January 25, 2018

Alex Azar  
Secretary  
U.S. Department of Health and Human Services  
Hubert H. Humphrey Building  
200 Independence Avenue, S.W.  
Washington, D.C. 20201

RE: Request for Information on the Promotion of Health Care Choice and Competition across the United States

Dear Mr. Azar:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, 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, the American Hospital Association (AHA) appreciates the opportunity to comment on the request for information (RFI) regarding barriers to choice and competition and proposed solutions to facilitate the development and operation of a health care system that provides high-quality care at affordable prices for the American people.

The AHA supports competition and choice in the health care system as a means to facilitating patient access to high-quality, affordable care and coverage. Because the availability of coverage and care is at risk in some communities, we also recommend ways to improve access as a precedent to choice and competition. We organize our recommendations into two categories: ensuring choice and competition of health plans and ensuring choice and competition of providers.

Specifically, the AHA recommends the following actions to reduce barriers to choice and competition in order to facilitate patient access to high-quality coverage and care at affordable prices.
Ensuring Choice and Competition of Health Plans

Consumers benefit when health plans compete – coverage is more affordable and consumers are more likely to find a product that meets their needs. Choice, however, should not come at the expense of quality. In order to be a true option, coverage must be comprehensive and broadly available. The AHA recommends the following actions to improve choice and competition of health plans while retaining important consumer protections.

Support Greater Oversight of Health Plan Mergers. The U.S. health insurance markets are highly concentrated, and the lack of competition can harm both patients and providers. The American Medical Association recently updated its annual analysis of competition in health insurance markets and found that 69 percent of the 389 markets studied were highly concentrated, and in 89 percent of markets, one insurer had at least 30 percent of the commercial market share. Such market concentration can result in fewer health plan choices and higher costs for consumers.

Lack of competition also can harm consumers by stymying provider efforts to improve the quality and efficiency of care. Our members have found that, in some markets, insurers with considerable market share are less motivated to work with providers’ on care delivery and payment innovations.

Last year, the courts recognized these concerns and blocked the proposed acquisitions involving four of the five major U.S. health insurance companies (Aetna’s proposed acquisition of Humana and Anthem’s proposed acquisition of Cigna). The court recognized that the purported benefits of these health insurance mega-mergers did not outweigh the likely harm to competition or consumers.

The AHA urges HHS to take a more active role providing expert advice to the federal antitrust agencies to assist them in evaluating the impact of health insurance deals on Medicare and Medicare Advantage (MA) patients.

Strengthen the Health Insurance Marketplaces. More than 10 million Americans rely on the Health Insurance Marketplaces for health coverage. While all marketplaces have at least one plan in 2018, some markets are not yet stable with volatility in health plan participation and double-digit premium increases. A number of factors have contributed to this instability. In some cases, demographic factors, such as a small population base and disproportionately unhealthy population, can make a market unattractive to health plans. The federal and state regulatory structure also plays a critical role. Most recently, the Administration’s decision to end the cost-sharing reduction subsidies and Congress’s repeal of the individual mandate to purchase health insurance will likely lead to both health plan exits and higher premiums for the 2019 plan year and beyond. Without further action, these market forces and policy decisions together will decrease affordable options for

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individuals purchasing marketplace coverage and it is possible that some communities will not have access to any coverage through the marketplace.

The AHA is committed to protecting this vital source of coverage, and we urge the Administration and Congress to take action to stabilize the marketplaces. Specifically, we recommend that the Administration, working with Congress as needed:

- fund the cost-sharing reduction subsidies to reduce premiums;
- create a federal reinsurance program to attract insurer participation and reduce premiums;
- ensure that the risk-adjustment program does not decrease competition and choice by disadvantaging smaller plans and new entrants;
- ensure stable risk pools and more affordable choices by disallowing the sale of health plans that do not comply with the consumer protections established by the Affordable Care Act, such as prohibitions against medical underwriting and pre-existing condition exclusions, and the essential health benefit package;
- increase enrollment to attract insurers by investing more in outreach and enrollment; and
- support state-level approaches to address market-specific challenges to stabilization.

For more information on these recommendations, please see an AHA fact sheet on Marketplace Stability & Fallback Options.

**Ensuring Choice and Competition of Providers**

Patients want and should have access to high quality providers they know and trust. Our recommendations focus on how to ensure that patients can see their preferred providers, as well as how to support those providers in organizing and delivering services in ways that improve access to and quality of care.

**Ensure Adequacy of Provider Networks and Directories.** Coverage alone is insufficient to ensure patient choice of preferred providers. The AHA supports minimum provider network adequacy standards for health plans in all markets – Medicaid, Medicare and private insurance. We have long advocated that health plans maintain provider networks sufficient in number and types of providers, including providers that specialize in mental and behavioral health and substance abuse services, to ensure that all services are accessible without unreasonable delay for both adults and children.

