disappearance of independent medical practices means the disappearance of thousands of good-paying healthcare jobs.

We urge the Trump administration and Congress to work together to make fundamental, permanent changes that tie physician reimbursement to practice cost inflation as measured by the Medicare Economic Index system.

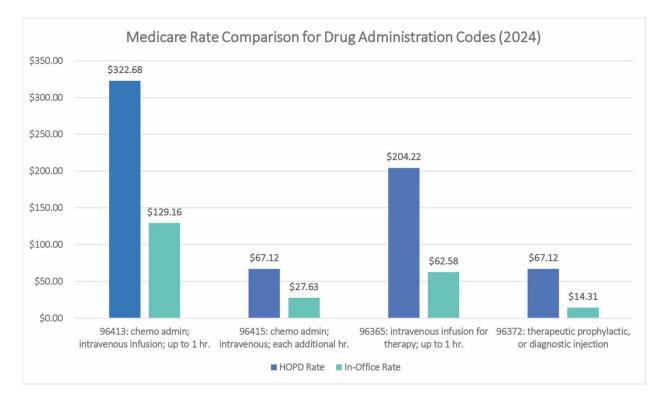
II. Additional Federal Laws and Regulations Undermining Competition in the Health Care Market

A. The Critical Need for Site-Neutral Payment Policy to Create a Level Playing Field

The increased adoption of site neutrality throughout the healthcare delivery system is critical for the viability of independent medical practices. Site-neutral payment policies mean Medicare would pay the same rate for services, regardless of the site of service at which patients receive care.

This would be a departure from the status quo, where there are only limited site-neutral policies in place. Our bifurcated reimbursement system harkens back to a time when hospitals did not provide nearly as many outpatient services and focused primarily on inpatient care. Even though hospitals now increasingly compete head-to-head with independent medical practices by offering more outpatient services identical to those offered in physicians' own medical practices, the bifurcated reimbursement model has not been amended. It incentivizes a higher-cost, more consolidated, and anticompetitive healthcare marketplace.

To illustrate one example of the extreme disparities in reimbursements, consider the following graphic showing that the administration fee for intravenously delivered drugs reimbursed by Medicare is significantly lower for drugs delivered in the independent practice setting than in a hospital outpatient department:

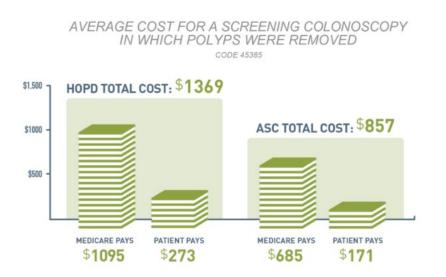


Credit: Infusion Providers Alliance



The current system incentivizes hospitals to acquire physician practices—not to improve care but to bill at higher hospital rates for identical services. One study shows that Medicare would have paid physicians <u>\$114,000 more in a certain year if</u> they had worked for a hospital system than if they practiced independently doing the same work. Studies also have found that physicians employed by hospitals also perform more services in higher-cost hospital outpatient departments than physicians in independent medical practices. For some procedures, hospital-employed physicians were seven times more likely to perform certain services in a higher-cost hospital outpatient department setting than independent physicians.

The resulting cost increases to Medicare affect all Americans. Medicare beneficiaries end up bearing more costs pursuant to their <u>cost-sharing obligations</u>. Private insurers pay approximately <u>double</u> Medicare rates for all hospital settings; users of commercial insurance in turn also face higher costs for procedures. The impact of this unjustifiable dual payment system—and its direct impact on Medicare beneficiaries—is clearly shown in the following chart with respect to colonoscopies.



The takeaway is that patients' healthcare costs rise when a hospital buys an independent medical practice, and the identical services shift to the higher hospital outpatient payment system.

Site-neutral payment policies would level the competitive landscape across healthcare delivery settings, reduce unnecessary healthcare spending, and encourage more efficient, cost-effective care delivery. Implementing site neutrality would improve healthcare cost control by removing incentives for hospital-led consolidation, boost access to care, and make care more affordable for patients.

There has been long-standing bipartisan support for site-neutral payments. As Alex Azar and Kathleen Sebelius, the former Secretaries of Health and Human Services under President Trump and President Obama, respectively, wrote in a 2024 joint op-ed: "Site-neutral payments represent a commonsense policy that will reduce costs for patients and taxpayer . . . diminish perverse incentives for consolidation, and incentivize care delivery in the right place for the right price. It's a no-brainer."



On May 9, 2025, Senator John Kennedy, R. La., introduced the <u>Same Care, Lower Cost Act</u>, which would take significant steps toward broadening the use of site-neutral payments in Medicare. The bill would potentially reduce deficits by <u>\$150 billion</u> over the next decade, according to the Congressional Budget Office. It would do so by directing the Secretary of Health and Human Services to make 66 ambulatory payment classifications eligible for site-neutral reimbursements and give the Secretary additional authority to add more services for site-neutral consideration. While several bipartisan bills have been introduced in the last few years to expand site-neutral payments, this bill is more comprehensive than the others.

