



Charles N. Kahn III
President and CEO

September 22, 2023

The Honorable Bill Cassidy
Ranking Member
Senate Health, Education, Labor, and Pensions Committee
455 Dirksen Senate Office Building
Washington DC 20510

Dear Ranking Member Cassidy:

On behalf of the Federation of American Hospitals (FAH), thank you for the opportunity to submit information in response to your [white paper](#), *Exploring Congress' Framework for the Future of AI*. As the Ranking Member of the Senate Committee on Health, Education, Labor, and Pensions (HELP), we commend your leadership and attention to “ensure AI technology is designed, developed, and deployed in a responsible manner that protects Americans’ rights and safety.” Our comments focus on the use of AI in the health care sector. Your white paper defines AI as “computers, or computer-powered machines, exhibiting human-like intelligent capabilities.” In health care, that can include using sensors, deploying analytic tools to support diagnosis or identify high-risk patients, or the automation of administrative tasks.

The FAH is the national representative of more than 1,000 leading tax-paying hospitals and health systems throughout the United States. FAH members provide patients and communities with access to high-quality, affordable care in both urban and rural areas across 46 states, plus Washington, DC, and Puerto Rico. Our members include teaching, acute, inpatient rehabilitation, behavioral health, and long-term care hospitals and provide a wide range of inpatient, ambulatory, post-acute, emergency, children’s, and cancer services.

Responsible Use of AI Tools Promises to Improve Health Care

While it is critical for developers and end users of AI to take steps that safeguard patients and promote privacy of health data, the responsible use of this technology can improve health care and address long-standing systemic issues. For example, the administrative burden on health care providers and clinicians has been a significant burden in optimizing performance and efficiency in health care delivery. Physicians and nurses often spend between 30-50 percent of their time on documentation, payer authorization processes, and other administrative processes. Generative AI, in particular, is capable of becoming a tool to assist in these processes, assisting in documentation, searching for and summarizing patient information, generating communication (e.g., with payers) and supporting communication with patients and families, as appropriate. These use cases are lower risk (i.e., they do not rely on the AI to directly answer clinical questions or support diagnosis or treatment) but high value in the form of returning time to the care teams so they can focus on patients, critical decision making, and improving the quality of care delivered.

The use of generative AI specifically targeted to simplify access, consumption, and readability of health care data should be encouraged by policymakers. For example, a voice assistant for clinicians to extract specific information from large patient history can encourage evidence-based practice and reduce clinical errors. Generative AI tools can contextually summarize, sequence, and modularize data better than static digital systems.

AI also can unlock efficiency and improve care delivery through management and orchestration of care activities. Care delivery, in particular acute care, is a complex matrix of activities that requires coordination between numerous stakeholders (e.g., nurses, physicians, pharmacists, technicians, patients, and family members). This complexity leads to significant variation. AI is capable of understanding this complexity and orchestrating care delivery by identifying the next best action to take at any step in the process, ensuring precious time and resources as deployed in the most efficient and effective manner. For example, regarding bed management, AI could unlock bottlenecks in a hospital through understanding the interdependencies of moving patients within a hospital (e.g., from the emergency room to an inpatient unit). It could select the correct next action (which patient moves next and where) that balances the needs of the patients, the bandwidth and proficiency of the staff, and geography of the care teams assuming responsibility. Optimizing these decisions can unlock significant capacity in hospitals on a daily basis.

AI also is capable of providing intelligent management of health care data. Providing a “safety net” via continuous monitoring of data across numerous sources (e.g., electronic health records, health information exchange, real time monitoring systems, and new data sources such as RTLS and machine vision) to ensure the right signals are presented to the care team at the right time with the right urgency. Filtering out the noise and focusing on the signals in health care data and alerting can have a dramatic impact on safety events, missed diagnoses, or changes in condition (such as onset of sepsis), and timeliness of treatment. Alarm fatigue also is a source

of burnout for clinicians – respecting their valuable time by delivering meaningful signals is one example of where AI can help tackle the burnout problem.

A key factor in the deployment of AI in many circumstances in health care is that a human clinician remains in the loop as the ultimate decision maker, with the AI acting as an assistant, to augment human decision making, not replace it. In such use cases, AI lowers risk by not exposing patients directly to the output or decision making of AI, but the use of AI in these circumstances is nonetheless powerful in its impact on health care delivery.

