January 25, 2018

Eric D. Hargan
Acting Secretary
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: Request for Information – Promoting Healthcare Choice and Competition Across the United States

Dear Acting Secretary Hargan:

The Physicians Advocacy Institute (PAI) appreciates the opportunity to provide comments on the Department of Health and Human Services (HHS) Request for Information (RFI) – Promoting Healthcare Choice and Competition Across the United States. Through the RFI, HHS is seeking input from stakeholders on identifying existing state and federal laws, regulations, guidance, requirements, and other policies that limit choice and competition across health care markets, as well as suggestions on laws and policies that can be put in place to address these issues and promote the development and operation of a more competitive health care system that provides high-quality care at affordable prices.

PAI is a not-for-profit organization that was established to advance fair and transparent policies in the health care system to sustain the profession of medicine for the benefit of patients. As part of this mission, PAI seeks to better understand the challenges facing physicians and their patients and to educate policymakers about these challenges. PAI also develops tools to help physicians prepare for and respond to policies and marketplace trends that impact their ability to practice medicine. PAI’s Board of Directors is comprised of CEOs and former CEOs from nine state medical associations: California Medical Association, Connecticut State Medical Society, Medical Association of Georgia, Nebraska Medical Association, Medical Society of the State of New York, North Carolina Medical Society, South Carolina Medical Association, Tennessee Medical Association, and Texas Medical Association, and a physician member from Kentucky. As a physician-based organization, PAI is equipped to provide comments and insight into many of the challenges facing the medical profession.

Overview
PAI strongly supports HHS’ effort to adopt policies that promote a health care system that provides high-quality care at affordable prices, promotes competition, ensures fair and transparent policies, and prevents excessive consolidation. PAI supports policies that promote patient choice and access by ensuring that physicians are able to practice medicine in a variety of practice settings, from individual and small group practices to highly-integrated health system—all of which must aim to improve quality and population health and encourage innovative care models.
As we discuss in detail below, current economic trends and the legislative and regulatory environment contribute to anticompetitive elements in the market for health care services that limit patient choice and physicians’ practice options, with implications for patient access and quality of care. They also inhibit the development of new financing and delivery arrangements that could enhance care coordination and improve clinical outcomes.

We believe that opportunities exist to improve the health care system with innovative approaches to physician collaboration, which will bring the benefits of competition to patients while, at the same time, address anticompetitive forces and excess consolidation. In this letter, we provide comments and suggested solutions in response to questions posed in the RFI, organized as follows:

- Current economic trends that reduce competition in the health care system;
- Regulatory modernization to encourage and support choice and competition; and
- Legislative and regulatory barriers that inhibit competition and choice.

**Current Economic Trends that Reduce Competition in the Health Care System**

**Horizontal and Vertical Market Integration**

Over the last decade, integration in the health care sector has led to increased consolidation in local areas in the hospital and payer sectors, with variation in degree across communities. There have been a substantial number of hospital mergers and acquisitions, leaving many service areas only served by a small number of facilities, often part of large health systems. The result of this horizontal integration has been increased prices that raise costs for consumers and public and private purchasers of health care, contributions to challenges with access to care, and heavy influence local practice patterns. Research demonstrates that price increases exceeded 20 percent when hospital mergers occurred in concentrated markets.¹ While in some markets payer consolidation serves as a counterweight to those provider arrangements, in others, similar concerns can arise for physician practices, particularly where there is one dominant insurer with a limited number of competitors.

Additional trends include an increasing array of organizations involved in vertical integration; specifically, powerful health systems are expanding their ownership and control over outpatient facilities, clinics, and physician practices to develop more integrated and coordinated approaches to care. Payers are also entering into relationships with providers to expand their role in the care delivery sector. For many, horizontal/vertical integration may take the form of accountable care organizations (ACOs), entities holding some risk for the populations they serve and that are incentivized to pursue a range of clinical programs, and alternative payment models (APMs) to meet cost and quality targets. While expectations exist for those entities to increase coordination across the system, substantial concerns remain about whether those integrated systems are contributing to higher costs overall.