AIMPA urges the DOJ and FTC, along with HHS and the Trump Administration more broadly, to support passage of this critically important legislation.

B. Addressing the Anticompetitive 340B Drug Pricing Program

The 340B Program is part of the 1992 Public Health Service Act and provides outpatient drugs at discounts of 20% to 50% to certain covered entities that are supposed to be safety-net providers. The idea behind the program is that the profits these 340B entities make from purchasing drugs at such steep discounts enable them to serve indigent, uninsured, and underinsured patients.

Unfortunately, the 340B program has been distorted in direct conflict with its original mission. It is now a source of cash for hospitals to use in virtually any manner they choose. In many cases, 340B entities are spending their proceeds from the program in ways that have little to do with caring for indigent and uninsured patients.

Indeed, there is a <u>growing body of evidence</u> that calls into question whether the 340B program actually serves vulnerable communities. Some hospitals are using the 340B program to increase their market power and profit margins in <u>wealthier areas</u>. Hospitals leverage 340B discounts to generate revenue that they then use to purchase <u>competing</u> independent physician practices.

Independent practices are at a competitive disadvantage. They cannot secure the lower 340B prices that their hospital competitors can. They must subsist on lower margins – or acquiesce to hospital buyouts.

The 340B program has become a flashpoint because there is much more money at stake now than in previous years. In 2010, the Health Resources and Services Administration (HRSA) allowed hospitals to expand the number of contract pharmacies covered under the program. Hospitals used this new authority to build bigger networks of affiliated retail pharmacies. As a result, more patients received 340B drugs, and hospital profits surged.

The share of participating pharmacies grew from about 1% of retail pharmacies in 2009 to 41% in 2022. The contract pharmacy expansion, plus the rising cost of drugs generally, has increased the value of 340B discounts nearly tenfold, from <u>\$6 billion in 2015</u> to <u>\$56.1 billion in 2023</u>.

As 340B discounts have grown, pharmaceutical companies have started pushing back. In some cases, they have refused to offer discounts to contract pharmacies, contrary to <u>HRSA's guidance</u>.



In turn, hospitals and other covered entities are fighting to preserve their discounts. When Medicare cut pharmaceutical reimbursement rates to reflect the discounted prices that 340B hospitals enjoyed, 340B hospitals went to the Supreme Court and had the cuts <u>overturned on the basis</u> that a survey had not been conducted regarding acquisition costs to support the cuts to the discounts hospitals had been receiving. After the Supreme Court ruling in June 2022, the prior Administration did not even try to complete the required survey.

President Trump's recent <u>Executive Order</u> dated April 15, 2025, directs HHS to survey hospital acquisition costs for medications and reduce Medicare payments to 340B covered entities to the hospitals' actual acquisition costs. Additionally, the Executive Order directs HHS to evaluate and propose regulations within 180 days to ensure that payment within Medicare does not encourage the shift in drug administration volume away from physician offices to more expensive hospital outpatient departments.

This is a step in the right direction. But it is critical that DOJ, FTC, and the Administration more broadly work with HHS and Congress to reduce the rampant overreach by hospitals under the 340B program.

For example, the Administration should implement regulations to ensure that the 340B program benefits those who it is intended to benefit—the indigent and uninsured—and that hospitals are only eligible to dispense 340B drugs to patients who are truly in the care of those hospitals.

Hospitals claim that 340B savings allow them to provide free care for uninsured patients, offer free vaccines, deliver services in mental health clinics, and implement medication management and community health programs. But there is no regulation that forces them to do so, and there is no transparency about how hospitals use the significant windfall they realize under 340B.

Moreover, while hospitals must achieve a certain level of Medicaid patient share to qualify for 340B discounts, once they qualify, financial support from 340B <u>does not appear to increase</u> the rates of uncompensated care that these hospitals provide to vulnerable communities compared with non-participating hospitals. A 2024 study found that nonprofit hospitals did <u>not increase</u> their provision of generally unprofitable services such as psychiatric treatment or obstetric care after joining the 340B program.

These findings rebut hospitals' statements that 340B discounts allow them to offer more free care or essential services.

In sum, the 340B program has provided hospitals and health systems with enormous resources to thwart competition from independent medical practices and, in some cases, eliminate competition altogether by facilitating the acquisition of independent practices. As a result, services previously billed in the lower-cost physician office setting migrate to the higher-cost hospital setting. That, in turn, can generate more 340B revenue for hospitals, and the cycle repeats.

Ultimately, patients suffer. As independent medical practices disappear, patients may be forced to seek care in the higher-cost, less convenient hospital setting—or forego care altogether.