The AHA, in general, supports the use of time and distance standards for provider networks. However, we encourage CMS to allow for special circumstances for the unique medical needs of children and adults with complex and chronic medical conditions, as well as an exceptions process for networks of providers who are working together in an integrated approach to improve access, quality and efficiency. Provider network adequacy standards should include such elements as geographic location of providers, the health
needs of the population, the numbers and types of health providers, the availability of providers to accept new patients, and the need for special accommodations for patients who are disabled or who have limited English proficiency.

Moreover, consumers need updated provider directories to identify which providers are in their networks. The AHA supports requiring health plans to maintain and update provider directories and make the directories available in electronic and/or paper form. The obligation and responsibility for maintaining and updating the provider directories lies with the health plans. As such, managed care plans should be required, as a condition of their contract, to update periodically their directory by proactively reaching out to the providers in their network to confirm the currency of the information.

**Provide Accurate Information on Providers to Support Patient Choice.** Patients, families and communities deserve accurate, clear and meaningful quality information to help them make important health care choices. The AHA has long supported quality transparency and continues to share CMS’s goal of making the data on Hospital Compare easier for consumers to understand and use. Unfortunately, the flawed approach taken in CMS’s hospital star ratings undermines this goal by providing an inaccurate, misleading picture of hospital quality. While the Dec. 2017 update of star ratings corrected some important calculation errors, we continue to have significant concerns about the conceptual underpinnings of the star ratings. The measures included in the ratings were never intended to create a single, representative score of hospital quality. Furthermore, the ratings often do not reflect the aspects of care most relevant to a particular patient’s needs.

In order to help consumers make the best choices for their care, the AHA urges the Administration to suspend star ratings from the Hospital Compare website and to work with the hospital field, consumers and others to develop a more sound approach to reporting quality information.

**Ensure Availability of Critical Health Care Services in All Communities.** Millions of Americans live in communities where access to critical health care services is at risk. Rural hospitals often struggle with their remote location, limited workforce and constrained resources. Inner-city urban hospitals often struggle to achieve financial stability while pursuing their charitable mission. The loss of such a critical health care access point could be devastating to the individuals living in these vulnerable communities, and the concern for them is only growing as significant pressures on the health care sector continue. As communities grapple with the challenge of maintaining access to health care services, it will be necessary for payers and health care providers to work together to develop alternative payment and delivery strategies that support the preservation of health care services. An AHA task force report identified nine options communities may explore based on their unique needs, support structures and preferences. In addition to these options, the task force identified federal policies that serve as barriers to successful implementation of these strategies. These include, but are not limited to, fraud and abuse laws and Medicare payment rules, as discussed elsewhere in our comments.
We encourage the Administration to work with Congress to eliminate barriers so that communities may successfully implement new, innovative strategies to retain access to essential services in vulnerable communities. For more information, please see the AHA’s report on preserving access to care in vulnerable communities.

Support Patient Access through Enhanced Care Coordination and Delivery. Providers are working to improve the quality of care and patient access to services. These efforts include redesigning how care is delivered to increase access points, improve care coordination and meet patient needs and preferences. These delivery system strategies require that hospitals, physicians and other providers move out of silos and into collaborative clinical integration arrangements. In developing such approaches, providers often encounter impediments caused by outdated regulations, gaps in technology, or other barriers that the Department of Health and Human Services (HHS) could help address. The AHA specifically recommends that:

- CMS provide hospitals participating in clinical integration arrangements with maximum flexibility to identify and direct beneficiaries to the clinical setting that best serves their short- and long-term recovery goals. This includes providing waivers of, for example, the inpatient rehabilitation facility (IRF) “60 percent rule,” the inpatient rehabilitation facility “three-hour rule,” the long-term care hospital 25 percent rule, and the home health homebound rule.

- The Office of the Inspector General (OIG) create Anti-Kickback safe harbors for clinical integration arrangements and for providing the assistance patients need to achieve and maintain health; and CMS create a Stark regulatory exception for clinical integration arrangements. Hospitals cannot succeed in their efforts to coordinate care, participate in new payment models, and maintain secure information exchange with community partners because of outdated regulations, such as the Anti-Kickback Statute and the “Stark” law.

Hospitals and other providers are now more accountable than ever for financial and patient outcomes across the entire spectrum of care, and this collective accountability requires hospitals, physicians, and other providers to work together in new ways. They must be able to financially align themselves with shared incentives, shared resources, seamless technology and pooled information. However, current laws impede innovation. The principal obstacle to innovation is an overly complex legal framework grounded in the increasingly outdated fee-for-service payment structure. Hospitals and physicians cannot safely partner on innovative programs unless the arrangement meets highly technical requirements of both an exception under Stark Law and safe harbor under the Anti-Kickback Law. However, the core requirements of existing laws are not in sync with collaborative models that reward value and outcomes.

