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John R. Graham
Acting Assistant Secretary for Planning and Evaluation
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Acting Assistant Secretary Graham:

On behalf of the physician and medical student members of the American Medical Association (AMA), we commend the Assistant Secretary for Planning and Evaluation (ASPE) at the U.S Department of Health and Human Services (HHS) for recognizing the need to promote competition and choice in health care markets and limit the excessive consolidation throughout the health care system.

The AMA strongly supports and encourages competition between and among health care providers, facilities, and insurers as a means of promoting the delivery of high quality, cost-effective health care. Providing patients with more choices for health care services and coverage stimulates innovation and incentivizes improved care, lower costs, and expanded access.

We appreciate the opportunity to provide our views regarding the barriers to choice and competition and to propose solutions that could facilitate the development and operation of a health care system that provides high quality care. Specifically, to promote choice and competition, we recommend:

- Eliminating state certificate of need laws;
- Repealing the ban on physician-owned hospitals;
- Reducing the administrative burden to enable physicians to compete with hospitals;
- Modernizing existing program integrity laws to allow for physician innovation; and
- Setting minimum standards to ensure patient choice and access to care.

Additionally, we believe that repealing the McCarran-Ferguson antitrust exemption for insurers would have little to no effect on choice or competition in health care markets.

Eliminating State Certificate of Need Laws

Many hospital markets are highly concentrated and noncompetitive.[1] Moreover, embedded hospital market concentration is fast becoming an intractable problem for which antitrust provides no remedy.[2]

[1] *See* Martin Gaynor and Robert Town, *The Impact of Hospital Consolidation-Update, the Synthesis Project*, Robert Wood Johnson Foundation (June 2012) ("Synthesis Project").
[2] *See e.g.,* Thomas Greaney, *The Affordable Care Act and Competition Policy*, 89 OR. L. REV. 811 (2011) ("Antitrust does not break up legally acquired monopolies or oligopolies.").

Fortunately, regulators can take steps to encourage new entry.[3] The AMA supports the removal of any harmful regulatory barrier to health care market entry that the government itself has erected. This would include the elimination of state certificate of need (CON) laws.

Thirty-five states currently maintain some form of a CON program. CON laws require that any health care entity planning to enter a health care market with a hospital, ambulatory surgical center (ASC), or many other types of facilities must be reviewed by a state agency and determined to be "needed." This applies to an entity's new entry and to entry by an existing entity offering a new service. According to the National Conference of State Legislatures, the existing CON programs concentrate activities on outpatient facilities and services that constitute an increasing segment of the health care market.[4]

Numerous studies have shown that CON laws have failed to achieve their intended goal of containing costs. Instead, CON has taken on particular importance as a way for community hospitals to claim territory and to restrict the entry of new competitors.[5] Consequently, CON laws lead to higher health care costs without improving health care quality.[6]

Community hospitals use CON to block the entry of freestanding, physician-owned facilities such as ASCs, that are a competitive threat. This is unfortunate because ASCs, as a class of provider, have been found in numerous studies of quality to have complication rates that are low and patient satisfaction that is high.[7] Also, a study published in *Health Affairs* concluded that ASCs "provide a lower-cost alternative to hospitals as venues for outpatient surgeries."[8] Physicians controlling Accountable Care Organizations and/or participating in value-based reimbursement programs could lower their costs, improve their quality, and become more competitive in the marketplace if they did not have to turn to their community hospital competitors for facility services. Physicians should have the ability to better control facility costs and supervise the overall health care product sold.

The principal criticism to physician-owned facilities has come from the hospital community, which argues that physician facility ownership leads to self-referral and overutilization. This concern has never been documented and has no application to today's marketplace that is transitioning to value-based care. Doctor-owners should be better able to take advantage of the new value-based incentives and derive better value than the lay-controlled existing hospitals in the marketplace.

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[3] *Id.*

[4] *See* National Conference of State Legislatures. *Certificate of Need: State Health Laws and Programs* (July 2014), available at http://www.ncsl.org/research/health/con-certificate-of-need-state-laws.aspx.