AIMPA encourages DOJ and FTC to work with HHS to reform 340B so that the program no longer distorts the healthcare marketplace and increases prices for consumers.

C. The Need for the FTC and DOJ to Work with HHS to Restore Competition through a Leveling of the Playing Field under the Stark Law and Regulations.

The Physician Self-Referral ("Stark") Law prohibits a physician from referring patients for designated health services to entities with which the physician has a financial relationship. <u>Designated Health Services</u> are specific healthcare services identified in the Stark Law, including clinical laboratory services, physical therapy, occupational therapy, radiology and other imaging services, radiation therapy, outpatient drugs, durable medical equipment, and others.

The purpose of the Stark Law is to prevent conflicts of interest that could unduly influence patient care. The statute and supporting regulations purport to ensure that referrals are based on the best interests of patients, rather than any financial incentive on the part of the referring physician.

There are various exceptions to Stark under which a referral of designated health services from a physician to an entity with which the physician has a financial relationship is not unlawful. For these exceptions to apply, the amounts paid to a physician cannot be determined in a way that considers the volume or value of that physician's referrals for designated health services.

This is one of the requirements of meeting the definition of a group practice under <u>42 C.F.R. §</u> <u>411.352</u> (Group Practice) within the Stark Law. When a physician group meets this definition, it can take advantage of two broad exceptions found under <u>42 C.F.R. §§ 411.355(a) and (b)</u> (General exceptions to the referral prohibition related to both ownership/investment and compensation): the Physician Services and In-Office Ancillary Services exceptions. Notably, neither exception requires that the payments made to a physician be at fair market value.

The Physician Services exception to Stark Law prohibitions allows a physician to refer patients to another physician in the same group practice for a designated health service.

The In-Office Ancillary Services (IOAS) exception is a provision in the Stark Law that allows physicians within a group practice to refer patients for designated health services if those services are provided in the office of the group practice itself and billed by the group practice. In other words, the IOAS exception allows physicians to refer patients for a variety of ancillary services within their own practice without violating the Stark Law's referral prohibitions.

It is logical that the original reasoning for the group practice definition and the tie to the very broad Physician Services and IOAS exceptions was to allow physician practices to provide designated health services to patients when the physician practice is performing or supervising all the work within the practice but not compensating its physicians based on their volume or value of such referrals. Usually, within a physician practice, monies paid by Medicare would be paid subject to the Medicare Physician Fee Schedule (MPFS). Physician practices generally are responsible for providing both the professional portion of the service (e.g., the portion that requires a licensed



provider to furnish services) and the technical portion of the service (e.g., the payment for equipment, space, staff, etc.).

For example, a physician group that provides an x-ray would have a physician read and interpret the x-ray (professional component), own and maintain the x-ray machine within a space in their office, have an x-ray technician take the image (the technical component), and bill the professional and technical components to Medicare as an office-based service under the MPFS. The physician practice provides all aspects of the service and pays for all related overhead. There is an inherent cap on the pool of funds available to compensate physicians based on the amount paid by Medicare and the amount it costs to provide all aspects of the service. Functionally, a typical physician group cannot pay more money than it receives. With such a cap, the Stark Law and implementing regulations prudently protect a physician practice's ability to pay profits from designated health services to physician-owners and employees, without a fair market value cap, as long as the profits are not paid in a manner that is based on the volume or value of referrals.

However, the definition of group practice can be broadly construed so that hospitals and health systems that create their own medical groups to employ or contract with physicians (i.e., "Captive Medical Groups") can meet the requirements of a group practice and take advantage of the two broad exceptions.

When hospitals and health systems furnish outpatient services, they typically have their Captive Medical Group bill the MPFS for the professional (physician) component of a designated health service. There is no other method to bill Medicare for such services. The profits from such services are included in the Captive Medical Group's compensation pool.

However, hospitals and health systems will not provide what would normally be technical services within the Captive Medical Group's office. Instead, the Captive Medical Group refers the patient to the hospital's outpatient department for the technical component of the designated health service, and the hospital charges a "facility fee" to Medicare under the Hospital Outpatient Prospective Payment System (OPPS), which generally means a higher payment for the same service than when the service is provided in the office of the Captive Medical Group. Thus, the hospital or health system makes more each time the Captive Medical Group refers the service to a separate outpatient department. Although this means the Captive Medical Group will not be reimbursed for the technical component of the designated health service and will not have the technical component available for funding its compensation pool to pay its physicians, hospitals find other ways to supplement the compensation pool.

For example, hospitals and health systems may provide subsidies or other funds to their Captive Medical Groups in a manner that is not based on referrals to the hospital. Under the Stark Law, provided the Captive Medical Group is otherwise structured as a group practice and can meet the Physician Services or IOAS exception for the professional component of the designated health services it provides, the Captive Medical Group can pay physicians without a fair market value restriction. Such subsidies are generally not available to most independent physician practices, or if monies are paid, the independent physician practice can only receive the fair market value of their services from the hospital.



