

September 22, 2023

The Honorable Bill Cassidy, M.D.
Senate Committee on Health, Education, Labor and Pensions
United States Senate
Washington, DC 20510

***Re: Exploring Congress' Framework for the Future of AI — The Oversight and
Legislative Role of Congress over the Integration of Artificial Intelligence in
Health, Education, and Labor***

Dear Dr. Cassidy:

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, the American Hospital Association (AHA) appreciates the opportunity to comment on the readiness of legislative and regulatory frameworks to ensure appropriate oversight of artificial intelligence (AI).

We understand and support your goals of ensuring the regulation of AI is flexible and will keep up with the rapid pace of innovation. It is critical to both mitigate patient risk and allow hospitals and clinicians to harness the benefits of these powerful technologies for the good of their patients. We support a careful review of existing regulatory frameworks and urge Congress to consider the challenge of effectively regulating AI. Regulation should not strictly be rooted in the effectiveness of the frameworks, but also on the mindset and methodology of the agencies tasked with adapting them to technologies with a continuous and high frequency cycle of change.

In considering the general regulatory approach to AI, AHA would support a sector specific approach, which has worked well for software applications. This approach would allow the relevant oversight organizations to tailor the specifics of their regulation to the particular risks associated with the uses of the software. AI is not a monolithic technology, and a one-size-fits-all approach could stifle innovation in patient care and hospital operations and could prove inadequate at addressing the risks to safety and privacy that are unique to health care. Just as software is regulated based on its use in different sectors, the AHA urges Congress to consider regulating AI use in a similar manner.



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Existing frameworks provide a solid foundation for this approach. They have been tested and refined over time and are familiar to stakeholders. Adapting these frameworks to accommodate the unique aspects of AI would be a more efficient and effective approach.

The AHA recognizes health care applications of AI may pose novel challenges and not adequately addressed by existing regulatory frameworks. AI systems that provide diagnosis, prognosis or specific treatment recommendations for patients could offer significant positive impacts on health outcomes and quality of life; however, these systems may also raise ethical, legal and social issues such as privacy, accountability, transparency, bias and consent that are not addressed in the existing medical device framework, including even the Food and Drug Administration's more recent Software as Medical Device guidance. Additionally, AI systems that generate or analyze health data may create new opportunities and threats for data security, ownership and governance. These systems may enable more personalized and preventive care, but also expose sensitive information to potential misuse or abuse.

The AHA supports continued focus on this topic with consideration given to the need for more specific and robust standards and guidelines for evaluating the safety, efficacy, privacy, transparency and fairness of AI systems and their impact on the patients interacting with these systems.

Sincerely,

/s/

Stacey Hughes
Executive Vice President