[5] *Id.;* Gaynor, Mostashari and Ginsberg, *Making Health Care Markets Work: Competition Policy for Health Care*, Carnegie Mellon University/Center for Health Policy, Brookings/USC Schaeffer Center for Health Policy and Economics (April, 2017) at 23 available at https://www.brookings.edu/research/making-health-care-markets-work-competition-policy-for healthcare/?utm_campaign=Economic%20Studies&utm_source=hs_email&utm_medium=email&utm_content= 50778822 (hereinafter "Brookings Competition Report'); Tracy Yee et al., *Health Care Certificate-of-Need Laws: Policy or Politics,* Research Brief 4, National Institute for Health Care Reform (May 2011).

[6] Mitchell, M. & Koopman, C. (2016), *40 Years of Certificate-of-Need Laws Across America*, Mercatus Center, George Mason University, available at https://www.mercatus.org/publication/40-years-certificate-need-laws-across-america; Stratmann, T., & David Wille, D. (2016), *Certificate-of-Need Laws and Hospital Quality,* Mercatus Center, George Mason University, available at https://www.mercatus.org/publications/certificate-needlaws-and-hospital-quality; Rivers, P. A., Fottler, M.D., & Frimpong, J.A., *The Effects of Certificate-of-Need Regulation on Hospital Costs*. Journal of Health Care Finance 36(4), 1–16 (2010); Ginsburg, P. B., *Wide Variation in Hospital and Physician Payment Rates Evidence of Provider Market Power,* Center for Studying Health System Change. HSC Research Brief No. 16. 94 (2010).

[7] *See* L. Casalino et al, *Focused Factories? Physician-owned Specialty Facilities*, Health Affairs 22(6): 56-67 (2003).

[8] *See* Munnich and Parente, *Procedures Take Less Time at Ambulatory Surgery Centers, Keeping Costs Down and Ability to Meet Demand Up*, Health Affairs 33(5): 764-769 (2014).

Competition requires competitors. By restricting the entry of competitors, especially physician-owned facilities, CON laws have weakened the markets' ability to contain health care costs, undercut consumer choice, and stifled innovation. Therefore, the AMA urges HHS to advocate for the elimination of state CON laws. States should be urged either to repeal their CON laws or allow them to sunset, as recommended by the Brookings Competition Report.[9]

Repealing the Ban on Physician-Owned Hospitals

The federal ban on physician-owned hospitals reduces and restricts competition and choice in health care markets. Prior to the enactment of the Affordable Care Act (ACA), physicians enjoyed a "whole hospital exception" from the Physician Self-Referral Law (also known as the Stark law). If physicians had an ownership interest in an entire hospital and were authorized to perform services there, physicians could refer patients to that hospital. However, provisions within the ACA eliminated the Stark exception for physicians who do not have an ownership interest as of December 31, 2010.[10] Furthermore, existing physician-owned hospitals cannot expand their treatment capacity unless certain restrictive exceptions can be met. In order to promote competition and choice in health care markets, the federal ban on physician-owned hospitals must be repealed.

The AMA believes physician-owned hospitals should be allowed to compete equally with other hospitals in the delivery system. Limiting the role of physician-owned hospitals only reduces access to high quality health care for patients. Physician-owned hospitals are a benefit to patients and their communities and represent the type of coordinated care that is needed for the future of health care delivery. These hospitals provide: patient access to the best quality health care available; tens of thousands of jobs nationally; and a local economic engine through property taxes and higher-wage jobs. Furthermore, the presence of physician-owned hospitals has not had an impact on the financial viability of surrounding hospitals showing no effect on inpatient volumes, revenues, or profits.[11]

Physician-owned hospitals can also serve the role of adding much-needed competition into the hospital market. Hospitals continue to merge and consolidate. For example, during one week in December 2017: Advocate Health Care and Aurora Health Care announced a merger that creates a $10.8 billion dollar system in Illinois and Wisconsin; Catholic Health Initiatives and Dignity Health formalized a deal with an annual revenue of $28.4 billion; and Ascension Health and Providence St. Joseph merged to create a health system with an annual revenue of $44.8 billion.[12] Hospital mergers and consolidation generally results in higher prices. This is true across geographic markets and different data sources. When hospitals merge in already concentrated markets, the price increases can be dramatic, often exceeding 20 percent.[13] Thus, the appropriate role of physician-owned hospitals includes having physician-owned hospitals act as a true competitor with other hospitals. Competition forces traditional hospitals to improve and innovate.