The result is that Captive Medical Groups can have larger pools of funds available to pay their physicians than independent physician practices because the independent practices are functionally capped in the amount they can make from third-party payors. In other words, hospitals and health systems can help their Captive Medical Groups pay more to physicians in the group using the higher reimbursements the hospital received for the same services that could have been provided in the lower-cost office setting, without a Stark Law-related cap. Independent medical practices lack the ability to pay this increased compensation because of declining reimbursements in the independent practice setting.

Some may argue that there is language in the Stark regulations that require compensation to be set at fair market value when a physician's compensation arrangement is conditioned on directing referrals to the hospital. But the reality is that physicians in a hospital or health system's Captive Medical Group are more likely to refer within the hospital or health system for a variety of other reasons, even without their compensation being specifically conditioned in this manner (e.g., interoperability of systems, referral restrictions within an electronic health record, an understanding of the general economic benefit of—and potential non-economic incentives for keeping services within the health system). As noted above, hospital-employed physicians were seven times more likely to use hospital-based services than their independent physician counterparts.

The result is that hospitals and health systems have an unfair competitive advantage in the physician market when using a Captive Medical Group that meets the "group practice" definition to compensate their physicians because the Captive Medical Group has access to additional funds to pay physicians.

Therefore, we respectfully submit that the FTC and DOJ work with HHS to (a) stop the ability of Captive Medical Groups to qualify for the "group practice" definition under 42 C.F.R. 411.352, which currently allows Captive Medical Groups to use the exceptions that do not have a fair market value cap such as the Physician Services and In-Office Ancillary Services exceptions under 42 C.F.R. § 411.355; or (b) otherwise require Captive Medical Groups to compensate their physicians subject to a fair market value cap. If hospitals and health systems are restricted from paying above fair market value rates, then independent medical practices will be able to compete on a more level playing field, recruit physicians who are more likely to keep care in the lower-cost physician office and ASC settings, and reduce costs to patients and the healthcare system.

III. The Need for DOJ and FTC to Weigh in on Anticompetitive State Certificate of Need Laws

We appreciate the DOJ's and FTC's continued commitment to having the Administration's voice heard with respect to private litigation and state legislation that pose barriers to competition. One such area that is worthy of scrutiny is state certificate of need (CON) laws that require state approval for new entry and expansions by healthcare providers. These CON laws stand out as examples of regulations that squelch the beneficial effects of competition in healthcare markets without delivering valuable public benefits in return.



These laws date back to the 1960s, when there was concern about over-investment in health care that would lead to higher costs. However, data has shown that output restrictions mandated by governments create artificial shortages and drive up costs, rather than bringing costs down. There is no empirical evidence to suggest that the basic laws of economics do not apply to healthcare markets.

To be sure, we are aware that sovereign actions of the states in our federal system are not subject to federal antitrust laws. But state CON laws are restraints of trade all the same and should be analyzed as such when determining whether they constitute sound public policy. These laws funnel benefits to incumbent healthcare providers, often without any meaningful political oversight or public transparency. They displace the free market with anticompetitive regulation shown to lead to <u>fewer healthcare services</u> by discouraging potential market entrants from even applying for a CON, which gives existing market participants a de facto competitor's veto. Indeed, <u>research shows</u> that patients in states with these laws on the books have access to fewer hospitals, fewer ASCs, fewer dialysis centers, fewer imaging services, and fewer rural hospitals per capita.

We ask that DOJ and FTC continue their tradition of engaging in advocacy against anticompetitive state laws, whether by publishing white papers, filing statements of interest and amicus briefs in ongoing litigation, or commenting on proposed legislation.

AIMPA thanks the DOJ and FTC for spearheading the Administration's efforts to eliminate anticompetitive laws and regulations. This effort is critical if we hope to fix our healthcare delivery system and ensure access to high-quality, affordable care for millions of Americans. AIMPA stands ready to serve as a continued resource to the Administration as we tackle this issue together. Please do not hesitate to reach out to AIMPA President and Board Chair Dr. Paul Berggreen (paul.berggreen@gialliance.com; 602-421-2408) if AIMPA can be of further assistance.

Sincerely,

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Dr. Paul Berggreen AIMPA President and Board Chair

John Felor ND

Dr. Jack Feltz AIMPA Chair, Federal Health Policy

CC: The Honorable Robert F. Kennedy Jr. Secretary Department of Health and Human Services 200 Independence Ave. SW Washington, DC 20201

The Honorable Dr. Mehmet Oz Administrator Centers for Medicare & Medicaid Services 7500 Security Boulevard Baltimore, MD 21244