That said, we recognize the risks that automated solutions can pose, including unintended outcomes such as misdiagnosis, biased analyses, inappropriate denials of service by payers, or inappropriate use and disclosure of sensitive health information. Thus, we urge a balanced approach with flexibility to allow the appropriate use of AI while protecting patients and their privacy at the same time.

Congress Should Recognize the Existing Risk Management Frameworks in Health Care

The unique capabilities of generative AI and the automation of repetitive tasks in health care pose unique risks. However, health care providers have extensive experience in, and have long deployed, risk management approaches to ensure the safety of health care services and the privacy and security of health information. At the federal level, this includes a range of safety requirements, such as the Medicare Conditions of Participation, as well as the HIPAA Privacy and Security Rules. There are also many other federal, state, and local laws that address safety, privacy, and security in health care.

As Congress considers approaches for regulating AI, we urge you and your colleagues to recognize that the health care sector has an existing set of risk management frameworks. To be most successful at realizing the promise of AI and protecting against negative outcomes, the health care sector will need tools, standards, and guidance to incorporate the use of AI-enabled tools into existing risk management structures. Any AI regulatory requirements that conflict with existing risk management processes will slow down progress in realizing the benefits of technology and could inadvertently result in less effective risk management of complex health care systems and organizations.

Congress should consider an AI framework that is risk-based and focuses on processes to ensure algorithms are transparent, auditable, ethical, fair, non-biased, and safe – as this would provide health care stakeholders with the necessary information for responsible use similar to HIPAA.

In addition, AI policy should distinguish generative AI from other, more mature, forms of Data Science/AI (e.g., optimization, forecasting, classification, pattern/anomaly/trend recognition) which have long been used to improve care delivery safely under the current regulatory structures.

Guardrails

The white paper points to possible guardrails that could support responsible use of AI tools. It will be important for Congress, regulators, developers of AI tools, and users of AI tools to collaborate on appropriate frameworks to maximize the safety and efficacy of AI within the health care sector. We note that a layered approach would be most appropriate, and legislative and regulatory policy should distinguish between whether a health care system or organization is developing their own platform and tools for internal use, creating a commercial product, or contracting with an outside vendor for internal use of a commercial product. It also should differentiate between AI uses to augment human decision making versus a situation where the output of algorithms is patient facing or directing patient care.

Further, guardrails should address topics such as transparency measures from the developers of commercial products that embed AI tools that address issues such as how a model works, the data used to train it, appropriate and inappropriate uses of the tool, and results of any testing that has been done to assess bias or other adverse outcomes. Guardrails also should address ethical use, i.e., when it is necessary to have “a human in the loop,” as well as the oversight of AI tools that are in use to ensure that they are functioning appropriately.

The most effective way to regulate AI is to focus on the processes by which AI is developed, rather than on the individual algorithms themselves. When companies and organizations are developing AI products using a trusted process and framework, they have more ability to innovate new products and versions while mitigating risk. By focusing on the processes by which AI is developed, we can ensure that AI is developed in a manner that is safe and ethical.

One approach would be to establish a committee of experts from the public-private sector to define the standards for health care AI development processes. These experts should be drawn from the country's leading AI and health care companies. In collaboration with the FDA, they should define the standards for health care AI development processes. These processes should ensure that the AI product is:

- Fair and impartial
- Transparent and explainable
- Robust and reliable
- Safe and secure
- Used responsibly.

With common practices and standards defined, the FDA could validate that health care AI companies follow these standards when developing AI products.

Finally, Congress also should give thoughtful consideration to the topic of liability, which is a new and challenging aspect of AI. While health care providers bear responsibility for the

care they provide, the developers of commercial AI products must also be accountable if safety, bias, or other harms are caused by a flaw in the tool itself.

We appreciate the opportunity to address these important issues and look forward to working with you as you continue to consider how best to mitigate the risks of AI while allowing its benefits to be realized by patients, providers, and society at large. If you have any questions or wish to discuss these issues further, please do not hesitate to contact me or a member of my staff at 202-624-1500.

Sincerely,

A handwritten signature in black ink, appearing to read "Andrew M. ...". The signature is fluid and cursive, with a large initial letter and a long horizontal stroke extending to the right.