In our view, necessary safeguards should be in place and appropriate scrutiny should be demonstrated in cases of horizontal and vertical integration as described above since those involved are most directly impacting patient care—both physically (e.g., providers) and structurally (e.g., systems and facilities). It is important to have policies that do not limit choice or access, and that support fair practices, bargaining power, and market conditions, so physicians and practices already in the market can continue to provide care to their patients, as well as enabling new entrants and competition into the market.

Significant Growth in Hospital Acquisitions of Physician Practices and Hospital and Health System Employment of Physicians

The drive to consolidation presents substantial challenges to physicians’ ability to sustain independent medical practices. PAI supports physicians’ ability and choice to practice in various types of arrangements, but is concerned that today’s financial and regulatory environments can make it exceedingly difficult for physicians to survive independently and lead them to seek employment. PAI feels strongly that the decline of the independent medical practice has negative implications for continuity of patient care, quality, and innovation in the health care system.

PAI and Avalere Health partnered to study the trend of hospital acquisitions of physician practices and physician employment, as well as the impact on spending by Medicare and beneficiaries. This research confirms significant shifts towards employment and reductions in independent physician practices across the nation. Between 2012 and 2015, hospital acquisitions of physician practices increased by 86 percent. Over that same three-year period, physician employment grew dramatically—by over 50 percent.\(^2\) A soon-to-be released follow-up study shows that the trend toward a decline in independent practice continued in 2016.

Hospital-driven consolidation has significant financial implications for the health care system. Another PAI-Avalere study considered the impact of this trend, which results in more care being provided in hospital-owned settings over an episode of care and generally involves higher Medicare payments for the same services than the physician-office setting.\(^3\) Avalere researchers studied Medicare spending for four cardiology, gastroenterology, and orthopedic services and found that Medicare spent $2.7 billion more for services provided in hospital-owned settings and beneficiaries paid $411 million more in cost-sharing over the three-year study period than if those services had been provided in the physician-office setting.

The economic considerations driving hospital-led consolidation include a financial interest in securing greater control over physician practices, referrals, and clinical decision-making, as well as the need for hospital-employed physicians to support the growth of hospital-owned APMs. Another major factor in hospital consolidation has been the site-of-service payment differential that rewards care delivered in hospital-owned settings with higher reimbursements than the same services provided in the physician office setting. These payment policies have fueled the trend towards hospital acquisition of physician practices and the proliferation of off-site hospital outpatient departments that are paid at significantly higher rates.\(^4\)

From the physician perspective, selling a medical practice to a hospital or entering into an employment arrangement presents an attractive alternative to dealing with ever-increasing administrative and regulatory burdens and high costs associated with running a medical practice in today’s environment. Furthermore, this has implicated patient access issues. In some localities, our members report that hospital

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closures have led physicians to relocate to other areas as they seek employment opportunities, leaving patient communities with little or no alternatives to care.

**PAI Recommendation**

PAI believes it is important to monitor and assess the impact of this trend and encourages the Department to determine whether and how it is impacting quality of care, costs, and patient access. Advancement of policies that encourage and support independent practices and allow them to continue to be competitors in the health care market is an important goal. We note that in raising these concerns, employment, such as with a health system, can provide physicians with important practice options. However, it is equally important that options for sustaining an independent practice are also supported, to include approaches for ensuring that the environmental trends described here do not limit physician options or effectively prescribe a particular path.

PAI supports site neutral payment policies to ensure against artificial incentives to drive health care services into the costlier hospital-owned setting. In addition, given the need to ensure balance, PAI recommends that the Department focus on programs and policies that create opportunities for independent physician practices, including solo and small group practices, recognizing the significant contributions these practices make to the nation’s health care. We encourage the Department to take into consideration the differences between practice sizes and the value of each, and to account for those differences as it develops new policies. For example, the Department may consider policies that encourage collaboration (instead of consolidation), such as the virtual groups option currently available in the Quality Payment Program (QPP), or policies that allow smaller practices to participate in risk- and value-based programs and APMs. Those approaches can enable physicians to practice alongside larger practices or integrated systems under similar terms.