In addition, hospital responsibility for patient care no longer begins and ends in the hospital setting or any other site of care provided by the hospital. Supporting the
well-being of a person in the community requires more than direct patient care. It includes encouraging, supporting or helping patients access care, or making it more convenient. It also includes removing barriers or hurdles for patients as well as filling gaps in needed support. However, current laws impede hospitals from providing such assistance. The general prohibition on providing anything of value to “induce” the use of services paid for by the Medicare program also applies to assistance to patients.

Advance Interoperability among Providers and Patients. Patient choice is enhanced when health information can be shared seamlessly across different providers. The creation of a nationwide approach to efficient and effective sharing of health information is also central to the efforts of hospitals and health systems to provide high-quality, coordinated care, support new models of care and engage patients in their health. For the end-users of health IT systems, the goal of exchange is simple: to connect once to the exchange network of their choice, which then becomes a gateway to all of the other networks that may have information pertinent to the care of an individual or a population shared seamlessly across different providers and with individuals.

We recognize that today’s health information exchange landscape is comprised of a complex set of existing networks that include large national networks, regional and state networks, and networks maintained by individual electronic health record vendors. Some of the networks are already working to connect. And, importantly, there are also initiatives that have frameworks in place to connect across networks.

The AHA encourages the Office of the National Coordinator for Health IT (ONC) to avoid disrupting existing, working exchanges and focus on creating a more seamless network-of-networks approach. Specifically, ONC should work with the private sector to accelerate connectivity across platforms. The provider community has a sense of urgency to accomplish this work, but also understands that starting from scratch would likely create even more delays than working to align existing efforts.

Increase Access and Choice through Expanded Coverage of Telehealth Services. Telehealth connects patients to vital health care services through videoconferencing, remote monitoring, electronic consults and wireless communications. Telehealth strategies offer a wide-range of benefits that promote choice among care treatment options, including around-the-clock access to physicians, specialists and other health care providers that otherwise would not be available in many communities; and less expensive and more convenient care options for patients. Value-based care requires telehealth.

There are many barriers impeding wide use of telehealth, including statutory restrictions on how Medicare covers and pays for telehealth. In addition, limited access to adequate broadband services, as well as the infrastructure costs for establishing adequate and reliable connectivity, hamper the ability of some facilities to deploy telehealth. The challenge of cross-state licensure looms as a major issue. Other policy and operational issues include credentialing and privileging, online prescribing, privacy and security, and
fraud and abuse. To promote more convenient treatment options as well as patient access to those options, it is imperative that the federal government modernize the telehealth rules.

The AHA urges Congress to expand telehealth capacity by establishing a grant program to fund telehealth start-up costs. We further urge removal of Medicare’s limitations on telehealth by:

- eliminating geographic and setting requirements so patients outside of rural areas can benefit from telehealth;
- expanding the types of technology that can be used, including remote monitoring; and
- covering all services that are safe to provide, rather than a small list of approved services.

Additionally, the government could promote the adoption of telehealth care options by factoring into reimbursement the nursing and other costs incurred at the site where the patient is located (the originating site) and resolving legal and regulatory challenges that hinder the provision of telehealth services.

**Facilitate Greater Competition and Choice in Drug Therapies.** The high and rising prices for prescription drugs has reduced patient access to care. Competition for prescription drugs generally results in increased patient options for lower cost therapies, particularly through the introduction of one or more generic competitors. The AHA recommends that HHS continue to increase the introduction of generic alternatives and discourage anti-competitive tactics while maintaining incentives for the development of innovative new therapies. Specifically, we recommend that HHS:

- Fully resource the Food and Drug Administration (FDA) review and approval offices for generic drugs and biosimilars.
- Fast-track generic applications when no or limited generic competition exists and incentivize generic manufacturers with fast-track voucher rewards.
- Deny patents for “evergreened” products.
- Deem “pay-for-delay” tactics to be presumptively illegal and increase oversight.
- Limit orphan drug incentives to true orphan drugs.
- Investigate potential abuses of the Risk Evaluation and Mitigation Strategies (REMS) program that prevent generic manufacturers from accessing sufficient samples for purposes of bioequivalency testing or from participating in safety protocols.
- Disallow co-pay assistance cards that steer patients towards higher-cost drugs.

More information on our specific policy recommendations to achieve sustainable drug pricing can be found [here](#).

Thank you for your focus on this critical issue. Please contact me if you have questions or feel free to have a member of your team contact Molly Smith, vice president of coverage and state issues, at [mollysmith@aha.org](mailto:mollysmith@aha.org) or (202) 626-4639.
Sincerely,

/s/

Thomas P. Nickels
Executive Vice President
Government Relations and Public Policy