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[9] Brookings Competition Report, *supra* note 5.
[10] ACA § 6001 (42 U.S.C. § 1395nn)
[11] D M Blumental, *Access, quality, and costs of care at physician owned hospitals in the United States: observational study*, British Medical Journal (2015), available at https://doi.org/10.1136/bmj.h4466.
[12] Alex Kacik, *Health care Mega-Mergers Dominate 2017,* Modern Health care (Dec. 26, 2017), available at http://www.modernhealth care.com/article/20171226/NEWS/171229957/health care-mega-mergers-dominate-2017.
[13] Martin Gaynor & Robert Town, *The Impact of Hospital Consolidation – Update*, Robert Wood Johnson Foundation (June 2012), available at http://www.rwjf.org/content/dam/farm/reports/issue_briefs/2012/rwjf73261

This benefits patients and the health care system as we work to improve care. In addition, in physician-owned hospitals, physicians—who are fundamentally responsible for the existence of the hospital and the maintenance of its standards—can manage hospital costs through innovation and improved efficiency, which increases value. Physician-owned hospitals already are more likely to have operating rooms that they use more efficiently than traditional hospitals.[14] Physician-owned hospitals are also more engaged in general medical and surgical care than other hospitals.[15] Accordingly, by lifting the ban and allowing physician-owned hospitals to compete with other hospitals, the delivery system benefits by increasing competition and patient choice.

The current restrictions on physician-owned hospitals have also had a negative effect on health care delivery and patient choice. The restrictions on physician-owned hospitals have effectively eliminated the formation of new hospitals and additional choices for patients to receive quality care. For example, the restrictions resulted in freezes on the construction and expansion of 45 partially completed physician-owned hospitals.[16] In Texas, 13 physician-owned hospitals were formed after enactment of the ACA; however, because of the restrictions; they did not accept any Medicare or Medicaid patients.[17] Currently, all of these physician-owned hospitals have either been sold or are part of bankruptcy filings.[18]

The restrictions on physician-owned hospitals are without merit and have no valid justifications. Physician-owned hospitals provide better or same quality care at the same costs as other hospitals and do not cherry pick or lemon drop patients. Several studies have shown high levels of quality care and patient satisfaction in physician-owned hospitals. Recently, the *British Medical Journal* found that physician-owned hospitals performed comparably with other hospitals on both disease specific and composite measure of mortality, congestive heart failure, readmissions for myocardial infarction, and pneumonia.[19] Studies have also shown that these hospitals provide more net community benefits through uncompensated care and taxes than not-for-profit competitors as a share of total revenues.

Accordingly, physician-owned hospitals should play an integral role in the delivery system as a true competitor with no restrictions. The inability of physician-owned hospitals to address the growing demand for high quality health care services in their community is bad for the entire health care market and does nothing but penalize patients who should have the right to receive care at the hospital of their choice. Thus, the federal ban on physician-owned hospitals should be repealed.

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[14] Elizabeth Plummer & William Wempe, *The Affordable Care Act's Effects on the Formation, Expansion, and Operation of Physician-Owned Hospitals*, Health Affair 35, no. 8 (2016), available at http://content.healthaffairs.org/content/35/8/1452.full.pdf+html.

[15] *Id.*

[16] D M Blumental, *Access, quality, and costs of care at physician owned hospitals in the United States: observational study*, British Medical Journal (2015), available at https://doi.org/10.1136/bmj.h4466.

[17] Elizabeth Plummer & William Wempe, *The Affordable Care Act's Effects on the Formation, Expansion, and Operation of Physician-Owned Hospitals*, Health Affair 35, no. 8 (2016), available at http://content.healthaffairs.org/content/35/8/1452.full.pdf+html.

[18] *Id.*

[19] D M Blumental, *Access, quality, and costs of care at physician owned hospitals in the United States: observational study*, British Medical Journal (2015), available at https://doi.org/10.1136/bmj.h4466.