**Regulatory Modernization to Encourage and Support Choice and Competition**

As referenced throughout this comment letter, one of the key recommendations that PAI would like to emphasize is the need for “regulatory modernization.” Many of the policies, laws, and regulations that are currently in place were enacted and implemented in response to historical concerns and rationale that were relevant and a priority at that time. Given changes in the health care economy and the growing need for innovation and improvements to quality and clinical outcomes, many of these policies and regulations need to be revisited and “modernized.” There are many rules and regulations that have not kept pace with the evolution of a high-performance health system, particularly with regards to the important role of physicians.

Given the dynamic nature of health care which is constantly changing and innovating, there is a need to ensure that the guiding laws and regulations are updated and keep up with health care delivery system innovations and advancements. PAI strongly encourages the Department and other lawmakers to revisit enacted policies on a regular basis to ensure they foster, rather than hinder, increased competition and choice that will lead to further innovations and higher quality care. In this regard, we were pleased to hear of the Administration’s potential efforts to consider potential changes to the Physician Self-Referral Law (Stark Law) and regulations with a focus on modernization, and would encourage similar efforts.5

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Legislative and Regulatory Barriers that Inhibit Competition and Choice

In addition to the current economic trends and overarching need for regulatory modernization, certain legislative and regulatory factors governing physician practices’ relationships with each other impede competition. Four specific areas of concern discussed in greater detail below include: restrictions on physician-owned hospitals; State Certificate of Need (CON) programs; APM participation requirements; and limited application of antitrust guidance.

Restrictions on Physician-Owned Hospital (POHs)

The restrictions placed on POHs has been a topic of debate for over a decade. Current restrictions on the formation and expansion of POHs were implemented in response to self-referral concerns and criticism, including that physicians would refer patients to a hospital in which they shared an ownership interest, and that physicians may overutilize the services in those hospitals. Physician organizations have vocally opposed these restrictions as creating an unfair barrier to the development of physician-led delivery systems, which many patients would prefer over those run by hospital administrators.

Recent studies have challenged the validity of these restrictive policies, finding that these policy concerns are often “overstated,” and instead show that POHs perform equally well as non-POHs in quality and cost, and in some cases, provide even higher quality care at a lower cost.6 Furthermore, a 2017 Becker’s Hospital Review survey showed that 38 of the 57 “Best Overall Patient-Rated Hospitals” were POHs, and that those POHs had care ratings of 9 or 10 in more than 90% of their Patient’s Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) surveys.7

Studies have found that, because POHs are not paid the same subsidies as other facilities, they are able to provide high-quality care at a lower cost to the Medicare program, with one study showing that, on average, a patient treated at a POH cost Medicare 4.6% less than if the patient had received those services at a non-POH.8 Estimates suggest that under similar regulatory structures, “POHs would generate about $10 billion in savings over a 10-year period.”9 Furthermore, a study did not find any evidence that POHs “cherry-picked” their patients and did “not seem to systematically select more profitable or less disadvantaged patients or to provide lower value care.”10

PAI Recommendation

By imposing restrictions on POHs, current laws and regulations are restricting the development and expansion of these entities that have demonstrated the ability to increase quality and decrease costs at a competitive level with non-POHs. PAI requests that these restrictions be revisited and lifted to encourage more competition among physicians and between physicians and larger integrated health systems and hospitals, as well as increase patient choice for where and from whom they receive their care. Similarly,

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9 Avalon Health Economics Study.
10 British Medical Journal Article.
PAI recommends that the Department develop policies and implement APMs that encourage more physician leadership in APMs and APM entities (e.g., ACOs), providing equal opportunities for physician-led APMs and ACOs and ensuring that APMs are not by design health-system centric. Additionally, we believe this would contribute to addressing some of the vertical integration concerns discussed above.

State Certificate of Need (CON) Programs
State CON laws limit which entities can have imaging and certain surgical equipment. This restriction on who can provide certain services limits competition and resulting innovation in improvements in patient care. Furthermore, challenging CONs is often a costly process that creates a barrier for individual and small group practices who may have limited resources, even though winning exception to a challenged CON may be beneficial to improving patient care.

