

July 9, 2018

Alex M. Azar, II
Secretary of Health and Human Services
U.S. Department of Health and Human Services
200 Independence Ave SW
Washington, DC 20201

RE: RFI Regarding Healthcare Sector Innovation and Investment Workgroup

Dear Secretary Azar:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, and our clinician partners – including more than 270,000 affiliated physicians, 2 million nurses and other caregivers – and the 43,000 health care leaders who belong to our professional membership groups, the American Hospital Association (AHA) appreciates the opportunity to respond to the Department of Health and Human Services' (HHS) Request for Information (RFI) regarding the facilitation of a public-private dialogue to increase innovation and investment in the health care sector.

With this RFI, HHS seeks comment on the development of a workgroup to facilitate constructive, high-level dialogue between HHS and those focused on innovating and investing in the health care field. Specifically, HHS requests input on who should participate in such a workgroup and on what issues the workgroup should focus, as well as any broader opportunities to increase the engagement and dialogue between HHS and health care innovators and investors.

The AHA strongly supports HHS's efforts to bring together a wide range of stakeholders to spur innovation and investment and increase competition to advance patient care. Hospitals and health systems are a key contributor to health care innovations, through not only the development of breakthrough clinical advancements but also in the use of precision medicine, predictive analytics, artificial intelligence (AI) and other technological advancements. Moreover, in the past few years, several hospitals and health systems have launched their own investment funds to seed the innovations that traditional health care investors overlook. Given hospital and health system engagement in innovation and investment, we urge HHS to include hospital representation on the workgroup. We would welcome the opportunity to convene with health care innovators and investors to share ideas, best practices, and challenges, and the proposed workgroup would provide an ideal forum for doing so.



The comments below are intended to help HHS build the agenda and structure of the workgroup and, in doing so, increase the impact of innovation and investment on the health and well-being of all Americans.

AREAS OF FOCUS FOR INNOVATION AND INVESTMENT

Over the past few years, innovation in health care, and the opportunity to scale that innovation, has grown increasingly complex, as have the barriers to rapid diffusion of innovations across the country. The AHA's members, including rural, safety-net, academic and community providers, all face a diverse set of priorities and challenges, impacted not only by their organizational structure, but also by the unique communities and populations they serve. This diversity of experience demonstrates the importance of avoiding "one-size-fits-all" approaches to innovation or investment. **We urge HHS to consider the areas of focus we have outlined below and use these ideas to tailor an investment and innovation program to the variety of providers and patients that comprise our nation's health care system.**

Establishing provider-innovator partnerships. **We urge HHS to include on the workgroup agenda a focus on establishing new mechanisms to foster provider-innovator partnerships to expand innovation in health care and attract investment in those arrangements.** A number of hospitals and health systems are engaging in innovative partnerships with private entities. For example:

- Geisinger Health has a partnership with Regeneron Pharmaceuticals to conduct a research program to sequence certain parts of patients' DNA with their consent. Regeneron uses de-identified medical records linked to genetic code for drug discovery research, and Geisinger patients and doctors receive a notification if the sequencing shows results that could lead to different medical care.
- Intermountain Healthcare has a Healthcare Transformation Lab through which it facilitates cooperation between key innovators in the health care sector and front-line providers to create solutions to clinical and other challenges.
- Jefferson Health has formed an innovative arrangement with GE Healthcare, which involves an eight-year, shared-risk relationship that will focus on removing redundancies and maximizing sourcing efficiencies. This arrangement has the potential to generate significant efficiencies that can be directed toward services that best meet patient needs.

HHS also could consider the opportunity that venture funds provide to drive public-private partnerships. Some health systems are already partnering with other organizations to create venture funds that invest in life sciences, technology and other companies, driving long-term value for patients and the systems that serve them. Venture funds also can act as a regional strategy to improve the health and well-being of specific communities, opening a pathway for new relationships across state lines that could bring innovation to patients who have not yet benefited.

In determining its focus, we urge the workgroup to draw from these and other examples by inviting a range of providers, innovators and investors to share their ideas and perspectives on how changes to regulations and guidance could create a pathway for innovation to spread. We also recommend that the process and strategic actions of the workgroup draw from, and are consistent with, the guiding principles in the RFI released by the Centers for Medicare and Medicaid Innovation around the future of that agency's work in payment and delivery models.

Establishing level playing fields. **In addition, the AHA strongly urges HHS to include in workgroup discussions a focus on the barriers to innovation and competition in the health care field.** Regulatory requirements set a baseline for consumer protection and safety and serve an important purpose in establishing minimum expectations. However, in some cases, these same requirements can slow needed innovation, as well as prevent hospitals, health systems, and post-acute care (PAC) providers from enhancing consumer experiences, improving care coordination and increasing use of technology. Regulatory requirements that differ for hospitals, health systems, and PAC providers and new entrants into the health care sector also create an un-level playing field, hampering innovation by health care providers and exposing consumers to new risks.