Reducing the Administrative Burden to Enable Physicians to Compete with Hospitals

Mounting administrative burdens raise the fixed cost of practice, making it harder for smaller practices to compete.[20] The AMA applauds HHS' and CMS' commitment to reducing physicians' administrative burden by focusing on patient-centered care and working with physicians to improve outcomes. Physicians are overburdened with paperwork, electronic health record documentation, and bureaucratic "administrivia," such as obtaining prior authorization, and these administrative burdens are a major factor in why physicians are pushed to give up independence in exchange for health system employment where physicians can obtain clerical help to address these burdens. This, concludes the Brookings Competition Report, leads to market consolidation and a decrease in the number of physician practices—precisely the type of adverse impact that the Regulatory Flexibility Act, 5 USC § 601 seeks to avoid.[21]

The Brookings Competition Report rightly observes that "policy changes are needed to reduce unnecessary administrative burdens, both because those steps may produce direct savings but also because they will increase competition by making it more feasible for physician practices to remain smaller or independent."[22]

Prior authorization and other utilization management programs can create significant barriers for patients by delaying the start or continuation of necessary treatment and negatively affecting patient health outcomes. Additionally, the very manual, time-consuming processes used in these programs burden physicians and other health care providers and divert valuable resources away from direct patient care.

A survey conducted by the AMA last year showed that 75 percent of surveyed physicians described prior authorization burdens as high or extremely high, and more than a third of surveyed physicians reported having staff who work exclusively on prior authorization. Physician practices on average complete 37 prior authorizations per physician per week, representing 16 hours or two full business days of clinician and staff time. For physician practices, particularly smaller ones, managing these administrative burdens can be unsustainable.

The AMA, in collaboration with other physician, hospital, pharmacist, and consumer organizations, has developed a set of principles that are reasonable in scope, but would significantly reduce the burden of prior authorization on both patients and physicians. Among other policy changes, these principles encourage the use of accurate and up-to-date clinical criteria as the basis for prior authorization requirements, streamlined appeals processes, transparency of program requirements, advanced notice of changes, and the use of electronic prior authorization using standard transactions. The AMA encourages HHS to consider reducing the impact of prior authorization and other administrative burdens on physicians via such policy changes to help ensure the viability of small physician practices and improve patient access to care.

We also have a host of other regulatory relief concerns that would reduce the regulatory burden for physicians, while also simplifying the health care system and ensuring patients receive optimal care.

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[20] Brookings Competition Report, *supra* note 5 at 23.
[21] *Id.* at 12-14.
[22] *Id.* at 13.

Modernizing Existing Program Integrity Laws to Allow for Physician Innovation

The AMA believes that clarification of the Anti-kickback Statute, the Physician Self-Referral Law (also known as the Stark Law), and the Civil Monetary Penalties (hereinafter "program integrity laws") would help promote choice, competition, and innovative arrangements that pose little risk of fraud and abuse. We urge HHS to examine ways to modernize existing laws and requirements to reflect a more coordinated approach to delivering care while not limiting choice and competition.

Indeed, in its proposed rule on the 2016 Medicare Physician Fee Schedule, the Centers for Medicare & Medicaid Services (CMS) explicitly recognized stakeholder concerns regarding the impact of the self-referral regulations on health care delivery and payment reform. As CMS noted, significant changes in health care delivery and payment have occurred since the enactment of the self-referral law, including numerous initiatives to align payment under Medicare, Medicaid, and non-federal programs with the quality of care delivered. Physician leadership in these new efforts is instrumental to optimizing care, improving population health, and reducing costs.

Programs run by the Center for Medicare and Medicaid Innovation (CMMI) pose little risk of fraud and abuse because they have built-in safeguards, including careful monitoring by CMS. For CMMI's programs to succeed, physicians and other participants need to fully assess how care can and cannot be provided to patients. Without bright line guidance, program integrity provisions can deter the adoption of payment and delivery reforms and lead to more consolidation. Currently, CMMI has addressed the applicability of fraud and abuse laws through the contract process on a case-by-case basis. Program applicants therefore do not have up-front guidance regarding the challenges and restrictions that will apply.