PAI Recommendation
PAI understands the historical intent and rationale for the development of CON laws as a tool to address overutilization. However, the current health care environment has evolved, and it is necessary to revisit these to ensure that they are still appropriate, such as in particular areas of care, given the needs of patients and system today and the desire to foster clinical integration.

APM Participation Requirements
Physicians and other clinicians face multiple challenges to APM participation, including the lack of understanding of the different models, what is specifically required of them individually and/or collectively as a group or entity, and how they would go about joining and participating in the different models, either directly or through an existing entity. Even when physicians can understand the models and requirements, the challenge then evolves into physicians and practices being able to successfully participate in the models and do so competitively with their peers.

An obstacle to successful participation in an APM is the ability for practices to meet the threshold participation requirements, which include, for example, meeting minimum patient alignment/attribution thresholds and taking on a minimum level of risk. Based on feedback PAI has heard from physicians, these minimum participation thresholds are often set too high for many practices, especially those in individual and small practices, preventing them from being able to competitively participate in APMs and contribute to reducing costs while improving the quality of care for patients. Additionally, the need for regulatory modernization, as highlighted, above is important to providing greater clarity and flexibility in regard to independent physician collaboration and participation in APMs.

PAI Recommendation
PAI believes that future enhancements of the QPP should include a reduction in complexity related to participation. In the context of this response, we encourage the Department to provide opportunities for physician collaboration in APMs, which promotes the ability of independent and small practices to collaborate and participate in these innovative, value-based payment models. Policies should also provide an “on-ramp” for these practices, allowing smaller practices to participate in risk- and value-based programs and APMs and compete on an equal footing rather than having smaller practices compete with highly-resourced larger practices or integrated systems/entities.

The Department should also ensure more detailed, step-by-step guidance and information is developed to better equip physicians and other clinicians with knowledge about collaborative arrangements in the APMs and APM entities available in their region and/or specialty, as well as how to join them. Additionally, it is
important to address laws and regulations that could be impediments or obstacles to participation in potential models, and that appropriate exemptions should be extended and applied (such as in the case of physicians participating in at-risk models), for example, anti-kickback or Stark Law exemptions.

**Limited Application of Antitrust Guidance**

More strategic application of antitrust laws may also increase competition in the health system, particularly in concentrated markets, while encouraging collaboration that improves patient care. The Federal Trade Commission (FTC) and Department of Justice (DOJ) issued a joint Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations (ACOs) Participating in the Medicare Shared Savings Program (MSSP). The policy statement intended to ensure that the necessary clarity and guidance was provided for ensuring the providers could form procompetitive ACOs. The policy statement also applies a rule of reason analysis to determine if an ACO is likely to have anticompetitive effects, and if so, whether its efficiencies are likely to outweigh the effects. However, this policy statement, which encourages the collaboration but also promotes competition, has been limited in its application.

**PAI Recommendation**

PAI encourages the agency to work with DOJ and the FTC to extend, as appropriate, the application of the policy statement and consider updating other guidance that would provide greater clarity and support of physicians seeking to collaborate in order to participate in value-based payment and APM arrangements. The lack of similar guidance applicable to models beyond the MSSP and broader collaborative opportunities, where related and similar antitrust issues might arise, is currently an obstacle to participation. It is important to take these actions so that physicians and practices can retain their independence while more readily operating under APMs and value-based payments on a joint-contracting basis, recognizing the pro-competitive benefits of these arrangements, and the encouragement of their creation across the public and private sectors.

**Conclusion**

Overall, PAI supports the Department’s efforts to address the anticompetitive policies, laws, and regulations currently in place. The associations represented on the PAI Board of Directors welcome the opportunity to work with the Department to advance policies that increase competition and choice in the health care market for patients and physicians. We reaffirm our belief that opportunities exist to improve the health system by enacting policies and modernizing antiquated regulations, which serve to foster innovative approaches to physician collaboration that will bring the benefits of competition to patients.

If you have any questions, please contact me at rseligson@ncmedsoc.org, or Kelly C. Kenney, PAI’s Executive Vice President and CEO, at k2strategiesllc@gmail.com.

Sincerely,

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