We urge the workgroup to address the following areas that pose legal and regulatory hurdles to innovation or place different requirements on new entrants as compared to established health care organizations:

- **Fraud and abuse requirements.** While some advanced payment models include waivers, there is still a need to remove barriers to care transformation, such as creating a “safe harbor” under the Anti-Kickback Statute and reforming the Stark Law and certain Civil Monetary Penalties to foster and protect arrangements that promote value-based care.
- **Limitations on the use of telehealth.** Virtual connections can create convenience and ensure access to specialists in areas with shortages. While providing waivers for some advanced payment models, Medicare still limits the locations, services, and technology that it will pay for telehealth. And, variations in state licensure requirements create an expensive administrative burden when providing care across state lines.
- **Billing requirements.** The billing process can be difficult for consumers. However, improving the billing process requires collaboration with payers and the government to streamline steps such as benefits determination and prior authorization, and create a more consumer-friendly experience.
- **Accreditation standards.** The conditions of participation need to be streamlined and modernized to focus on compliance with requirements that are essential to achieving better outcomes for patients.

- **Interoperability.** We encourage the new Centers for Medicare & Medicaid Services (CMS) Chief Health Informatics Officer to play an important role as a liaison between the agency and the private sector. This individual will be important in developing the public-private partnerships that can develop and spread innovation.
- **Privacy rules.** Analytics and AI are expected to fuel innovation and care coordination in the coming years. However, the Health Insurance Portability and Accountability Act of 1996 (HIPAA) privacy rules that apply to health care providers, insurers, and clearing houses strictly limit how information gathered during the care process can be shared and used. Increasingly, technology companies not covered by HIPAA are collecting health information directly from patients, as well as from health care providers (with patient consent). The data-driven future of health care will need a set of privacy rules that offers reasonable protections while ensuring providers have access to the data that will support medical decision-making and care coordination.

WORKGROUP STRUCTURE

The AHA believes there are many potential opportunities between providers and new entrants that could improve patient outcomes and experiences throughout the health care sector. This is especially true in light of the increasingly complex and rapidly changing environment in which our members deliver care. **To that end, in addition to innovation, start up and investment-focused companies, the AHA strongly recommends that HHS invite hospitals, health systems, and PAC providers to serve on the workgroup to share the clinical and technical innovations they have achieved. This would include successes at scaling those innovations to other types of providers and/or other areas across the country.**

Additionally, we recommend HHS structure the workgroup to facilitate open dialogue and partnerships between the private sector, investors and federal, state and local government(s). Many observers have noted that public-private partnerships are one of the most promising models for financing successful health care innovations. By combining public interest with private-sector research and development, these partnerships have delivered innovative solutions to numerous industries, especially health care.

INCREASING ENGAGEMENT WITH THE HEALTH CARE INNOVATION COMMUNITY

Public-private partnerships offer a creative alternative to traditional government outsourcing contracts, as they help not only contain the cost curve but also instill a sense of urgency, increase operational efficiencies, and focus on measurable outcomes. Working together, the public and private sector (including non-profits) are often able to accomplish far more than each can do alone.

We support HHS's initiative, and encourage the department to examine other successful public-private stakeholder efforts as potential models. For example, HHS's Health Care Payment and Learning Action Network (LAN) has been successful in aligning public and private-sector stakeholders in moving towards a value-based payment system. The LAN provides a forum for

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generating evidence, sharing best practices, developing common approaches to alternative payment models, and removing barriers to health care transformation. Additionally, HHS's Innovation, Design, Entrepreneurship, Action (IDEA) Lab could provide an avenue to facilitate a public-private dialogue to increase innovation and investment in the health care sector. The IDEA Lab is an internal resource to solve complex problems with innovative approaches and best practices from federal agencies, industry, and non-profits. The Lab's "ignite accelerator," venture fund, and entrepreneurs in residence program offer the opportunity for partnerships that help facilitate innovation. **We encourage HHS to examine lessons learned from current public-private partnerships, as well as explore the use of current programs and offerings to best bring together all segments of the health care sector.**

Again, we thank you for your focus on spurring innovation for patients through greater public-private partnership and the reduction of regulatory barriers that impede innovation and investment. The AHA looks forward to continuing our work with HHS to support innovation. If you have any questions, please feel free to contact me or have a member of your team contact Andrew Shin, chief operating officer for the Health Research & Educational Trust, at (312) 422-2687 or ashin@aha.org or Shira Hollander, AHA Senior Associate Director, Policy, at (202) 626-2329 or shollander@aha.org.

Sincerely,

/s/

Maryjane Wurth
Executive Vice President and Chief Operating Officer
American Hospital Association