However, outside of models for where CMS and the Office of Inspector General have explicitly established waivers of the federal program integrity laws, physicians may be wary of pursuing participation in innovative delivery and payment models due to real or perceived prohibitions under the compensation standards of the self-referral regulations. In particular, the narrowness of the self-referral exceptions with respect to physician compensation arrangements can make it exceedingly difficult to structure incentive payments tied to quality improvement criteria. In fact, the Government Accountability Office has found that stakeholders' concerns about the legal framework for program integrity "may hinder implementation of financial incentive programs to improve quality and efficiency on a broad scale." Relatedly, existing safe harbors and exceptions like bona fide employment may lead to further consolidation of the health care market which limits choice and competition.

Unfortunately, the fraud and abuse waivers for physicians who participate in the alternative payment models are overly narrow. The AMA believes that lawmakers and regulators should consider expanding these exemptions to encourage other forms of innovative delivery and payment models to help promote choice and competition. More options and flexibility are needed to encourage physician-led value-based arrangements on a wider scale. While waivers minimize fraud and abuse exposure, they only apply to participants of the particular payment and may have fact-specific technical requirements that are difficult to meet.

Furthermore, among the greatest regulatory and compliance burdens placed on small physician practices are those imposed by existing program integrity laws and requirements that CMS administers. Many of these program integrity requirements were aimed at preventing overutilization in a predominantly

fee-for-service marketplace where that abuse may have been a reasonable concern. However, value-based payment is replacing fee-for-service as the customary reimbursement mode, which rewards value or quality of care provided over the volume of services.

The AMA has continually advocated that HHS set forth clear and commonsense fraud and abuse rules concerning the formation of innovative delivery models so that physicians can pursue integration options that are not hospital driven. Physicians should not have to become employed by a hospital or sell their practice to a hospital in order to participate in innovative delivery models. Ultimately, physicians should be able to maintain their independent practices while at the same time have access to the infrastructure and resources necessary to participate in alternative payment models.

Therefore, to promote choice and competition, the AMA recommends that HHS:

- Create new exceptions or safe harbors to facilitate coordinated care and promote value-based reimbursement. These exceptions or safe harbors should be broad, cover both the development and operation of a value-based arrangement, and provide adequate protection for downstream entities and manufacturers who are linking outcomes and value to the services or products provided.
- Publish up-front guidance regarding the waiver of federal program integrity laws for physicians participating in programs developed by the CMMI. More explicit and predictable guidance on when an arrangement will or will not prompt action under the fraud and abuse laws could have the dual effect of safeguarding against patient or program abuse while facilitating choice, competition, and desired delivery system reform.
- Consult the AMA and the state and specialty societies in examining ways to modernize existing program integrity laws and requirements that the Department administers to reflect a more coordinated approach to delivering care.

Setting Minimum Standards to Ensure Patient Choice and Access to Care

The AMA supports the role of states in serving as the primary regulators of the business of health insurance and is frequently supportive of proposals that allow state flexibility in determining the most effective and comprehensive way to deliver care. However, the AMA also supports a strong federal role in setting minimum standards on which states can build patient protections and ensure that patients are able to access the care they need.

For example, to increase choice and competition, a federal floor for network adequacy requirements is needed for patients. While many states have network adequacy requirements in place, most are insufficient to address the needs of patients in this new environment of very narrow and tiered networks. This insufficiency has led regulators, including the National Association of Insurance Commissioners, legislators, patient groups, provider organizations, and many other stakeholders to push for changes to network adequacy requirements in the states. While a few states have been successful in making meaningful changes to address narrower networks, most states have not acted. Initially, CMS recognized the immediate need for stronger federal direction and established a minimum federal standard for network adequacy that included quantitative, measurable standards. Such action by CMS created a strong but workable basis for network regulation and a starting point for state action; but unfortunately, CMS quickly removed that floor. As a result, patients continue to face access issues as many states fail to meaningfully measure the ability of networks to meet patients' needs.

In addition, a primary purpose of regulations governing the individual and small-group markets to date is to help ensure that insurers are competing and operating on an even playing field in which all insurers and plans must play by the same rules. The AMA stresses that exchanges need to offer patients with choices to spur competition, and would be concerned with any proposals that cause a race to the bottom in terms of benefits offered and covered, therefore contributing to instability in the individual and small-group ACA markets. Mechanisms to facilitate competition in health insurance should ensure critical patient protections remain in place, including the ban on pre-existing condition exclusions, as well as critical cost protections guaranteed in the ACA, e.g., the annual cap on out-of-pocket costs and the ban on annual and lifetime limits, which are linked to the definition of essential health benefits (EHBs). For example, a benefit within a required benefit category that is no longer considered to be an essential benefit would no longer be protected under the out-of-pocket cost cap or the annual and lifetime limits. The AMA believes that using the current benchmark approach to EHBs, while requiring 10 categories of EHBs, strikes a balance between offering meaningful coverage and maintaining patient choice in health plans and their respective benefits packages, while allowing for appropriate state variation.

Finally, an important federal role remains to ensure that proposals to promote competition in health insurance promote ACA marketplace stability, a balanced risk pool, and not lead to adverse selection in the marketplace. Consideration should be taken in any proposals moving forward to not divide the individual and small-group markets between healthier consumers being drawn to skimpier plans, and individuals with health needs being drawn to plans following ACA requirements and offering more comprehensive coverage. Such a division in the market could result in rising—in some cases, unaffordable—premiums for those individuals who want to buy more comprehensive coverage. In addition, plans that do not offer meaningful coverage have the potential to cause significant financial exposure for patients. Health insurance must provide meaningful coverage for hospital, surgical, medical and behavioral care; protect patients against catastrophic expenses; and promote preventive services. Federal regulation plays a critical role ensuring that baseline.

Repealing McCarran-Ferguson has No Impact

The McCarran-Ferguson Act is the federal law authorizing state regulation of insurance. It specifically preempts federal laws that would "invalidate, supersede, or impair" such state laws. It also provides a limited federal antitrust exemption for the business of insurance, subject to state regulation and oversight, for activities such as joint collection of actuarial data. It does not exempt insurance companies from the antitrust laws in the context of anti-competitive business practices such as boycott, coercion, or exercise of monopoly or monopsony power.

In identifying federal laws that reduce or restrict competition, other stakeholders may reference or call for the repeal of McCarran-Ferguson. The AMA believes that repealing this antitrust exemption for insurers would have little to no effect on choice or competition in health care markets. For instance, repealing this exemption would have no effect on the antitrust barriers that hinder physicians' ability to collectively negotiate with health insurers.

Moreover, health insurer consolidation activity, health insurer and provider contract issues, provider arrangements, peer review, fixed benefits schedules, fee schedules, bid rigging, insurance reimbursement, claims handling, and settlement all fall outside the scope of the antitrust exemption. Furthermore, the Congressional Budget Office estimates that the repeal of McCarran-Ferguson will have no significant net effect on premiums that insurers would charge and that increased costs for any federal government

enforcement would be less than $500,000.[23] Therefore, repealing McCarran-Ferguson would have little to no impact in promoting choice or competition in the health care markets.

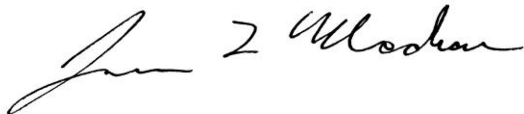
Conclusion

Competition and choice play major roles in enabling consumers to access the high quality care they deserve at a reasonable cost. We strongly believe that further erosion of competition in health care markets is not in the best interests of patients or physicians. The AMA applauds ASPE's efforts to examine health care industry consolidation and enhance access, choice, and quality through improved competition.

We recommend that ASPE publicly post all of the comments it receives in response to this Request for Information and also detail its reaction and responses to those comments. If there are barriers that ASPE faces in implementing ideas, we would encourage the agency to inform stakeholders about those barriers and seek help in overcoming them.

Thank you for the opportunity to comment. If you have any questions, please contact Margaret Garikes, Vice President for Federal Affairs, at margaret.garikes@ama-assn.org or call 202-789-7409.

Sincerely,



James L. Madara, MD

[23] Congressional Budget Office, *H.R. 372 Competitive Health Insurance Reform Act of 2017*, (Mar. 10, 2017), available at https://www.cbo.gov/sites/default/files/115th-congress-2017-2018/costestimate/hr372.pdf.